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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1004

[DA–95–24]

Milk in the Middle Atlantic Marketing Area; Suspension of Certain Provisions of the Order

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Suspension of rule.

SUMMARY: This document suspends certain pooling provisions of the Middle Atlantic Federal milk marketing order for the months of September 1995 through February 1996, or until such prior time that the rulemaking proceeding to correct the market's pooling problems is concluded. The suspension reduces the percentage of receipts that must be disposed of as Class I disposition by pool distributing plants, provides automatic pool plant status for supply plants and reserve processing plants that were pool plants during the preceding months of September through February, and removes the limits on the amount of milk that may be diverted to nonpool plants by cooperative associations and pool plant operators. The suspension was requested by several Middle Atlantic cooperatives and handlers. The action is necessary to assure that producer milk historically associated with the market will continue to be pooled and priced under the order without incurring unnecessary and uneconomic movements solely for the purpose of maintaining pool status.

EFFECTIVE DATE: September 1, 1995, through February 29, 1996.

FOR FURTHER INFORMATION CONTACT: Gino M. Tosi, Marketing Specialist, USDA/AMS/Dairy Division, Order Formulation Branch, Room 2971, South Building, P.O. Box 96456, Washington, DC 20090–6456, (202) 690–1366.

SUPPLEMENTARY INFORMATION: Prior documents in this proceeding:

Notice of Hearing: Issued February 25, 1994; published March 4, 1994 (59 FR 10326).

Recommended Decision: Issued July 10, 1995; published July 14, 1995 (60 FR 36239).

The Regulatory Flexibility Act (5 U.S.C. 601–612) requires the Agency to examine the impact of a proposed rule on small entities. Pursuant to 5 U.S.C. 605(b), the Administrator of the Agricultural Marketing Service has certified that this rule will not have a significant economic impact on a substantial number of small entities. This rule lessens the regulatory impact of the order on certain milk handlers and tends to ensure that dairy farmers will continue to have their milk priced under the order and thereby receive the benefits that accrue from such pricing.

The Department is issuing this final rule in conformance with Executive Order 12866.

This final rule has been reviewed under Executive Order 12778, Civil Justice Reform. This rule is not intended to have a retroactive effect. This rule will not preempt any state or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with the Secretary a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with the law and requesting a modification of an order or to be exempted from the order. A handler is afforded the opportunity for a hearing on the petition. After a hearing, the Secretary would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has its principal place of business, has jurisdiction in equity to review the Secretary's ruling on the petition, provided a bill in equity is filed not later than 20 days after the date of the entry of the ruling.

This order of suspension is issued pursuant to the provisions of the Agricultural Marketing Agreement Act and of the order regulating the handling of milk in the Middle Atlantic marketing area.

It is hereby found and determined that for the months of September 1, 1995, through February 29, 1996, the following provisions of the order do not tend to effectuate the declared policy of the Act:

1. In § 1004.7(a), the words "40 percent in the months of September through February, and" and the words "in the months of March through August,".
2. In § 1004.7(e), the word "immediately" and the words "for each of the following months of March through August,".
3. In the introductory text of § 1004.12(d), the words "in accordance with the conditions of paragraphs (d)(1) and (d)(2) of this section".
4. In § 1004.12, paragraphs (d)(1) and (d)(2).

Statement of Consideration

This suspension reduces the total Class I disposition standard for pool distributing plants, provides automatic pool plant status for supply plants and reserve processing plants that were pool plants during each of the preceding months of September through February, and removes the limits on the amount of milk that may be diverted to nonpool plants by cooperative associations and pool plant operators. The provisions will be suspended starting with the month of September 1995 and continuing through February 1996 or until such earlier time as the hearing proceeding (DA–93–30) which addresses these issues is completed.

The first provision suspended reduces the percentage of a distributing plant's receipts that must be disposed of as Class I milk to qualify the plant as a pool plant. With the suspension, a pool distributing plant must use at least 30 percent, rather than 40 percent, of its monthly milk receipts as Class I milk during September 1995 through February 1996.

The second provision suspended permits supply plants and reserve processing plants that were pool plants during the months of September 1994 through February 1995 to retain pool status for the months of September 1995 through August 1996. The shipping

requirements that normally would have applied to such plants during the months of September 1995 through February 1996 are eliminated by the suspension action.

The third provision included in the suspension removes the limits on the amount of milk that may be diverted to nonpool plants by a cooperative association or a pool plant operator for the period of September 1995 through February 1996.

The suspension was requested by Pennmarva Dairymen's Federation, Inc., Atlantic Processing, Inc., Dairylea, Inc., Milk Marketing, Inc., and Lehigh Valley Dairies. Together these organizations represent over 90 percent of the market's producer milk.

As proponents contended in their request, there is ample evidence to support this suspension action on the basis of the record of the May 3, 1994, hearing proceeding (DA–93–30) for the Middle Atlantic market. On July 10, 1995, a recommended decision in that proceeding, which dealt with the same pooling issues involved in this suspension, was issued and published on July 14, 1995, (60 F.R. 36239). The recommended changes would reduce the pooling standards for distributing plants and reserve processing plants and allow cooperatives and pool plant operators to divert more milk to nonpool plants. These changes were recommended primarily because the market's Class I use of producer milk has declined during the past several years.

Proponents stated that the market's supply/demand balance has deteriorated further since the hearing. In April 1995 only 37 percent of the market's producer milk was used in Class I compared with 41 percent in April last year, they indicated.

Since the amendatory relief resulting from the May 1994 hearing cannot be effective by September 1, 1995, when more stringent pooling standards take effect, it is necessary to suspend the aforementioned pooling provisions. The suspension will begin on September 1, 1995, and continue through February 29, 1996 or until such earlier time as the rulemaking proceeding (AO–160–A71;DA–93–30) may adopt proposed changes to the order.

It is hereby found and determined that notice of proposed rulemaking, public procedure thereon and thirty days' notice of the effective date hereof are impractical, unnecessary and contrary to the public interest in that:

(a) The suspension is necessary to reflect current marketing conditions and to assure orderly marketing conditions in the marketing area, in that such rule is necessary to permit the continued pooling of the milk of dairy farmers who have historically supplied the market without the need for making costly and inefficient movements of milk; and

(b) This suspension does not require of persons affected substantial or extensive preparation prior to the effective date.

Therefore, good cause exists for making this order effective less than 30 days from the date of publication in the **Federal Register**.

List of Subjects in 7 CFR Part 1004

Milk marketing orders.

For the reasons set forth in the preamble, the following provisions in Title 7, Part 1004 are amended as follows effective September 1, 1995 through February 29, 1996:

PART 1004—MILK IN THE MIDDLE ATLANTIC MARKETING AREA

1. The authority citation for 7 CFR Part 1004 continues to read as follows:

Authority: 7 U.S.C. 601–674.

§ 1004.7 [Suspended in part]

2. In § 1004.7(a) introductory text, the words "40 percent in the months of September through February, and" and the words "in the months of March through August," are suspended.

3. In § 1004.7(e) introductory text, the word "immediately" and the words "for each of the following months of March through August," are suspended.

§ 1004.12 [Suspended in part]

4. In the introductory text of § 1004.12(d), the words "in accordance with the conditions of paragraphs (d)(1) and (d)(2) of this section" are suspended.

5. In § 1004.12, paragraphs (d)(1) and (d)(2) are suspended.

Dated: August 17, 1995.

Patricia Jensen,

Acting Assistant Secretary, Marketing and Regulatory Programs.

[FR Doc. 95–20967 Filed 8–23–95; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

8 CFR Parts 242 and 299

[INS No. 1672–94; AG Order No. 1984–95]

RIN 1115–AD76

Administrative Deportation Procedures for Aliens Convicted of Aggravated Felonies Who Are Not Lawful Permanent Residents

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Final rule.

SUMMARY: This final rule establishes administrative deportation procedures for aliens not admitted for permanent residence and not statutorily eligible for any relief from deportation who have been convicted of aggravated felonies. This regulation is being promulgated to implement the statutory measure eliminating the requirement for a hearing before an Immigration Judge and limiting judicial review. While incorporating procedural safeguards, it will expedite the deportation process in certain cases involving aliens who have committed serious criminal offenses.

EFFECTIVE DATE: This rule is effective September 25, 1995.

FOR FURTHER INFORMATION CONTACT: Leonard C. Loveless, Detention and Deportation Officer, Immigration and Naturalization Service, 425 Street, NW., Washington, D.C. 20536, Telephone (202) 514–2865.

SUPPLEMENTARY INFORMATION: The Immigration and Naturalization Service ("the Service") published a proposed rule on March 30, 1995, at 60 FR 16386. This final rule, which incorporates changes based on the comments received on the proposed rule, establishes an expedited administrative deportation procedure for aliens who have committed aggravated felonies and who are not lawful permanent residents. Congress authorized such a procedure in section 130004 of the Violent Crime Control and Law Enforcement Act of 1994, Public Law 103–322, which amended section 242A of the Immigration and Nationality Act ("the Act"), effective September 14, 1994. (The Immigration and Nationality Technical Corrections Act of 1994, Public Law 103–416, enacted October 25, 1994, made minor technical changes to section 242A.) Section 242A(b)(4) of the Act authorizes the Attorney General to implement an expedited deportation procedure that eliminates hearings before Immigration Judges for certain aliens convicted of serious criminal

offenses. Section 242A(b)(3) provides that aliens subject to this administrative deportation procedure shall be entitled to limited judicial review upon filing of a petition for review within 30 days after a Final Administrative Deportation Order is issued.

Before enactment of Public Law 103–322, all deportation and exclusion proceedings were required to be conducted before an Immigration Judge pursuant to section 242(b) of the Act (except in the case of certain security-related cases, Visa Waiver nonimmigrants, stowaways, and crewman violators). By enactment of Public Law 103–322, Congress authorized a more streamlined deportation process for aliens who have been convicted of aggravated felonies and who are not lawful permanent residents. Section 242A(b)(4) requires the Attorney General to prescribe regulations for such expedited proceedings. This final rule authorizes district director or chief patrol agent to issue a Final Administrative Order of Deportation in accordance with section 242A(b) of the Act. Under section 242A(b)(2)(B), the administrative procedure can be used only if an alien does not satisfy the statutory conditions that would make the alien eligible for possible relief from deportation under the provisions of the Act.

The final rule requires the Service to afford aliens certain procedural protections during the administrative deportation process:

a. An alien will be given reasonable notice of the charge of deportability on Form I–851, Notice of Intent to Issue a Final Administrative Deportation Order. The Notice must set forth allegations of fact and conclusions of law establishing that the alien is not a lawful permanent resident, is deportable under section 241 (a)(2)(A)(iii) of the Act (relating to conviction for an aggravated felony), and is not statutorily eligible for relief from deportation.

b. The charge of deportability must be supported by clear, convincing, and unequivocal evidence.

c. An alien will be afforded the opportunity to be represented by counsel in the deportation proceedings at no expense to the Government and will be provided a list of available free legal services.

d. An alien will be afforded a reasonable opportunity to inspect the evidence supporting the charge, and to rebut the charge within 10 days, with an extension granted by the district director or chief patrol agent for good cause shown

e. The person who renders the final decision will not be the same person who issues the charge.

f. A record of the proceedings must be maintained for judicial review.

g. An alien is able to seek review of the final order by filing a petition for judicial review within 30 days.

The Service cannot take action to commence the administrative deportation proceedings unless there is evidence establishing the statutory preconditions for deportation. If an alien appears to be statutorily eligible for relief from deportation, the Service will not commence proceedings under section 242A(b) of the Act.

An alien may obtain judicial review of a Final Administrative Deportation Order by filing a petition for review in accordance with section 106 of the Act. Such review, however, is limited under section 106(d) to: (1) Whether the person is in fact the alien described in the order; (2) whether the person was not lawfully admitted for permanent residence at the time at which deportation proceedings commenced; (3) whether the person is not eligible for any relief from deportation; (4) whether the alien has been convicted of an aggravated felony and such conviction has become final; and (5) whether the alien was afforded the procedures required by section 242A(b)(4) of the Act.

Section 242(a)(2) of the Act requires the Service to take into custody any alien who has been convicted of an aggravated felony, upon the alien's release from incarceration. An alien who has been lawfully admitted may be released from the Service's custody if the alien demonstrates to the satisfaction of the Attorney General that the alien is not a threat to the community and is likely to appear for any scheduled proceedings. The Attorney General may not release from custody any alien who has not been lawfully admitted. An alien can seek review of a custody determination by filing a writ of habeas corpus with the district court.

The final rule differs from the proposed rule in the following respects: The rule amends 8 CFR 242.25(b)(2) by adding subparagraph (iii) to require the Service to provide a list of free legal-aid services to an alien in conjunction with the Notice of Intent. The final rule also amends 8 CFR 242.25(b)(2) by adding subparagraph (iv) to require the Service either to provide the alien a written translation of the Notice of Intent or to explain the contents of the Notice of Intent in the alien's native language or in a language the alien understands. The final rule also amends 8 CFR 299.1 by adding the entries for Forms I–851 (Notice of Intent to Issue a Final Administrative Deportation Order) and I–851A (Final Administrative Deportation Order) to the listing of forms, to ensure that Service personnel and the public are aware of these new forms and their proper edition dates. The rule also makes non-substantive changes to the provisions of the proposed rule for clarification.

In response to the proposed rule, the Service received several comment letters and memoranda of law from various independent attorneys, law enforcement officials, and legal defense organizations. The following sections summarize the comments and explain the revisions adopted.

The comments principally focused upon the following topics: aliens' entitlement to due process; the absence of an "in person" hearing in the administrative deportation procedure; the competence of the deciding Service officer; the complexity of determining whether an alien has been convicted of an "aggravated felony" or is entitled to relief from deportation; the form and content of the notice provided to the alien; the deadlines imposed upon the alien for responding to the Notice of Intent; aliens' opportunity to obtain counsel; aliens' opportunity to rebut charges; the impartiality of the deciding Service officer; the risk of deportation of United States citizens or lawful permanent residents; the lack of review of the deciding Service officer's decision by an Immigration Judge or by the Service's General Counsel; and the termination without prejudice of Immigration Judge proceedings when it appears that an alien is subject to administrative proceedings under section 242A(b) of the Act.

1. Procedural Due Process in the Absence of an In-Person Hearing

Comments: Several commenters contended that the proposed rule violated constitutional requirements of procedural due process. In particular, the commenters argued that the process is constitutionally inadequate because of the failure to provide an in-person hearing before the deciding Service officer.

Response and Disposition: Congress decided to permit expedited deportation procedures for a certain class of aliens with respect to whom the decision to deport typically is straightforward and not subject to discretionary or equitable considerations. Because deportation of such aliens involves no discretionary factors, and because there rarely will be any factual disputes bearing upon deportability that cannot be resolved

through documentary evidence, a testimonial hearing for such aliens rarely if ever will serve a useful purpose. Accordingly, Congress authorized the "[e]limination of [a]dministrative [h]earing[s]" for such aliens. Public Law 103–322, Section 130004(a), 108 Stat. 2026. The Service is merely implementing this congressional decision. Both the statute and the rule provide all the process that is due.

It is well established that the Fifth Amendment entitles aliens to due process of law in deportation proceedings. *See Reno* v. *Flores*, 113 S. Ct. 1439, 1449 (1993). As the Supreme Court explained in *Landon* v. *Plasencia*, 459 U.S. 21, 34 (1982), whether deportation procedures satisfy due process depends upon three factors: (i) The interest at stake for the alien; (ii) the risk of an erroneous deprivation of the interest through the procedures used and the probable value of additional or different procedural safeguards; and (iii) the interest of the government in using the given procedures rather than additional or different procedures. As these three factors suggest, the constitutional sufficiency of procedures provided in any particular situation is dependent on context; it will vary with the particular circumstances, and what is sufficient for one type of deportation determination may not be sufficient for another. *Landon*, 459 U.S. at 34–35. In the context of deportation of aliens who are aggravated felons and who are not lawful permanent residents, consideration of the three factors compels the conclusion that the procedures provided in this rule satisfy due process.

With respect to the first factor, the Service recognizes that the interest at stake for the alien—remaining in the United States—can be substantial. An alien stands to lose the right "to stay and live and work in this land of freedom," *Landon*, 459 U.S. at 34, and may lose the right to rejoin his or her immediate family, *id.* However, the aliens covered by this rule have somewhat lesser cognizable interests than aliens who are either permanent lawful residents, or who are not aggravated felons, or both. The aliens in question, because they will either have been admitted on a temporary basis or will have entered the country unlawfully, will not have "develop[ed] * * * ties" to the United States, see *Landon*, 459 U.S. at 32, equivalent to those enjoyed by permanent resident aliens. Moreover, this discrete class of aliens has demonstrated a disregard for the laws of the United States, as evidenced by their aggravated felony convictions. Those aliens who have been incarcerated will already have had their ties to this country diminished as a result; and even aliens who originally had been lawfully admitted should have less of an expectation to those ties because, by virtue of their commission of an aggravated felony, they will have failed to fulfill the conditions under which they gained entry and under which they were entitled to developed such ties.

As to the third factor in the due process calculation, the government's interest in ensuring expedited deportation of this class of aliens is substantial. To begin with, it "weighs heavily in the balance" that control of immigration matters "is a sovereign prerogative." *Landon*, 459 U.S. at 34. In addition, the government also has a "weighty" interest "in efficient administration of the immigration laws." *Id.* Considerable weight must be given to "the administrative burden and other societal costs that would be associated with requiring * * * an evidentiary hearing upon demand in all cases." *Mathews* v. *Eldridge*, 424 U.S. 319, 347 (1976).

With regard to "the administrative burden," the interest of the government and the public "in conserving scarce fiscal and administrative resources" is critical. *Mathews*, 424 U.S. at 348. The administrative process encouraged by Congress and established by this rule addresses Congress' concern that aliens who are serious criminal offenders have not heretofore been deported swiftly. Presently, without the expedited proceedings provided by this rule, many of these aliens, particularly those who serve short sentences for their convictions, remain in the custody of the Service for prolonged periods. Congress recognized that the present hearing procedure, with its "repeated appeals," "can consume several years." 139 Cong. Rec. E749 (Mar. 24, 1993) (statement of Rep. McCollum). The cost of incarcerating these aliens during that period is substantial, and Congress authorized the expedited deportation procedures in large part to ameliorate that cost. *Id.* See also 140 Cong. Rec. S3068 (Mar. 16, 1994) (statement of Sen. Roth). The expedited procedure also serves to address "other societal costs." *Mathews*, 424 U.S. at 347. Because aliens presently can invoke the more formal procedures, their custody continues for an extended period. This exacerbates the "problem of limited detention capacity" that the Service faces, 139 Cong. Rec. E749 (Mar. 24, 1993) (statement of Rep. McCollum), and permits alien felons extended opportunity to commit further crime in this country. See 140 Cong. Rec. S3068 (Mar. 16, 1994) (statement of Sen. Roth).

Finally, with respect to the second due process factor, there is little risk that the administrative procedures established by this rule—in particular, the lack of an in-person hearing—will result in an erroneous deprivation of aliens' interests, and the probable value of additional or different procedural safeguards is minimal, at best.

It is worth noting, as an initial matter, that a number of aliens who are aggravated felons and who are not lawful permanent residents may choose not to contest deportation, since such deportation is based on objective, nondiscretionary criteria for aliens who fall within the class covered by section 242A of the Act.

Some aliens will, however, challenge deportation under section 242A of the Act; and due process requires that in any deportation proceeding, an alien must be entitled to notice of the nature of the charge and "a fair opportunity to be heard" on the charge. *Kwong Hai Chew* v. *Colding*, 344 U.S. 590, 597–98 (1953). As in other contexts, "[t]he fundamental requirement of due process" in a deportation proceeding "is the opportunity to be heard 'at a meaningful time and in a meaningful manner.'" *Mathews*, 424 U.S. at 333 (citation omitted). See, *e.g.*, *Rafeedie* v. *INS*, 880 F.2d 506, 524 (D.C. Cir. 1989). An alien must, therefore, be apprised of clearly defined charges, have a fair opportunity to present evidence in his or her favor, and have the right to inspect the evidence on which the matter is to be decided. See, *e.g.*, *Kaczmarczyk* v. *INS*, 933 F.2d 588, 595–96 (7th Cir.), *cert. denied*, 502 U.S. 981 (1991). Due process in the deportation context does not, however, require the same procedural protections as would be provided in a criminal trial, see *Dor* v. *District Director*, 891 F.2d 997, 1003 (2d Cir. 1989), nor does it automatically dictate and opportunity for an alien to be heard upon a regular, set occasion, and according to the forms of judicial procedure; instead, due process merely requires that an alien be given an opportunity to be heard "that will secure the prompt, vigorous action contemplated by Congress, and at the same time be appropriate to the nature of the case." *Yamataya* v. *Fisher*, 189 U.S. 86, 101 (1903).

An alien's due process rights to be heard and to defend are protected by this rule. An alien will have been questioned by an immigration officer, and will be given reasonable notice of the charges, the right to counsel, and a reasonable opportunity to inspect the evidence and rebut the charges. An

alien can submit whatever evidence he or she wishes to rebut the charges, and the deportation decision will be made by an immigration official other than the official who issues the charging document. The burden of proof is upon the Service to establish deportability by clear, convincing, and unequivocal evidence. The decision is subject to judicial review by the court of appeals on a petition for review.

The fact that an in-person hearing before the deciding Service officer typically will be unavailable under the administrative proceedings does not automatically result in a denial of due process. To begin with, in the usual case the alien will already have had a face-to-face interview, when the Service takes into custody or otherwise first encounters the alien. During such an interview, the investigative officer may take a sworn statement or affidavit from the alien and then complete Form I–213, Record of Deportable Alien. See 8 U.S.C. 1357(b); 8 CFR 287.5(a). The results of this interview typically will form a basis for both the initiation of administrative deportation proceedings and the charge of deportability; thus, the alien has an opportunity at that initial interview to rebut the facts upon which administrative deportation would be predicated. Little, if anything, would be gained by requiring another interview before the deciding Service officer. And, since many aliens in administrative deportation proceedings will be detained by other law enforcement agencies, a requirement of another "in-person" hearing would result in further delays by requiring Service officers to travel to remote locations to repeat the interview with each alien.

Even more significantly, in a deportation proceeding under this rule the risk of making an erroneous decision will be minimal, and the value of an in-person hearing would be speculative at best. The only issues to be decided in such proceedings are "relatively straightforward matters," *Califano* v. *Yamasaki*, 442 U.S. 682, 696 (1979), namely: alienage, lawful permanent resident status, conviction of an aggravated felony, and statutory eligibility for relief. The Service can determine alienage, lawful permanent resident status, and eligibility for relief based solely upon documentary evidence, such as information contained in the alien registration file and computer databases, and can supplement that evidence with the statement of the alien at the initial interview. The Service can determine whether the alien has been convicted of an aggravated felony based upon the record of conviction. Most importantly, unlike many determinations that can arise in other types of deportation proceedings, these determinations must be made by the Service without consideration of any equities or discretionary factors. Accordingly, there are unlikely to be any "issues of witness credibility and veracity," *Mathews*, 424 U.S. at 343–44, that might justify an in-person, testimonial hearing.

The Supreme Court has held that due process does not require an in-person, testimonial hearing in front of the deciding official where the decision in question "will turn, in most cases, upon 'routine, standard, and unbiased'" documentary evidence. *Mathews*, 424 U.S. at 344 (citation omitted). Where the facts on which the ultimate decision are to be based are "sharply focused and easily documented," *id.* at 343, as in the case of aliens who have committed aggravated felonies and who are not permanent resident aliens, more formal testimonial hearings are not constitutionally required. The facts on which deportation will depend for these aliens are "relatively straightforward matters," *Califano*, 442 U.S. at 696, and are "typically more amenable to written than to oral presentation," *Mathews*, 424 U.S. at 345. See also *id.* at 344 n.28.

Several commenters suggested that there may be certain cases in which testimony will be necessary to determine such issues as alienage or possible statutory eligibility for relief from deportation. Because of the nature of these determinations, the Service believes that the cases will be few and far between in which such determinations cannot be made on the basis of documentary evidence. But even if there are such isolated cases, that would not mean that the rule itself is unconstitutional.

To begin with, although the regulation does not require an in-person hearing, the deciding Service officer can request further evidence after the alien's initial submission, if that officer determines that such evidence will aid in the decision. Under 8 CFR 242.25(d)(2)(ii), if the deciding Service officer finds that the alien's written response raises a genuine issue of material fact regarding the preliminary findings, the officer may request additional evidence, as he or she may deem appropriate. Thus, if any testimony is required, it can and should be heard.

More fundamentally, "procedural due process rules are shaped by the risk of error inherent in the truth-finding process as applied to the generality of cases, not the rare exceptions." *Mathews*, 424 U.S. at 344. And "[i]t would be inconsistent with that principle to require a hearing * * * when review of [an alien's] written submission is an adequate means of resolving all but a few * * * disputes." *Califano*, 442 U.S. at 696. If an alien believes that due process requires additional protections because of the particular exigencies of his or her case, the alien can raise the issue in the record of proceedings, and the alien thereafter can, in appropriate circumstances, seek judicial review to redress any alleged constitutional deprivation. But the mere possibility of such as-applied due process challenges does not justify the enormous cost that would be entailed in providing an in-person hearing for every deportation determination. See *Mathews*, 424 U.S. at 909; *Califano*, 442 U.S. at 696. Therefore, the rule is not susceptible to a "facial challenge" on procedural due process grounds. *Cf. Reno* v. *Flores*, 113 S. Ct. at 1450–51 (because due process would not be denied in the majority of cases, facial due process challenge is rejected).

Accordingly, the provisions of the proposed rule requiring a documentary record and not requiring an in-person hearing have been adopted without substantive amendment in the final rule.

2. Reasonable Notice

Comments: Several commenters stated that the Notice provided to the alien pursuant to 8 CFR 242.25(b)(2) should advise the alien of eligibility for relief, be translated into the alien's native language if he or she is not proficient in English, and be explained to the alien. Other commenters stated that aliens often do not understand that nature of the proceedings; that aliens may be incompetent or mentally ill; and that proper notice should include more information regarding the law and legal rights. One comment stated that if the alien receives the Notice while detained, the regulation should provide that the alien be given writing materials and postage stamps for a response.

Response and Disposition: In conformity with the statute and the final rule, the Notice of Intent to Issue a Final Administrative Deportation Order (Form I–851) will contain legally sufficient factual allegations, conclusions of law, charge of deportability, and advice to the respondent (similar to an Order to Show Cause). These elements of notice satisfy due process requirements. The Notice will instruct the alien to identify which findings supporting deportation he or she is challenging, if any, and to corroborate any challenge with documentation or other evidence. To facilitate the process, page two of the Notice of Intent also will provide easy-to-understand boxes that an alien

should check to indicate the nature of the alien's response. It would be inappropriate for the regulation to recommend which kinds of evidence an alien should choose to present in defending against the charge or in presenting a claim to relief, given the variety of evidence that might be germane to the determinations at issue.

Both the Act and the regulations set forth the various forms of relief that may or may not be available in deportation proceedings. Moreover, under the rule, aliens will have a reasonable opportunity to obtain counsel of their choosing who may assist them in determining whether relief is available. If an alien submits evidence supporting a prima facie claim that he or she may be statutorily eligible for some relief from deportation, § 242.25(d)(2)(iii) of the rule requires the Service to terminate the administrative proceedings and, where appropriate, to initiate proceedings before an Immigration Judge. If an alien appears to satisfy the statutory conditions for eligibility for relief from deportation, the Service would not then have jurisdiction to commence or to continue proceedings under 242A(b) of the Act. In light of these protections, the proposed rule will not be changed to require that the Service advise the alien of the various forms of statutory eligibility for relief.

The Form I–851 (Notice of Intent) will advise respondent aliens of the availability of a list of free legal services. The rule is amended to require the Service to provide such a legal aid list in conjunction with the Notice of Intent. Service of the Notice must, in accordance with 8 CFR 292.5(a), be made upon an attorney or representative of record, if the alien is so represented. The Notice of Intent will clearly provide the address to which the alien must send a response.

The Service agrees that it is important that the alien understand the Notice of Intent. Therefore, to enhance fairness and ensure that the notice of the charges is reasonable, the proposed rule is amended to add subparagraph (iv) to 8 CFR 242.25(b)(2), which will require that the Service either provide the alien a written translation of the Notice of Intent or explain the contents of the Notice of Intent in the alien's native language or in a language that the alien understands.

The Service agrees that, in certain particular cases, an alien may be unable to read or understand the nature of proceedings because of his or her incompetence or mental illness. This rule provides a reasonable opportunity for an alien to seek the services of counsel, a relative, or friend. Providing further protections in a particular proceeding where circumstances warrant such protections will be the responsibility of the deciding Service officer, who may, for example, schedule an interview, where appropriate. The Service officer's decision on what, if any, additional notice and/or procedure to provide the alien will be subject to judicial review. The possibility that the Notice of Intent might not suffice to provide constitutionally adequate notice in rare circumstances does not suffice to call into question the constitutionality of the rule itself, which will provide constitutionally sufficient notice in the vast majority of cases. See *Mathews*, 424 U.S. at 909; *Califano*, 442 U.S. at 696.

3. Fair Opportunity To Respond to the Notice and To Inspect and Rebut the Evidence Supporting Deportation

Comments: Several commenters stated that the proposed rule would not provide sufficient time for an alien to respond to the Notice, and suggested that the response period be changed to one month. Commenters state that respondents who are incompetent, mentally ill, or who do not understand the nature of the proceedings, may need more time to obtain counsel and to rebut the charge. The comments outlined the numerous obstacles that detained aliens may face, such as: language impediments; mail delays; an inability to communicate with family, attorneys, and potential witnesses; lack of access to law libraries or writing materials; and difficulty in producing affidavits, identification documents, or birth records. One commenter stated that requiring the response to be supported by an affidavit is unnecessary because the regulation can provide that any response shall be considered to be made under oath. Finally, some commenters stated that the record of proceeding should be provided automatically to all aliens, rather than only upon an alien's request.

Response and Disposition: The Service believes that the proposed rule provides a fair opportunity for aliens to inspect evidence and rebut charges of deportability. Pursuant to 8 CFR 242.25(c)(2), "[i]f an alien's written response requests the opportunity to review the Government's evidence, the Service shall serve the alien with a copy of the evidence in the record of proceeding upon which the Service is relying to support the charge." The alien then has ten additional days following service of the Government's evidence (thirteen days if service is by mail), to furnish a final response in accordance with 8 CFR 242.25(c) (1)–(2). Pursuant to 8 CFR 242.25(d)(2)(ii)(B), if, after the alien's rebuttal of the Notice, the deciding Service officer considers additional evidence from a source other than the alien, that evidence will also be provided to the alien and still another extension of time to respond shall be given. Thus, these regulations already provide respondents ample opportunity to inspect all evidence relied upon by the Government and contained in the record of proceeding.

The Service believes that any further increase in the time periods for response would contravene Congress' intent that the Service expeditiously adjudicate the deportation cases of the serious criminal offenders described under section 242A(b) of the Act. Many aliens in this class, particularly in county and local jails, are inmates who are incarcerated less than a year, and frequently less than six months. Expeditious proceedings under section 242A(b) of the Act will prevent "spillover" detention of these short-term inmates into the Service's detention, thereby relieving the aliens of further incarceration while saving substantial costs to the Service and to the public. Nonetheless, if an alien makes a timely written request for more time and explains the reasons for doing so—for instance, that the alien needs to contact family members or potential witnesses—the deciding Service officer may grant an extension for the alien to file a response under 8 CFR 242.25(c)(1). The deciding Service officer must ensure fairness in the adjudicative process. Accordingly, the Service believes that this rule provides sufficient opportunity for aliens to respond to the Notice.

The Service believes that the requirement that the alien request access to the evidence in order to receive it is constitutional and salutary. As explained above, it is unlikely that the majority of aliens covered by the administrative proceedings will contest their deportability. This fact counsels against expending the considerable cost and burden of sending all evidence to all aliens in the first instance. Those aliens who do wish to contest deportation readily can receive the evidence upon a simple request. Moreover, section 291 of the Act expressly provides that in presenting proof of time, manner, and place of entry into the United States, the alien "shall be entitled to the production of his visa or other entry document, if any, and of any other documents and records * * * pertaining to such entry in the custody of the Service." The Service must therefore produce any such documents that are in its possession in accordance with that section of the Act.

The Service agrees that an alien should not be required to submit an accompanying affidavit with his or her response. It is incumbent upon the alien to choose his or her own corroborating evidence in rebutting a charge. Accordingly, § 242.25(c)(2) has been modified to provide that the alien should submit with the response "affidavit(s), documentary evidence, or other specific evidence supporting the challenge."

4. Impartial Fact-Finder

Comments: Several commenters stated that the rule was unfair or unconstitutional because it will permit the issuing Service officer and the deciding Service officer both to be enforcement officials who may be agents of the same party, such as a District Director. One commenter recommended that the rule should explicitly prohibit the deciding Service officer from engaging in ex parte communication with the issuing Service officer or otherwise considering evidence outside the record, because due process requires that the decisionmaker make an independent evaluation and consider only evidence on the record that the alien has had a fair opportunity to rebut. Another commenter urged that the initiation of proceedings under the rule be subject to review by the Service's General Counsel, and another expressed concern that the rule does not provide adequate checks against Service misconduct.

Response and Disposition: Congress has provided for administrative deportation proceedings to be conducted without a hearing before an Immigration Judge. The officers of the Service are in the best position to perform such proceedings. The statute mandates that the Final Administrative Deportation Order not be issued by the same person who issues the Notice of Intent, and the rule reflects this protection.

The Service believes that the rule reasonably ensures that decisions are made by an impartial fact-finder. In order to prevent any "blurring" of investigative and adjudicative functions, the statute and the rule expressly forbid the "deciding" officer from being the same person who issues the charging document. It has been clear for at least 40 years that due process is not violated in deportation proceedings simply because the deciding official is subject to the control of officials charged with investigative and prosecuting functions. *Marcello* v. *Bonds*, 349 U.S. 302, 311 (1955).

Since the Service's attorney work force is available to provide legal advice to Service personnel, there is no need in the regulation to require General Counsel review of administrative proceedings.

The deciding Service officer is authorized under 8 CFR 242.25(d) to issue an order of deportation only if the "evidence in the record of proceeding" establishing deportability is clear, convincing and unequivocal. Thus, that officer is duty-bound to make an independent evaluation only of the evidence contained in the four corners of the record of proceeding, and may not rely upon evidence outside the record of proceeding. In addition, since the deciding Service officer is not authorized to make discretionary determinations on eligibility for relief in section 242A(b) proceedings, he or she may not consider any discretionary factors. Accordingly, the proposed rule has not been modified.

5. Termination of Immigration Judge Proceedings Without Prejudice to the Service

Comment: The proposed rule provides that the Service may request that proceedings before an Immigration Judge be terminated so that administrative deportation proceedings may be initiated. One commenter stated that if the Government moves to terminate an Immigration Judge proceeding commenced under section 242(b) of the Act, such termination should be with prejudice to the Service because the Service should not be allowed to "forum shop" and reinstate the deportation process in a setting where the alien has fewer procedural protections.

Response and Disposition: The Service may initiate or continue proceedings under this rule only if there is no evidence that an alien is prima facie eligible for relief. Thus, for example, if after a Notice of Intent is issued, the Service discovers that an alien appears to be statutorily eligible for relief from deportation, then, pursuant to 8 CFR 242.25(d)(2)(iii), the Service must terminate administrative deportation proceedings and, where appropriate, initiate deportation proceedings under section 242(b) of the Act.

Conversely, if the Service discovers that an alien who has been placed in proceedings before an Immigration Judge in fact is amenable to proceedings under section 242A(b) of the Act, it would implement Congress' intent for the Service to exercise its prosecutorial discretion to move to terminate the Immigration Judge proceedings in order to expedite the deportation process. In such a case, the alien's eligibility for expedited deportation renders the Immigration Judge proceedings unnecessary. Transfer to administrative proceedings in such a case would not be "forum shopping"; rather, it would simply be a move to a more efficient and appropriate forum, in accord with Congress' intent that administrative proceedings be used for aliens who have committed aggravated felonies and who are not lawful permanent residents. There is, therefore, no reason that the termination of Immigration Judge proceedings should be with prejudice to the Service, particularly since the Immigration Judge will have made no decision on the substantive issues of deportability under section 241 of the Act or relief from deportation. The final rule therefore will remain unchanged.

6. Lack of Administrative Appeal

Comment: A commenter cautioned that execution of Final Administrative Deportation Orders should not be completed without allowing appeal to the Board of Immigration Appeals ("BIA"), to permit an independent review of the evidence by the BIA. This commenter stated that such appeals would not delay deportations because appeals would be completed while the alien is serving his or her sentence. Another commenter stated that, by eliminating any meaningful administrative hearing or review, the regulations will place an added burden on federal courts, which will be forced to decide issues more appropriately resolved on the administrative level.

Response and Disposition: Congress authorized administrative deportation in order to streamline deportation proceedings for a certain class of aliens with respect to whom the decision to deport typically is straightforward and not subject to discretionary or equitable considerations. The rule affords the alien the right to petition for judicial review on limited issues, and such a petition will be entertained by a federal appellate court, which is an independent tribunal with jurisdiction to decide any due process claims properly raised. As noted above, many of the inmates described by the provisions of section 242A(b) of the Act serve short sentences. County and city jail terms of less than a year, and frequently less than six months, are often too short to permit Institutional Hearing Program hearings prior to Service detention of such aliens. This rule permits the Service to serve Notices of Intent to issue a Final Administrative Deportation Order upon short-term inmates and more rapidly adjudicate their cases before the inmates are released from incarceration. The rule

thus prevents costly detention at Service expense and appropriately eliminates a layer of administrative hearings and administrative appeals, which will in turn make it more likely that deportation proceedings will be completed before inmates' release from incarceration. In addition, some aliens convicted of aggravated felonies who have completed their sentences might not be incarcerated when first encountered by the Service. The Service must detain and hold in custody such aliens, at great expense. The rule reduces the length of detention in those cases, as well. Allowing an appeal to the BIA would undermine Congress' intent by recreating the undesirable cost, delay and detention problems that prompted Congress to act in the first instance to permit expedited deportation. Accordingly, the proposed rule remains unchanged.

7. Ensuring That Responses Are Timely Included in Records of Proceeding

Comment: Two commenters expressed concern that, since many offices of the Service are not in a position to process mail received on a timely basis, the Service may not be able to include an alien's timely responses in a record of proceeding in time to prevent the alien from receiving a final order of deportation for failure to timely file a response. The comments stated that, in such a case, the case should be reopened.

Response and Disposition: The rule specifically requires the Service to create and maintain a full record of proceeding in each case. The Notice of Intent will facilitate the matching of responses to the record of proceeding by providing the alien with the contact person to whom the response must be submitted, and an address for that person. Like any other court proceeding, Service personnel will be responsible for matching documents to the record of proceeding for review and adjudication by the deciding Service officer in the district or sector where the charging document was issued.

The deciding Service officer is not precluded from correcting any mistake discovered with respect to the timeliness of receipt of any document, or any other mistake that is pertinent to the final decision. To the contrary, the deciding Service officer may render whatever ruling is deemed appropriate that is supported by the record in carrying out his or her responsibilities as an adjudicator. Furthermore, the integrity of the process in a particular case remains subject to judicial review on a petition for review, based upon the full record of proceeding.

8. Risk of Deporting U.S. Citizens, Permanent Residents, or Other Aliens Ineligible for Deportation or Eligible for Relief From Deportation

Comments: Several commenters stated that the process creates an unacceptable risk of deporting a United States citizen or lawful permanent resident alien. Commenters also questioned the training and expertise of issuing Service officers, arguing that the issues of aggravated felony conviction, derivative citizenship, and relief from deportation are too complex and should be left to an Immigration Judge. One commenter warned that Service officers may initiate expedited proceedings against aliens who have a right to hearings before Immigration Judges or who are citizens and are not aware of it, and the Service will have no incentive to verify derivative citizenship. These commenters even recommended that the Attorney General withdraw the proposed rule for these reasons.

Response and Disposition: As previously stated, Congress authorized administrative deportation for aliens who are aggravated felons and who are not lawful permanent residents. The due process safeguards incorporated in this rule are designed precisely to minimize the risk of an erroneous determination of deportability, while ensuring fairness. As explained above, "procedural due process rules are shaped by the risk of error inherent in the truth-finding process as applied to the generality of cases, not the rare exceptions." *Mathews*, 424 U.S. at 344. Under this rule, the risk of making an erroneous decision in the generality of cases is minimal. The questions of citizenship, alienage, lawful permanent resident status, conviction for an aggravated felony, and statutory eligibility for relief, are matters that are well within the expertise and competence of Service officers to decide. Indeed, pursuant to other provisions of the Act and other regulations, immigration officers already regularly determine issues germane to deportability, including: whether an alien is finally convicted of an aggravated felony (for purposes of issuing charging documents); acquisition of citizenship at birth; derivation of citizenship; eligibility for adjustment of status or naturalization; and eligibility for any of the forms of relief under the Act. Under current law, district directors are authorized to adjudicate a variety of applications for immigration benefits, including the authority to grant or deny petitions for naturalization.

Because of the straightforward, nondiscretionary nature of the determinations under this rule, there is no reason to believe that United States citizens would face a greater risk of deportation before the deciding Service officer than before an Immigration Judge. If, after the Notice of Intent is issued, an alien appears to be statutorily eligible for relief or raises a genuine issue of material fact regarding the preliminary findings, then the deciding Service officer must either seek additional evidence bearing on the disputed issue, or terminate the administrative deportation proceedings.

9. Typographical and Other Non-Substantive Corrections

Comment: A commenter pointed out that the title for proposed 8 CFR 242.25(d)(iii) does not make sense as it presently reads.

Response and Disposition: The commenter is correct that the word "Secretary" in the heading of 8 CFR 242.25(d)(iii) is a typographical error, and should read "Statutory." Accordingly, the word "Secretary" is replaced by the word "Statutory" in the final rule. The substantive text of the above section, nevertheless, was correct and sufficiently clear to allow for meaningful comment on this provision of the proposed rule. This final rule also makes other non-substantive corrections to the language of the proposed rule.

10. Favorable Comments

Comment: One respondent, a metropolitan Chief of Police, pledged to give this procedure his full support because it is a positive step in dealing with the problems created by criminal undocumented aliens, a growing and dangerous segment of the criminal population.

Response and Disposition: The Service agrees with the commenter that the process under the rule will help combat criminal activity of deportable aliens in many parts of the country, as Congress intended.

Attorney General Certifications

The Attorney General, in accordance with 5 U.S.C. 605(b), certifies that this rule does not have a significant adverse economic impact on a substantial number of small entities.

This rule is not considered to be a "significant regulatory action" within the meaning of section 3(f) of E.O. 12866, Regulatory Planning and Review, and the Office of Management and Budget has waived its review process under section 6(a)(3)(A).

This rule is not considered to have Federalism implications warranting the

preparation of a Federalism Assessment in accordance with section 6 of Executive Order 12612.

List of Subjects

8 CFR Part 242

Administrative practice and procedure, Aliens.

8 CFR Part 299

Immigration, Reporting and recordkeeping requirements.

Accordingly, part 242 of chapter I of title 8 of the Code of Federal Regulations is amended as follows:

PART 242—PROCEEDINGS TO DETERMINE DEPORTABILITY OF ALIENS IN THE UNITED STATES: APPREHENSION, CUSTODY, HEARING, AND APPEAL

1. The authority citation for part 242 is revised to read as follows:

Authority: 8 U.S.C. 1103, 1182, 1186a, 1251, 1252, 1252 note, 1252a, 1252b, 1254, 1362; 8 CFR part 2.

2. In part 242, a new section 242.25 is added to read as follows:

§ 242.25 Proceedings under section 242A(b) of the Act.

(a) *Definitions.* As used in this section—*Deciding Service officer* means a district director, chief patrol agent, or another immigration officer designated by a district director or chief patrol agent, who is not the same person as the issuing Service officer. *Issuing Service officer* means any Service officer listed in § 242.1(a) as authorized to issue orders to show cause. *Prima facie claim* means a claim that, on its face and consistent with the evidence in the record of proceeding, demonstrates an alien's present statutory eligibility for a specific form of relief from deportation under the Immigration and Nationality Act ("the Act").

(b) *Preliminary consideration and Notice of Intent to issue a Final Administrative Deportation Order; commencement of proceedings.* (1) *Basis of Service charge.* An issuing Service officer shall cause to be served upon an alien a Notice of Intent to issue a Final Administrative Deportation Order (Notice of Intent, Form I–851), if the officer is satisfied that there is sufficient evidence, based upon questioning of the alien by an immigration officer and upon any other evidence obtained, to support a finding that the individual:

(i) Is an alien;

(ii) Has not been lawfully admitted for permanent residence;

(iii) Has been convicted (as demonstrated by one or more of the sources listed in § 3.41 of this chapter) of an aggravated felony and such conviction has become final;

(iv) Is deportable under section 241(a)(2)(A)(iii) of the Act; and

(v) Does not appear statutorily eligible for any relief from deportation under the Act.

(2) *Notice.* (i) Deportation proceedings under section 242A(b) of the Act shall commence upon personal service of the Notice of Intent upon the alien, as prescribed by §§ 103.5a(a)(2) and 103.5a(c)(2) of this chapter. The Notice of Intent shall set for the preliminary determinations and inform the alien of the Service's intention to issue a Final Administrative Deportation Order (Final Administrative Deportation Order, Form I–851A) without a hearing before an Immigration Judge. This Notice shall constitute the charging document. The Notice of Intent shall include allegations of fact and conclusions of law. It shall advise that the alien: has the privilege of being represented by counsel of the alien's choosing, at no expense to the Government, as long as counsel is authorized to practice in deportation proceedings; may inspect the evidence supporting the Notice of Intent; and may rebut the charges within ten (10) calendar days after service of such Notice (or thirteen (13) calendar days if service of the Notice was by mail).

(ii) The Notice of Intent also shall advise the alien that he or she may designate in writing, within ten (10) calendar days of service of the Notice of Intent (or thirteen (13) calendar days if service is by mail), the country to which he or she chooses to be deported in accordance with section 243 of the Act, in the event that a Final Administrative Deportation Order is issued, and that the Service will honor such designation only to the extent permitted under the terms, limitations, and conditions of section 243 of the Act.

(iii) The Service shall provide the alien with a list of available free legal services programs qualified under part 292a of this chapter and organizations recognized pursuant to part 292 of this chapter, located within the district or sector where the Notice of Intent is issued.

(iv) The Service must either provide the alien with a written translation of the Notice of Intent or explain the contents of the Notice of Intent to the alien in the alien's native language or in a language that the alien understands.

(c) *Alien's response.* (1) *Time for response.* The alien will have ten (10) calendar days from service of the Notice of Intent, or thirteen (13) calendar days if service is by mail, to file a response to the Notice. If the final date for filing such a response falls on a Saturday, Sunday, or legal holiday, the response shall be considered due on the next business day. In the response, the alien may: Designate his or her choice of country for deportation; submit a written response rebutting the allegations supporting the charge and/or requesting the opportunity to review the Government's evidence; and/or request in writing an extension of time for response, stating the specific reasons why such an extension is necessary. Alternatively, the alien may, in writing, choose to accept immediate issuance of a Final Administrative Deportation Order. The deciding Service officer may extend the time for response for good cause shown. A request for extension of time for response will not automatically extend the period for the response. The alien will be permitted to file a response outside the prescribed period only if the deciding Service officer permits it. The alien must send the response to the deciding Service officer at the address provided in the Notice of Intent.

(2) *Nature of rebuttal or request to review evidence.* (i) If an alien chooses to rebut the allegations contained in the Notice, the alien's written response must indicate which finding(s) are being challenged and should be accompanied by affidavit(s), documentary information, or other specific evidence supporting the challenge. If the alien asserts that he or she is entitled to statutory relief from deportation, the alien also should include with the response a completed and signed application designed for the relief sought.

(ii) If an alien's written response requests the opportunity to review the Government's evidence, the Service shall serve the alien with a copy of the evidence in the record of proceeding upon which the Service is relying to support the charge. The alien may, within ten (10) calendar days following service of the Government's evidence (thirteen (13) calendar days if service is by mail), furnish a final response in accordance with paragraph (c)(1) of this section. If the alien's final response is a rebuttal of the allegations, such a final response should be accompanied by affidavit(s), documentary information, or other specific evidence supporting the challenge. If the alien asserts that he or she is entitled to statutory relief from deportation, the alien also should include with the final response a completed and signed application designed for the relief sought.

(d) *Determination by deciding Service officer.* (1) *No response submitted or concession of deportability.* If the deciding Service officer does not receive

a timely response and the evidence in the record of processing establishes deportability by clear, convincing, and unequivocal evidence, or if the alien concedes deportability, then the deciding Service officer shall issue and cause to be served upon the alien a Final Administrative Deportation Order that states the reasons for the deportation decision. The alien may knowingly and voluntarily waive in writing the 30-day waiting period before execution of the final order of deportation provided in paragraph (f) of this section.

(2) *Response submitted.* (i) *Insufficient rebuttal; no prima facie claim or genuine issue of material fact:* If the alien timely submits a rebuttal to the allegations, but the deciding Service officer finds that deportability is established by clear, convincing, and unequivocal evidence in the record of proceeding, and that the alien has not demonstrated a prima facie claim of eligibility for relief from deportation under the Act, the deciding Service officer shall issue and cause to be served upon the alien a Final Administrative Deportation Order that states the reasons for the deportation decision.

(ii) *Additional evidence required.* (A) If the deciding Service officer finds that the record of proceeding, including the alien's timely rebuttal, raises a genuine issue of material fact regarding the preliminary findings, the deciding Service officer may either obtain additional evidence from any source, including the alien, or cause to be issued an order to show cause to initiate deportation proceedings under section 242(b) of the Act. The deciding Service officer also may obtain additional evidence from any source, including the alien, if the deciding Service officer deems that such additional evidence may aid the officer in the rendering of a decision.

(B) If the deciding Service officer considers additional evidence from a source other than the alien, that evidence shall be made a part of the record of proceeding, and shall be provided to the alien. If the alien elects to submit a response to such additional evidence, such response must be filed with the Service within ten (10) calendar days of service of the additional evidence (or thirteen (13) calendar days if service is by mail). If the deciding Service officer finds, after considering all additional evidence, that deportability is established by clear, convincing, and unequivocal evidence in the record of proceeding, and that the alien does not have a prima facie claim of eligibility for relief from deportation under the Act, the deciding Service officer shall issue and cause to be served upon the alien a Final Administrative Deportation Order that states the reasons for the deportation decision.

(iii) *Statutory eligibility for relief; conversion to proceedings under section 242(b) of the Act.* If the deciding Service officer finds that the alien is not amenable to deportation under section 242A(b) of the Act or has presented a prima facie claim of statutory eligibility for a specific form of relief from deportation, the deciding Service officer shall terminate the expedited proceedings under section 242A(b) of the Act, and shall, where appropriate, cause to be issued an order to show cause for the purpose of initiating an Immigration Judge proceeding under section 242(b) of the Act.

(3) *Termination of proceedings by deciding Service officer.* Only the deciding Service officer may terminate proceedings under section 242A(b) of the Act, in accordance with this section.

(e) *Proceedings commenced under section 242(b) of the act.* In any proceeding commenced under section 242(b) of the Act, if it appears that the respondent alien is subject to deportation pursuant to section 242A(b) of the Act, the Immigration Judge may, upon the Service's request, terminate the case and, upon such termination, the Service may commence administrative proceedings under section 242A(b) of the Act. However, in the absence of any such request, the Immigration Judge shall complete the pending proceeding commenced under section 242(b) of the Act.

(f) *Executing final deportation order of deciding Service officer.* (1) *Time of execution.* Upon the issuance of a Final Administrative Deportation Order, the Service shall issue a warrant of deportation in accordance with 8 CFR 243.2; such warrant shall be executed no sooner than 30 calendar days after the date the Final Administrative Deportation Order is issued, unless the alien knowingly, voluntarily and in writing waives the 30-day period. The 72-hour provisions of § 243.3(b) of this chapter shall not apply.

(2) *Country to which alien is to be deported.* The deciding Service officer shall designate the country of deportation in the manner prescribed by section 243(a) of the Act.

(g) *Arrest and detention.* At the time of issuance of a Notice of Intent or at any time thereafter and up to the time the alien becomes the subject of a warrant of deportation, the alien may be arrested and taken into custody under the authority of a warrant of arrest issued by an officer listed in § 242.2(c)(1) of this chapter. Pursuant to section 242(a)(2)(A) of the Act, the deciding Service officer shall not release an alien who has not been lawfully admitted. Pursuant to section 242(a)(2)(B) of the Act, the deciding Service officer may release an alien who has been lawfully admitted if, in accordance with § 242.2(h) of this chapter, the alien demonstrates that he or she is not a threat to the community and is likely to appear at any scheduled hearings. The decision of the deciding Service officer concerning custody or bond shall not be administratively appealable during proceedings initiated under section 242A(b) of the Act and this section.

(h) *Record of proceeding.* The Service shall maintain a record of proceeding for judicial review of the Final Administrative Deportation Order sought by any petition for review. The record of proceeding shall include, but not necessarily be limited to: the charging document (Notice of Intent); the Final Administrative Deportation Order (including any supplemental memorandum of decision); the alien's response, if any; all evidence in support of the charge; and any admissible evidence, briefs, or documents submitted by either party respecting deportability or relief from deportation.

PART 299—IMMIGRATION FORMS

3. The authority citation for part 299 continues to read as follows:

Authority: 8 U.S.C. 1101, 1103; 8 CFR part 2.

4. Section 299.1 is amended by adding the entries for Forms "I–851" and "I–851A" to the listing of forms, in proper numerical sequence, to read as follows:

§ 299.1 Prescribed forms.

* * * * *

Form No.	Edition date	Title
*	*	* * *
I–851	04–06–95	Notice of Intent to Issue Final Administrative Deportation Order.
I–851A	04–06–95	Final Administrative Deportation Order.
*	*	* * *

Dated: August 17, 1995.

Janet Reno,

Attorney General.

[FR Doc. 95–20946 Filed 8–23–95; 8:45 am]

BILLING CODE 4410–01–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 95–ANE–40; Amendment 39–9345; AD 95–15–51]

Airworthiness Directives; Pratt and Whitney Model JT8D–9A Turbofan Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule, request for comments.

SUMMARY: This document publishes in the **Federal Register** an amendment adopting Airworthiness Directive (AD) T95–15–51 that was sent previously to all known U.S. owners and operators of Pratt and Whitney (PW) Model JT8D–9A engines by individual telegrams. This AD requires inspection, and replacement, if necessary, of suspect 7th through 12th stage HPC disks. This amendment is prompted by a report of an uncontained engine failure during takeoff. The actions specified by this AD are intended to prevent an uncontained HPC disk failure and damage to the aircraft.

DATES: Effective September 8, 1995, to all persons except those persons to whom it was made immediately effective by telegraphic AD T95–15–51, issued July 10, 1995, which contained the requirements of this amendment.

Comments for inclusion in the Rules Docket must be received on or before October 23, 1995.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), New England Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 95–ANE–40, 12 New England Executive Park, Burlington, MA 01803–5299.

FOR FURTHER INFORMATION CONTACT: Mark A. Rumizen, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803–5299; telephone (617) 238–7137, fax (617) 238–7199.

SUPPLEMENTARY INFORMATION: On July 10, 1995, the Federal Aviation Administration (FAA) issued telegraphic airworthiness directive (AD) T95–15–51, applicable to certain Pratt & Whitney (PW) Model JT8D–9A turbofan engines, which requires inspection, and replacement, if necessary, of suspect 7th through 12th stage high pressure compressor (HPC) disks. That action was prompted by a report that on June 8, 1995, a PW JT8D–9A engine, installed on a McDonnell Douglas DC–9–32 aircraft, experienced an uncontained engine failure during takeoff at the William B. Hartsfield International Airport in Atlanta, Georgia. After the engine failure, the takeoff was aborted and the aircraft was stopped on the runway. Engine fragments penetrated the cabin, struck a fuel line, and initiated a fire that destroyed the aircraft. The FAA's on-going investigation has revealed that the 7th stage HPC disk failed due to a fatigue crack that originated at a corrosion pit in a shielding hole. The aircraft records showed that the engine was one of a total of 24 acquired from Turk Hava Yollari (THY), a Turkish domestic and international airline that also operates a PW JT8D engine overhaul and maintenance facility. The FAA has determined that THY may not have performed the inspection of the subject disk in accordance with all practices and procedures specified by the FAA and PW. This condition, if not corrected, could result in an uncontained HPC disk failure and damage to the aircraft.

Since the unsafe condition described is likely to exist or develop on other engines of the same type design, the FAA issued Telegraphic AD T95–15–51 to prevent an uncontained HPC disk failure and damage to the aircraft. The AD requires inspection, and replacement, if necessary, of suspect 7th through 12th stage HPC disks.

Since it was found that immediate corrective action was required, notice and opportunity for prior public comment thereon were impracticable and contrary to the public interest, and good cause existed to make the AD effective immediately by individual telegrams issued on July 10, 1995, to all known U.S. owners and operators of engines. These conditions still exist, and the AD is hereby published in the **Federal Register** as an amendment to Section 39.13 of part 39 of the Federal Aviation Regulations (14 CFR part 39) to make it effective to all persons.

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES.** All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 95–ANE–40." The postcard will be date stamped and returned to the commenter.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and is not a "significant regulatory action" under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 USC 106(g), 40101, 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

95–15–51 Pratt and Whitney: Amendment 39–9345. Docket 95–ANE–40

Applicability: Pratt and Whitney (PW) Model JT8D–9A turbofan engines identified by the following Serial Numbers: 656953, 656981, 657299, 657308, 657607, 657608, 657612, 666862, 666868, 666906, 666912, 666915, 666948, 666955, 666957, 666967, 666973, 666987, 667136, 667137, 667143, 667154, and 667165. These engines are installed on but not limited to Boeing 727 and 737 series, and McDonnell Douglas DC–9 series aircraft.

Note: This airworthiness directive (AD) applies to each engine identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For engines that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must use the authority provided in paragraph (d) to request approval from the Federal Aviation Administration (FAA). This approval may address either no action, if the current configuration eliminates the unsafe condition, or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any engine from the applicability of this AD.

Compliance: Required as indicated, unless accomplished previously.

To prevent an uncontained high pressure compressor (HPC) disk failure and damage to the aircraft, accomplish the following:

(a) For engines that contain any 7th through 12th stage HPC disk that has accumulated 2,900 or more cycles in service (CIS) on the effective date of this AD since HPC disk inspection performed by Turk Hava Yollari (THY), visually inspect each 7th through 12th stage HPC disk within 10 days, or 100 CIS after the effective date of this AD, whichever occurs first, for evidence of corrosion pitting and cracks in accordance with PW JT8D Engine Manual, Part Number (P/N) 481672, Section 72–36–41 through –46, as applicable. Pay particular attention to the inspection of the bolt holes, and shielding holes, as applicable. Replace all corroded or cracked disks with a serviceable part prior to further flight.

(b) For engines that contain any 7th through 12th stage HPC disk that has accumulated less than 2,900 CIS on the effective date of this AD since HPC disk inspection performed by THY, visually inspect each 7th through 12th stage HPC disk prior to the accumulation of 3,000 CIS since HPC inspection performed by THY for evidence of corrosion pitting and cracks in accordance with PW JT8D Engine Manual, P/N 481672, Section 72–36–41 through –46, as applicable. Pay particular attention to the inspection of the bolt holes, and shielding holes, as applicable. Replace all corroded or cracked disks with a serviceable part prior to further flight.

(c) No AD action is required for those engines that contain 7th through 12th stage HPC disks that were all inspected by an FAA-approved repair station after the last 7th through 12th stage HPC disk inspection performed by THY.

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Engine Certification Office. The request should be forwarded through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Engine Certification Office.

Note: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the Engine Certification Office.

(e) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the aircraft to a location where the requirements of this AD can be accomplished.

(f) This amendment becomes effective September 8, 1995, to all persons except those persons to whom it was made immediately effective by telegraphic AD T95–15–51, issued July 10, 1995, which contained the requirements of this amendment.

Issued in Burlington, Massachusetts, on August 15, 1995.

Jay J. Pardee,

Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 95–20852 Filed 8–23–95; 8:45 am]

BILLING CODE 4910–13–U

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14 CFR Part 95

[Docket No. 28305; Amdt. No. 391]

IFR Altitudes; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts miscellaneous amendments to the required IFR (instrument flight rules) altitudes and changeover points for certain Federal airways, jet routes, or direct routes for which a minimum or maximum en route authorized IFR altitude is prescribed. This regulatory action is needed because of changes occurring in the National Airspace System. These changes are designed to provide for the safe and efficient use of the navigable airspace under instrument conditions in the affected areas.

EFFECTIVE DATE: 0901 UTC, September 14, 1995.

FOR FURTHER INFORMATION CONTACT: Paul J. Best, Flight Procedures Standards Branch (AFS–420), Technical Programs Division, Flight Standards Service Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267–8277.

SUPPLEMENTARY INFORMATION: This amendment to part 95 of the Federal Aviation Regulations (14 CFR part 95) amends, suspends, or revokes IFR altitudes governing the operation of all aircraft in flight over a specified route or any portion of that route, as well as the changeover points (COPs) for Federal airways, jet routes, or direct routes as prescribed in part 95.

The Rule

The specified IFR altitudes, when used in conjunction with the prescribed changeover points for those routes, ensure navigation aid coverage that is adequate for safe flight operations and free of frequency interference. The reasons and circumstances that create the need for this amendment involve matters of flight safety and operational efficiency in the National Airspace System, are related to published aeronautical charts that are essential to the user, and provide for the safe and efficient use of the navigable airspace. In addition, those various reasons or circumstances require making this amendment effective before the next scheduled charting and publication date of the flight information to assure its timely availability to the user. The effective date of this amendment reflects those considerations. In view of the close and immediate relationship between these regulatory changes and safety in air commerce, I find that notice and public procedure before adopting this amendment are impracticable and contrary to the public interest and that good cause exists for making the amendment effective in less than 30 days. The FAA has determined that this regulation only involves an established

body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current.

It, therefore—(1) Is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 95

Airspace, Navigation (air)

Issued in Washington, DC on August 15, 1995.

Thomas C. Accardi,

Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, part 95 of the Federal Aviation Regulations (14 CFR part 95) is amended as follows effective at 0901 UTC,

PART 95—[AMENDED]

1. The authority citation for part 95 is revised to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113; 49 U.S.C. 106(g) (Revised Pub. L. 97–449, January 12, 1983); and 14 CFR 11.49(b)(2).

2. Part 95 is amended to read as follows:

REVISIONS TO MINIMUM ENROUTE IFR ALTITUDES AND CHANGEOVER POINTS

[Amendment 391 Effective Date, September 14, 1995]

From	To	MEA
§ 95.6026 VOR Federal Airway 26 Is Amended To Read In Part		
Huron, SD VORTAC *3200—MOCA	Obitt, SD FIX	*4000
§ 95.6033 VOR Federal Airway 33 Is Amended To Read In Part		
Faged, VA FIX	Colin, VA FIX	4000
§ 95.6181 VOR Federal Airway 181 Is Amended To Read In Part		
Sioux Falls, SD VORTAC *3300—MOCA	Obitt, SD FIX	*4000
Obitt, SD FIX *3100—MOCA	Watertown, SD VORTAC	*4000
§ 95.6220 VOR Federal Airway 220 Is Amended To Read In Part		
Sioux Falls, SD VORTAC *3200—MOCA	Watertown, SD VORTAC	*4000

From	To	MEA	MAA
§ 95.7505 Jet Route No. 505 Is Amended To Read In Part			
Seattle, WA VORTAC	U.S. Canadian Border	#24000	45000

#MEA is established with a gap in navigation signal coverage.

Airway segment		Changeover points	
From	To	Distance	From
§ 95.8005 Jet Routes Changeover Points. Is Amended by Adding			
Seattle, WA VORTAC	Cranbrook, Canada VOR/DME	108	Seattle.

[FR Doc. 95–21015 Filed 8–23–95; 8:45 am]
BILLING CODE 4910–13–M

14 CFR Part 97

[Docket No. 28298; Amdt. No. 1679]

Standard Instrument Approach Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, addition of new obstacles, or changes in air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: An effective date for each SIAP is specified in the amendatory provisions.

Incorporation by reference-approved by the Director of the Federal Register on December 31, 1980, and reapproved as of January 1, 1982.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination—

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591;

2. The FAA Regional Office of the region in which the affected airport is located; or

3. The Flight Inspection Area Office which originated the SIAP.

For Purchase—Individual SIAP copies may be obtained from:

1. FAA Public Inquiry Center (APA–200), FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591; or

2. The FAA Regional Office of the region in which the affected airport is located.

By Subscription—Copies of all SIAPs, mailed once every 2 weeks, are for sale by the Superintendent of Documents,

U.S. Government Printing Office, Washington, DC 20402.

FOR FURTHER INFORMATION CONTACT: Paul J. Best, Flight Procedures Standards Branch (AFS–420), Technical Programs Division, Flight Standards Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267–8277.

SUPPLEMENTARY INFORMATION: This amendment to part 97 of the Federal Aviation Regulations (14 CFR part 97) establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs). The complete regulatory description of each SIAP is contained in official FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and § 97.20 of the Federal Aviation Regulations (FAR). The applicable FAA Forms are identified as FAA Forms 8260–3, 8260–4, and 8260–5. Materials incorporated by reference are available for examination or purchase as stated above.

The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained in FAA form documents is unnecessary. The provisions of this amendment state the affected CFR (and FAR) sections, with the types and effective dates of the SIAPs. This amendment also identifies the airport, its location, the procedure identification and the amendment number.

The Rule

This amendment to part 97 is effective upon publication of each separate SIAP as contained in the transmittal. Some SIAP amendments may have been previously issued by the FAA in a National Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for some SIAP amendments may require making them effective in less than 30 days. For the remaining SIAPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Approach Procedures (TERPS). In developing these SIAPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs and safety in air commerce, I find that notice and public procedure before adopting these SIAPs are impracticable and contrary to the public interest and, where applicable, that good cause exists for making some SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air traffic control, Airports, Navigation (air).

Issued in Washington, DC on August 11, 1995.

Thomas C. Accardi,

Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, part 97 of the Federal Aviation Regulations (14 CFR part 97) is amended by establishing, amending, suspending, or revoking Standard Instrument Approach Procedures, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

1. The authority citation for part 97 is revised to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120, 44701; and 14 CFR 11.49(b)(2).

2. Part 97 is amended to read as follows:

§§ 97.23, 97.25, 97.27, 97.29, 97.31, 97.33, 97.35 [Amended]

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, ISMLS, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, identified as follows:

*** * * Effective September 14, 1995**

Searcy, AR, Searcy Muni, NDB OR GPS RWY 1, Amdt 3
Sacramento, CA, Sacramento Metropolitan, ILS RWY 16L, Orig
Jacksonville, FL, Craig Muni, ILS RWY 32, Amdt 3
Meade, KS, Meade Muni, NDB RWY 17, Amdt 1, CANCELLED
Odenton, MD, Col. William F. (Shorty) Tipton, NDB or GPS RWY 10, Orig
Marquette, MI, Marquette County, ILS RWY 8, Amdt 10
Marquette, MI, Marquette County, LOC BC RWY 26, Amdt 9
Cleburne, TX, Cleburne Muni, VOR/DME RNAV OR GPS RWY 15, Amdt 3
Cleburne, TX, Cleburne Muni, VOR/DME RNAV OR GPS RWY 33, Amdt 4
Rice Lake, WI, Rice Lake Muni, NDB RWY 36, Amdt 7, CANCELLED
Rice Lake, WI, Rice Lake Muni, VOR or GPS RWY 36, Amdt 1, CANCELLED
Rice Lake, WI, Rice Lake Muni, VOR or GPS RWY 18, Amdt 1, CANCELLED
Rice Lake, WI, Rice Lake Regional—Carl's Field, NDB RWY 19, Orig

*** * * Effective October 12, 1995**

Dunnellon, FL, Dunnellon, VOR/DME RWY 23, Amdt 1
Sandpoint, ID, Dave Wall Field, LOC/DME–A, Orig
Sandpoint, ID, Dave Wall Field, NDB/DME–C, Orig
Coatsville, PA, Chester County G. O. Carlson, ILS RWY 29, Amdt 6
Langhorne, PA, Buehl Field, VOR RWY 6, Amdt 6A, CANCELLED

*** * * Effective November 9, 1995**

Grants Pass, OR, Grants Pass, GPS–A, Orig
Lakeview, OR, Lake County, GPS RWY 34, Orig
Laredo, TX, Laredo Intl, VOR/DME OR TACAN OR GPS RWY 14, Amdt 9
Laredo, TX, Laredo Intl, LOC BC RWY 35L, Amdt 1
Friday Harbor, WA, Friday Harbor, GPS RWY 34, Orig

Note: Portland, OR, Portland Intl, LOC BC RWY 10L, AMDT 14, published in TL 95–15 with a cancellation date of 20 JUL 95 is rescinded. The LOC BC RWY 10L, Amdt 14 will remain in effect until further notice.

Note: Reference TL95–14 dated June 16, 1995 . . . The following procedures were mentioned in the index but not included in the transmittal package:
Cleburne, TX, Cleburne Muni, VOR/DME RNAV OR GPS RWY 15, Amdt 3

Cleburne, TX, Cleburne Muni, VOR/DME RNAV OR GPS RWY 33, Amdt 4

Note: The FAA published an Amendment in Docket No. 28286, Amdt No. 1677 to Part 97 of the Federal Aviation Regulations (VOL 60 FR No. 151 Page 40071; dated Monday August 7, 1995) under Section 97.23 effective 14 SEP 95 which is hereby amended as follows:

Jacksonville, FL. Craig Muni, should read VOR or GPS Rwy 32, Amdt 2, CANCELLED

Note: The FAA published an Amendment in Docket No. 28266, Amdt No. 1674 to Part 97 of the Federal Aviation Regulations (VOL 60 FR No. 136 Page 36349; dated Monday July 17, 1995) under Section 97.27 effective 14 SEP 95, which is hereby amended as follows:

Loris, SC. Twin City, should read NDB or GPS Rwy 26, Amdt 2, CANCELLED

[FR Doc. 95–21014 Filed 8–23–95; 8:45 am]
BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. 93N–0027]

Neurological Devices; Effective Date of Requirement for Premarket Approval of Cranial Electrotherapy Stimulators

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the cranial electrotherapy stimulator (CES), a medical device. This action is being taken under the Medical Devices Amendments Act of 1976. Commercial distribution of this device must cease, unless a manufacturer or importer has filed with FDA a PMA for its version of the cranial electrotherapy stimulator device within 90 days of the effective date of this regulation.

EFFECTIVE DATE: August 24, 1995.

FOR FURTHER INFORMATION CONTACT: Janine M. Morris, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8517.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 4, 1979 (44 FR 51770), FDA published § 882.5800 (21 CFR 882.5800) classifying the CES into class III (premarket approval). Section 882.5800 applies to (1) Any CES that was in commercial distribution before May 28, 1976, the date of enactment of the Medical Devices Amendments of 1976 (the amendments) (Pub. L. 94–295), and (2) any device that FDA has found to be substantially equivalent to the CES and that has been marketed on or after May 28, 1976.

In the **Federal Register** of August 31, 1993 (58 FR 45865), FDA published a proposed rule to require the filing under section 515(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(b)) of a PMA or a notice of completion of a PDP for the CES. In accordance with section 515(b)(2)(A) of the act, FDA included in the preamble to the proposal the agency's proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the evice to meet the premarket approval requirements of the act, and the benefits to the public from use of the device (58 FR 45865 at 45867). The August 31, 1993, proposed rule also provided an opportunity for interested persons to submit comments on the proposed rule and the agency's proposed findings. Under section 515(b)(2)(B) of the act (21 U.S.C. 360e(b)(2)(B)), FDA also provided an opportunity for interested persons to request a change in the classification of the device based on new information relevant to its classification. Any petition requesting a change in the classification of the cranial electrotherapy stimulator was required to be submitted by September 15, 1993. The comment period closed on November 1, 1993.

FDA received two petitions requesting a change in the classification of the device from class III to class II. FDA reviewed the petitions and found them deficient based on the lack of new information that was relevant to the device's classification. Each petitioner was sent a deficiency letter dated February 4, 1994, requiring a response to the reported deficiencies. Both petitions were deemed closed August 23, 1994, based on the petitioners' lack of response.

II. Summary and Analysis of Comments and FDA's Response

The comments addressed issues relating to valid scientific studies pertaining to behavioral science and risks associated with the use of the CES device. (See 58 FR 46865 at 46867 and 46868 for a discussion of the benefits and risks of the CES device.) The comments are summarized as follows:

1. A few comments were concerned that FDA's proposed findings were not evaluated by qualified behavioral scientists who could read and understand the literature. The comments noted that several references cited in the proposal do not meet the behavioral science criteria of a reliable "dependent vector" and would not have appeared in a knowledgeable behavioral science review. The comments further noted that the review conducted by a National Research Council panel on Electrosleep and Electroanesthesia did not include any behavioral scientists, and 90 percent of the studies reviewed by the panel were behavioral science studies.

FDA recognizes that the proposed rule did not present critical reviews of all the literature. FDA also agrees that many of the studies in the literature do not meet the minimum criteria of behavioral science review. FDA has cited these publications only to show that the valid scientific evidence that is required to demonstrate the safety and effectiveness of CES devices in the form of well-controlled clinical studies is not presented in published data. FDA believes the data presented in the literature are not sufficient to fulfill the requirements of valid scientific evidence. Some of the studies were controlled studies that may have indicated some effect; however, information in the literature does provide a reasonable assurance that the device produces a reliable, repeated treatment effect. The few studies that presented controlled data were studying different clinical endpoints on a small number of patients so that an effect could not be established.

2. One comment said that the risks to health identified in the proposed rule (worsening of the condition being treated, potential risk of seizure, skin irritation, and blurred vision) appear exaggerated, as discussed below:

a. The comments said the risk of worsening of the condition being treated could easily be controlled by informing the patient when he or she should expect the treatment effect to occur. The comments stated that, for the case of a depressed patient, the perceived worsening effect is due to the patient's expectations for immediate effect.

FDA agrees that the risk of worsening of the condition being treated might be controlled. However, until the CES is proved effective through valid scientific evidence, the agency believes that patients should not be subjected to the risk of worsening their condition by an ineffective treatment.

b. One individual commented on personal involvement in a number of studies comprising a total of 800 patients where 26 of the patients were

known seizure patients, and no seizures were reported.

FDA observes that research relating electrical stimulation to epileptiform seizures has been studied only at higher levels of stimulation. The risk associated with the lower levels of electrical stimulation used with CES has not been systematically studied.

c. The same comment stated that over 10,000 users of CES devices manufactured in the United States have never reported a burn.

FDA agrees that there have been few reports of burns associated with CES devices; however, the device has the potential for causing burns. This risk appears to be unreasonable in the absence of established device effectiveness.

d. One comment stated that blurred vision as a risk factor should not be considered because of a misconception about how electrodes are placed. The comment states that placing electrodes over the eyes was an early Russian technique that was abandoned in the United States by 1970.

FDA agrees that risks, such as blurring of vision, could be minimized; however, the existence of these potential risks is cited as evidence that premarket approval is appropriate, particularly in the absence of established device effectiveness. FDA believes that it is not clear whether placing of electrodes is the sole cause of blurred vision.

3. One comment stated that the Weschler Adult Intelligence Scale and the Beta Examination Intelligence Quotient test are proven psychological measures of human intelligence.

FDA intended to convey that many of the study measures of treatment effect are subjective and may not be considered valid as sole measures. However, FDA believes that it should review the validity of other measures including psychological measures, in the form of a PMA to provide reasonable assurance of the safety and effectiveness of this device.

4. Another comment stated that the lack of followup data is not an adequate reason to invalidate a study reviewed in the literature because most of the studies were conducted by researchers who were not interested in study followup.

FDA agrees that the absence of followup data should not be the sole reason not to accept clinical data on CES. However, FDA believes followup data are important in evaluating the long-term effects of CES devices and are components that should be considered to determine the safety and effectiveness of this device.

5. One comment said that studies published by behavioral scientists include data that meet a statistical confidence of 95 percent and that their probability tables take into consideration whether the population is 5 or 500 subjects. The comment further stated that FDA was incorrect to say that the small sample size used in the study conducted by M. F. Weiss (58 FR 45865 at 45870 (Ref. 32)) would not demonstrate statistical significance for treatment effect.

FDA believes that there was not sufficient information to determine that the Weiss study demonstrated a statistically significant effect. In addition, a single study of 10 subjects is not adequate to support a repeatable effect for the purposes of determining the safety and effectiveness of this device.

6. One comment stated that FDA's review of the study by F. Ellison (58 FR 45865 at 45870 (Ref. 5)) in the proposal) was not complete. The comment said that Ellison's findings were that a single day of treatment was too short a duration to control withdrawal symptoms effectively and that 2 days of treatment were effective.

FDA agrees that the purpose of the second experiment was to determine if 24 hours of treatment was sufficient to show an effect and that the purpose of the first experiment was to determine if there was a treatment effect after 48 hours. However, FDA believes the conclusions made in Ellison's study were based on the premise that CES was effective treatment. Based on the data that were presented, FDA could not draw the same conclusions.

7. One comment stated that the references cited by V. Krauthamer (58 FR 45865 at 45870 (Refs. 14 and 15)) did not support the concept that electrical stimulation by CES is harmful.

FDA did not cite these references to show that CES is harmful. The references by Krauthamer addressing the risk of potential adverse effects from electrical stimulation of the brain were cited to show that the effects of electrical stimulation are still unknown and have not been systematically evaluated, particularly for lower levels of stimulation.

8. Several comments asserted that FDA did not review all the data available on CES devices. One comment referenced to four randomized controlled trials that were not cited in the references listed in the proposed rule. Another comment reported on data submitted to FDA in PMA's.

FDA attempted to review all the published data available in the United States, and referenced in the proposed rule those the agency believes to be the most significant studies. Because the comments did not include copies of the four studies referred to, or citations to them, FDA cannot determine whether these studies were reviewed. Regarding the data submitted to FDA under a PMA, these data are considered proprietary information and are not intended for public release. However, they may be submitted as part of a PMA in response to this final rule.

9. One comment submitted by a physician endorsed treating patients with addictions, and reported that CES has been a helpful adjunctive therapy in the treatment of psychoactive drug withdrawal syndromes.

FDA believes that the comment that CES is helpful as an adjunctive therapy in drug withdrawal is anecdotal and does not represent valid scientific evidence.

10. One comment objected to the fact that FDA did not make available to the public all references cited in the proposed rule at the Dockets Management Branch and requested an extension of the comment period for an additional 2 months.

FDA considered comments received after the close of the official comment period and believes, therefore, that there was a sufficient comment period in which manufacturers, physicians, consumer organizations, researchers, and individuals could comment and present new information to determine whether FDA has a reasonable basis to require PMA's or notices of completed PDP's for the CES. Copies of the references cited were put on display at the Dockets Management Branch within 7 days of the proposed rule's publication.

11. Two comments offered recommendations regarding the design of future studies to ensure high quality. One comment stated that published literature on CES devices has not shown through valid scientific evidence that these devices are effective.

FDA agrees that the current literature is not adequate to support the safety and effectiveness of CES's and welcomes all recommendations for future studies to determine the safety and effectiveness of CES's.

12. One comment stated that FDA's decision to require the submission of PMA's or notices of completed PDP's for CES devices is too costly and too time consuming.

FDA has examined the economic consequences of the rule. The agency believes that only a small number of firms will be affected by this final rule. FDA's mission to protect the public health requires that the safety and

effectiveness of these medical devices must be demonstrated.

FDA believes that the comments presented insufficient information on which to base special controls that could assure safety and effectiveness. The agency concludes that its proposed findings and its conclusion discussed in the preamble to the proposed rule are appropriate. Accordingly, FDA is issuing a final regulation requiring premarket approval of the CES under section 515(b)(3) of the act.

III. Final Rule

Under section 515(b)(3) of the act, FDA is adopting the findings as published in the preamble to the proposed rule and is issuing this final rule to require premarket approval of the generic type of device, the cranial electrotherapy stimulator device, by revising § 882.5800(c).

Under the final rule, a PMA or a notice of completion of a PDP is required to be filed with FDA within 90 days of the effective date of this regulation for any CES device that was in commercial distribution before May 28, 1976, or any device that FDA has found to be substantially equivalent to such a device on or before November 22, 1995. An approved PMA or declared completed PDP is required to be in effect for any such device on or before 180 days after FDA files the application. Any other CES device that was not in commercial distribution before May 28, 1976, or that FDA has not found, on or before November 22, 1995, to be substantially equivalent to a CES device that was in commercial distribution before May 28, 1976, is required to have an approved PMA or declared completed PDP or declared completed in effect before it may be marketed.

If a PMA or notice of completion of a PDP for a CES device is not filed on or before November 22, 1995, that device will be deemed adulterated under section 501(f)(1)(A) of the act (21 U.S.C. 351(f)(1)(A)), and commercial distribution of the device will be required to cease immediately. The device may, however, be distributed for investigational use, if the requirements of the investigational device exemption (IDE) regulations (21 CFR part 812) are met.

Under § 812.2(d) (21 CFR 812.2(d)) of the IDE regulations, FDA hereby stipulates that the exemptions from the IDE requirements in § 812.2(c)(1) and (c)(2) will no longer apply to clinical investigations of the CES device. Further, FDA concludes that investigational CES devices are significant risk devices as defined in § 812.3(m) and advises that as of the effective date of § 882.5800(c), requirements of the IDE regulations regarding significant risk devices will apply to any clinical investigation of a CES device. For any CES device that is not subject to a timely filed PMA or notice of completion of a PDP or notice of completion of a PDP, an IDE must be in effect under § 812.20 on or before November 22, 1995, or distribution of the device for investigational purposes must cease. FDA advises all persons currently sponsoring a clinical investigation involving the CES device to submit an IDE application to FDA no later than October 23, 1995, to avoid the interruption of ongoing investigations.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) and (e)(4) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because PMA's for this device could have been required by FDA as early as March 4, 1982, and because firms that distributed this device prior to May 28, 1976, or whose device has been found to be substantially equivalent to the CES in commercial distribution before May 28, 1976, will be permitted to continue marketing cranial electrotherapy stimulators during FDA's review of the PMA or notice of completion of the PDP, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

List of Subjects in 21 CFR Part 882

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 882 is amended as follows:

PART 882—NEUROLOGICAL DEVICES

1. The authority citation for 21 CFR part 882 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. Section 882.5800 is amended by revising paragraph (c) to read as follows:

§ 882.5800 Cranial electrotherapy stimulator.

* * * * *

(c) *Date a PMA or notice of completion of a PDP is required.* A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before November 22, 1995, for any cranial electrotherapy stimulator that was in commercial distribution before May 28, 1976, or that has on or before November 22, 1995, been found to be substantially equivalent to the cranial electrotherapy stimulator that was in commercial distribution before May 28, 1976. Any other cranial electrotherapy stimulator shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: July 31, 1995.

D. B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 95–20960 Filed 8–23–95; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1952

Approved State Plans for Enforcement of State Standards; Approval of Supplements to the Nevada State Plan

AGENCY: Occupational Safety and Health Administration, Labor.

ACTION: Approval of supplements to the Nevada State Plan.

SUMMARY: This document gives notice of Federal approval of supplements to the Nevada State occupational safety and health plan. These supplements are: Nevada's procedure for issuance of notices of violation in lieu of citations in certain situations; amendments to the Nevada Occupational Safety and Health Act enacted in 1981, 1989 and 1993; the Nevada Field Operations Manual; the Nevada Training and Consultation Section Policies and Procedures Manual; the Nevada Occupational Safety and Health Administration Technical Manual; and a regulation concerning pre-construction conferences.

EFFECTIVE DATE: August 24, 1995.

FOR FURTHER INFORMATION CONTACT: Director, Office of Information and Consumer Affairs, Occupational Safety and Health Administration, Room N3647, 200 Constitution Avenue, N.W., Washington, D.C. 20210. Telephone: (202) 523–8148.

SUPPLEMENTARY INFORMATION:

Background

The Nevada Occupational Safety and Health Plan was approved under section 18(c) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 667(c)) (hereinafter referred to as the Act) and Part 1902 of this chapter on January 4, 1974 (39 FR 1008). Part 1953 of this chapter provides procedures for the review and approval of State change supplements by the Assistant Secretary of Labor for Occupational Safety and Health (hereinafter referred to as the Assistant Secretary).

Description of Supplements

A. Notices of Violation

On October 29, 1980, the State submitted a procedure for issuing notices of violation in lieu of citations for certain other than serious violations. In order to expedite inspections and concentrate resources on serious violations, compliance officers may issue notices of violation for other than serious violations for which monetary penalties would not be proposed. If the employer agrees to abate the violation and not to file a contest, the compliance officer will issue the notice on-site. For serious, willful, repeat and/or failure to abate violations, citations continue to be issued in accordance with established procedures.

Review of the supplement raised several issues which needed to be resolved before approval of the notice of violation procedure. Because the Nevada Occupational Safety and Health Act required that citations be issued where violations were identified, statutory authority for issuance of notices was necessary. In 1981, § 618.465(1)(b) was added to the State's law, allowing for a notice in lieu of a citation for violations which are not serious and which the employer agrees to correct within a reasonable time.

There was also concern that a notice be able to serve as the basis for a future willful, repeat, or failure to abate citation, and that documentation of the violations for which the notice was issued be adequate to serve as the basis for such a citation. The State amended its enforcement regulations to provide that for future proceedings involving a repeat, willful, or failure to abate violation, the notice of violation shall have the same effect as if a citation has originally been issued and become a final order (section 618.6458(9)) and that notices of violations contain all the provisions required for citations (section 618.6458(6)). In addition, the State was asked to ensure that if it is learned following the inspection that a violation for which a notice of violation has been issued is actually a repeat violation, a citation for a repeat violation would be issued. Section 618.6458 of the State's enforcement regulations now provides that a citation may be issued even if a notice has already been issued, and the State's Field Operations Manual directs the compliance officer to check for previous violations upon returning to the office. Finally, the right of employees to contest the reasonableness of the abatement period needed to be established. The State's enforcement regulations (§ 618.6458(6)) now provide that the notice shall inform employees of their right to contest the abatement period. Based on these changes made by the State, the notice of violation procedure is now deemed approvable.

B. Amendments to Nevada Occupational Safety and Health Act

In 1981, 1989 and 1993, the State enacted amendments to its Occupational Safety and Health Act. The 1981 amendments, submitted as a plan supplement on July 10, 1981, made the following changes:

(1) As discussed above, § 618.465(1)(b) was added to allow the State to issue a notice in lieu of a citation for violations which are not serious and which the employer agrees to correct within a reasonable time.

(2) Section 618.415 was revised to delete the legislative authority for temporary variances for other than new standards. As in the Federal program, temporary variances may now only be granted from new standards.

(3) Section 618.585(2) was added to allow the Nevada Occupational Safety and Health Appeals Board to employ legal counsel.

(4) Section 618.625(3) was amended to streamline penalty collection procedures by allowing collection actions to be brought in any court of competent jurisdiction, rather than only the district court.

(5) Section 618.367 was amended to ensure confidentiality to employees making statements to the Division of Occupational Safety and Health, as well as those filing complaints. This section was extensively revised in 1989, as discussed below.

The 1989 amendments, submitted as a plan supplement on October 17, 1989, made the following changes:

(1) Section 618.336 requires the maintenance of specific logs relating to complaints received concerning occupational safety and health violations and their outcomes.

(2) Section 618.341 provides public access to records on complaints, except for confidential information.

(3) Section 618.341(3) provides confidentiality for those employees who file complaints or make statements, even when confidentiality is not specifically requested, as well as for files relating to open cases.

(4) Section 618.370 was amended to clarify that representatives of employees and former employees are entitled to access to any records in the possession of their employers or former employers which indicate their exposure to toxic materials or harmful physical agents. "Representative of an employee or former employee" is defined as an authorized representative of the employee bargaining unit, an attorney, a spouse, parent or child, or a person designated by a court.

(5) Section 618.425 was amended to add health care providers, and government employees whose primary duty is to ensure public safety, such as building inspectors, to those who may file complaints of hazardous working conditions.

(6) Section 618.425 was also amended to allow for oral as well as written complaints, and to require the division to respond to valid complaints of serious violations immediately and of other violations within 14 days.

(7) Section 618.435 provides that an employee who accompanies a compliance officer on the inspection is entitled to be paid for the time spent, but that only one employee may accompany the compliance officer during the inspection.

(8) Section 618.545 was amended to allow the Administrator of the Nevada Division of Occupational Safety and

Health to issue an emergency order to restrain an imminent danger situation.

(9) All maximum monetary penalties in sections 618.645 through 618.705 were doubled. At the time of their enactment, these statutory penalty levels were higher than those contained in the Federal Act. (In 1991, statutory maximum penalties for violations of the State Act were raised again. That increase was approved by OSHA on March 15, 1994 (59 FR 14556).)

The 1993 amendments, submitted on October 27, 1993, reflect a reorganization of the Nevada State government. The previous Division of Enforcement for Industrial Safety and Health and Division of Preventive Safety are now sections in the Division of Industrial Relations of the Department of Business and Industry.

C. Field Operations Manual

On December 14, 1989, Nevada submitted its Field Operations Manual in response to a revised Federal Field Operations Manual (CPL 2.45B). The State has submitted revisions to this manual on May 31, 1991, July 5, 1991, December 15, 1992 and June 13, 1994, in response to Changes 1 through 4 of the Federal manual. The Nevada Field Operations Manual is comparable to the Federal manual and has been found to be at least as effective as the Federal manual.

D. Consultation Manual

On August 12, 1987, the State submitted its Training and Consultation Section Policies and Procedures Manual. This manual includes previously approved sections of the State's Field Operations Manual on the conduct of consultation visits to employers. In addition, it incorporates chapters on safety and health program assistance and training by consultants which are nearly identical (with organization changes and adapted to the State's program structure) to Part I of the Federal Consultation Policies and Procedures Manual.

E. Industrial Hygiene Technical Manual

On March 30, 1990, the State submitted notice of its adoption of the Federal OSHA Technical Manual. The State has incorporated a cover sheet indicating that the Federal manual has been adopted for State use, how references to the Federal program in the Federal manual correspond to the State administrative structure, and how it will be applied. In addition, on March 6, 1991, June 22, 1993 and December 16, 1994, the State submitted notice of its adoption of Changes 1, 2 and 3 to the Technical Manual. These changes also incorporate updates to the Federal manual, with appropriate changes to apply to the State's organizational structure.

F. Pre-construction Conferences

On August 20, 1993, Nevada submitted a temporary regulation requiring pre-construction conferences with the Division of Industrial Relations for certain types of construction projects including high rise, structural steel erection, precast concrete erections, cast in place structures above ground level, and tilt-up wall construction. At the conference, the contractor will identify those safety measures which will be utilized to protect employees working on the project. On September 8, 1994, Nevada submitted permanent regulations covering pre-construction conferences.

G. Revised Plan

On October 2, 1992, Nevada submitted a reorganized State plan, incorporating the plan supplements approved herein as well as previously approved plan changes and other supplements still under review.

H. Other Submissions

In addition, on October 17, 1989, the State submitted legislation enacted in 1989 and implementing regulations concerning the licensing and registration of asbestos removal projects. The new procedures require any contractor engaging in asbestos removal work to be licensed by the Division of Occupational Safety and Health and to meet certain training and work practice requirements. The licensing program is administered separately from the Division's occupational safety and health enforcement program. While these provisions are not part of the State plan, and thus activities pursuant to them are not eligible for funding under section 23(g) of the Act, OSHA will monitor these activities to ensure that they do not detract from the State's ability to meet its commitments under the plan.

Location of Supplements for Inspection and Copying

A copy of the plan and the supplements may be inspected and copied during normal business hours at the following locations: Office of the Regional Administrator, Occupational Safety and Health Administration, Room 415, 71 Stevenson Street, San Francisco, California 94105; Director, Division of Occupational Safety and Health, Nevada Division of Industrial Relations, 1370 South Curry Street, Carson City, Nevada 89710; and the Office of the Director of Federal-State Operations, Room N3700, 200 Constitution Avenue, N.W., Washington, D.C. 20210.

Public Participation

A notice was published on April 3, 1981 (46 FR 20229), announcing the submission of the Nevada program for issuance of notices of violation. Interested persons were afforded 30 days to submit written comments or request a hearing concerning the supplement. One comment favoring the program was received.

With regard to the other supplements, under § 1953.2(c) of this chapter, the Assistant Secretary may prescribe alternative procedures to expedite the review process or for any other good cause which may be consistent with applicable law. The Assistant Secretary finds that the legislative amendments, Field Operations Manual, Consultation Manual, Industrial Hygiene Technical Manual and regulations concerning pre-construction conferences are consistent with Federal requirements and with commitments contained in the plan and previously made available for public comment. Good cause is therefore found for approval of these supplements, and further public participation would be unnecessary.

Decision

After careful consideration and extensive review by the Regional and National Offices, the Nevada plan supplements described above are found to be in substantial conformance with comparable Federal provisions and are hereby approved under Part 1953 of this chapter. The decision incorporates the requirements and implementing regulations applicable to State plans generally.

List of Subjects in 29 CFR Part 1952

Intergovernmental relations, Law enforcement, Occupational safety and health.

Signed at Washington, D.C., this 11th day of August, 1995.

Joseph A. Dear,

Assistant Secretary.

Accordingly, 29 CFR Part 1952 is hereby amended as follows:

PART 1952—[AMENDED]

The authority citation for Part 1952 continues to read:

Authority: Secs. 8, 18 Pub. L. 91–596, 84 Stat. 1608 Occupational Safety and Health Act of 1970 (29 U.S.C. 657, 667); Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), or 9–83 (48 FR 35736), as applicable.

2. Paragraphs (b) through (h) are added to § 1952.297 of Subpart W to read as follows:

§ 1952.297 Changes to approved plans.

* * * * *

(b) *Notices of violation.* The State submitted a procedure for issuing notices of violation in lieu of citations for certain other than serious violations which the employer agrees to abate. The procedure as modified was approved by the Assistant Secretary on August 24, 1995.

(c) *Legislation.* The State submitted amendments to its Occupational Safety and Health Act, enacted in 1981, which: provide for notices of violation in lieu of citations for certain other than serious violations; delete the authority for temporary variances for other than new standards; allow the Nevada Occupational Safety and Health Appeals Board to employ legal counsel; allow penalty collection actions to be brought in any court of competent jurisdiction; and ensure confidentiality to employees making statements to the Division of Occupational Safety and Health. Further amendments, enacted in 1989: require the maintenance of specific logs relating to complaints; provide public access to records on complaints, except for confidential information; provide confidentiality for those employees who file complaints or make statements, as well as for files relating to open cases; allow representatives of employees and former employees access to any records which indicate their exposure to toxic materials or harmful physical agents; define representative of employees or former employees; allow health care providers and government employees in the field of public safety, to file complaints; allow for oral complaints; require the division to respond to valid complaints of serious violations immediately and of other violations within 14 days; provide that an employee who accompanies a compliance officer on the inspection is entitled to be paid for the time spent, but that only one employee may accompany the compliance officer during the inspection; allow the Administrator of the Division of Occupational Safety and Health to issue an emergency order to restrain an imminent danger situation; and, double maximum authorized penalty levels. Amendments enacted in 1993 reflect the new State organizational structural by designating the previous Divisions as sections in the Division of Industrial Relations of the Department of Business and Industry. The Assistant Secretary approved these amendments on August 24, 1995.

(d) *Field Operations Manual.* The State's Field Operations Manual, comparable to the Federal Field Operations Manual, through Change 4, was approved by the Assistant Secretary on August 24, 1995.

(e) *Consultation Manual.* The State's Training and Consultation Section Policies and Procedures Manual was approved by the Assistant Secretary on August 24, 1995.

(f) *Occupational Safety and Health Administration Technical Manual.* The State's adoption of the Federal OSHA Technical Manual, through Change 3, with a cover sheet adapting Federal references to the State's administrative structure, was approved by the Assistant Secretary on August 24, 1995.

(g) *Pre-construction conferences.* A State regulations requiring pre-construction conferences with the Division of Industrial Relations for certain types of construction projects was approved by the Assistant Secretary on August 24, 1995.

(h) *Reorganized Plan.* The reorganization of the Nevada plan was approved by the Assistant Secretary on August 24, 1995.

[FR Doc. 95–20863 Filed 8–23–95; 8:45 am]
BILLING CODE 4510–26–M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 925

Missouri Abandoned Mine Land (AML) State Reclamation Plan

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is approving a proposed amendment to the Missouri AML State Reclamation Plan (hereinafter referred to as the "Missouri plan") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). Missouri proposed changes to its statutes, rules, and certain sections of the Missouri plan pertaining to contractor responsibility, exclusion of certain noncoal reclamation sites, reporting requirements, creation of a future reclamation set-aside program, and general reclamation requirements. The amendment is intended to revise the Missouri plan to be consistent and in compliance with the corresponding Federal standards, and to improve operational efficiency.

EFFECTIVE DATE: August 24, 1995.

FOR FURTHER INFORMATION CONTACT: Robert L. Markey, Acting Director, Kansas City Field Office, 934 Wyandotte St., Room 500, Kansas City, Missouri 64105, Telephone: (816) 374–6405.

SUPPLEMENTARY INFORMATION:

I. Background on Title IV of SMCRA

Title IV of SMCRA established an abandoned mine land reclamation (AMLR) program for the purpose of reclaiming and restoring lands and waters adversely affected by past mining. The Secretary of the Interior adopted regulations at 30 CFR 870 through 888 that implement Title IV of SMCRA. The program is funded by a reclamation fee levied on the production of coal.

Title IV provides for State submittal to OSM of an AMLR plan. The Federal regulations at 30 CFR Part 884 specify the content requirements of a State reclamation plan and the criteria for plan approval. Under these regulations, the Secretary reviewed the plans submitted by States and solicited and considered comments of State and Federal agencies and the public. Based upon the comments received, the Secretary determined whether a State had the ability and necessary legislation to implement the provisions of Title IV. After making such a determination, the Secretary decided whether to approve the State program. Approval granted the State exclusive authority to administer its plan. Upon approval of a State plan by the Secretary, the State may submit to OSM, on an annual basis, an application for funds to be expended by that State on specific projects that are necessary to implement the approved plan. Such annual requests are reviewed and approved by OSM in accordance with the requirements of 30 CFR part 886.

The Federal regulations at 30 CFR 884.15 provide that a State may submit to OSM a proposed amendment or revision to its approved reclamation plan. If the amendment or revision changes the objective, scope, or major policies followed by the State in the conduct of its reclamation program, the Director must follow the procedures set out in 30 CFR 884.14 for approval or disapproval of an amendment or revision to the State's AML plan.

Title IV of SMCRA, as enacted in 1977, provided that lands and waters eligible for reclamation were those that were mined or affected by mining and abandoned or inadequately reclaimed prior to August 3, 1977, and for which there was no continuing reclamation responsibility under State, Federal, or

other laws. The Abandoned Mine Reclamation Act of 1990 (Pub. L. 101–508, Title VI, Subtitle A, Nov. 5, 1990, effective Oct. 1, 1991) amended Title V of SMCRA to allow AML funds to be used to reclaim or abate mining-related problems at coal sites where the mining occurred after August 3, 1977. Such coal sites include (1) Interim program sites where mining occurred between August 4, 1977, and the date the Secretary approved a State's regulatory program in accordance with section 503 of SMCRA, and where bond forfeiture proceeds are insufficient for adequate reclamation and (2) bankrupt surety sites where mining occurred between August 4, 1977, and November 5, 1990, and as of November 5, 1990, funds available from the bankruptcy proceedings are not sufficient to provide for adequate reclamation or abatement. New Federal regulations at 30 CFR Subchapter R were adopted to implement the Abandoned Mine Reclamation Act of 1990 amendments to Title IV of SMCRA (see 59 FR 28136, May 31, 1994).

II. Background on the Missouri Plan

On January 29, 1982, the Secretary of the Interior approved the Missouri plan. General background information, including the Secretary's findings, the disposition of comments, and the approval of the Missouri plan can be found in the January 29, 1982, **Federal Register** (47 FR 4253). Subsequent actions concerning Missouri's plan and plan amendments can be found at 30 CFR 925.25.

III. Proposed Amendment

By letter dated November 29, 1995 (administrative record No. AML–MO–89), Missouri submitted a proposed amendment to the Missouri plan pursuant to SMCRA. Missouri submitted the proposed amendment in response to a September 26, 1994, letter (administrative record No. AML–MO–88) that OSM sent to Missouri in accordance with 30 CFR 884.15(d). Missouri proposed to amend its statutes at (1) Revised Statutes of Missouri (RSMo) 444.810.2, rulemaking procedures of the Land Reclamation Commission (Commission) and (2) RSMo 444.915.3, lands and water eligible for expenditures of the abandoned mine reclamation fund. Missouri also proposed to amend its regulations at 10 Code of State Regulations (CSR) 40–9.020(1) (D) and (E), and (3), other coal lands and waters eligible for reclamation activities. In addition, Missouri proposed to amend certain provisions of its AML State Reclamation Plan at (1) Section 884.13(C)(2), project ranking and selection procedures, (2) Section 884.13(D)(3), purchasing and procurement procedures, and (3) Section 884.13(D)(4), accounting procedures.

OSM announced receipt of the proposed amendment in the December 13, 1994, **Federal Register** (59 FR 64176), provided an opportunity for a public hearing or meeting on its substantive adequacy, and invited public comment on its adequacy (administrative record No. AML–MO–91). The public comment period ended on January 12, 1995. At the request of the Missouri Department of Natural Resources, OSM held a public meeting in Jefferson City, Missouri on March 1, 1995. OSM entered a summary of the public meeting into the administrative record (administrative record No. AML–MO–96).

During its review of the proposed amendment, OSM identified concerns relating to the provisions of (1) RSMo 44.915.3(3), reclamation of coal sites where mining occurred between certain dates and the surety company became insolvent, (2) 10 CSR 40–9.020(1) (D) and (E), eligible coal lands and water, and (3) Section 884.13(D)(4) of the Missouri AML State Reclamation Plan, creation of a future reclamation set-aside program. OSM notified Missouri of the concerns by letter dated February 16, 1995 (administrative record No. AML–MO–93).

Missouri responded in a letter dated May 16, 1995, by submitting a revised amendment and additional explanatory information (administrative record No. AML–MO–100). Missouri proposed revisions to and additional explanatory information for (1) RSMo 444.915.3(3), reclamation of insolvent surety coal sites, (2) 10 CSR 40–9.020(1), priorities of eligible coal lands and waters for reclamation and reimbursement for the cost of reclamation, and (3) Section 884.13(D)(4) of the Missouri AML State Reclamation Plan, use of AML State-share funds to establish a future set-aside program in Missouri.

Based upon the revisions to and additional explanatory information for the proposed plan amendment submitted by Missouri, OSM reopened the public comment period in the May 25, 1995, **Federal Register** (60 FR 27708, administrative record No. AML–MO–91). The public comment period ended on January 12, 1995.

IV. Director's Findings

As discussed below, the Director, in accordance with SMCRA and 30 CFR 884.14 and 884.15, finds that the proposed Missouri plan amendment submitted by Missouri on November 29, 1994, and as revised by it and supplemented with additional explanatory information on May 16, 1995, is not inconsistent with SMCRA and is in compliance with the corresponding Federal regulations at 30 CFR Subchapter R. Accordingly, the Director approves the proposed amendment.

1. Nonsubstantive Revisions to Missouri's Statutes, Rules, and Sections of the AML State Reclamation Plan

Missouri proposed revisions to the following previously approved statutes, rules, and sections of the Missouri plan that are nonsubstantive in nature and consist of minor editorial, punctuation, grammatical, and recodification changes (corresponding SMCRA or Federal regulation provisions are listed in parentheses):

RSMo 444.810.1, .1(8), and .1(10), powers of the Commission (sections 413 (a) and (c) of SMCRA),

RSMo 444.915.1(1), expenditures from the abandoned mine reclamation fund (sections 404 and 409 of SMCRA),

RSMo 444.915.2 (4) and (5), [recodification] priorities for expenditures of moneys from the abandoned mine reclamation fund (section 403(a) of SMCRA),

10 CSR 40–9.020(1) (B) and (C), general requirements for reclamation (30 CFR 874.12(b) and (c)),

Section 884.13(c)(2) of the Missouri AML State Reclamation Plan, Figure 1 [deleted] and Figure 2 [recodified] (no counterpart SMCRA or Federal regulation provisions), and

Section 884.13(c)(2), Step 3, No. 8, of the Missouri AML State Reclamation Plan, project evaluation and ranking (no counterpart SMCRA or Federal provisions).

Because the proposed revisions to these previously-approved statutes, rules, and sections of the Missouri AML State Reclamation Plan are nonsubstantive in nature, the Director finds that these proposed statutes, rules, and sections of the ANL State Reclamation Plan are consistent with SMCRA and in compliance with the implementing Federal regulations. Accordingly, the Director approves the proposed revisions.

2. Substantive Revisions to a Missouri Rule and Section of the AML State Reclamation Plan That Are Substantively Identical to the Corresponding Provisions of SMCRA and the Federal Regulations

Missouri proposed revisions to the following rule and section of the Missouri plan that are substantive in nature and contain language that is substantively identical to the requirements of the corresponding

Federal regulations provisions (listed in parentheses):

10 CSR 40–9.020(3)(A), definition of "left or abandoned in either an unreclaimed or inadequately reclaimed condition" (30 CFR 870.5) and

Section 884.13(D)(3) of the Missouri AML State Reclamation Plan, contractor eligibility (30 CFR 874.16 and 875.20).

Because the proposed revisions to this Missouri rule and section of the Missouri AML State Reclamation Plan are substantively identical to the corresponding provisions of the counterpart Federal regulations, the Director finds that they are consistent with SMCRA and in compliance with the Federal regulations. Therefore, the Director approves the proposed revisions.

3. RSMo 444.810.2 Through 444.810.8, Rulemaking Procedures

Missouri proposed the addition of new provisions at RSMo 444.810.2 through 444.810.8 to provide additional administrative procedures for rulemaking. These proposed rulemaking procedures set forth guidelines for processing rules through the Missouri joint committee on administrative rules concurrently with filing a proposed rule with the Secretary of State. The procedures proposed are in addition to those approved in the Missouri plan and do not restrict or require public participation and involvement as required at 30 CFR 884.14(c)(7). They specify internal State review procedures and are not in conflict with or inconsistent with Title IV of SMCRA and the implementing Federal regulations at 30 CFR Subchapter R. Therefore, the Director finds that the proposed additional rulemaking procedures at RSMo 444.810.2 through 444.810.8 are not inconsistent with SMCRA and the Federal regulations. The Director approves the proposed statutes.

4. RSMo 444.915.3, Reclamation of Interim Program and Bankrupt Surety Coal Sites

Missouri proposed to revise RSMo 444.915.3 by adding new language to provide that additional lands and water are eligible for reclamation or drainage abatement expenditures from the abandoned mine reclamation fund. Such lands include those (1) where the surface coal mining operation occurred during the period beginning on August 4, 1977, and ending on or before November 21, 1980 [the date in which the Secretary of the Interior approved Missouri's program pursuant to section 503 of SMCRA], and that funds for reclamation or abatement which are available pursuant to a bond or other form of financial guarantee or from any other source are not sufficient to provide for adequate reclamation or abatement at the site or (2) where the surface coal mining operation occurred during the period beginning on August 4, 1977, and ending on or before *October 1, 1991,* and that the surety of such mining operator became insolvent during such period, and as of *October 1, 1991,* funds immediately available from proceedings relating to such insolvency, or from any financial guarantee or other source are not sufficient to provide for adequate reclamation or abatement at the site (emphasis added).

The proposed revisions at RSMo 444.915.3 are similar to the requirements of Section 402(g)(4) of SMCRA, except that SMCRA limits the dates for which insolvency of the surety occurred to the period beginning on August 4, 1977, and ending on or before *November 5, 1990.* OSM, in its February 16, 1995, issue letter to Missouri (administrative record No. AML–MO–93), discussed the difference in dates between RSMo 444.915.3(3) and section 402(g)(4) of SMCRA (issue No. 1). Missouri responded on May 16, 1995, by providing an explanation concerning the reason for the difference and stated that it would correct the date at RSMo 444.915.3(3) at the first available opportunity (administrative record No. AML–MO–100). Missouri also stated that it believes the State AML reclamation plan is adequate to ensure that expenditures of AML funds are limited to insolvent surety sites that were abandoned on or before November 5, 1990, because the State's rules at 10 CSR 40–9.020(1)(D)(3) contain the correct date for the eligibility period (see finding No. 5). In addition, Missouri provided a memorandum prepared by its attorney general's office dated March 5, 1995 (administrative record No. AML–MO–100), indicating that only one abandoned site in Missouri meets the insolvent surety criteria and for this site, the dates of abandonment and insolvency occurred before November 5, 1990.

Therefore, with the requirement that Missouri revise RSMo 444.915.3(3) to correct the date of "October 1, 1991," to "November 5, 1990," the Director finds that the revisions proposed by Missouri at RSMo 444.915.3 are consistent with section 402(g)(4) of SMCRA. The Director approves the proposed statute.

5. 10 CSR 40–9.020(1), Eligible Coal Lands and Water

Missouri proposed to revise its rules at 10 CSR 40–9.020(1) to provide that coal lands and water damaged and abandoned after August 3, 1977, are eligible for reclamation activities if certain criteria are met. These criteria include findings that (1) the mining occurred and the site was left in either an unreclaimed or inadequately reclaimed condition between August 4, 1977, and November 21, 1980, and that funds available for reclamation or abatement pursuant to a bond or other form of financial guarantee or from any other source are insufficient to reclaim or abate the site, or (2) the mining occurred and the site was left in either an unreclaimed or inadequately reclaimed condition during the period beginning on August 4, 1977, and ending on or before November 5, 1990, and that the surety of the mining operator became insolvent during such period, and as of November 5, 1990, funds immediately available from proceedings relating to such insolvency, or from any financial guarantee or other source are insufficient to provide for adequate reclamation or abatement at the site, and (3) the coal site meets the eligibility requirements and priority objectives of 10 CFS 40–9.020 and the reclamation priority of the site is the same or more urgent than the reclamation priority for other eligible lands and water, and that priority be given to those sites which are in the immediate vicinity of a residential area or which have an adverse economic impact upon a community.

In addition, Missouri proposed to add provisions at 10 CSR 40–9.020(1) to require that (1) monies available from sources outside the fund or recovered from responsible parties involving lands eligible pursuant to 10 CSR 40–9.020 shall either be used to offset the cost of the reclamation or transferred to the fund if not required for further reclamation activities, (2) if reclamation of a site covered by an interim or permanent program permit is carried out under the State reclamation program, the permittee of the site shall reimburse the AML reclamation fund for the cost of reclamation in excess of any bond forfeited to ensure reclamation, and (3) the Commission, in performing reclamation activities under this rule, shall not be held liable for any violations of any performance standards or reclamation requirements specified in Chapter 444 RSMo (1994) nor shall a reclamation activity undertaken on such lands or waters be held to any standards set forth in Chapter 444 RSMo (1994).

The revisions proposed by Missouri at 10 CSR 40–9.020(1) provide similar requirements to those found in the counterpart Federal regulations at 30 CFR 874.12 (d) through (g). Therefore, the director finds that the proposed

revisions at 10 CSR 40–9.020(1) are in compliance with the Federal regulations. The Director approves the revisions to this rule.

6. Section 884.13(C)(2) of the Missouri AML State Reclamation Plan, Procedures for Project Ranking and Selection

Section 884.13(C)(2) of the Missouri plan amendment contains updates on policies and procedures concerning project ranking and selection. Section 884.13(C)(2), Step 1, references Form OSM–76, "Abandoned Mine Land Problem Area Description," and requires that such form be used to show site condition and to report actual reclamation accomplishments upon project completion to OSM. This is in compliance with the Federal regulation at 30 CFR 886.23(c) which provides for the submission of Form OSM–76 upon project completion to report the accomplishments achieved through the project. Section 884.13(C)(2), Step 2, provides for the elimination of selected problem sites and provides a list of circumstances when Missouri will eliminate a site from further consideration. These circumstances are consistent with the provisions of sections 402(g) and 411(d) of SMCRA and are in compliance with the Federal regulations at 30 CFR 874.12(d)(2) (i) and (ii) and 875.16.

Missouri submitted these proposed revisions to Section 884.13(C)(2) to satisfy the requirements of OSM's 884.15(d) letter dated September 26, 1994 (administrative record No. AML–MO–88). The Director finds that the revisions at Section 884.13(C)(2) of the Missouri AML State Reclamation Plan satisfy the requirements of and are consistent with SMCRA and the implementing Federal regulations at 30 CFR Subchapter R concerning reports and project ranking and selection. The Director approves the proposed revisions to Section 884.13(C)(2) of the Missouri AML State Reclamation Plan.

7. Section 884.13(D)(4) of the Missouri AML State Reclamation Plan, Future Reclamation Set-Aside Program

Missouri proposed to revise its accounting procedures at Section 884.13(D)(4) of the Missouri plan by adding language to provide that (1) up to 10 percent of the annual grants received under sections 402(g) (1) and (5) of SMCRA may be requested annually for use in treating acid mine drainage problems or for the future reclamation set-aside program in Missouri, and (2) such funds will be placed into the State Abandoned Mine Land Reclamation Fund (Fund No. 0697), an interest-bearing account which has been approved by OSM for these purposes, and will be expended solely to achieve the priorities of section 403(a) of SMCRA after September 30, 1995.

The proposed language at Section 884.13(D)(4) is similar to the Federal provisions concerning the future reclamation set-aside program at sections 402(g) (6) and (7) of SMCRA and the implementing Federal regulations at 30 CFR 873.12(a) and 876.12(a). The Director finds that the addition of provisions at Section 884.13(D)(4) pertaining to a set-aside program for Missouri is consistent with SMCRA and in compliance with the Federal regulations for such a program. The Director approves this revision to Section 884.13(D)(4) of the Missouri AML State Reclamation Plan.

V. Summary and Disposition of Comments

Following are summaries of all substantive written comments on the proposed amendment that were received by OSM, and OSM's responses to them.

1. Public Comments

OSM invited public comments on the proposed amendment, but none were received.

2. Agency Comments

Pursuant to 30 CFR 884.15(a) and 884.14(a)(2), OSM solicited comments on the proposed amendment from various Federal agencies with an actual or potential interest in the Missouri plan (administrative record No. AML–MO–90). No comments were received.

VI. Director's Decision

Based on the above findings, the Director approves, with an additional requirement, Missouri's proposed plan amendment as submitted on November 29, 1994, and as revised and supplemented with explanatory information on May 16, 1995.

The Director approves, as discussed in: Finding No. 1, RSMo 444.810.1, .1(8), and .1(10), concerning the powers of the Commission; RSMo 444.915.1(1), concerning expenditures from the abandoned mine reclamation fund; RSMo 444.915.2 (4) and (5), concerning recodification of the priorities for expenditures of moneys from the abandoned mine reclamation fund; 10 CSR 40–9.020(1) (B) and (C), concerning general requirements for reclamation; Section 884.13(C)(2) of the Missouri AML State Reclamation Plan, concerning deletion of Figure 1 and recodification of Figure 2; and Section 884.13(C)(2), Step 3, No. 8, of the Missouri AML State Reclamation Plan, concerning project evaluation and ranking; finding No. 2, 10 CSR 40–9.020(3)(A), concerning the definition of "left or abandoned in either an unreclaimed or inadequately reclaimed condition;" and Section 884.13(D)(3) of the Missouri AML State Reclamation Plan, concerning contractor eligibility; finding No. 3, RSMo 444.810.2 through 444.810.8, concerning rulemaking procedures; finding No. 5, 10 CSR 40–9.020(1), concerning eligible coal lands and water; finding No. 6, Section 884.13(C)(2) of the Missouri AML State Reclamation Plan, concerning procedures for project ranking and selection; and finding No. 7, Section 884.13(D)(4) of the Missouri AML State Reclamation Plan, concerning the future reclamation set-aside program.

With the requirement that Missouri further revise its statute, the Director approves, as discussed in finding No. 4, RSMo 444.915.3, concerning reclamation of interim program and bankrupt surety coal sites.

The Director approves the statutes, rules, and sections of the Missouri AML State Reclamation Plan as proposed by Missouri with the provision that they be fully promulgated in identical form to the statutes, rules, and sections of the Missouri AML State Reclamation Plan submitted to and reviewed by OSM and the public.

The Federal regulations at 30 CFR Part 925, codifying decisions concerning the Missouri plan, are being amended to implement this decision. This final rule is being made effective immediately to expedite the State plan amendment process and to encourage States to bring their plans into conformity with the Federal standards without undue delay. Consistency of State and Federal standards is required by SMCRA.

VII. Procedural Determinations

1. Executive Order 12866

This rule is exempted from review by the Office of Management and budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

2. Executive Order 12778

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 (Civil Justice Reform) and has determined that this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State abandoned mine land reclamation (AMLR) plans and revisions thereof since each such

plan is drafted and promulgated by a specific State, not by OSM. Decisions on proposed State AMLR plans and revisions thereof submitted by a State are based on a determination of whether the submittal meets the requirements of Title IV of SMCRA (30 U.S.C. 1231–1243) and the applicable Federal regulations at 30 CFR Parts 884 and 888.

3. National Environmental Policy Act

No environmental impact statement is required for this rule since agency decisions on proposed State AMLR plans and revisions thereof are categorically excluded from compliance with the National Environmental Policy Act (42 U.S.C. 4332) by the Manual of the Department of the Interior (516 DM 6, appendix 8, paragraph 8.4B(29)).

4. Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

5. Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal which is the subject of this rule is based upon Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements established by SMCRA or previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions in the analyses for the corresponding Federal regulations.

List of Subjects in 30 CFR Part 925

Intergovernmental relations, Surface mining, Underground mining.

Dated: August 14, 1995.

Brent Wahlquist,

Regional Director, Mid-Continent Regional Coordinating Center.

For the reasons set out in the preamble, Title 30, Chapter VII, Subchapter T of the Code of Federal Regulations is amended as set forth below:

PART 925—MISSOURI

1. The authority citation for Part 925 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

2. Section 925.20 is revised to read as follows:

§ 925.20 Approval of the Missouri Abandoned Mine Land Reclamation Plan.

The Missouri Abandoned Mine Land Reclamation Plan, as submitted on September 11, 1981, is approved effective January 29, 1982. Copies of the approved plan are available at:

(a) Missouri Department of Natural Resources, Land Reclamation Program, 205 Jefferson Street, Jefferson City, MO 65102.

(b) Office of Surface Mining Reclamation and Enforcement, Kansas City Field Office, 934 Wyandotte Street, Room 500, Kansas City, MO 64105.

3. Section 925.25 is amended by adding paragraph (c) to read as follows:

§ 925.25 Approval of AML plan amendments.

* * * * *

(c) The Missouri plan amendment, as submitted to OSM on November 29, 1994, and as revised on May 16, 1995, is approved effective August 24, 1995.

[FR Doc. 95–21022 Filed 8–23–95; 8:45 am]

BILLING CODE 4310–05–M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD01–95–051]

RIN 2115–AE46

Special Local Regulation: Stonington Lobster Boat Races, Deer Island Thoroughfare, Stonington, ME

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing a permanent special local regulation for a racing event called the Stonington Lobster Boat Race. The event will be held on Saturday, July 22, 1995, from 10 a.m. to 4 p.m., and thereafter annually on the third or fourth Saturday in July in the waters of Deer Island Thoroughfare, Stonington, ME. This regulation is needed to protect the boating public from the hazards associated with high speed powerboat racing in confined waters.

EFFECTIVE DATE: This regulation is effective July 22, 1995.

FOR FURTHER INFORMATION CONTACT: Lieutenant (Junior Grade) B.M. Algeo, Chief, Boating Affairs Branch, First Coast Guard District, (617) 223–8311.

SUPPLEMENTARY INFORMATION:

Drafting Information: The drafters of this rule are Lieutenant (Junior Grade) B. M. Algeo, Project Manager, First Coast Guard District, and Lieutenant Commander S.R. Watkins, Project Counsel, First Coast Guard District Legal Office.

Background and Purpose

On March 29, 1995, the sponsor, Deer Island-Stonington Chamber of Commerce, submitted a request to hold a powerboat race in Deer Island Thoroughfare, Stonington, ME. The Coast Guard is establishing a permanent regulation in Deer Island Thoroughfare for this event known as the "Stonington Lobster Boat Races." The final rule establishes a regulated area in Deer Island Thoroughfare and provides specific guidance to control vessel movement during the race.

This event will include up to 100 power-driven lobster boats competing on a rectangular course at speeds approaching 20 m.p.h. Due to the inherent dangers of racing in a confined area and the large wakes produced, vessel traffic will be temporarily restricted to provide for the safety of the spectators and participants.

The sponsor will provide five committee boats to augment the Coast Guard patrol assigned to the event. The race course will be well marked and patrolled, but due to the speed and proximity of the participating vessels, it is necessary to establish a special local regulation to control spectator and commercial vessel movement within this confirmed area.

Regulatory History

A Notice of Proposed Rulemaking (NPRM) was published for this rule on May 11, 1995 (60 FR 25189), no comments were received and no changes were made to the original proposal. Good cause exists for making this rule effective in less than 30 days after Federal Register publication. The Coast Guard has recently adopted new procedures for making environmental assessments (EA) of various classes of marine events before granting final approval. Due to these new procedures, publication of this final rule for the Stonington Lobster Boat Races was delayed awaiting completion of the EA. Given current resources, the Coast Guard has been unable to complete the necessary EAs for various marine events thirty days prior to the event due to the volume and their extensive content. The Coast Guard does not believe publishing the final rule less than thirty days before the event creates a significant impact on

the affected public because a NPRM was published two months prior to the event and the event is a longstanding, popular tradition in the local area.

Discussion of Rule

The Coast Guard is establishing a special local regulation on specified waters of Deer Island Thoroughfare, Stonington, ME. The regulated area will be closed to all traffic from 10 a.m. to 4 p.m. on July 22, and thereafter annually on the third or fourth Saturday in July, at the same prescribed times. In emergency situations, provisions will be made to establish safe escort by a Coast Guard or designated Coast Guard vessel for mariners requiring transit through the regulated area. This regulation is needed to protect spectators and participants from the hazards that accompany a high speed powerboat race in a confined area.

Regulatory Evaluation

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has been exempted from review by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact to be so minimal that a full Regulatory Evaluation, under paragraph 10e of the regulatory policies and procedures of DOT, is unnecessary. This conclusion is based on the limited duration of the race, the extensive advisories that have been and will be made to the affected maritime community, and the fact that the event is taking place in an area where there is little commercial interest except the race participants.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard must consider whether this rule will have a significant economic impact on a substantial number of small entities. "Small entities" include independently owned and operated small businesses that are not dominant in their fields and that otherwise qualify as "small business concerns" under section 3 of the Small Business Act (15 U.S.C. 632).

For the reasons discussed in the Regulatory Evaluation, the Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

Collection of Information

This rule contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et. seq.*).

Federalism

The Coast Guard has analyzed this rule in accordance with the principles and criteria contained in Executive Order 12612 and has determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard has considered the environmental impacts of this special local regulation as well as the Stonington Lobster Boat Races. An Environmental Assessment (EA) was prepared for the Stonington Lobster Boat Races for which a Coast Guard Marine Event Permit will be issued. A Finding of No Significant Impact (FONSI) was made; a copy of the EA and FONSI statement are available in the docket. Under paragraph 2.B.2.e.34(h) of the Coast Guard's Implementing Procedures and Policy for Considering Environmental Impacts, COMDTINST 16475.1B, this special local regulation is categorically excluded from further environmental documentation.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons set out in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

PART 100—[AMENDED]

1. The authority citation for Part 100 continues to read as follows:

Authority: 33 U.S.C. 1233; 49 CFR 1.46 and 33 CFR 100.35.

2. A permanent section, § 100.111, is added to read as follows:

§ 100.111 Stonington Lobster Boat Races, Stonington, ME.

(a) *Regulated area.* The regulated area includes all waters within the following points:

Latitude	*Longitude*
44° 08.57′ N	068° 40.12′ W
44° 09.05′ N	068° 40.12′ W
44° 09.15′ N	068° 39.05′ W
44° 09.05′ N	068° 39.00′ W

(b) *Special local regulations.*

(1) Commander, U.S. Coast Guard Group Southwest Harbor reserves the right to delay, modify, or cancel the race as conditions or circumstances require.

(2) No person or vessel may enter, transit, or remain in the regulated area during the effective period of regulation unless participating in the event or unless authorized by the Coast Guard patrol commander.

(3) Vessels desiring to transit Deer Island Thoroughfare may do so without Coast Guard approval as long as the vessel remains outside the regulated area at specified times. No vessel will be allowed to transit through any portions of the regulated area during the actual race. Provisions will be made to allow vessels to transit the regulated area between race heats. In the event of an emergency, the Coast Guard patrol commander may authorize a vessel to transit through the regulated area with a Coast Guard designated escort. Vessels encountering emergencies which require transit through the regulated area should contact the Coast Guard patrol commander on VHF Channel 16.

(4) Spectator craft are authorized to watch the race from any area as long as they remain outside the designated regulated area. Spectator craft are expected to remain outside the regulated area from 10 a.m. to 4 p.m. unless permission has been granted by the patrol commander.

(5) All persons and vessels shall comply with the instructions of the Commander, U.S. Coast Guard Group Southwest Harbor or the designated on-scene patrol commander. On-scene patrol personnel include commissioned, warrant, and petty officers of the U.S. Coast Guard. Upon hearing five or more short blasts from a U.S. Coast Guard vessel, the operator of a vessel shall stop immediately, then proceed as directed. Members of the Coast Guard Auxiliary will also be present to inform vessel operators of this regulation and other applicable laws.

(c) *Effective period.* This section is effective from 10 a.m. to 4 p.m. on Saturday, July 22, 1995, and thereafter annually on the third or fourth Saturday in July, at the same prescribed times, as published in an annual **Federal Register** notice, unless otherwise specified in the Coast Guard Local Notice to Mariners and a notice in the **Federal Register**.

Dated: July 19, 1995.

R.R. Clark

Captain, U.S. Coast Guard, Acting Commander, First Coast Guard District.

[FR Doc. 95–20941 Filed 8–23–95; 8:45 am]

BILLING CODE 4910–14–M

33 CFR Part 100

[CGD 05–95–048]

Special Local Regulations for Marine Events; Barnegat Bay Classic; Toms River, NJ

AGENCY: Coast Guard, DOT.

ACTION: Notice of implementation.

SUMMARY: This notice announces that 33 CFR 100.502 will be in effect for the Barnegat Bay Classic, an annual event to be held on August 26, 1995 in Barnegat Bay, between Island Beach and the mainland. These special local regulations are needed to provide for the safety of the participants and spectators on navigable waters during this event. This rule will restrict general navigation in the regulated area.

EFFECTIVE DATES: The regulations in 33 CFR 100.502 are effective from 9:30 a.m. to 5 p.m., August 26, 1995. If the event is postponed due to weather conditions, 33 CFR 100.502 is effective from 9:30 a.m. to 5 p.m., August 27, 1995.

FOR FURTHER INFORMATION CONTACT: Stephen L. Phillips, Chief, Boating Affairs Branch, Fifth Coast Guard District, 431 Crawford Street, Portsmouth, Virginia 23704–5004 (804) 398–6204, or Commander, Coast Guard Group Cape May (609) 884–6981.

SUPPLEMENTARY INFORMATION:

Drafting Information: The drafters of this notice are QM1 Gregory C. Garrison, project officer, Boating Affairs Branch, Boating Safety Division, Fifth Coast Guard District, and CDR Thomas R. Cahill, project attorney, Fifth Coast Guard District Legal Staff.

Discussion of Rule

On August 26, 1995, the United States Offshore Racing Association will hold the Barnegat Bay Classic in Barnegat Bay between Island Beach and the mainland. If weather conditions do not allow the Barnegat Bay Classic to be held on August 26, 1995, it will be held, weather permitting, on August 27, 1995. The event will consist of approximately fifty to sixty powerboats, ranging from 24 to 36 feet in length, racing on a designated course within the regulated area described in 33 CFR 100.502(a). To enhance the safety of the participants in and spectators of the Barnegat Bay Classic, Commander, Fifth Coast Guard District is placing 33 CFR 100.502 in effect during this event. Although this rule will restrict general navigation within the designated area, waterbourne traffic will not be severely disrupted because the Intracoastal Waterway will remain open for passage.

Dated: August 11, 1995.

W.J. Ecker,

Rear Admiral, U.S. Coast Guard Commander, Fifth Coast Guard District.

[FR Doc. 95–20942 Filed 8–23–95; 8:45 am]

BILLING CODE 4910–14–M

33 CFR Part 100

[CGD 09–95–024]

Special Local Regulation; 1995 Offshore Series Grand Prix, Lake Erie, Geneva-on-the-Lake, OH

AGENCY: Coast Guard, DOT.

ACTION: Temporary rule.

SUMMARY: A special local regulation is being adopted for the 1995 Offshore Series Grand Prix. This event will be held on Lake Erie, Geneva-on-the-Lake, OH, on September 10, 1995. The Geneva Offshore Grand Prix will have an estimated 30 offshore race boats racing a closed course race on Lake Erie which could pose hazards to navigation in the area. This regulation will restrict general navigation on Lake Erie between Cowles Creek and the Redbrook Boat Club and is needed to provide for the safety of life, limb, and property on navigable waters during the event.

EFFECTIVE DATE: This regulation is effective from 11 a.m. until 3 p.m. September 10, 1995.

FOR FURTHER INFORMATION CONTACT: Marine Science Technician Second Class Jeffrey M. Yunker, Ninth Coast Guard District, Aids to Navigation and Waterways Management Branch, Room 2083, 1240 East Ninth Street, Cleveland, Ohio 44199–2020, (216) 522–3990.

SUPPLEMENTARY INFORMATION: In accordance with 5 U.S.C. 553, a Notice of Proposed Rulemaking has not been published for this regulation and good cause exists for making it effective in less than 30 days from the date of publication. Following normal rulemaking procedures would have been impracticable. The application to hold this event was not received by the Commander, Ninth Coast Guard District, until August 3, 1995, and there was not sufficient time remaining to publish a proposed final rule in advance of the event.The Coast Guard has decided to proceed with a temporary rule for this year's event and publish a NPRM, as part of the Great Lakes annual marine events list, prior to next year's event.

Drafting Information: The drafters of this notice are Lieutenant Junior Grade Byron D. Willeford, Project Officer, Ninth Coast Guard District, Aids to Navigation and Waterways Management Branch, and Lieutenant Charles D. Dahill, Project Attorney, Ninth Coast Guard District Legal Office.

Discussion of Regulation

The Geneva Offshore Grand Prix will be held on Lake Erie between Cowles Creek and the Redbrook Boat Club on September 10, 1995. This event will have an estimated 30 offshore race boats racing a closed course race on Lake Erie which could pose hazards to navigation in the area. The effect of this regulation will be to restrict general navigation on that portion of Lake Erie, in an area rectangular in shape, from the mouth of Cowles Creek, east along the shoreline approximately 4.4 statute miles, extending offshore approximately 0.7 statute mile, for the safety of spectators and participants. This regulation is necessary to ensure the protection of life, limb, and property on navigable waters during this event. Any vessel desiring to transit the regulated area may do so only with prior approval of the Patrol Commander (Officer in Charge, U.S. Coast Guard Station Ashtabula, OH).

This regulation is issued pursuant to 33 U.S.C. 1233 as set out in the authority citation for all of Part 100.

Federalism Implications

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that the rulemaking does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard is conducting an environmental analysis for this event pursuant to section 2.B.2.c of Coast Guard Commandant Instruction M16475.1B, and the Coast Guard Notice of final agency procedures and policy for categorical exclusions found at (59 FR 38654; July 29, 1994).

Economic Assessment and Certification

This regulation is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has been exempted from review by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this regulation to be so minimal that a full Regulatory Evaluation under paragraph

10e of the regulatory policies and procedures of the DOT is unnecessary.

Collection of Information

This regulation will impose no collection of information requirements under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

Temporary Regulation

In consideration of the foregoing, Part 100 of Title 33, Code of Federal Regulations, is amended as follows:

1. The authority citation for Part 100 continues to read as follows:

Authority: 33 U.S.C. 1233; 49 CFR 1.46 and 33 CFR 100.35.

2. A temporary section 100.35–T09–024 is added to read as follows:

§ 100.35–T09–024 1995 Offshore Series Grand Prix, Lake Erie, Geneva-on-the-Lake, OH.

(a) *Regulated area*: That portion of Lake Erie from:

Latitude	*Longitude*
41°51.5′ N	080°58.2′ W, thence to
41°52.4′ N	080°53.4′ W, thence to
41°53.0′ N	080°53.4′ W, thence to
41°52.2′ N	080°58.2′ W, thence to
41°51.5′ N	080°58.2′ W, thence to

Datum: NAD 83

(b) *Special local regulation:* This section restricts general navigation in the regulated area for the safety of spectators and participants. Any vessel desiring to transit the regulated area may do so only with prior approval of the Patrol Commander.

(c) *Patrol commander:*

(1) The Coast Guard will patrol the regulated area under the direction of a designated Coast Guard Patrol Commander (Officer in Charge, U.S. Coast Guard Station Ashtabula, OH). The Patrol Commander may be contacted on channel 16 (156.8 MHZ) by the call sign "Coast Guard Patrol Commander."

(2) The Patrol Commander may direct the anchoring, mooring, or movement of any boat or vessel within the regulated area. A succession of sharp, short signals by whistle or horn from vessels patrolling the area under the direction of the U.S. Coast Guard Patrol Commander shall serve as a signal to stop. Any vessel so signaled shall stop and shall comply with the orders of the Patrol Commander. Failure to do so may result in expulsion from the area, citation for failure to comply, or both.

(3) The Patrol Commander may establish vessel size and speed limitations and operating conditions.

(4) The Patrol Commander may restrict vessel operation within the regulated area to vessels having particular operating characteristics.

(5) The Patrol Commander may terminate the marine event or the operation of any vessel at any time it is deemed necessary for the protection of life, limb, or property.

(6) All persons in the area shall comply with the orders of the Coast Guard Patrol Commander.

(d) *Effective Date:* This section is effective from 11 a.m. until 3 p.m. on September 10, 1995, unless extended or terminated sooner by the Coast Guard Group Commander, Buffalo, NY.

Dated: August 11, 1995.

G.F. Woolever,

Rear Admiral, U.S. Coast Guard Commander, Ninth Coast Guard District.

[FR Doc. 95–20943 Filed 8–23–95; 8:45 am]

BILLING CODE 4910–14–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[FRL–5282–6]

Tennessee; Final Authorization of Revisions to State Hazardous Waste Management Program

AGENCY: Environmental Protection Agency.

ACTION: Immediate final rule.

SUMMARY: Tennessee has applied for final authorization of revisions to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). Tennessee's revisions consist of the provisions contained in rules promulgated between January 26, 1983, and June 30, 1986, otherwise known as the Non-HSWA requirements prior to Non-HSWA Cluster I and Non-HSWA Clusters I and II. These requirements are listed in Section B of this notice. The Environmental Protection Agency (EPA) has reviewed Tennessee's applications and has made a decision, subject to public review and comment, that Tennessee's hazardous waste program revisions satisfy all of the requirements necessary to qualify for final authorization. Thus, EPA intends to approve Tennessee's hazardous waste program revisions. Tennessee's applications for program revisions are available for public review and comment.

DATES: Final authorization for Tennessee's program revisions shall be effective October 23, 1995, unless EPA publishes a prior **Federal Register** action withdrawing this immediate final rule. All comments on Tennessee's program revision applications must be received by the close of business, September 25, 1995.

ADDRESSES: Copies of Tennessee's program revision applications are available during normal business hours at the following addresses for inspection and copying: Tennessee Department of Environment and Conservation, 5th Floor, L & C Tower, 401 Church Street, Nashville, Tennessee 37243–1535; U.S. EPA Region 4, Library, 345 Courtland St. NE, Atlanta, Georgia 30365; (404) 347–4216. Written comments should be sent to Al Hanke at the address listed below.

FOR FURTHER INFORMATION CONTACT: Al Hanke, Chief, State Programs Section, Waste Programs Branch, Waste Management Division, U.S. Environmental Protection Agency, 345 Courtland Street, NE, Atlanta, Georgia 30365; (404) 347–2234.

SUPPLEMENTARY INFORMATION:

A. Background

States with final authorization under Section 3006(b) of the Resource Conservation and Recovery Act ("RCRA" or "the Act"), 42 U.S.C. 6926(b), have a continuing obligation to maintain a hazardous waste program that is equivalent to, consistent with, and no less stringent than the Federal hazardous waste program. In addition, as an interim measure, the Hazardous and Solid Waste Amendments of 1984 (Pub. L. 98–616, November 8, 1984, hereinafter "HSWA") allows States to revise their programs to become substantially equivalent instead of equivalent to RCRA requirements promulgated under HSWA authority. States exercising the latter option receive "interim authorization" for the HSWA requirements under Section 3006(g) of RCRA, 42 U.S.C. 6926(g), and later apply for final authorization for the HSWA requirements.

Revisions to State hazardous waste programs are necessary when Federal or State statutory or regulatory authority is modified or when certain other changes occur. Most commonly, State program revisions are necessitated by changes to EPA's regulations in 40 CFR Parts 260–268 and 124 and 270.

B. Tennessee

Tennessee initially received final authorization for its base RCRA program effective on February 5, 1985. Tennessee

has received authorization for revisions to its program on August 11, 1987, October 1, 1991, and July 31, 1992. On February 16, 1989, Tennessee submitted a program revision application for additional program approvals. Today, Tennessee is seeking approval of its program revisions in accordance with 40 CFR 271.21(b)(3).

EPA has reviewed Tennessee's applications and has made an immediate final decision that Tennessee's hazardous waste program revisions satisfy all of the requirements necessary to qualify for final authorization. Consequently, EPA intends to grant final authorization for the additional program modifications to Tennessee. The public may submit written comments on EPA's immediate final decision up until September 25, 1995.

Copies of Tennessee's applications for these program revisions are available for inspection and copying at the locations indicated in the "Addresses" section of this notice.

Approval of Tennessee's program revisions shall become effective October 23, 1995, unless an adverse comment pertaining to the State's revisions discussed in this notice is received by the end of the comment period.

If an adverse comment is received EPA will publish either (1) a withdrawal of the immediate final decision or (2) a notice containing a response to comments which either affirms that the immediate final decision takes effect or reverses the decision.

EPA shall administer any RCRA hazardous waste permits, or portions of permits that contain conditions based upon the Federal program provisions for which the State is applying for authorization and which were issued by EPA prior to the effective date of this authorization. EPA will suspend issuance of any further permits under the provisions for which the State is being authorized on the effective date of this authorization.

Tennessee is today seeking authority to administer the following Federal requirements promulgated on July 1, 1988–June 30, 1989, and March 29, 1990.

Checklist	Federal requirement	FR Promulgation date and page	State authority
1	Biennial report	1/28/83—48 FR 3977	TRC 1200–1–11–.03(5)(a)2; .03(5)(b)1&3; .06(5)(a-c); .05(5)(a); .05(5)(a)5; .05(6)(a); .07(8)(a)12(ix); TCA 68–46–107(d)(6).
3	Interim status standards; applicability.	11/22/83—48 FR 52718	TRC 1200–1–11–.05(1)(b)1; TCA 68–46–106(a)(3); 68–46–108; 68–46–107(d)(2–4).
4	Chlorinated aliphatic hydrocarbon listing.	2/10/84—49 FR 5308	TRC 1200–1–11–.02(4)(a); .02(5)(a); TCA 68–46–106(a)(1); 68–46–107(d)(1).
6	Permit rules; settlement agreement.	4/24/84—49 FR 17716	TRC 1200–1–11–.07(3)(a); TCA 68–46–108.
7	Warfarin and zinc phosphide listing.	5/10/84—49 FR 19922	TRC 1200–1–11–.02(4)(a); TCA 68–46–106(a)(1); 68–46–107(d)(1).
8	Lime stabilized pickle liquor sludge	6/5/84—49 FR 23284	TRC 1200–1–11–.02(1)(c)3(II); TCA 68–46–106(a)(1); 68–46–107(d)(1).
9	Household waste	11/13/84—49 FR 44978	TRC 1200–1–11–.02(1)(d)2(i); TCA 68–46–106(a)(1); 68–46–107(d)(1).
10	Interim status standards; applicability.	11/21/84—49 FR 46094	TRC 1200–1–11–.05(1)(a); .05(1)(b)1; TCA 68–46–106(a)(3); 68–46–108; 68–46–107(d)(2–4).
11	Corrections to test methods manual.	12/4/84—49 FR 47390	TRC 1200–1–11–.01(2)(b)1; .01(3)(b); TCA 68–46–106(a)(1); 68–46–107(d)(1)
12	Satellite accumulation	12/20/84—49 FR 49568	TRC 1200–1–11–.03(4)(e)4; TCA 68–46–108(a)(2).
13	Definition of solid waste	1/4/85—50 FR 614	TRC 1200–1–11–.01(2)(a); .01(4)(a); .01(4)(b); .01(5)(a); .01(4)(c)1; .01(5)(b)1; .01(4)(c)2; .01(5)(b)2; .01(6)(a); .01(6)(b); .02(1)(a); .02(1)(b); .02(1)(c)3(ii); .02(1)(d)1(ii-iii); .06(1)(b)2(ii); .06(15)(a); .05(1)(b)2(iii); .02(1)(e); .02(1)(f); .02(4)(a); .05(15)(a); .05(16)(a); .09(1)(a); TCA 68–46–104(7); 68–46–104(17); 68–46–106(a); 68–46–107(d).
15	Interim status standards for treatment, storage, and disposal facilities.	4/23/85—50 FR 16044	TRC 1200–1–11–.05(11)(a); .05(13)(a); .05(14)(a); TCA 68–46–107(d); 68–46–108.
24	Financial responsibility; settlement agreement.	5/2/86—51 FR 16422	TRC 1200–1–11–.01(2)(a); .06(7)(a); .06(8)(b); .06(8)(c); .06(8)(d); .06(8)(e); .06(8)(f); .06(8)(m)4&8; .05(7)(a); .05(8)(a); .05(8)(b); .05(8)(c); .05(8)(d); .05(8)(e); .05(8)(f); .05(8)(k); .07(5)(a); .07(9)(e)5; .07(3)(a); TCA 68–46–107(d); 68–46–108.
26	Listing of spent pickle liquor	5/28/86—51 FR 19320	TRC 1200–1–11–.02(4)(a); TCA 68–46–106(a)(1); 68–46–107(d)(1).

C. Decision

I conclude that Tennessee's applications for these program revisions meet all of the statutory and regulatory requirements established by RCRA. Accordingly, Tennessee is granted final authorization to operate its hazardous waste program as revised.

Tennessee now has responsibility for permitting treatment, storage, and disposal facilities within its borders and carrying out other aspects of the RCRA program, subject to the limitations of its program revision application and previously approved authorities. Tennessee also has primary enforcement responsibilities, although EPA retains the right to conduct inspections under Section 3007 of RCRA and to take enforcement actions under Section 3008, 3013, and 7003 of RCRA.

Compliance With Executive Order 12866

The Office of Management and Budget has exempted this rule from the requirements of Section 6 of Executive Order 12866.

Certification Under the Regulatory Flexibility Act

Pursuant to the provisions of 5 U.S.C. 605(b), I hereby certify that this

authorization will not have a significant economic impact on a substantial number of small entities. This authorization effectively suspends the applicability of certain Federal regulations in favor of Tennessee's program, thereby eliminating duplicative requirements for handlers of hazardous waste in the State. It does not impose any new burdens on small entities. This rule, therefore, does not require a regulatory flexibility analysis.

List of Subjects in 40 CFR Part 271

Administrative practice and procedure, Confidential business information, Hazardous materials transportation, Hazardous waste, Indian lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Water pollution control, Water supply.

Authority: This notice is issued under the authority of Sections 2002(a), 3006 and 7004(b) of the Solid Waste Disposal Act as amended (42 U.S.C. 6912(a), 6926, 6974(b)).

Dated: August 10, 1995.

Patrick M. Tobin,

Acting Regional Administrator.

[FR Doc. 95–20764 Filed 8–23–95; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 93–100; RM–8175]

Radio Broadcasting Services; Cleveland and Ebenezer, MS

AGENCY: Federal Communications Commission.

ACTION: Final rule; petition for reconsideration.

SUMMARY: The Commission denies the petition filed by Afro-American Broadcasters of Mississippi for reconsideration of the *Report and Order* in MM Docket No. 93–100, 58 FR 65673, December 16, 1993, which modified the license of Station WCLD(FM), Cleveland, Mississippi, to operate on Channel 280C3 in lieu of Channel 280A and deleted vacant Channel 280A at Ebenezer, Mississippi. The Commission determined that the deletion of the vacant allotment at Ebenezer was within the scope of this proceeding and was warranted because Ebenezer does not qualify as a community for allotment purposes.

FOR FURTHER INFORMATION CONTACT: Pam Blumenthal, Mass Media Bureau, (202) 418–2180.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

Douglas W. Webbink,

Chief, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 95–20952 Filed 8–23–95; 8:45 am]

BILLING CODE 6712–01–F

47 CFR Part 73

[MM Docket No. 95–45; RM–8605]

Radio Broadcasting Services; Pahrump, NV

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of Gregory P. Wells, allots Channel 236A to Pahrump, NV, as the community's second local FM service. *See* 60 FR 19561, April 19, 1995. Channel 236A can be allotted to Pahrump with a site restriction of 4.1 kilometers (2.5 miles) west, at coordinates 36–13–12 North Latitude; 16–01–43 West Longitude, to avoid a short-spacing to Station KWNR, Channel 238C, Henderson, NV. With this action, this proceeding is terminated.

DATES: Effective October 2, 1995. The window period for filing applications will open on October 2, 1995, and close on November 2, 1995.

FOR FURTHER INFORMATION CONTACT: Leslie K. Shapiro, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order*, MM Docket No. 95–45, adopted August 8, 1995, and released August 18, 1995. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, Inc., (202) 857–3800, 2100 M Street, NW., Suite 140, Washington, DC 20037.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: Secs. 303, 48 Stat., as amended, 1082; 47 U.S.C. 154, as amended.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Nevada, is amended by adding Channel 236A at Pahrump.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 95–21009 Filed 8–23–95; 8:45 am]

BILLING CODE 6712–01–F

47 CFR Part 73

[MM Docket No. 90–647; RM–7180]

Radio Broadcasting Services; Ladysmith and Hallie, WI

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document reallots Channel 279C1 from Ladysmith, Wisconsin, to Hallie, Wisconsin, and modifies the license for Station WWBI to specify Hallie as its community of license in response to a petition filed by Stewards of Sound, Inc. *See* 56 FR 1509, January 15, 1991. The coordinates for Channel 279C1 at Hallie are 45–06–35 and 91–09–43. With this action, this proceeding is terminated.

EFFECTIVE DATE: October 5, 1995.

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Report and Order*, MM Docket No. 90–647, adopted August 11, 1995, and released August 21, 1995. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Services, Inc., 2100 M Street, NW., Suite 140, Washington, DC 20037, (202) 857–3800.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

Authority: Secs. 303, 48 Stat., as amended, 1082; 47 U.S.C. 154, as amended.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Wisconsin, is amended by removing Ladysmith, Channel 279C1 and adding Hallie, Channel 279C1.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 95–21008 Filed 8–23–95; 8:45 am]

BILLING CODE 6712–01–F

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 10

[Docket No. 48438; Amdt. 10–2]

RIN 2105–AC05

Privacy Act; Implementation

AGENCY: Department of Transportation (DOT), Office of the Secretary.

ACTION: Final rule.

SUMMARY: DOT amends its rules implementing the Privacy Act of 1974 to add to the list of systems of records exempt from certain provisions of the Act the Coast Guard's Joint Maritime Information Element Support System.

DATES: This amendment takes effect September 25, 1995.

FOR FURTHER INFORMATION CONTACT: Robert I. Ross, Office of the General Counsel, C–10, Department of Transportation, Washington, DC 20590, telephone (202) 366–9154, FAX (202) 366–9170.

SUPPLEMENTARY INFORMATION: Public comment was invited on this proposal (May 26, 1995, 60 FR 27946); none was received.

1. What is JMIE? The Joint Maritime Information Element (JMIE) Support System is a multi-agency database of vessel movements around the world that can assist in virtually any maritime support mission, including petroleum traffic movement, sea and defense zone surveillance, fisheries operations, and emergency sealift management, as well as prevention of illegal technology transfer, general cargo/commodity smuggling, and illegal immigration. DOT's Coast Guard is one of the participating agencies and the agency that has been selected by the others as the Executive Agent to manage the database. All participating agencies will have access to data in the system.

Each record in the database will consist of two parts. The first will cover the vessel; every participating agency will have access to that; it will refer to a second record about the individuals (*e.g.*, owner, master, crew) associated with the vessel. Only the law enforcement agencies will be able to access that second record. This part of each record comes within the Privacy Act, although the entire record does not. The computer that houses the database has been programmed to grant access only to the Law Enforcement agencies that are members of JMIE.

2. What agencies are members of JMIE? The following are the members of JMIE; each is designated below by whether it is a law enforcement agency (L), member of the intelligence community (I), or other (O), only those designated '(L)' having direct access to Privacy Act information:

1. Office of National Drug Control Policy—Executive Office of the President (I)
2. Bureau of International Narcotics Matters—Department of State (I)
3. Customs Service—Department of the Treasury (L)
4. Office of Naval Intelligence—Department of Defense (I)
5. Military Sealift Command—Department of Defense (O)
6. Defense Intelligence Agency—Department of Defense (I)
7. National Security Agency—Department of Defense (I)
8. Drug Enforcement Administration—Department of Justice (L)
9. Immigration and Naturalization Service—Department of Justice (L)
10. US National Central Bureau—INTERPOL—Department of Justice (O)
11. Bureau of the Census—Department of Commerce (O)
12. Coast Guard—Department of Transportation (L)
13. Maritime Administration—Department of Transportation (O)
14. Office of Intelligence and Port Security—Department of Energy (I)
15. Central Intelligence Agency (I)

The only members of JMIE that will have direct access to the Privacy Act information that will be maintained as part of JMIE are the following, all of which are criminal law enforcement agencies; shown with each is its principal criminal law enforcement authority:

(1) Customs Service—19 USC 1589a.[1]

(2) Immigration and Naturalization Service—8 USC 1324.[2]

(3) Drug Enforcement Administration—21 USC 878.[3]

(4) Coast Guard—14 USC 89.[4]

1. *General exemption.* Under Subsection (j)(2) of the Privacy Act (5 USC 552a(j)(2)), a system of records may be exempted from almost all provisions of the Act, so long as the system: (1) Is maintained by an agency, or a component of an agency, that performs as its principal function any activity pertaining to the enforcement of criminal laws; and (2) contains: (A) Information compiled for the purpose of identifying individual criminal

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[1] Enforcement authority of Customs officers.

Subject to the direction of the Secretary of the Treasury, an officer of the customs may—

(1) carry a firearm;

(2) execute and serve any order, warrant, subpoena, summons, or other process issued under the authority of the United States;

(3) make an arrest without a warrant for any offense against the United States committed in the officer's presence or for a felony, cognizable under the laws of the United States committed outside the officer's presence if the officer has reasonable grounds to believe that the person to be arrested has committed or is committing a felony; and

(4) perform any other law enforcement duty that the Secretary of the Treasury may designate.

[2] Bringing in and harboring certain aliens.

* * * * *

(c) *Authority to arrest.* No officer or person shall have authority to make any arrest for a violation of any provision of this section except officers and employees of the [Immigration and Naturalization] Service designated by the Attorney General, either individually or as a member of a class, and all other officers whose duty it is to enforce criminal laws.

[3] Powers of enforcement personnel.

(a) Officers or employees of the Drug Enforcement Administration or any State or local law enforcement officer.

Any officer or employee of the Drug Enforcement Administration or any State or local law enforcement officer designated by the Attorney General may—

(1) carry firearms;

(2) execute and serve search warrants, arrest warrants, administrative inspection warrants, subpoenas, and summonses issued under the authority of the United States;

(3) make arrests without warrant (A) for any offense against the United States committed in his presence, or (B) for any felony, cognizable under the laws of the United States, if he has probable cause to believe that the person to be arrested has committed or is committing a felony;

(4) make seizures of property pursuant to the provisions of this subchapter; and

(5) perform such other law enforcement duties as the Attorney General may designate.

* * * * *

[4] Law enforcement.

(a) The Coast Guard may make inquiries, examinations, inspections, searches, seizures, and arrests upon the high seas and waters over which the United States has jurisdiction, for the prevention, detection, and suppression of violations of laws of the United States * * *. When * * * it appears that a breach of the laws of the United States rendering a person liable to arrest is being, or has been committed, by any person, such person shall be arrested or, if escaping to shore, shall be immediately pursued and arrested on shore, or other lawful and appropriate action shall be taken * * *.

* * * * *

offenders and alleged offenders and consisting only of identifying data and notations of arrests, the nature and disposition of criminal charges, sentencing, confinement, release, and parole and probation status; (B) information compiled for the purpose of a criminal investigation, including reports of informants and investigators, and associated with an identifiable individual; or (C) reports identifiable to an individual compiled at any stage of the process of enforcement of the criminal laws from arrest or indictment through release from supervision. Those provisions of the Act from which such a system may not be exempted are subsections (b) (Conditions of Disclosure); (c)(1) and (2) (Accounting of Certain Disclosures); (e)(4)(A) through (F) (Publication of Existence and Character of System); (e)(6) (Ensure Records are Accurate, Relevant, Timely, and Complete), (7) (Restrict Recordkeeping on First Amendment Rights), (9) (Rules of Conduct), (10) (Safeguards), and (11) (Routine Use Publication); and (i) (Criminal Penalties).

DOT is exempting JMIE under subsection (j)(2) accordingly.

2. *Specific exemptions.* Under subsection (k) of the Privacy Act (5 USC 552a(k)), qualifying records may be exempted from various provisions of the Act. Among these provisions are the requirement in subsection (c)(3) to maintain an accounting of disclosures of information from a system of records and make that accounting available on request to the record subject; in subsection (d) to grant to a record subject access to information maintained on him/her under the Act; in subsection (e)(1) to maintain only such information as is relevant and necessary to accomplish a purpose of the agency under statute or Executive Order; in subsection (e)(4)(G), (H), and (I) to advise record subjects of the agency procedures to request if a system of records contains records pertaining to them, how they can gain access to such records and contest their content, and the categories of sources of such records; and in subsection (f) to establish rules governing the procedures above.

a. Under Subsection (k)(1) of the Privacy Act (5 USC 552a(k)(1)), portions of a system of records that are subject to 5 USC 552(b)(1), in that they contain information that is properly classified in the interest of national security, may be exempted from these provisions, and DOT exempts JMIE accordingly.

b. Under Subsection (k)(2) of the Privacy Act (5 USC 552a(k)(2)), investigatory material compiled for law enforcement purposes, other than material encompassed within Subsection (j)(2), may be exempted from these provisions, and DOT exempts JMIE accordingly.

Analysis of regulatory impacts. This amendment is not a "significant regulatory action" within the meaning of Executive Order 12866. It is also not significant within the definition in DOT's Regulatory Policies and Procedures, 49 FR 11034 (1979), in part because it does not involve any change in important Departmental policies. Because the economic impact should be minimal, further regulatory evaluation is not necessary. Moreover, I certify that this amendment will not have a significant economic impact on a substantial number of small entities.

This amendment does not significantly affect the environment, and therefore an environmental impact statement is not required under the National Environmental Policy Act of 1969. It has also been reviewed under Executive Order 12612. Federalism, and it has been determined that it does not have sufficient implications for federalism to warrant preparation of a Federalism Assessment.

Finally, the amendment does not contain any collection of information requirements, requiring review under the Paperwork Reduction Act of 1980.

List of Subjects in 49 CFR Part 10

Penalties; Privacy.

In accordance with the above, DOT amends 49 CFR part 10 as follows:

PART 10—[AMENDED]

1. The authority citation to part 10 continues to read as follows:

Authority: 5 USC 552a; 49 USC 322.

2. Part I of Appendix A is amended by republishing the introductory text and adding a new paragraph F; Part II.A. is amended by adding a new paragraph 14; and Part II.F is amended by adding a new paragraph 4, all to read as follows:

* * * * *

Appendix A to Part 10—Exemptions

Part I. General Exemptions

Those portions of the following systems of records that consist of (a) information compiled for the purpose of identifying individual criminal offenders and alleged offenders and consisting only of identifying data and notations of arrests, the nature and disposition of criminal charges, sentencing, confinement, release, and parole and probation status; (b) information compiled for the purpose of a criminal investigation, including reports of informants and investigators, and associated with an identifiable individual; or (c) reports identifiable to an individual compiled at any stage of the process of enforcement of the criminal laws from arrest or indictment through release from supervision, are exempt from all parts of 5 USC 552a except subsections (b) (Conditions of disclosure); (c)(1) and (2) (Accounting of certain disclosures); (e)(4)(A) through (F) (Publication of existence and character of system); (e)(6) (Ensure records are accurate, relevant, timely, and complete before disclosure to person other than an agency and other than pursuant to a Freedom of Information Act request), (7) (Restrict recordkeeping on First Amendment rights), (9) (Rules of conduct), (10) (Safeguards), and (11) (Routine use publication); and (i) (Criminal penalties):

* * * * *

F. Joint Maritime Intelligence Element (JMIE) Support System, maintained by the Operations Systems, Center, US Coast Guard (DOT/CG 642).

Part II. Specific exemptions.

A. The following systems of records are exempt from subsection (c)(3) (Accounting of Certain Disclosures), (d) (Access to Records), (e)(4)(G), (H), and (I) (Agency Requirements), and (f) (Agency Rules) of 5 USC 552a, to the extent that they contain investigatory material compiled for law enforcement purposes in accordance with 5 USC 552a(k)(2):

* * * * *

14. Joint Maritime Intelligence Element (JMIE) Support System, maintained by the Operations Systems, Center, US Coast Guard (DOT/CG 642).

* * * * *

F. Those portions of the following systems of records that consist of information properly classified in the interest of national defense or foreign policy in accordance with 5 USC 552(b)(1) are exempt from sections (c)(3) (Accounting of Certain Disclosures), (d) (Access to Records), (e)(4)(G), (H), and (I) (Agency Requirements), and (f) (Agency Rules) of 5 USC 552a, to the extent that they contain investigatory material compiled for law enforcement purposes in accordance with 5 USC 552a(k)(1):

* * * * *

4. Joint Maritime Intelligence Element (JMIE) Support System, maintained by the Operations Systems Center, US Coast Guard (DOT/CG 642).

Issued in Washington, DC, on August 17, 1995.

Federico Peña,

Secretary of Transportation.

[FR Doc. 95–21084 Filed 8–23–95; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 661

[Docket No. 950426116–5116–01; I.D. 081695B]

Ocean Salmon Fisheries off the Coasts of Washington, Oregon, and California; Inseason Adjustment, U.S.-Canadian Border to Carroll Island, WA

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Inseason adjustment.

SUMMARY: NMFS announces that the possession and landing limit in the commercial salmon fishery in the area from the U.S.-Canada border to Carroll Island, WA, was increased to 200 coho per opening beginning August 12, 1995. This adjustment is intended to provide additional fishing opportunity to commercial fishermen.

DATES: Effective 0001 hours local time, August 12, 1995, through September 15, 1995. Comments will be accepted through September 7, 1995.

ADDRESSES: Comments may be mailed to William Stelle, Jr., Director, Northwest Region, National Marine Fisheries Service, NOAA, 7600 Sand Point Way NE., BIN C15700–Bldg. 1, Seattle, WA 98115–0070. Information relevant to this notice has been compiled in aggregate form and is available for public review during business hours at the office of the Director Northwest Region, NMFS (Regional Director).

FOR FURTHER INFORMATION CONTACT: William L. Robinson, 206–526–6140.

SUPPLEMENTARY INFORMATION: In the annual management measures for ocean salmon fisheries (60 FR 21746, May 3, 1995), NMFS announced that the 1995 commercial fishery in the area between the U.S.-Canadian border and Carroll Island, WA, would open on August 5 and fishing would follow a cycle of 4 days open and 3 days closed. The fishery would close the earliest of September 15, attainment of the adjusted 25,000 coho salmon quota (60 FR 40302, August 8, 1995), or attainment of the 160,000 pink salmon guideline. Each vessel would be able to possess, land and deliver no more than 80 coho per open period.

The best available information on August 10 indicated that commercial catch and effort rates were low during August 5 to 8, the first open period, with catches totaling 3,300 coho salmon and 6,000 pink salmon. The preseason objective for the possession and landing limit was to provide commercial fishermen a minimal allowance for coho salmon while providing access to pink salmon. Pink salmon are currently available in the fishery. Increasing the possession and landing limit to 200 coho salmon per opening would provide additional fishing opportunity to commercial fishermen by increasing access to coho salmon without exceeding the ocean share allocated to the commercial fishery in this area. Modification of limited retention regulations is authorized by regulations at 50 CFR 661.21(b)(1)(ii). All other restrictions that apply to this fishery remain in effect as announced in the annual management measures.

The Regional Director consulted with representatives of the Pacific Fishery Management Council and the Washington Department of Fish and Wildlife regarding this adjustment. The State of Washington will manage the commercial fishery in State waters adjacent to this area of the exclusive economic zone in accordance with this Federal action. In accordance with the inseason notice procedures of 50 CFR 661.23, actual notice to fishermen of the fishing season action was given prior to 0001 hours local time, August 12, 1995, by telephone hotline number (206) 526–6667 or (800) 662–9825 and by U.S. Coast Guard Notice to Mariners broadcasts on Channel 16 VHF-FM and 2182 KHz. Because of the need for immediate action to provide commercial fishermen with additional fishing opportunity, NMFS has determined that good cause exists for this notice to be issued without affording a prior opportunity for public comment. This notice does not apply to treaty Indian fisheries or to other fisheries that may be operating in other areas.

Classification

This action is authorized by 50 CFR 661.21 and 661.23 and is exempt from review under E.O. 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 21, 1995.

Richard H. Schaefer,

Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 95–21090 Filed 8–23–95; 8:45 am]

BILLING CODE 3510–22–F

50 CFR Part 675

[Docket No. 950206040–5040–01; I.D. 081595C]

Groundfish of the Bering Sea and Aleutian Islands Area; Pollock by Vessels Using Non-pelagic Trawl Gear

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Closure.

SUMMARY: NMFS is closing the directed fishery for pollock by trawl vessels using non-pelagic trawl gear in the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the BSAI bycatch allowance of halibut specified for the trawl pollock/Atka mackerel/"other species" fishery category.

EFFECTIVE DATE: 12 noon, Alaska local time (A.l.t.), August 22, 1995, until 12 midnight, A.l.t., December 31, 1995.

FOR FURTHER INFORMATION CONTACT: Andrew N. Smoker, 907–586-7228.

SUPPLEMENTARY INFORMATION: The groundfish fishery in the BSAI exclusive economic zone is managed by NMFS according to the Fishery Management Plan for the Groundfish Fishery of the Bering Sea and Aleutian Islands Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson Fishery Conservation and Management Act. Fishing by U.S. vessels is governed by regulations implementing the FMP at 50 CFR parts 620 and 675.

The 1995 bycatch allowance of halibut specified for the trawl pollock/Atka mackerel/"other species" fishery category, which is defined at § 675.21(b)(1)(iii)(F), was established as 555 metric tons by the final 1995 harvest specifications of groundfish (60 FR 8479, February 14, 1995).

The Director, Alaska Region, NMFS, has determined, in accordance with § 675.21(c)(1)(iii), that the bycatch allowance of halibut specified for the trawl pollock/Atka mackerel/"other species" fishery category has been reached. Therefore, NMFS is closing the directed fishery for pollock by trawl vessels using non-pelagic trawl gear in the BSAI.

Directed fishing standards for applicable gear types may be found in the regulations at § 675.20(h).

Classification

This action is taken under 50 CFR 675.20 and is exempt from OMB review under E.O. 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 17, 1995.

Richard H. Schaefer,

Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 95–20937 Filed 8–21–95; 11:38 am]

BILLING CODE 3510–22–F

Proposed Rules

Federal Register
Vol. 60, No. 164
Thursday, August 24, 1995

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Parts 1005, 1011, and 1046

[Docket No. AO–388–A8, et al.; DA–94–12]

Milk in the Carolina, Tennessee Valley, and Louisville-Lexington-Evansville Marketing Areas; Recommended Decision and Opportunity to File Written Exceptions on Proposed Amendments to Tentative Marketing Agreements and to Orders

7 CFR Part	Marketing area	AO Nos.
1005	Carolina	AO–388–A8
1011	Tennessee Valley	AO–251–A39
1046	Louisville-Lexington-Evansville.	AO–123–A66

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This recommended decision would amend the pooling standards of the Tennessee Valley and Carolina orders; modify the marketing areas of the Tennessee Valley and Louisville-Lexington-Evansville orders; change the location adjustment under the Carolina order for plants located in the Middle Atlantic marketing area; and change the base-paying months under the Carolina order.

DATES: Comments are due on or before September 25, 1995.

ADDRESSES: Comments (four copies) should be filed with the Hearing Clerk, Room 1083, South Building, United States Department of Agriculture, Washington, DC 20250.

FOR FURTHER INFORMATION CONTACT: Nicholas Memoli, Marketing Specialist, Order Formulation Branch, USDA/AMS/Dairy Division, Room 2971, South Building, P.O. Box 96456, Washington, DC 20090–6456, (202) 690–1932.

SUPPLEMENTARY INFORMATION: This administrative action is governed by the provisions of sections 556 and 557 of Title 5 of the United States Code and, therefore, is excluded from the requirements of Executive Order 12866.

The Regulatory Flexibility Act (5 U.S.C. 601–612) requires the Agency to examine the impact of a proposed rule on small entities. Pursuant to 5 U.S.C. 605(b), the Administrator of the Agricultural Marketing Service has certified that this proposed rule will not have a significant economic impact on a substantial number of small entities. The amendments would permit plants to be regulated under the order in which they are physically located.

The amendments to the rules proposed herein have been reviewed under Executive Order 12778, Civil Justice Reform. They are not intended to have a retroactive effect. If adopted, the proposed amendments would not preempt any state or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with the Secretary a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with the law and requesting a modification of an order or to be exempted from the order. A handler is afforded the opportunity for a hearing on the petition. After a hearing, the Secretary would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has its principal place of business, has jurisdiction in equity to review the Secretary's ruling on the petition, provided a bill in equity is filed not later than 20 days after the date of the entry of the ruling.

Prior document in this proceeding: *Notice of Hearing:* Issued November 21, 1994; published November 25, 1994 (59 FR 60574).

Preliminary Statement

Notice is hereby given of the filing with the Hearing Clerk of this recommended decision with respect to proposed amendments to the tentative marketing agreements and the orders regulating the handling of milk in the Carolina, Tennessee Valley, and Louisville-Lexington-Evansville marketing areas. This notice is issued pursuant to the provisions of the Agricultural Marketing Agreement Act and the applicable rules of practice and procedure governing the formulation of marketing agreements and marketing orders (7 CFR part 900).

Interested parties may file written exceptions to this decision with the Hearing Clerk, U.S. Department of Agriculture, Washington, DC 20250, by the 30th day after publication of this decision in the Federal Register. Four copies of the exceptions should be filed. All written submissions made pursuant to this notice will be made available for public inspection at the office of the Hearing Clerk during regular business hours (7 CFR 1.27(b)).

The proposed amendments set forth below are based on the record of a public hearing held at Charlotte, North Carolina, on January 4, 1995, pursuant to a notice of hearing issued November 21, 1994 (59 FR 60574).

The material issues on the record of hearing relate to:

1. Marketing area modifications to the Tennessee Valley and Louisville-Lexington-Evansville orders;
2. Where to regulate a distributing plant that meets the pooling standards of more than one order;
3. Supply plant pooling standards under the Tennessee Valley order;
4. Distributing plant pooling standards under the Carolina order;
5. Location adjustments under the Carolina order; and
6. Base-paying months under the Carolina order.

Findings and Conclusions

The following findings and conclusions on the material issues are based on evidence presented at the hearing and the record thereof:

1. Marketing Area Modifications to the Tennessee Valley (Order 11) and Louisville-Lexington-Evansville (Order 46) Orders

Six now-unregulated Kentucky counties between the Order 11 and Order 46 marketing areas should be added to the Order 11 marketing area and one county that is now part of the Order 46 marketing area should be removed and added to the Order 11 marketing area.

A spokesman for Southern Belle Dairy Company, Inc., testified that the six

unregulated counties—Clay, Jackson, Laurel, McCreary, Owsley, and Rockcastle—and the one Order 46 county—Pulaski—are in an area that is closely associated with the Tennessee Valley marketing area. He pointed out, for example, that two Order 11 pool plants—the Flav-O-Rich plant at London and the Southern Belle plant at Somerset—are in Laurel and Pulaski Counties, respectively.

The witness indicated that Southern Belle had sales in each of the counties proposed to be added to the marketing area. He also introduced data showing that 79 percent of the fluid milk sales in the seven-county area came from the Southern Belle and Flav-O-Rich plants. He said that a majority of the sales in Pulaski County also came from Order 11 plants.

There was no opposition to this proposal either at the hearing or in post-hearing briefs.

The six now-unregulated Kentucky counties should be added to the Order 11 marketing area and Pulaski County should be removed from the Order 46 marketing area and added to the Order 11 marketing area. This seven-county area is closely associated with the Tennessee Valley market and its addition to the Order 11 marketing area, in conjunction with the pooling standards adopted in this decision, will add regulatory stability for the plants with sales in this area. There are no plants in this seven-county area other than the Southern Belle and Flav-O-Rich plants and none outside of this area that would become regulated as a result of the addition of this territory to the Tennessee Valley marketing area.

2. Where to Regulate a Distributing Plant That Meets the Pooling Standards of More Than One Order

The pooling standards of the Tennessee Valley and Carolina orders should be modified to fully regulate a distributing plant that is located within their respective marketing areas and that meets the pooling standards of §§ 1011.7(a) or 1005.7(a), respectively, even if the plant meets the pooling standards of another order and has more route disposition in such other order's marketing area.

These amendments will allow a distributing plant at Kingsport, Tennessee, that is located within the Tennessee Valley marketing area and that meets all of the pooling standards of the Tennessee Valley order to be regulated under that order rather than under the Carolina order, despite the plant's having greater sales in the Carolina marketing area. Similarly, they will allow a distributing plant located at Somerset, Kentucky—which, as recommended under Issue No. 1, would be part of the Order 11 marketing area—to be regulated under Order 11 even if the plant should develop greater sales in the marketing area of Order 46 or some other order's marketing area. Finally, the amendments will permit a plant located at Greenville, South Carolina (in the Order 5 marketing area), to be regulated under Order 5 even if the plant has more sales in the Southeast marketing area (Order 7).

These recommendations and the proposals which prompted them stem from various pricing problems under these orders that have come about for a variety of reasons, including the fact that the marketing areas may not have grown as fast as handlers' distribution areas. The pricing problems identified on the record of this proceeding relate to Land-O-Sun Dairies, Inc., at Kingsport, Tennessee; Southern Belle Dairy Company at Somerset, Kentucky; and Superbrand Dairy Products, Inc., at Greenville, South Carolina.

Land-O-Sun Dairies, Inc., operates a plant at Kingsport, Tennessee, which is in the Tennessee Valley marketing area. Because of this plant's greater route disposition in the Carolina marketing area, it has been regulated under that order. During the past three years (January 1992–November 1994), the blend price at Kingsport under Order 5 has averaged 14 cents below the blend price at that location under Order 11. In some months, the difference has been as high as 32 cents. Although the Class I price at Kingsport is identical under both of these orders, the Tennessee Valley order's higher Class I utilization—e.g., 82.03 percent for Order 11 compared to 77.96 percent for Order 5 during the first 10 months of 1994—has led to a higher blend price under that order at Kingsport during nearly every month for the past three years.

A spokesman for Land-O-Sun testified that the Kingsport plant handles approximately 12 million pounds of milk per month and that about one-third of its Class I sales are distributed on routes within the Tennessee Valley marketing area and the remaining two-thirds within the Carolina marketing area.

The witness testified that Land-O-Sun purchases its raw milk supply from 140 dairy farmers located in northeast Tennessee and southwest Virginia within 100 miles of the Kingsport plant. He noted that this area is also the supply area for other Order 11 pool plants. As a result, he said, any blend price difference to producers in this common supply area leads to market instability. Because the Order 11 blend price is higher than the Order 5 blend price, he stated, Land-O-Sun is forced to pay over-order prices to retain its producers. He indicated that Land-O-Sun could not consistently pay these higher prices and remain a viable business entity.

Southern Belle Dairy at Somerset, Kentucky, has been regulated under Order 11 since 1989. In recent years, the plant has had nearly equal sales in the Order 46 and Order 11 marketing areas. If regulation of the plant had shifted to Order 46, the applicable Class I differential price would be 19 cents lower than under Order 11 (i.e., $2.26 compared to $2.45), but the blend price difference would be even more substantial. For example, in the past 35 months (January 1992–November 1994), the Order 46 blend price averaged 30 cents below the Order 11 blend price at Somerset. In some months during this period, the difference in blend prices was as much as 67 cents.

At the hearing, a Southern Belle spokesman testified that the handler sought the marketing stability that would be provided by regulating the plant under Order 11 based upon its location within the Order 11 marketing area. The spokesman stated that Southern Belle would experience procurement problems if it could only pay its producers the Order 46 blend price in competition with Order 11 handlers—such as the Flav-O-Rich plant at London, Kentucky, 37 miles east of Somerset—which also procure milk from the same supply area. He also cited the marketing instability that would result from the plant shifting back and forth between the two orders, particularly in view of the differing base and excess payment plans to producers in each of these orders.

Superbrand Dairy Products at Greenville, South Carolina, has been regulated under the Georgia order since May 1992 despite the fact that it is located within the marketing area of the Carolina order and meets the pooling standards of that order.

A spokesman for Mid-America Dairymen, Inc. (Mid-Am), which has a full supply contract with the Superbrand plant, testified that the Carolina order should be amended to provide the same type of pooling standard that has been proposed for the Tennessee Valley order and that was incorporated in the Department's recommended (and final) decisions for the new Southeast order.[1] Inclusion of

[1] Official notice is taken of the final decision for the Southeast order issued on May 3, 1995 (60 FR 25014).

this provision in each of these orders will provide regulatory compatibility throughout the Southeast, he said.

The witness stated that the Mid-Am proposal would return the Superbrand plant to its former status as a pool plant under Order 5. In terms of its sales and procurement pattern, the plant is more closely associated with the Carolina market, he added.

The Mid-Am spokesman testified that the proposed change in pooling standards is a departure from the traditional method of determining where a distributing plant should be regulated when it meets the pooling standards of more than one order. The traditional method, he explained, regulated a plant wherever it had the most sales. He said that the principle behind that practice was to insure that all handlers having sales in an order area were subject to the same regulatory provisions as their competition. However, he added, with the advent of large processing plants with sales distribution over wide geographic areas, the traditional method of pooling distributing plants has become obsolete.

There was no opposition to this proposal either at the hearing or in post-hearing briefs.

For the most part, Federal milk orders have traditionally regulated plants according to where they had the most sales. The reasoning behind that policy has been to ensure that all handlers having sales in a Federal order marketing area were subject to the same minimum prices (adjusted for plant location) and other regulatory provisions as their competition. When these provisions were first incorporated in orders, markets were primarily local in nature. At any given location, it was common for Class I prices to differ among orders, and it was common for each order to have a unique set of provisions.

Most of the provisions in Federal milk orders today are standardized. For example, all orders have uniform classification and allocation provisions. Similarly, most Federal order Class I prices are properly aligned. As noted above, for example, the Class I price at Kingsport, Tennessee, is the same whether Land-O-Sun's plant is regulated under Order 5 or Order 11; the Southern Belle plant at Somerset, Kentucky, would be subject to a higher Class I price under Order 11 than would apply at the plant under Order 46; and the Superbrand plant at Greenville would be subject to the same Class I price whether it was regulated under Order 5 or Order 7.

Consequently, it must be concluded that the competitive equity that was, and continues to be, sought by having competing handlers subject to the same rules and Class I prices can be achieved in these marketing areas by pooling distributing plants under the orders applicable to the marketing areas in which the plants are located. Specifically, the pooling standards of the Tennessee Valley and Carolina orders should be amended to fully regulate all distributing plants that meet the orders' pooling standards and that are located within their respective marketing areas.

Under the provisions adopted here for the Carolina and Tennessee Valley orders, a plant that qualifies as a pool distributing plant and which is located within the marketing area will be regulated under the order applicable to that marketing area even if it meets the pooling standards of another order and has greater sales in such other order's marketing area. The nearby Southeast order, Louisville-Lexington-Evansville order, and Upper Florida order contain provisions (§§ 1007.7(g)(4), 1046.7(e)(3), and 1006.7(d)(3), respectively) that conform to the proposed provisions by yielding regulation of such plants to the other order.

Orders 5 and 11 also should be modified to recognize another order's primacy to regulate a plant that meets such other order's pooling standards and that is within the other order's marketing area. This is accomplished in §§ 1005.7(e)(3) and 1011.7(e)(3).

A clarifying change should also be made to §§ 1005.7(e)(5) and 1011.7(e)(5). At present, these paragraphs, which are designated as §§ 1005.7(d)(4) and 1011.7(d)(4), state that "the term pool plant shall not apply to a plant qualified pursuant to paragraph (b) of this section which also meets the pooling requirements for the month under another Federal order." A problem could arise with this language because during certain months of the year a supply plant may qualify as a pool plant by shipping less than 50 percent of its receipts to distributing plants. For example, if a supply plant shipped 40 percent of its receipts to pool distributing plants under Order 5 and 40 percent of its receipts to distributing plants under Order 11, both orders, pursuant to the language quoted above, would yield regulation of the plant to the other order, leaving the plant in a state of regulatory limbo. To prevent this unlikely event from occurring, the paragraph should be modified to read: "The term pool plant shall not apply to a plant qualified pursuant to paragraph (b) of this section if the plant has automatic pooling status under another Federal order or if the plant meets the pooling requirements of another Federal order during the month and makes greater qualifying shipments to plants regulated under such other order than to plants regulated under this order."

3. Supply Plant Pooling Standards Under the Tennessee Valley Order

The supply plant pooling provisions for the Tennessee Valley order should be amended to provide automatic pooling status for a supply plant which met the order's shipping standards during the preceding months of July through February.

Armour Food Ingredients Company (Armour) proposed the change in supply plant pooling standards. A spokesman for Armour testified that the company operates a supply plant at Springfield, Kentucky, that has been a pool plant under Order 11 since August 1992. He said that the facility is a "dual Grade A/Grade B plant." The Grade A part of the plant is used to assemble Grade A milk from producers' farms for transshipment to pool distributing plants, while the Grade B facility is used to process surplus milk into Class III products, he explained.

The witness testified that Order 11 now requires Armour to ship milk to distributing plants every month of the year. However, much less milk is needed from Armour during the spring than during the other months of the year, he said. Consequently, he concluded, Armour and its distributing plant customers are incurring receiving and hauling costs for no other purpose than to satisfy the order's shipping requirements.

The witness introduced an exhibit which showed that from August 1992 through October 1994 Armour shipped a monthly average of 71 percent of its receipts to pool distributing plants. The exhibit also showed that when shipments of surplus milk from these same pool distributing plants to Armour were subtracted from the receipts from Armour, the distributing plants, on average, kept 34 percent of the milk that was sent to them.

There was no opposition to this proposal either at the hearing or in post-hearing briefs.

The provision proposed by Armour is included in many Federal milk orders because of the seasonal variation in milk production. This variation is also evident in the Tennessee Valley market. In 1993, the average daily production per producer in this market was 2,220 pounds. However, this daily average reached a low of 1,941 pounds during the month of July and peaked at 2,481 pounds during May. As a group, the months of March through June had a

daily average of 2,375 pounds, compared to 2,149 pounds during the months of July through February.

There is no merit in requiring supply plants to receive, reload, and ship milk to distributing plants if the milk is not needed or if closer milk is available directly from producers' farms. In addition to the statistics suggesting that supply plant shipments during the months of March through June are unnecessary, the lack of any contradictory testimony from Order 11 distributing plant operators must be interpreted as concurrence with the view that supply plant shipments are simply not needed during the months of March through June. In view of this evidence, the proposal should be adopted.

Section 1011.7(b)(3) of the Tennessee Valley order, as proposed to be amended here, also should be modified to clarify what would happen if a shipping requirement were instituted during the months of March through June pursuant to § 1011.7(b)(4). First, it should be understood that a new supply plant or one that did not meet the order's shipping requirements during the months of July through February would be subject to the 40 percent supply plant shipping requirement now in the order.

If the market is short of milk during the "free-ride" months of March through June and the market administrator determines that additional milk is needed from pool supply plants pursuant to § 1011.7(b)(4), any increase in shipping percentage would be added to the percentage that is then applicable to the plant. For instance, if the market administrator determines that a 10-percentage point increase in shipments is needed, a plant that would have had to ship 40 percent of its receipts would be required to ship 50 percent. However, a plant in "free-ride" status, which normally would not have had to make any shipments, would have to ship 10 percent. The market administrator's ability to require additional milk from supply plants, even during the free-ride period of March through June, will help to ensure that the market has adequate supplies of milk for fluid use during all months of the year.

At the present time, §§ 1005.7(b) and 1011.7(b) of the Carolina and Tennessee Valley orders, respectively, authorize the Director of the Dairy Division to adjust supply plant shipping standards to obtain needed shipments of milk or to prevent uneconomic shipments. This provision was not an issue at the hearing. However, in conjunction with the other changes in pooling provisions recommended in this decision, it is recommended that authority to adjust supply plant shipping standards be given to the market administrator of Orders 5 and 11.

With all of the marketing information immediately available to him or her, the market administrator is in an ideal position to sense the changing needs of the market and to obtain industry views concerning the desirability of adjusting supply plant shipping requirements. As a result, the market administrator will be able to attend to the need for such temporary revisions in a timely fashion. Since this change was not discussed at the hearing, it will not be carried forth to the final decision in the face of industry opposition. It is being recommended here as a modification that would better serve the changing needs of handlers and producers under the Carolina and Tennessee Valley orders.

A similar conforming change also should be made in § 1011.13(e)(3) of the Tennessee Valley order for the same reasons. This change would allow the market administrator to increase or decrease, by 10 percentage points, the diversion limitations applicable to a proprietary bulk tank handler.

4. Distributing Plant Pooling Standards Under the Carolina Order

Proposals to amend the Order 5 in-area route disposition requirement for pool distributing plants should not be adopted.

At the present time, a distributing plant must dispose of at least 60 percent of its fluid milk product receipts in Class I during the months of August through November, January, and February and at least 40 percent in each of the other months to qualify as a pool plant under Order 5. In addition, at least 15 percent of the plant's route disposition must be in the marketing area.

Milkco, Inc., testified in support of its proposal to change the in-area route disposition standard of Order 5 from 15 percent to 10 percent. At the hearing, Milkco modified its proposal to the lesser of 1500 pounds daily or 10 percent of a plant's fluid milk receipts sold as Class I.

A witness representing Milkco, Carolina Dairies, Hunter Farms, Inc., Dairy Fresh, Inc., and Pine State Creamery testified that the original proposal had been modified to include language similar to that contained in the recommended decision of the proposed Southeast Federal order.

The witness testified that the reason for proposing a change in the in-area route disposition requirement was that partially regulated handlers were constantly increasing their Class I distribution into the Order 5 marketing area. He estimated that the average distribution for 1994 was between 25 million and 35 million pounds. He claimed that this distribution is attributed to sales from partially regulated plants located in Virginia.

The witness explained that the Virginia State Milk Commission prices Class I sales made outside the State of Virginia at the Federal order Class II price. He said that this creates a problem of accountability for those Class I sales moving from Virginia to another State. He claimed that the possibility exists that, in some instances, not all of those sales may be accounted for and paid for at the appropriate price.

The witness stated that the proposed amendment would provide uniformity between Order 5 and surrounding orders. He also claimed that the proposed change would not be burdensome to handlers located in Virginia if these handlers are already paying prices equivalent to, or greater than, the Order 5 Class I price.

The general manager for Carolina Virginia Milk Producers Association (CVMPA) also testified in support of the revised proposal. He stated that the proposal would provide uniformity between Order 5 and neighboring orders and that it would eliminate potential inequities between Order 5 handlers and handlers regulated by the Virginia Milk Commission.

The CVMPA representative asserted that the proposal would regulate some partially regulated plants that may be subject to a lower price for milk used in fluid milk products than fully regulated plants under Order 5. He explained that handlers regulated under Order 5 must pay at least the minimum Federal order class prices for their milk. He claimed that plants located in Virginia and regulated by the Virginia Milk Commission have a competitive advantage on raw milk costs compared to handlers fully regulated under Order 5. The witness indicated that the Class I price established and regulated by the Virginia Milk Commission has historically been higher than the Order 5 price but that the Commission requires that only the Class II price be paid for sales out of the State.

The CVMPA witness testified that sales from partially regulated handlers located in Virginia into the Carolina marketing area have a significant impact on the market. Since January 1992, he pointed out, sales from these plants have ranged from one to three million pounds of Class I sales or between .84

and 2.26 percent of total route disposition in Order 5. He said that while these Class I sales from Virginia partially regulated plants are confined to a small portion of the marketing area, they have had a disruptive effect on the market in eastern North Carolina.

The CVMPA representative testified that Federal orders contiguous to the Carolina marketing area have more restrictive pool plant requirements than the Carolina order. He noted that the Tennessee Valley order's in-area route disposition requirement was 10 percent and that the recommended Southeast order would fully regulate handlers if a plant distributed either 10 percent of its total fluid milk receipts or at least 1500 pounds of Class I sales per day in the marketing area. Such requirements are appropriate for orders with relatively high Class I utilization, he said.

Maryland & Virginia Milk Producers Cooperative Association, Inc. (MVMPCA), proposed a change to the Order 5 in-area route disposition requirement that would have exactly the opposite effect of Milkco's proposal. The MVMPCA proposal would base the in-area requirement on 15 percent of "dairy farmer receipts" rather than 15 percent of "total route disposition." Because dairy farmer receipts would be larger than total route disposition, the proposal would have the effect of making it more difficult to qualify for full regulation under Order 5.

A spokesman for MVMPCA testified that the proposed change would amend the Order 5 provision to conform more closely with the provisions of the Middle Atlantic order (Order 4). He said that these definitions should be more closely aligned to allow distributing plants in the Commonwealth of Virginia, which are partially regulated under both Orders 4 and 5, to be subject to the same in-area route distribution standard under either Federal order.

Without alignment of these provisions, he said, there could be results which are neither intended nor orderly. For instance, he stated, a plant could have more route sales in Order 4 but become fully regulated under Order 5.

The witness stated that there are currently three dairies partially regulated in both Orders 4 and 5: Richfood at Richmond, Virginia; Land-O-Sun Dairies, Inc., at Portsmouth, Virginia; and Marva Maid Dairy at Newport News, Virginia. He said that these Virginia plants are the only partially regulated distributing plants subject to Order 5 other than the several plants which distribute long-shelf-life fluid milk products in a broad geographic area over most of the United States. Consequently, he concluded, the MVMPCA proposal would not have a substantial impact upon any other plants.

A witness representing Richfood Dairy, Inc. (Richfood), Richmond, Virginia, testified in opposition to Milkco's proposal to reduce the Order 5 in-area route disposition requirement and in support of Richfood's proposal to increase the requirement from 15 percent to 20 percent.

The witness stated that Richfood has about 83 percent of its fluid milk product sales in that part of Virginia that is outside the Middle Atlantic (Order 4) marketing area. The plant has approximately 12 percent of its sales in the Carolina marketing area, 4 percent in the Order 4 marketing area, and the remaining 1 or 2 percent in the Ohio Valley marketing area. Richfood's sales into the Carolina marketing area account for about 1 percent of the market's total in-area sales, according to the witness.

The Richfood witness stated that Richfood primarily has fluid milk sales in the eastern Virginia market with some in the western Virginia market. During October 1994, the witness noted, the eastern and western markets' Class I prices were $16.29 and $16.02, respectively. He said that these Virginia prices, based on the way in which Federal order Class I prices are set, would represent October Class I differentials of $4.56 for the eastern market and $4.29 for the western market. Federal order Class I differentials of this magnitude, he emphasized, are not even found in Miami, the highest priced location under the Federal order system. These facts, he claimed, show that purchasers of raw milk in Virginia do not have an unfair competitive advantage over handlers regulated under a Federal order. He concluded that a plant with 10 percent of its sales in the Carolina marketing area and 80 percent in Virginia should not be forced to be fully regulated under Order 5.

The administrator of the Virginia State Milk Commission (the Commission) testified in opposition to Milkco's original proposal. The administrator stated that pooling Virginia plants that have less than 15 percent of their total sales in a Federal order marketing area would be disruptive to the Commission's ability to price and pool milk in the Virginia marketing areas. He argued that there are less intrusive ways to accomplish class price integrity for pooling producer milk.

The witness stated that the Commission was willing to assist the Department to ensure proper reporting and pricing within Federal milk marketing areas to alleviate the concerns of those who have doubts that Virginia's out-of-area prices are being enforced. The witness explained that the Commission has the ability to report sales by Virginia plants into Federal orders in a timely and accurate manner, and is willing to provide such information to the appropriate Federal order market administrator to help enforce proper pricing.

Neither Milkco's proposal, which would make it easier to fully regulate an out-of-area plant, nor MVMPCA's or Richfood's proposal, which would make it harder to fully regulate an out-of-area plant, should be adopted.

Proponents of Milkco's proposal argued that the amount of sales into the Carolina marketing area from partially regulated plants located in Virginia is constantly increasing due to the presence of these plants. Record evidence does not support this argument. For instance, route disposition in Order 5 by partially regulated plants during the months of July through October 1994 was lower than for the same period of 1993. In addition, statistics show that in-area route disposition into Order 5 from partially regulated plants located in Virginia have been at a relatively constant level over the past two years. For example, in 1993 and 1994, the average share of total Order 5 Class I route disposition from these plants was 2.05 and 1.95 percent, respectively.

No evidence presented at the hearing supported the arguments advanced by Milkco and CVMPA concerning the alleged competitive advantage that partially regulated plants in Virginia have in the Carolina marketing area. The record is devoid of any data to support this claim.

With respect to proponents' arguments that changes in Order 5 would bring this order into conformance with the Middle Atlantic order or the Southeast order, marketing conditions in the Carolina order do not warrant any change to the in-area route disposition requirement for this reason. Moreover, it is not clear why differences in the in-area route disposition requirements of these orders would matter in most circumstances. The only area where this issue seems to be particularly acute is in Virginia. Even in Virginia, however, there is an insufficient basis to conclude that any competitive advantage exists that would warrant undermining of the Virginia State Milk Commission regulation.

The in-area route disposition requirement is a locally tailored standard that indicates when a plant is

sufficiently associated with a market to warrant full regulation under the order regulating that marketing area. Whether the standard should be 10 percent or 15 percent depends upon particular circumstances in that area and the demonstrated need for one standard or the other. Based on the testimony and data in this hearing record, the present 15 percent in-area route disposition requirement under Order 5 should remain unchanged.

5. Location Adjustments Under the Carolina Order

The location adjustment under the Carolina order for a location within the Middle Atlantic Federal order marketing area should be determined by subtracting the Order 4 Class I price at that location from the base zone Class I price specified in Order 5.

At the present time, the Order 5 location adjustment for a plant located in the State of Maryland is based upon the shortest hard-surfaced highway distance, as determined by the market administrator, that such plant is from Greensboro, North Carolina. Once that distance is determined, it is broken down into 10-mile increments (except for the last increment, which may be smaller than 10 miles), which are then multiplied by 2.5 cents to determine the location adjustment. Thus, for example, the location adjustment for a plant that is located 295 miles from Greensboro would be 75 cents (i.e., $30 \times 2.5 = .75$).

Maryland and Virginia Milk Producers Cooperative Association proposed a change in the location adjustment applicable to its butter/powder plant at Laurel, Maryland. Initially, the cooperative proposed treating the Laurel plant as if it were within the State of Virginia; this would result in a zero location adjustment at Laurel. However, at the hearing a spokesman for the cooperative stated that it would support an alternative proposal that would subtract the Order 4 Class I differential price at Laurel (i.e., $3.03) from the Order 5 Class I price at Greensboro (i.e., $3.08), which results in a location adjustment of minus 5 cents. The witness stated that "our only caveat to this pricing formula is that the Order 5 language should be amended so that the price at Strasburg, Virginia, is established on the same basis as the price at Laurel, Maryland."

The cooperative's spokesman testified that MVMPCA supplies the Kroger Westover Dairy Order 5 pool distributing plant at Lynchburg, Virginia, on a year-round basis. In addition, he said that since 1992 the cooperative has supplied supplemental milk to nine other Order 5 distributing plants on a seasonal basis.

The witness said that MVMPCA has served as a seasonal balancing agent in supplying Order 5 plants. He introduced an exhibit showing that MVMPCA's monthly sales to Order 5 plants reach a peak during the short production months of July through October.

The witness stated that when producers' milk is not needed by Order 5 plants, it is diverted to MVMPCA's butter-powder plant at Laurel, which serves as a major balancing plant for the Middle Atlantic region. The witness also noted that there is another balancing facility for Order 5 surplus milk—the Valley Milk butter/powder plant located at Strasburg, Virginia—which is approximately 80 miles west of Laurel and outside of any Federal order marketing area. He said that Order 5 now prices milk in an inequitable manner by providing a base zone uniform price for milk that is diverted to Strasburg, but a minus 75-cent location adjustment for milk that is diverted to Laurel.

There was no opposition to this proposal either at the hearing or in the post-hearing briefs that were filed.

MVMPCA's argument and alternative proposal for pricing milk at Laurel is persuasive and should be adopted. The location adjustment at Laurel clearly should not be minus 75 cents. It should be minus 5 cents, the difference between the Order 5 base zone Class I price and the Order 4 Class I price at Laurel.

The appropriate Federal order Class I price at Laurel, Maryland, is the price established for that location under the Middle Atlantic Federal order, which encompasses Laurel. Thus, if a distributing plant located at Laurel were to become regulated under Order 5, its Class I price would be the same as the price that would apply under Order 4. This would ensure competitive pricing among competing handlers. Determining location adjustments for plants in this manner helps to assure the proper alignment of Class I prices throughout the Federal order system and to minimize procurement problems for plants that are located in one Federal order marketing area but regulated under a different order.

The evidence introduced by MVMPCA shows that its producers supplying the Order 5 market are located as far south as the Virginia/North Carolina border and as far north as Cumberland County, Maryland. The exhibit, for example, shows that MVMPCA has producers in Halifax County, Virginia, just north of the Order 5 base zone. When producer milk from Halifax is delivered to a distributing plant at Lynchburg or to a North Carolina handler in the base zone, the milk is priced at the base zone price. Yet, under present order provisions, if the milk is not needed for fluid use by an Order 5 distributing plant and must be diverted to MVMPCA's butter-powder plant at Laurel, 247 miles away, it receives 75 cents less than the base zone price. Consequently, not only does MVMPCA receive a much lower price for this milk, it also absorbs the hauling cost to get the milk to Laurel.

A location adjustment of minus 5 cents at Laurel will narrow the difference to 5 cents between the Laurel and Strasburg plants. This adjustment should alleviate the inequity that now exists in pricing between the two plants. To further reduce the difference in price by imposing a minus 5-cent location adjustment at Strasburg, as suggested by MVMPCA, would entail changing location adjustments throughout the State of Virginia, which goes beyond the scope of the hearing proposals.

6. Base-Paying Months Under the Carolina Order

Maryland & Virginia Milk Producers Cooperative Association, Inc., originally submitted a proposal to delete the month of June from the base-paying period of the Order 5 base and excess payment plan. At the hearing, however, the cooperative modified its proposal to add the month of February as well as delete the month of June. As modified, the base-paying months would be February through May.

The MVMPCA witness stated that the purpose of the base-excess plan is to provide producers with an incentive to level their production on a seasonal basis. He indicated that the plan encourages production during the months when milk is needed for fluid use and discourages production during flush production months. Under current marketing conditions, he contended, June is not a surplus month but a month when supplemental supplies are frequently needed by Order 5 distributing plants. Likewise, he asserted that February is a month of substantial surplus production and should be added to the base-paying period rather than remain a base neutral month.

During 1992 and 1993, the MVMPCA witness noted, daily average production per Order 5 producer from May to June declined about 8 percent, from 4,259 pounds per day to 3,978, and from 4,424 to 4,076, respectively. However, he indicated that daily average production in Order 5 in February 1993 of 4,684 pounds was the highest production

month of the year, and production in February 1992 was the third highest month.

The witness also testified that a collateral consequence of including June as a base paying month is that when supplemental supplies are needed under Order 5, unnecessary and inefficient movements of milk are required to avoid the penalty of absorbing the excess price for supplies of milk that are required for the market's Class I needs. The witness explained that when supplemental milk is needed during the month of June, MVMPCA avoids the penalty of receiving only the excess price for milk delivered directly from producers' farms by instead delivering plant milk from its Laurel plant. To do this, however, the cooperative must receive the milk at Laurel, reload it onto a tank truck, and ship it to an Order 5 distributing plant. He said that the modified proposal would eliminate unnecessary and inefficient movements of milk for the sole purpose of avoiding the order's excess price.

There was no opposition to this proposal either at the hearing or in post-hearing briefs.

The modified proposal to change the base-paying period from March through June to February through May should be adopted. The removal of June and the addition of February to the base-paying period would bring the base-paying months into closer conformity with the Class I needs of the market.

For the past three years, the average Class I utilization in January has been 77.8 percent while the June Class I utilization has averaged 79.8 percent for this same time period. By comparison, the average Class I utilization for the months of February through May has been 75.6, 75.7, 73.9, and 75.1 percent, respectively. The record also shows that June is a month in which supplemental supplies of milk are needed to meet the Class I needs of the market.

On the basis of the statistical data and the testimony presented at the hearing, the month of February should be included in the base-paying period and June deleted to change the base-paying period to February through May. These changes should result in a base and excess plan that better serves the needs of the market and that will avoid the unnecessary and inefficient movements of needed supplemental milk described by MVMPCA.

Several conforming changes in order language have been made in response to the addition of February and the removal of June as a base-paying month. In § 1005.32(a), dealing with "other reports," the words "March through June" should be changed to "February through May". In the introductory text of § 1005.61(a) and in § 1005.61(a)(5), the words "July through February" must be changed to "June through January", and in § 1005.61(b) the words "March through June" must be changed to "February through May". In §§ 1005.90, 1005.91, and 1005.93(b) the words "March through June" must be changed to "February through May", and the words "February 1" in § 1005.93(b) and § 1005.94 should be changed to "January 1" to maintain the existing relationship between the start of the base-paying period and the time when transfers must be completed without the imposition of conditions concerning the receipt or transfer of additional base. Finally, "March 1" should be changed to "February 1" in § 1005.93(e).

Motion for a New Hearing

Purity Dairy and Fleming Dairy, both of Nashville, Tennessee, argued that the remedies proposed at this hearing were not sufficient to address some major problems. They maintain that while the proposed amendments would temporarily correct some problems, in the long run these remedies would only make the problems worse. They urged the Secretary to hold a new hearing to consider a merger of Orders 5, 11, and 46 or the merger of Orders 5 and 11 with the proposed Southeast marketing area.

A major study of Orders 5, 11, and 46 and other marketing areas is currently underway at Cornell University. One of the purposes of this study is to develop recommendations for a merged order in this area.

There have been several major changes in cooperative representation, supply arrangements, and plant ownership in these markets. Milk has been shifting among the markets. The alleged problem in south central Kentucky of misaligned uniform prices causing Purity and Fleming to be at a competitive disadvantage for milk supplies has been corrected by the association of additional milk with Order 11, which has lowered that order's Class I utilization. There is no point in considering a merger of orders in this area until such time as producers and handlers propose such a merger. For all of these reasons, the motion to hold a new hearing is denied.

Rulings on Proposed Findings and Conclusions

Briefs and proposed findings and conclusions were filed on behalf of certain interested parties. These briefs, proposed findings and conclusions, and the evidence in the record were considered in making the findings and conclusions set forth above. To the extent that the suggested findings and conclusions filed by interested parties are inconsistent with the findings and conclusions set forth herein, the requests to make such findings or reach such conclusions are denied for the reasons previously stated in this decision.

General Findings

The findings and determinations hereinafter set forth supplement those that were made when the aforesaid orders were first issued and when they were amended. The previous findings and determinations are hereby ratified and confirmed, except where they may conflict with those set forth herein.

(a) The tentative marketing agreements and the orders, as hereby proposed to be amended, and all of the terms and conditions thereof, will tend to effectuate the declared policy of the Act;

(b) The parity prices of milk as determined pursuant to section 2 of the Act are not reasonable in view of the price of feeds, available supplies of feeds, and other economic conditions which affect market supply and demand for milk in the marketing areas, and the minimum prices specified in the tentative marketing agreements and the orders, as hereby proposed to be amended, are such prices as will reflect the aforesaid factors, insure a sufficient quantity of pure and wholesome milk, and be in the public interest;

(c) The tentative marketing agreements and the orders, as hereby proposed to be amended, will regulate the handling of milk in the same manner as, and will be applicable only to persons in the respective classes of industrial and commercial activity specified in, marketing agreements upon which a hearing has been held; and

(d) All milk and milk products handled by handlers, as defined in the tentative marketing agreements and the orders as hereby proposed to be amended, are in the current of interstate commerce or directly burden, obstruct, or affect interstate commerce in milk or its products.

Recommended Marketing Agreements and Order Amending the Orders

The recommended marketing agreements are not included in this decision because the regulatory provisions thereof would be the same as those contained in the orders, as hereby proposed to be amended. The following order amending the orders, as amended, regulating the handling of milk in the aforesaid marketing areas is recommended as the detailed and

appropriate means by which the foregoing conclusions may be carried out.

List of Subjects in 7 CFR Parts 1005, 1011, and 1046

Milk marketing orders.

For the reasons set forth in the preamble, title 7, parts 1005, 1011, and 1046 are proposed to be amended as follows:

1. The authority citation for 7 CFR parts 1005, 1011, and 1046 continues to read as follows:

Authority: 7 U.S.C. 601–674.

PART 1005—MILK IN THE CAROLINA MARKETING AREA

2. In § 1005.7, the reference "(d)" in the introductory text is revised to read "(e)", in paragraph (b) the words "Director of the Dairy Division" and "Director" are changed to "market administrator" wherever they appear, paragraph (d) is redesignated as paragraph (e) and revised, and a new paragraph (d) is added to read as follows:

§ 1005.7 Pool plant.

* * * * *

(d) A plant located within the marketing area (other than a producer-handler plant or a governmental agency plant) that meets the qualifications described in paragraph (a) of this section regardless of its quantity of route disposition in any other Federal order marketing area.

(e) The term "pool plant" shall not apply to the following plants:

(1) A producer-handler plant;

(2) A governmental agency plant;

(3) A plant with route disposition in this marketing area that is located within the marketing area of another Federal order and that is fully regulated under such order;

(4) A plant qualified pursuant to paragraph (a) of this section which is not located within any Federal order marketing area but which also meets the pooling requirements of another Federal order and from which there is a greater quantity of route disposition, except filled milk, during the month in such other Federal order marketing area than in this marketing area; and

(5) A plant qualified pursuant to paragraph (b) of this section if the plant has automatic pooling status under another Federal order or if the plant meets the pooling requirements of another Federal order during the month and makes greater qualifying shipments to plants regulated under such other order than to plants regulated under this order.

§ 1005.32 [Amended]

3. In § 1005.32(a), the words "March through June" are revised to read "February through May" wherever they appear.

4. In § 1005.53, paragraph (a)(6) is redesignated as paragraph (a)(7) and revised, and a new paragraph (a)(6) is added to read as follows:

§ 1005.53 Plant location adjustments for handlers.

* * * * *

(a) * * *

(6) For a plant located within the Middle Atlantic Federal Order Marketing Area (Part 1004), the adjustment shall be computed by subtracting the base zone Class I price specified in § 1005.50(a) from the Class I price applicable at such plant under the Middle Atlantic Federal Order; and

(7) For a plant located outside the areas specified in paragraphs (a)(1) through (a)(6) of this section, the adjustment shall be a minus 2.5 cents for each 10 miles or fraction thereof (by the shortest hard-surfaced highway distance as determined by the market administrator) that such plant is from the nearer of the city halls in Greenville, South Carolina, or Charlotte or Greensboro, North Carolina.

* * * * *

§ 1005.61 [Amended]

5. In § 1005.61 paragraphs (a) introductory text and (a)(5), the words "July through February" are revised to read "June through January" and in paragraph (b) the words "March through June" are revised to read "February through May".

§§ 1005.90 and 1005.91 [Amended]

6. In §§ 1005.90 and 1005.91, the words "March through June" are revised to read "February through May" wherever they appear.

§ 1005.93 [Amended]

7. In § 1005.93 paragraph (b), the words "March through June" are revised to read "February through May" wherever they appear, the words "February 1" are revised to read "January 1", and in paragraph (e) the words "March 1" are revised to read "February 1".

§ 1005.94 [Amended]

8. In § 1005.94, the words "February 1" are revised to read "January 1".

PART 1011—MILK IN THE TENNESSEE VALLEY MARKETING AREA

9. Section 1011.2 is amended by revising paragraph (b) to read as follows:

§ 1011.2 Tennessee Valley Marketing Area.

* * * * *

(b) In Kentucky, the counties of Bell, Breathitt, Clay, Harlan, Jackson, Knott, Knox, Laurel, Leslie, Letcher, McCreary, Owsley, Perry, Pulaski, Rockcastle, and Whitley.

* * * * *

10. In § 1011.7, the reference "(d)" in the introductory text is revised to read "(e)", paragraph (b) is revised, paragraph (d) is redesignated as paragraph (e) and revised, and a new paragraph (d) is added to read as follows:

§ 1011.7 Pool plant.

* * * * *

(b) A plant, other than a plant described in paragraph (a) of this section, from which fluid milk products, except filled milk, are shipped to plants described in paragraph (a) of this section subject to the following additional conditions:

(1) During the months of August through November, January and February, such shipments must equal not less than 60 percent (40 percent during the months of December and March through July) of the total quantity of milk approved by a duly constituted regulatory agency for fluid consumption that is received during the month at such plant from handlers described in § 1011.9(c) and (d) and from dairy farmers, including milk that is diverted from the plant pursuant to § 1011.13 but excluding milk diverted to the plant;

(2) The operator of a plant described in this paragraph may include milk diverted from the plant to plants described in paragraph (a) of this section for up to one-half of the shipments required pursuant to this paragraph;

(3) A plant which meets the shipping requirements specified in this paragraph during the months of July through February shall be a pool plant during the following months of March through June unless the milk received at the plant does not continue to meet the requirements of a duly constituted regulatory agency, the plant fails to meet a shipping requirement instituted pursuant to paragraph (b)(4) of this section, or a written application is filed by the plant operator with the market administrator on or before the first day of any such month requesting that the plant be designated a nonpool plant for such month and for each subsequent month through June during which it would not otherwise qualify as a pool plant; and

(4) The shipping requirements described in paragraphs (b)(1) and (b)(3) of this section may be increased or

decreased up to 10 percentage points by the market administrator if he or she finds that revision is necessary to obtain needed shipments or to prevent uneconomic shipments. Before making such a finding, the market administrator shall investigate the need for revision either at his or her own initiative or at the request of interested persons. If the investigation shows that a revision may be appropriate, the market administrator shall issue a notice stating that the revision is being considered and invite data, views, and arguments.

(c) * * *

(d) A plant located within the marketing area (other than a producer-handler plant or a governmental agency plant) that meets the qualifications described in paragraph (a) of this section regardless of its quantity of route disposition in any other Federal order marketing area.

(e) The term "pool plant" shall not apply to the following plants:

(1) A producer-handler plant;

(2) A governmental agency plant;

(3) A plant with route disposition in this marketing area that is located within the marketing area of another Federal order and that is fully regulated under such order;

(4) A plant qualified pursuant to paragraph (a) of this section which is not located within any Federal order marketing area but which also meets the pooling requirements of another Federal order and from which there is a greater quantity of route disposition, except filled milk, during the month in such other Federal order marketing area than in this marketing area; and

(5) A plant qualified pursuant to paragraph (b) of this section if the plant has automatic pooling status under another Federal order or if the plant meets the pooling requirements of another Federal order during the month and makes greater qualifying shipments to plants regulated under such other order than to plants regulated under this order.

§ 10011.13 [Amended]

11. In § 1011.13 paragraph (e)(3), the words "Director of the Dairy Division" and "Director" are revised to read "market administrator" wherever they appear.

PART 1046—MILK IN THE LOUISVILLE-LEXINGTON-EVANSVILLE MARKETING AREA

§ 1046.2 [Amended]

12. In § 1046.2, under "Kentucky Counties" the word "Pulaski" is removed.

Dated: August 17, 1995.

Lon Hatamiya,

Administrator.

[FR Doc. 95–20968 Filed 8–23–95; 8:45 am]

BILLING CODE 3410–02–P

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7 CFR Part 1046

[DA–95–18]

Milk in the Louisville-Lexington-Evansville Marketing Area; Termination of Proceeding on Proposed Suspension/Termination of Base-Excess Plan

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Termination of proceeding of proposed suspension/termination of rule.

SUMMARY: This document terminates the proceeding that was initiated to consider a proposal to suspend or terminate the base-excess plan of the Louisville-Lexington-Evansville Federal milk marketing order effective September 1, 1995.

FOR FURTHER INFORMATION CONTACT: Nicholas Memoli, Marketing Specialist, USDA/AMS/Dairy Division, Order Formulation Branch, Room 2971, South Building, P.O. Box 96456, Washington, DC 20090–6456, (202) 690–1932.

SUPPLEMENTARY INFORMATION: Prior document in this proceeding: Proposed Suspension/Termination: Issued June 9, 1995; published June 15, 1995 (60 FR 31418).

This termination of proceeding is issued pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674). This proceeding was initiated by a notice of rulemaking published in the **Federal Register** on June 15, 1995 (60 FR 31418), concerning a proposed suspension/termination of certain provisions of the order regulating the handling of milk in the Louisville-Lexington-Evansville marketing area. The proposal would have suspended or terminated the base-excess plan provisions of Order 46. Interested parties were invited to comment on the proposal in writing by July 17, 1995. Four comments supporting and two comments opposing the proposed suspension/termination were received.

Statement of Consideration

This document terminates the proceeding initiated to suspend/terminate the base-excess plan under the Louisville-Lexington-Evansville Federal milk marketing order (Order 46). Holland Dairies, Inc. (Holland), a fully regulated distributing plant under Order 46, proposed the suspension/termination of the plan effective September 1, 1995.

Holland stated that the Order's base-excess plan had created significant milk procurement problems in the area in recent years and claimed that the plan limited its ability to obtain milk from new producers because these producers had no base. As a result, the handler concluded that it was forced to purchase supplemental milk during the summer months from producers located outside the region at an additional cost.

According to Holland, the cooperatives in the southern Indiana area which compete with it for producers do not pay their member-producers base and excess prices. Additionally, Holland stated that the Indiana and Ohio Valley Federal milk orders, which border Order 46 to the north, do not contain a producer base-excess plan. Holland contends that both of these factors place it at a competitive disadvantage in procuring milk and are unreasonable and detrimental to its long-term ability to retain nonmember producers.

Armour Food Ingredients Company (Armour) and three dairy farmers filed comment letters in support of the proposed suspension/termination of the Order 46 base-excess plan. Armour states that Order 46 no longer exhibits the highly seasonal changes in supply and demand which a base-excess plan is intended to curtail and, therefore, concludes that the suspension or termination of the plan would not have a detrimental impact on the market's seasonal supply-demand balance. Armour also contends the plan discourages new producers from starting a dairy operation. Three Indiana dairy farmers who filed comments stated that they favor the suspension or termination of the base-excess plan because the plan lowers the price they receive for their milk.

Milk Marketing Inc. (MMI), and Mid-America Dairymen, Inc. (Mid-Am), filed comments in opposition to the proposed suspension/termination of the Order 46 base-excess plan. MMI, a regional cooperative representing approximately 400 dairy farmers and 23 million pounds of milk per month pooled by handlers regulated under Order 46, states that a base-excess plan is designed to balance monthly production with consumption. MMI contends that producers have invested time and money and have adopted management

techniques to meet the needs of the marketplace. It argues that the suspension/termination would discourage producers from adopting production patterns that are needed to improve marketing efficiencies.

Mid-Am, a cooperative representing 451 producers who deliver milk to plants regulated under Order 46, contends Holland's claim that "the base-excess plan limits its ability to obtain milk from new producers because these producers have no base," is no basis to suspend or terminate the base-excess plan under Order 46. Mid-Am states that the volume of milk that would become available during the base-paying months would be an insignificant amount and that there is no need for Holland to procure supplemental milk from producers located outside the region during the base-paying months because there is more than an adequate supply of local milk available.

Mid-Am also points out that many cooperative member-producers in the southern Indiana area are being paid on the basis of a base-excess plan. During March through June 1995, Mid-Am indicated, over one-third of its member-producers with milk pooled on Order 46 were paid base and excess prices. The cooperative states that all of its member-producers will be paid on the basis of a base-excess plan during 1996. Finally, it argues that the plan helps to limit a handler's ability to shift milk between orders during the base-paying months of March through June when additional milk is not needed by handlers regulated under Order 46.

The comments submitted in response to the proposed suspension/termination reveal that there is overwhelming support for the continuation of the Order 46 base-excess plan by producers whose milk is pooled under the order. The comments indicate that there is an adequate supply of local milk available to Holland which should prevent Holland from having to purchase supplemental supplies of milk from producers located outside the region. In this regard, market data indicate that for the past two years Class I utilization under Order 46 has generally been between 65 and 75 percent during the base-paying months of March through June. The comments also reveal that the base-excess plan under Order 46 is currently used to pay many cooperative association member-producers now and will be used to pay many more next year. Therefore, the proceeding to suspend or terminate the plan is terminated.

List of Subjects in 7 CFR Part 1046

Milk marketing orders.

The authority citation for 7 CFR part 1046 continues to read as follows:

Authority: 7 U.S.C. 601–674.

Dated: August 17, 1995.

Patricia Jensen,

Acting Assistant, Secretary Marketing and Regulatory Programs.

[FR Doc. 95–20969 Filed 8–23–95; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 93–ANE–08]

Airworthiness Directives; Teledyne Continental Motors IO–360, TSIO–360, LTSIO–360, IO–520, and TSIO–520 Series Reciprocating Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Supplemental notice of proposed rulemaking; reopening of comment period.

SUMMARY: This notice revises a proposal to issue an airworthiness directive (AD), applicable to certain Teledyne Continental Motors (TCM) IO–360, TSIO–360, LTSIO–360, IO–520, and TSIO–520 series engines. Airworthiness directive 87–23–08 currently requires ultrasonic inspections for sub-surface fatigue cracks in crankshafts installed in TCM IO–520 and TSIO–520 series engines, and replacement of the crankshaft if a crack is found. The proposed AD would have superseded AD 87–23–08 by expanding the applicability of the AD to include IO–360, TSIO–360, LTSIO–360, and LTSIO–520 series engines, requiring the removal of all crankshafts manufactured using the airmelt process on all of the affected engine models, and replacement with crankshafts manufactured using the vacuum arc remelt (VAR) process. The proposed AD would have eliminated the ultrasonic inspections for the TCM IO–520 and TSIO–520 series engines. That proposed rule was prompted by reports of crankshaft failures due to sub-surface fatigue cracking on engines that had been inspected in accordance with the current AD. This action revises the proposed rule by superseding AD 87–23–08 and incorporating the ultrasonic inspection requirements in the proposed AD. The proposed action would still require removal of crankshafts manufactured using the airmelt process and replacement with crankshafts manufactured using the VAR process. The actions specified by this proposed AD are intended to prevent crankshaft failure and subsequent engine failure.

DATES: Comments must be received by October 23, 1995.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), New England Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 93–ANE–08, 12 New England Executive Park, Burlington, MA 01803–5299. Comments may be inspected at this location between 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Teledyne Continental Motors, P.O. Box 90, Mobile, AL 36601; telephone (334) 438–3411. This information may be examined at the FAA, New England Region, Office of the Assistant Chief Counsel, 12 New England Executive Park, Burlington, MA.

FOR FURTHER INFORMATION CONTACT: Jerry Robinette, Aerospace Engineer, Atlanta Aircraft Certification Office, FAA, Small Airplane Directorate, Campus Building, 1701 Columbia Ave., Suite 2–160, College Park, GA 30337–2748; telephone (404) 305–7371, fax (404) 305–7348.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following

statement is made: "Comments to Docket Number 93–ANE–08." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, New England Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 93–ANE–08, 12 New England Executive Park, Burlington, MA 01803–5299.

Discussion

A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to add an airworthiness directive (AD), applicable to certain Teledyne Continental Motors (TCM) IO–360, TSIO–360, LTSIO–360, IO–520, TSIO–520, and LTSIO–520 series engines, was published as a notice of proposed rulemaking (NPRM) in the **Federal Register** on July 23, 1993 (58 FR 39748). That proposal would have superseded AD 87–23–08, Amendment 39–5735 (52 FR 41937, October 30, 1987), which currently requires ultrasonic inspection of TCM IO–520 and TSIO–520 series engines for sub-surface cracks in the crankshaft, and replacement of the crankshaft, if a crack is found. The proposed AD would have eliminated the required ultrasonic inspections, but would have required removal of crankshafts that were manufactured using the airmelt process and required replacement with crankshafts that were manufactured using the vacuum arc remelt (VAR) process. The proposed AD would have also expanded the affected population of engines to add the TCM IO–360, TSIO–360, LTSIO–360, and LTSIO–520 series engines to the IO–520 and TSIO–520 series engines affected by AD 87–23–08. That proposal was prompted by reports of crankshaft failures due to subsurface fatigue cracking on engines that had been inspected in accordance with AD 87–23–08. That condition, if not corrected, could result in crankshaft failure and subsequent engine failure.

Since the issuance of that NPRM, the Federal Aviation Administration (FAA) has received numerous unfavorable comments, centering on the FAA's data and the economic impact of the proposed AD on small entities. The principal commenter, the Aeronautical Repair Station Association (ARSA), feels that the data presented by the FAA is not representative of the entire fleet. As a result, the FAA has decided to issue this Supplemental NPRM that revises the proposed AD and publishes additional data.

Teledyne Continental Motors has utilized two different processes in manufacturing crankshafts. Initially, TCM used an airmelt process, but later switched to the VAR process. The VAR process assures a better steel with less likelihood of impurities.

The crankshaft failures addressed by this AD are attributed to sub-surface fatigue cracks on engines with crankshafts having the three rear main bearing journal diameters as follows: for the 360 series engines 2.250 to 2.375 inches and for the IO/TSIO–520 series engines 2.375 to 2.625 inches. The FAA has received reports of crankshaft failures due to sub-surface fatigue cracks on 43 TCM IO–520 or TSIO–520 series engines and 9 IO–360 or TSIO–360 series engines. There are approximately 18,000 airmelt and 25,000 VAR TCM IO–520 or TSIO–520 series crankshafts in service as of February 1994. Between May 1986 and February 1994, on TCM IO–520 or TSIO–520 series engines, there were 40 failures of airmelt crankshafts and 3 failures of VAR crankshafts. In addition, there are approximately 5,000 airmelt and 10,800 VAR TCM IO–360 or TSIO–360 series crankshafts in service as of February 1994. During the same time frame there were 8 failures of airmelt crankshafts and 1 failure of a VAR crankshaft on TCM IO–360 or TSIO–360 series engines.

The Service Difficulty Report (SDR) database does not contain many of these failures and therefore was not used for this analysis. In addition, the SDR database contains the reports of service difficulties as submitted, and, therefore, a large number of those reports amount to the unconfirmed opinion of the submitter as to the cause of the failure. Further, the listings in the SDR database do not identify cracks as being sub-surface fatigue cracks, or, for example, cracks originating from manufacturing defects or resulting from propeller strikes. Lastly, the mix of VAR and airmelt crankshafts in service cannot be determined from the SDR database. The data used for this analysis, on the other hand, is gathered from sources such as FAA witnessed "teardown" reports and warranty claims, and pertains only to confirmed sub-surface fatigue cracks with the type crankshaft, VAR or airmelt, clearly identified.

The FAA has determined, however, that the ultrasonic inspections of crankshafts on TCM IO–520 and TSIO–520 series engines required by AD 87–23–08 should remain in order to continue to detect any sub-surface fatigue cracks that may occur in those crankshafts, regardless of manufacturing process. Therefore, this proposal will supersede AD 87–23–08 and would have the effect of making the repetitive ultrasonic inspection requirements applicable to all IO/TSIO/LTSIO–360 and IO/TSIO/LTSIO–520 series engines with small rear main bearing journals while requiring replacement of airmelt crankshafts with VAR crankshafts on all affected engine models at the next overhaul.

In addition, many commenters expressed general concern about the calculated economic impact of the proposed AD, and some specifically noted that they believe the price of the VAR crankshafts shown in the NPRM, $2,200, to be artificially low. The FAA disagrees. The FAA used the replacement cost of a crankshaft as reported by TCM, which has priced VAR crankshafts at a level to encourage owners to replace airmelt crankshafts with VAR crankshafts. TCM has also informed the FAA that the price will be competitively maintained; the FAA notes that TCM's last general price increase in May 1994 did not affect these crankshafts. While this price may differ significantly from the price that other manufacturers set for crankshafts on other engines, the FAA believes that $2,200 is a reasonable estimate of the replacement cost of a crankshaft on the affected engines.

The FAA has reviewed and approved the technical contents of TCM Mandatory Service Bulletin (SB) No. M92–16, dated September 29, 1992, that describes procedures for determining if crankshafts were manufactured using the airmelt process or VAR process.

Since an unsafe condition has been identified that is likely to exist or develop on other engines of this same type design, the proposed AD would require determining if the crankshafts installed on certain TCM IO–360, TSIO–360, LTSIO–360, IO–520, and TSIO–520 series engines were manufactured using the airmelt or VAR process, and replacing all crankshafts manufactured using the airmelt process with serviceable crankshafts manufactured using the VAR process at the next engine overhaul. The proposed AD would also require repetitive ultrasonic inspections of certain VAR crankshafts, and replacement, if a crack is found.

Since this change revises significantly the originally proposed rule, the FAA has determined that it is necessary to reopen the comment period to provide additional opportunity for public comment.

The FAA estimates that 15,500 engines installed on aircraft of U.S. registry would be affected by this proposed AD, that it would take approximately 1 work hour per engine

to determine the type of crankshaft, and that the average labor rate is $60 per work hour. Required parts would cost approximately $2,200 per engine to replace the crankshaft. In addition, the FAA estimates that it would cost $200 to perform the ultrasonic inspection at crankshaft removal including the costs of shipping and handling. The FAA estimates that approximately 10% of the affected engines will be overhauled per year. Based on these figures, the total annual cost impact of the proposed AD on U.S. operators is estimated to be $3,813,000.

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 USC 106(g), 40101, 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Teledyne Continental Motors: Docket No. 93–ANE–08.

Applicability: Teledyne Continental Motors (TCM) I0–360, TSIO–360, LTSIO–360, IO–520, and TSIO–520 series engines built on or prior to December 31, 1980; rebuilt I0–360, TSIO–360, LTSIO–360, IO–520, and TSIO–520 series engines with serial numbers lower than those listed in TCM Mandatory Service Bulletin (SB) No. M92–16, dated September 29, 1992; and factory overhauled I0–360, TSIO–360, LTSIO–360, IO–520, and TSIO–520 series engines with serial numbers of 901202H and lower. These engines are installed on but not limited to Beech Models 95–C55, 95–C55A, D55, D55A, E55, E55A, 58, 58A, 58P, 58PA, 58TC, and 58TCA; and Beech Models S35, V35, V35A, V35B, E33A, E33C, 35–C33A. 36, A36, F33A, F33C, and A36TC; Bellanca 17–30A; Cessna Models 172XP, 188, A185, A188, 206, T206, 207, T207, 210, T210, P210, 310R, T310P, T310Q, T310R, 320D, 320E, 320F, 336, 337, T337, P337, 340, 401, 402, 414, and T41B/C; Colemill Conversion of Commander 500A; Commander 2000; Goodyear Airship Blimp 22; Maule Model M–4; Mooney Models M20–K; Navion H; Pierre Robin HR100; Piper Models PA–28–201T, PA28R–201T, PA28RT–201T, PA34–200T, PA34–220T; Prinair Dehavilland Heron; and Reims Models FR172, F337, FT337.

Note: This AD applies to each engine identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For engines that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must use the authority provided in paragraph (b) to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition, or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any engine from the applicability of this AD.

Compliance: Required as indicated, unless accomplished previously.

To prevent crankshaft failure and subsequent engine failure, accomplish the following:

(a) At the next engine overhaul or whenever the crankshaft is next removed from the engine, after the effective date of this AD, whichever occurs first, determine if the crankshaft was manufactured using the airmelt or vacuum arc remelt (VAR) process in accordance with the identification procedures described in TCM Mandatory SB No. M92–16, dated September 29, 1992. If the crankshaft was manufactured using the airmelt process, or if the manufacturing process is unknown, prior to further flight, remove the crankshaft from service and replace with a serviceable crankshaft manufactured using the VAR process.

(b) For all engine models with VAR crankshafts identified in TCM Mandatory SB No. M92–16 dated September 29, 1992, regardless of serial number: at the next and every subsequent crankshaft removal from the engine case or installation of a replacement crankshaft, prior to crankshaft installation in the engine, conduct an ultrasonic inspection of the crankshaft in accordance with TCM Service Bulletin No. M87–5, Revision 1, dated May 25, 1987, and Crankshaft Ultrasonic Inspection Procedure, Form X30554, dated February 1981.

(1) If a crack is found, replace the crankshaft with a serviceable VAR crankshaft.

(2) If no crack is found, mark the propeller mounting flange in accordance with TCM Service Bulletin No. M87–5, Revision 1, dated May 25, 1987.

Note: Accomplishment of the ultrasonic inspection does not set aside any requirements for magnaflux or other inspections specified in TCM overhaul manuals.

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Atlanta Aircraft Certification Office. The request should be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Atlanta Aircraft Certification Office.

Note: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the Atlanta Aircraft Certification Office.

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the aircraft to a location where the requirements of this AD can be accomplished.

Issued in Burlington, Massachusetts, on August 17, 1995.

Jay J. Pardee,

Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 95–20991 Filed 8–23–95; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 35

[Docket No. RM95–8–000]

Promoting Wholesale Competition Through Open Access Non-Discriminatory Transmission Services by Public Utilities; Notice of Technical Conferences

August 17, 1995.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of technical conferences.

SUMMARY: The Federal Energy Regulatory Commission proposed

requirements related to ancillary services, *pro forma* transmission tariffs, and comparability for power pools in its Notice of Proposed Rulemaking in this docket. The Commission is issuing this notice to announce the dates of three technical conferences concerning these matters.

DATES: September 29, 1995: requests to speak and description of issues to be discussed; October 26, 1995: Commission technical conference on ancillary services; October 27, 1995: staff technical conference on *pro forma* tariffs; December 5 and 6, 1995: Commission technical conference on comparability for power pools.

ADDRESSES: File descriptions of issues with the Office of the Secretary, 825 N. Capitol St., NE, Washington, D.C. 20426; the conferences will be held in Washington, D.C. at locations to be announced in the future.

FOR FURTHER INFORMATION CONTACT:

Ancillary Services

James Newton, Office of Electric Power Regulation, 825 North Capitol Street, N.E., Washington, D.C. 20426, (202) 208–0578, (fax) (202) 208–0180

Pro Forma Tariffs

Richard Armstrong, Office of Electric Power Regulation, 825 North Capitol Street, N.E., Washington, D.C. 20426, (202) 208–0241, (fax) (202) 208–0180

Power Pools

Lawrence Anderson, Office of Electric Power Regulation, 825 North Capitol Street, N.E., Washington, D.C. 20426, (202) 208–0575, (fax) 208–0180

SUPPLEMENTARY INFORMATION: In addition to publishing the full text of this document in the **Federal Register**, the Commission also provides all interested persons an opportunity to inspect or copy the contents of this document during normal business hours in Room 3104 at 941 North Capitol Street, N.E., Washington, D.C. 20426.

The Commission Issuance Posting System (CIPS), an electronic bulletin board service, provides access to the text of formal documents issued by the Commission. CIPS is available at no charge to the user and may be accessed using a personal computer with a modem by dialing (202) 208–1397. To access CIPS, set your communications software to 19200, 14400, 12000, 9600, 7200, 4800, 2400, or 1200 bps, full duplex, no parity, 8 data bits and 1 stop bit. The full text of this document will be available on CIPS in ACSII and Wordperfect 5.1 format. The complete text on diskette in Wordperfect format may also be purchased from the Commission's copy contractor, La Dorn Systems Corporation, also located in Room 3104, 941 North Capitol Street, N.E., Washington, D.C. 20426.

The Commission proposed requirements related to ancillary services, *pro forma* transmission tariffs, and comparability for power pools in our Notice of Proposed Rulemaking (NOPR) in this docket.[1] Today we announce our intention to hold a Commission technical conference on ancillary services on October 26, 1995 from 9:30 until 5:00; a staff technical conference on *pro forma* tariffs on October 27, 1995, from 9:30 until 5:00; and a Commission technical conference on comparability for power pools on December 5, 1995, from 1:00 until 5:00, and on December 6 from 9:30 until 5:00. The three conferences will take place in Washington, D.C.

The conference on ancillary services will address what services are necessary to support the transmission of electric power from seller to buyer given the need to maintain reliable service, who should provide those services, and related issues. The conference on the *pro forma* tariffs will address the terms and conditions of non-discriminatory service, such as definitions of terms, the kinds of service available, reassignment rights, and other issues. The conference on power pools will address how to implement the comparability requirement for power pools.

Those wishing to attend any of these conferences should contact the relevant Commission staff person identified below no later than September 29, 1995. Persons wishing to speak at any of the conferences should file with the Secretary no later than September 29, 1995 a (maximum) one-page description of the issues they wish to discuss.

Ancillary Services

James Newton, Office of Electric Power Regulation, 825 North Capitol Street, N.E., Washington, D.C. 20426, (202) 208–0578, (fax) (202) 208–0180

Pro Forma Tariffs

Richard Armstrong, Office of Electric Power Regulation, 825 North Capitol Street, N.E., Washington, D.C. 20426, (202) 208–0241, (fax) (202) 208–0180

Power Pools

Lawrence Anderson, Office of Electric Power Regulation, 825 North Capitol Street, N.E., Washington, D.C. 20426, (202) 208–0575, (fax) 208–0180

Staff will publish a notice of the agenda and specific location of each conference.

Lois D. Cashell,

Secretary.

[FR Doc. 95–20971 Filed 8–23–95; 8:45 am]

BILLING CODE 6717–01–P

[1] 60 FR 17662 (April 7, 1995), IV FERC Stats. & Regs. ¶ 32,514 (1995).

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18 CFR Parts 141 and 388

[Docket No. RM95–9–000]

Real-Time Information Networks; Notice of Timetable and Opportunity for Participation in Industry Working Groups

August 10, 1995.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of Timetable and Opportunity to Participate in Industry Working Groups.

SUMMARY: The Federal Energy Regulatory Commission is issuing this notice to announce the timetable for further actions in this docket and the opportunity for participation in two industry working groups, with expected representation from all segments of the electric industry, to consider recommendations to the Commission concerning the requirements for Real-Time Information Networks.

DATES: Any submittals from the working groups should be filed by October 16, 1995.

ADDRESSES: Federal Energy Regulatory Commission, 825 N. Capitol St., NE, Washington, D.C. 20426.

FOR FURTHER INFORMATION CONTACT:

Marvin Rosenberg (Technical Information), Office of Economic Policy, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, (202) 208–1283

William Booth (Technical Information), Office of Electric Power Regulation, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, (202) 208–0849

Gary D. Cohen (Legal Information), Electric Rates and Corporate Regulation, Office of the General Counsel, Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, (202) 208–0321

SUPPLEMENTARY INFORMATION: In addition to publishing the full text of this document in the **Federal Register**, the Commission also provides all interested persons an opportunity to inspect or copy the contents of this document during normal business hours

in Room 3104 at 941 North Capitol Street, N.E., Washington, D.C. 20426.

The Commission Issuance Posting System (CIPS), an electronic bulletin board service, provides access to the text of formal documents issued by the Commission. CIPS is available at no charge to the user and may be accessed using a personal computer with a modem by dialing (202) 208–1397. To access CIPS, set your communications software to 19200, 14400, 12000, 9600, 7200, 4800, 2400, or 1200 bps, full duplex, no parity, 8 data bits and 1 stop bit. The full text of this document will be available on CIPS in ACSII and WordPerfect 5.1 format. The complete text on diskette in WordPerfect format may also be purchased from the Commission's copy contractor, La Dorn Systems Corporation, also located in Room 3104, 941 North Capitol Street, N.E., Washington, D.C. 20426.

Real-time Information Networks; Notice of Timetable and Opportunity for Participation in Industry Working Groups

[Docket No. RM95–9–000]

August 10, 1995.

On July 27, 1995, the Commission held an informal Technical Conference [1] to discuss, *inter alia*, the process for developing requirements for Real-Time Information Networks (RINs).[2]

Different panels representing a cross section of the electric industry discussed the efforts of the industry to date, what industry standards are needed, what information is needed on a RIN, how a RIN should be structured, and what actions the Commission should next take to resolve remaining issues and proceed to develop rules for RIN requirements. In particular, the North American Electric Reliability Council (NERC) and the Electric Power Research Institute (EPRI) described efforts they had been making, in conjunction with other parties, to work on issues related to RINs development.

Chair Elizabeth Moler stated the Commission's intention of issuing a supplemental notice of proposed rulemaking and request for comments late in 1995 that will propose mandatory requirements for an information system. She expressed the Commission's willingness to make use of consensus proposals that are submitted in advance of the supplemental NOPR in developing the proposed rule.

During the discussion at the Technical Conference, a consensus developed that two industry working groups should be formed, one dealing with "what" in formation should be posted on a RIN and the other dealing with "how" to design a RIN to communicate this information (interactively, if possible) to the industry and what, if any, national standards this would require.

Based on the consensus of the participants at the Technical Conference, the "what" group will be facilitated by the North American Electric Reliability Council (NERC) [3] and the "how" group will be facilitated by the Electric Power Research Institute (EPRI).[4] Staff intends to consult and participate in the activities of both working groups. Each working group will be composed of representatives of all segments of the electric industry. The two working groups will try to reach consensus on as many issues as possible and prepare reports to the Commission describing all areas of consensus as well as the issues where there are differences and what those differences are. Any consensus proposals or other materials that a working group wishes the Commission to consider in preparing the supplemental NOPR should be filed with the Commission no later than October 16, 1995.

Any working group reports submitted should be as specific as possible and include draft regulations implementing the recommended RIN requirements (and presenting alternative recommendations where consensus has not been reached).

The discussion at the Technical Conference indicated that it may be necessary to start out with a basic set of RIN requirements to be effective as of the effective date of a final rule on non-discriminatory open access transmission and stranded costs, with the possibility of later enhancements or refinements. Thus, any working group reports submitted should address whether the RIN requirements should be implemented in phases, and, if so, what RIN requirements should/must be included in the first phase. If the working group reports recommend a phased approach, they should consider the timetable for when basic and more complete systems can be developed and put in place. Ideally, if RIN requirements are developed in phases, later phases should make use of the investments made in earlier phases.

There was considerable discussion at the Technical Conference and in comments about the need for a commercially workable definition of "available transmission capacity." The report submitted by the "what" working group should address this issue and whether a phased approach to this issue also is appropriate.

The working groups are encouraged to continue their efforts, after the October 1995 submittals, to reach consensus on any remaining issues.

Lois D. Cashell,

Secretary.

[FR Doc. 95–21027 Filed 8–23–95; 8:45 am]

BILLING CODE 6717–01–M

[1] See 60 FR 17726 (April 7, 1995); 60 FR 33375 (June 28, 1995); and the unpublished notice of the preliminary agenda for the Technical Conference (issued on July 19, 1995).

[2] The Commission also previously announced, 60 FR at 17727–28, that it expected to enlist working groups, operating in consultation with Commission Staff, to reach consensus on RIN-related issues and that it expected to have RIN requirements in place no later than the date when it issues a final rule, in Docket No. RM95–8–000, an open access transmission, 60 FR at 17728.

[3] The NERC coordinator is Mr. David Nevius, telephone # (609) 452–8060, facsimile # (609) 452–9550.

[4] The EPRI coordinator is Mr. Gerry Cauley, telephone # (415) 855–2832, facsimile # (415) 855–8997.

RAILROAD RETIREMENT BOARD

20 CFR Part 230

RIN 3220–AA61

Reduction and Non-Payment of Annuities by Reason of Work; Correction

AGENCY: Railroad Retirement Board.

ACTION: Correction to proposed rule.

SUMMARY: This document contains a correction to the proposed rule which was published on Wednesday, August 16, 1995 (60 FR 42482). The proposed rule relates to the revision of the Railroad Retirement Board's regulation that explains how employment or self-employment performed after the beginning date of an annuitant's railroad retirement annuity may cause a reduction in, or non-payment of, the annuity.

DATES: The comment period has been extended to September 25, 1995.

ADDRESSES: Secretary to the Board, Railroad Retirement Board, 844 Rush Street, Chicago, Illinois 60611.

FOR FURTHER INFORMATION CONTACT: Thomas W. Sadler, Assistant General Counsel, Railroad Retirement Board, 844 Rush Street, Chicago, Illinois 60611, (312) 751–4513, TDD (312) 754–4701.

SUPPLEMENTARY INFORMATION: A line of text was inadvertently omitted from the document submitted for publication which could prove misleading to individuals reviewing the document. Therefore, § 230.17 of the proposed rule revising title 20, chapter II, part 230 of the Board's regulations, in the

publication on August 16, 1995 (60 FR 42482), is corrected as follows:

§ 230.17 [Corrected]

Paragraph 1. On page 42487, in the third column, in § 230.17, paragraph (a), line 5, is corrected by adding after the word "A", "report is required when the individual's total earnings or wages", before the word "exceed".

Dated: August 16, 1995.

By authority of the Board.

For the Board,

Beatrice Ezerski,

Secretary to the Board.

[FR Doc. 95–21073 Filed 8–23–95; 8:45 am]

BILLING CODE 7905–01–M

DEPARTMENT OF AGRICULTURE

Forest Service

36 CFR Part 242

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 100

Alaska Federal Subsistence Regional Advisory Council Meetings

AGENCIES: Forest Service, USDA; Fish and Wildlife Service, Interior.

ACTION: Notice of meetings.

SUMMARY: This notice informs the public of the Regional Council meetings identified above. The public is invited to attend and observe meeting proceedings. In addition, the public is invited to provide oral testimony before the Councils on proposals to change Subsistence Management Regulations for Public Lands in Alaska as set forth in a proposed rule on August 15, 1995 (60 FR 42085–42130).

The following agenda items will be discussed at each Regional Council meeting: Introduction of Regional Council members and guests; election of officers; old business; new business: agency reports; review and development of proposals to change Subsistence Management Regulations for Public Lands in Alaska; and annual report.

DATES: The Federal Subsistence Board announces the forthcoming public meetings of the Federal Subsistence Regional Advisory Councils (Regional Councils). The Regional Council meetings may last two-three days and will be held in the following Alaska locations, starting on the date indicated.

Region 1 (Southeast)—Klawock—September 28

Region 2 (Southcentral)—Anchor Point—September 27

Region 3 (Kodiak/Aleutians)—King Cove—October 5

Region 4 (Bristol Bay)—Dillingham—October 10

Region 5 (Yukon-Kuskokwim Delta)—Bethel—October 3

Region 6 (Western Interior)—Aniak—October 10

Region 7 (Seward Peninsula)—Nome—October 26

Region 8 (Northwest Arctic)—Kotzebue—October 12

Region 9 (Eastern Interior)—Fairbanks—October 4

Region 10 (North Slope)—Anchorage—October 16

Notice of specific times and locations will be placed in local and statewide newspapers and on local radio stations.

FOR FURTHER INFORMATION CONTACT: Chair, Federal Subsistence Board, c/o Richard S. Pospahala, Office of Subsistence Management, U.S. Fish and Wildlife Service, 1011 E. Tudor Road, Anchorage, Alaska 99503; telephone (907) 786–3467. For questions related to subsistence management issues on National Forest Service lands, inquires may also be directed to Ken Thompson, Regional Subsistence Program Manager, USDA, Forest Service, Alaska Region, P.O. Box 21628, Juneau, Alaska 99802–1628; telephone (907) 586–7921.

SUPPLEMENTARY INFORMATION: The Regional Councils have been established in accordance with Section 805 of the Alaska National Interest Lands Conservation Act, Public Law 96–487, and Subsistence Management Regulations for Public Lands in Alaska, subparts A, B, and C (57 FR 22940–22964). The Regional Councils advise the Federal Government on all matters related to the subsistence taking of fish and wildlife on public lands in Alaska and operate in accordance with provisions of the Federal Advisory Committee Act. The identified Regional Council meetings will be open to the public. The public is invited to attend these meetings, observe the proceedings, and provide comments to the Regional Councils.

Dated: August 18, 1995.

Mitch Demientieff,

Chair, Federal Subsistence Board.

[FR Doc. 95–21010 Filed 8–23–95; 8:45 am]

BILLING CODE 3410–11–P; 4310–55–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 372

[OPPTS–400094; FRL–4954–6]

Toxic Chemical Release Reporting; Community Right-To-Know; Denial of Petition

AGENCY: Environmental Protection Agency (EPA).

ACTION: Denial of Petition.

SUMMARY: EPA is denying a petition to delete manganese and manganese compounds contained in iron-making and carbon steel making slags from the list of toxic chemicals subject to section 313 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA). This action is based on EPA's conclusion that manganese and manganese compounds in slags do not meet the EPCRA section 313(d)(3) deletion criteria.

FOR FURTHER INFORMATION CONTACT: Maria J. Doa, Petitions Coordinator, 202–260–9592, e-mail: doa.maria@epamail.epa.gov, for specific information on this Denial of Petition, or for more information on EPCRA section 313, the Emergency Planning and Community Right-to-Know Hotline, Environmental Protection Agency, Mail Code 5101, 401 M St., SW., Washington, DC 20460, Toll free: 1–800–535–0202, in Virginia and Alaska: 703–412–9877 or Toll free TDD: 1–800–553–7672.

SUPPLEMENTARY INFORMATION:

I. Introduction

A. Statutory Authority

This action is issued under sections 313(d) and (e)(1) of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA), 42 U.S.C. 11023. EPCRA is also referred to as Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA) (Pub. L. 99–499).

B. Background

Section 313 of EPCRA requires certain facilities manufacturing, processing, or otherwise using listed toxic chemicals to report their environmental releases of such chemicals annually. Beginning with the 1991 reporting year, such facilities also must report pollution prevention and recycling data for such chemicals, pursuant to section 6607 of the Pollution Prevention Act of 1990 (PPA), 42 U.S.C. 13106. Section 313 established an initial list of toxic chemicals that was comprised of more than 300 chemicals and 20 chemical categories. Section 313(d) authorizes

EPA to add or delete chemicals from the list, and sets forth criteria for these actions. EPA has added and deleted chemicals from the original statutory list. Under section 313(e), any person may petition EPA to add chemicals to or delete chemicals from the list. EPA must respond to petitions within 180 days either by initiating a rulemaking or by publishing an explanation of why the petition is denied.

EPA issued a statement of petition policy and guidance in the **Federal Register** of February 4, 1987 (52 FR 3479), to provide guidance regarding the recommended content and format for submitting petitions. On May 23, 1991 (56 FR 23703), EPA published guidance regarding the recommended content of petitions to delete individual members of the section 313 metal compound categories. EPA has also published a statement clarifying its interpretation of the section 313(d)(2) criteria for adding and deleting chemical substances from the section 313 list (59 FR 61439, November 30, 1994).

II. Description of Petition

The American Iron and Steel Institute (AISI) petitioned the Agency on October 20, 1993, to qualify the listings of manganese and manganese compounds to exempt reporting of these substances when they are contained in slag generated from iron and carbon steel manufacturing operations. AISI (the petitioner) claims that, due to the tightly bound nature of the manganese-slag complex, the complex is relatively inert and does not present an unreasonable risk to human health or the environment. Moreover, the petitioner asserted that the manganese ion is not available to be leached from the complex due, again, to its tightly bound nature.

III. EPA's Technical Review of the Petition

The technical review of the petition to delete manganese and manganese compounds contained in iron-making slags and carbon steel-making slags included an analysis of the toxicological effects of manganese compounds as contained in the aforementioned slags. Based on the guidance published by EPA on petitions to delist individual members of the metal compound categories (56 FR 23703, May 23, 1991), EPA also reviewed the toxicity of manganese ion, as well as the availability of the ion from the aforementioned slags, (Refs. 1, 2, 3, and 4).

A. Chemistry Profile

1. *Manganese ion.* Manganese is a naturally occurring substance found in many rocks and as a constituent in several freshwaters and the ocean. Although pure manganese is silvery, much like iron in its appearance, manganese is rarely found in its pure state. Generally, it exists combined with other chemicals (such as oxygen, sulfur, and chlorine) (Ref. 5). As present in the slag, manganese is typically found as oxides and are relatively insoluble compounds.

2. *Manganese in slags.* Although manganese can be added directly into the iron and steel manufacturing process, generally the manganese found in the slags originates from iron ore. Slags containing manganese compounds can be generated from three processes: blast furnace; basic oxygen furnace; and electric arc furnaces. Slags are produced as the lighter fraction in each of the processes and are separated during the tapping procedure. After separation, the slag is cooled with water sprays and broken into smaller pieces. These smaller pieces are generally loaded in a truck for transport to an on-site landfill.

The slag may be used in concrete manufacture, as roadbed fill, as railroad ballasts, and as fertilizer components.

B. Toxicological Evaluation of Manganese Ion

It is generally recognized that manganese uptake and elimination are under homeostatic control, allowing for a wide range of dietary intakes considered to be safe. Further, manganese is an essential element, being required for normal human growth and maintenance of health (Refs. 3 and 4).

It has been reported that the average daily dose of manganese in the United States, England, and Holland ranges from 2.3 to 8.8 milligrams per day (mg/day). The Food and Nutrition Board of the National Research Council has determined a safe level of intake of manganese to be 2 to 5 mg/day for adults. In the normal adult, approximately 3 to 10 percent of dietary manganese is absorbed. However, dietary deficiencies of calcium and iron can increase that percentage. Therefore, it appears as if certain subpopulations, such as children, individuals with dietary deficiencies, pregnant women, and the elderly, may have an increased potential for heightened body burdens of manganese (Refs. 3, 4, and 6).

Manganese has been shown to readily penetrate the bloodbrain and placental barriers (Refs. 3 and 4). These findings are significant with respect to the well-known effects of manganese on the central nervous system (CNS) of adult humans and, probably, developing humans. Manganese elimination from the body is slow, and the clearance half-time from the brain is considerably longer than that for the whole body (Ref. 6).

1. *Acute toxicity.* In 1984, the Agency generated a comprehensive health assessment for manganese in which median lethal dose (LD_{50}) values for several inorganic manganese compounds were calculated. These values range from 400 to 830 milligrams per kilogram (mg/kg) by the oral route and 38 to 64 mg/kg by parenteral injection (Ref. 6).

2. *Neurotoxicity.* The CNS effects of manganese compounds have long been known. The first medical description of chronic manganese neurotoxicity (manganism) in workers is generally credited to Couper in the 1830s (Ref. 6). The disorder, manganism, has been described in workers in industries that typically involve exposure to manganese oxide fumes. Such industries include: Ore crushing; ferroalloy production; steel making; dry cell battery manufacture; and, welding rod manufacture. Those who develop chronic manganese poisoning initially exhibit a hyperactive maniacal state that progresses through lassitude and weakness to a later stage characterized by parkinsonism, dystonia, and cerebellar ataxia. Although the course and degree of manganese intoxication can vary greatly among individuals, the chronic state can develop without an initial manic state. However, once the chronic stage has developed, the neurologic dysfunction is irreversible (Ref. 6).

There is evidence of neurotoxic effects in adult humans and animals. These effects are also a probable hazard to human fetal and neonatal nervous systems (i.e., developmental neurotoxicity) based on circumstantial human data and on test data in animals. There is also human and animal evidence of acute toxicity (manganese pneumonia, metal fume fever in humans, severe lung damage in animals) and human and animal data on chronic pulmonary effects (Ref. 6).

Several studies have noted neurotoxic effects from soluble forms of manganese. As specified in the Integrated Risk Information System (IRIS) and other sources, neurotoxicity is the critical endpoint of concern. There are two epidemiological studies describing toxicologic responses in humans from excess amounts of manganese dissolved in drinking water (Ref. 6). The first, Kondakis et al. (1989) studies three

areas in northwest Greece (Ref. 6). The total population of the three areas (A, B, C) studied ranged from 3,200 to 4,350 people and manganese concentration in well water ranged from 3.6 micrograms per litre (ug/1) to 2300 ug/1. Individuals chosen for the study were submitted to neurological examination; whole blood and hair manganese concentration were also determined. The concentration of manganese in the whole blood did not differ between the three areas, but this is not considered to be a reliable indicator of manganese exposure. However, there was a significant difference noted in neurological scores for area C versus area A even when both age and sex are taken into account. A lowest observed adverse effect level (LOAEL) of 0.06 mg Mn/kg-day and a no observed adverse effect level (NOAEL) of 0.005 mg Mn/kg-day for the study were estimated from concentrations using default values (a water consumption of 2 litres/day, and a 70 Kg assumed adult body weight) (Ref. 6).

The second report is by Kawamura et al. (1941) and is the only epidemiological study describing toxicologic responses in humans consuming large amounts of manganese in drinking water (Ref. 6). Twenty-five cases of manganese poisoning were reported, with symptoms including lethargy, increased muscle tonus, tremors and mental disturbances. Elderly people showed the most severe symptoms. Although the intake of manganese in the diet was not determined, the approximate intake estimated for the study was 0.8 mg/kg-day. This supports the LOAEL estimated from the Kondakis et al. (1989) study (Ref. 6). It should be noted that the well water in the study was contaminated with zinc, and that this could have effected the results. The impacts of the zinc contamination were not evaluated.

Use of the Greek study is supported upon review in context of additional information. The spectrum of neurological dysfunction observed in chronic manganese neurotoxicity effects in humans can be reproduced, in part, in different animal species, including rats, rabbits, and monkeys (characteristic CNS signs were produced in monkeys exposed to manganese dioxide) (Ref. 6).

Roels et al. (1992) reported that workers who had chronically been exposed to manganese (0.215 mg manganese/m^3) for respirable dust and 0.948 mg manganese/m^3 for total dust with a duration of employment ranging from 0.2 to 17.7 years) performed worse than controls on several measures of neurobehavioral function (such as visual reaction time, eye-hand coordination, uncertainty, etc.) (Ref. 6). A LOAEL of 0.05 mg/m^3 was derived from the study. A previous study performed by Roels et al. (1987) found significant differences in mean scores between manganese-exposed and referenced subjects for visual reaction time, eye-hand coordination, hand steadiness, and audio-verbal short-term memory (Ref. 6). Total airborne manganese dust ranged from 0.07 to 8.61 mg/m^3 for a duration of employment spanning from 1 to 19 years. During the study it was also noted that there were a significantly greater prevalence of coughs during the cold season and episodes of acute bronchitis in the manganese-exposed group. A LOAEL of 0.34 mg/m^3 was derived from the study (Ref. 6).

As noted in IRIS (November 1993), there is a consistent pattern of evidence indicating that neurotoxicity is associated with low-level occupational manganese exposure (Ref. 6). More detail on the neurotoxic effects observed from chronic exposure to manganese is given above.

3. *Respiratory toxicity.* As specified in IRIS (November 1993), as a route of exposure, the respiratory tract is the most important route of entry (Ref. 6). Particles which deposit in the extrathoracic and tracheobronchial regions (greater than 2.5 micrometers (um)) are predominantly cleared by the mucociliary escalator into the gastrointestinal tract where absorption is low. Smaller mode particles (greater than 2.5 um) are deposited in the pulmonary region where 100 percent absorption is assumed. However, some researchers have suggested that neurotoxic metals can be directly transported to the brain olfactory bulbs (Ref. 6).

After absorption by the respiratory tract, manganese is transported directly to the brain via the blood stream, bypassing the liver. This direct path has been suggested to account for the difference in toxicity between inhaled and ingested manganese (Ref. 6).

4. *Reproductive/developmental toxicity.* There is insufficient information on the developmental toxicity of manganese by inhalation exposure, and the same is true for information on the female reproductive function. The study of the female reproductive toxicity of inhaled manganese in males also needs to be characterized more fully (Ref. 6).

5. *Carcinogenicity.* Manganese has been identified as Class D or not classifiable as to human carcinogenicity. Existing studies are inadequate to assess the carcinogenicity of manganese (Ref. 6).

6. *Ecological effects.* Manganese ion exhibits a moderate toxicity to aquatic and terrestrial organisms and has a high potential to bioaccumulate. Manganese is an essential tract element or micronutrient for microorganisms, plants and animals. It is a functional component of nitrate assimilation, in the Hill reaction of photosynthesis, and is an essential catalyst of many enzyme systems.

Acquatic chronic toxicity values are as low as 3.2 to 5.7 parts per million (ppm) for invertebrates and as low as 12 ppm for fish. Concentrations as low as 0.2 to 0.3 ppm were toxic to some marine algae. Aquatic chronic toxicity data are more limited. The no observed effect concentration (NOEC) for rainbow trout eggs exposed to manganese for 29 days is less than 370 parts per billion (ppb). The lowest observed effect concentration (LOEC) in this study was calculated to be approximately 370 ppb (Ref. 7).

Marine plants and animals may bioaccumulate manganese; bioconcentration values have been reported to be approximately 3,000. Furthermore, bioconcentraton values for shellfish range from 1,000 to 10,000; and for fish, marine algae, and plants, from 100 to 100,000 (Ref. 7).

C. Toxicological Evaluation of Manganese in Slags

1. *Human health effects.* The Agency has identified some potential hazards resulting from exposure to the manganese-slag complex. Generally, these hazards are associated with the slag in a granular or powdered form and are consistent with typical concerns of particulate exposure. These include: Eye irritation; lung overload; and lung irritation. The insolubility of the manganese-slag complex allays most systemic toxicity concerns with the exception of lung overload. The Agency does not consider the hazard of lung overload to be significant (Refs. 3 and 4).

2. *Ecological effects.* Manganese levels in leachate from slags as reported in the petition exceed the range of manganese reported in most natural freshwaters. The upper leachate level reported in the petition ranged from 28 to 32 ppm, with averages as high as 7 and 11 ppm. Manganese concentrations in natural freshwaters around the world normally range from 10 to 850 ppb, with an average of 35 ppb. However, some reservoirs may have concentrations of up to 150 ppm; subsurface and acid mine waters may contain 10 ppm (Ref. 7).

The petitioner contends that "manganese compounds in slags do not

dissociate or react to yield metal ions because the metal ion is tightly bound in a calcium-silica matrix and cannot be released." However, this conclusion is inconsistent with the information from other studies presented in the petition indicating high levels of manganese from leaching are possible.

D. Availability of Manganese ion from Slags

Although it is established that leaching of manganese from the slag occurs, there is insufficient information regarding the ultimate fate of the leachate for a detailed characterization. A variety of conditions (i.e., geology, pH, soil organic content, etc.) combine in a complex manner to severely limit modeling of the fate of the leachate.

Manganese may be leached from slags under acidic and reducing conditions, which are the conditions expected to prevail in landfilled slags that are in contact with the aquatic environment. Further, these same conditions are conducive to reduction of the manganese oxides normally found in slags to the water soluble manganous ion, (Mn^{+2}). Although Mn^{+2} often precipitates with carbonate ions as $MnCO_3$, this is not always the case, and various lines of evidence suggest that Mn^{+2} may enter ground water supplies and/or may reach surface waters. Evidence also shows that sorption of manganese to soil is highly variable, and that release may actually occur under certain conditions (Ref. 1). Thus, it cannot be concluded that "any manganese leached from slags is quickly adsorbed by the surrounding soil" as the petitioner claims.

The petitioner reports the slag to have a pH of 9 to 11 in which the manganese is present in an insoluble oxide form. Slag piles are generally fully exposed to weather conditions and are present in a wide range of sizes, very small particulates to large blocks. Under acidic conditions, such as those present in acid rain (pH 5.5), the predominant species of manganese is not the insoluble oxide form but the soluble ion form, manganese^{+2}. The petitioner also reports a range of manganese leachate measured from a variety of slag sources; the upper level being 22 to 32 mg/1 (ppm) of manganese ion (Refs. 1 and 6).

The soluble manganese ion can then hydrolyze, form insoluble oxides, exist as Mn^{+2} in solution, precipitate with carbonates and other anions, and form insoluble sulfides depending on the redox potential of the water media, pH, temperature, and the mix of anions present. Most of these reactions are catalyzed by biota. Adsorption of Mn^{+2} is favored in soils with a large percentage of clay particles and organic material. Anaerobic conditions and acidified conditions favor resolubilization of Mn^{+2} (Refs. 1 and 6).

E. Technical Summary

EPA's toxicological evaluation of manganese ion indicates that manganese can cause neurotoxic effects in humans, exhibits moderate toxicity to aquatic and terrestrial organisms, and has a high potential to bioaccumulate. EPA's assessment of the availability of manganese ion from iron-making and carbon steel-making slags indicates that a wide range of manganese leachate from slag piles has been documented (noted in the petition). This indicates that leaching of the manganese ion is expected. Measured leachate levels, as specified in the petition, exceed acute and chronic aquatic toxicity values and those reported as toxic to certain plants. Evidence also shows that sorption of manganese to soils is highly variable, and that release may actually occur under certain conditions (Refs. 1, 6, and 7).

IV. Rationale for Denial

EPA is denying the petition to delete manganese and manganese compounds in iron-making and carbon steel-making slag from the EPCRA section 313 list. EPA believes that manganese ion can become available at levels which can reasonably be anticipated to induce adverse human health and environmental effects. EPA believes that manganese and manganese compounds in iron-making and carbon steel-making slag meet the toxicity criteria of EPCRA section 313(d)(2)(B) based on available neurotoxicity data, and that they meet the toxicity criteria of EPCRA section 313(d)(2)(C) based on the available acute environmental toxicity and bioconcentration data.

V. References

(1) USEPA/OPPT, Boethling, Bob, *Environmental Fate of Manganese* dated January 18, 1994.

(2) USEPA/OPPT, Macek, Greg, *Final Report: Engineering Support for EPA Review of Section 313(e) Petition on Manganese and Manganese Compounds in Iron-Making and Carbon Steel-Making Slags* dated January 27, 1994.

(3) USEPA/OPPT, Murphy, James J., *Preliminary Review of Systemic Toxicity for EPCRA Section 313 Delisting Petition on Manganese and its Compounds in Slags* dated November 19, 1993.

(4) USEPA/OPPT, Murphy, James J., *Review of Systemic Toxicity of Manganese with Particular Reference to Manganese-Containing Slag* dated December 29, 1993.

(5) USEPA/OPPT, Rakshpal, Ram, *Section 313(e) Petition on Manganese and Manganese Compounds in Iron-Making Slags and Carbon Steel-Making Slags (Chemistry Report)* dated December 9, 1993.

(6) USEPA/OPPT, Rusak, Linda, *Technical Integrator Report* dated April 1995.

(7) USEPA/OPPT, Smerchek, Jerry C., *Ecological Hazard Review of the American Iron and Steel Institute Petition to Delist Manganese and Manganese Compounds Contained in Iron-Making Slags and Carbon Steel-Making Slags* dated December 9, 1993.

VI. Administrative Record

The record supporting this denial of petition is contained in the docket number OPPTS–400094. All documents, including an index of the docket, are available in the TSCA Nonconfidential Information Center (NCIC), also known as the TSCA Public Docket Office, from noon to 4 p.m., Monday through Friday, excluding legal holidays. The TSCA Public Docket Office is located at EPA Headquarters, Rm. NE–B607, 401 M St., SW., Washington, DC 20460.

List of Subjects in 40 CFR Part 372

Environmental protection, Chemicals, Community right-to-know, Reporting and reccordkeeping requirements, and Toxic chemicals.

Dated: August 15, 1995.

Lynn R. Goldman,

Assistant Administrator for Prevention, Pesticides and Toxic Substances.

[FR Doc. 95–21039 Filed 8–23–95; 8:45 am]

BILLING CODE 6560–50–F

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 95–134, RM–8679]

Radio Broadcasting Services; Sanford, NC

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission requests comments on a petition filed by Woolstone Corporation seeking the allotment of Channel 276A to Sanford, NC, as the community's second local FM service. Channel 276A can be allotted to Sanford in compliance with

the Commission's minimum distance separation requirements with a site restriction of 11.3 kilometers (7 miles) west, at coordinates 35–26–28 North Latitude; 79–17–11 West Longitude, to avoid a short-spacing to unoccupied but applied-for Channel 275A, Raleigh, NC.

DATES: Comments must be filed on or before October 12, 1995, and reply comments on or before October 27, 1995.

ADDRESSES: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: A. Wray Fitch, III, Esq., Gammon & Grange, Seventh Floor, 8280 Greensboro Drive, McLean, VA 22102–3807 (Counsel to petitioner).

FOR FURTHER INFORMATION CONTACT: Leslie K. Shapiro, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Notice of Proposed Rule Making*, MM Docket No. 95–134, adopted August 10, 1995, and released August 21, 1995. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Services, Inc., (202) 857–3800, 2100 M Street, NW., Suite 140, Washington, DC 20037.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

John A Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 95–21021 Filed 8–23–95; 8:45 am]

BILLING CODE 6712–01–F

[MM Docket No. 93–234; RM–8289]

47 CFR Part 73

Television Broadcasting Services; Boca Raton and Lake Worth, FL

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; denial.

SUMMARY: The Commission declines to amend the TV Table of Allotments to permit a proposed station and community of license swap between two TV permittees in Florida. The swap was originally proposed by the Commission at 58 FR 46152 (Sept. 1, 1993).

FOR FURTHER INFORMATION CONTACT: Jane Hinckley Halprin, Mass Media Bureau, (202) 776–1653.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order* in MM Docket No. 93–234, adopted August 10, 1995 and released August 21, 1995. The full text of this decision is available for public inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, Inc., (202) 857–3800, 2100 M Street, NW., Suite 140, Washington, DC 20037.

List of Subjects in 47 CFR Part 73

Television broadcasting.

Federal Communications Commission.

John Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 95–21007 Filed 8–23–95; 8:45 am]

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Notices

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This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

TV–4, Cote Blanche Hydrologic Restoration Project, St. Mary Parish, Louisiana

AGENCY: Natural Resources Conservation Service, USDA.

ACTION: Notice of a Finding of No Significant Impact.

SUMMARY: Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969; the Council on Environmental Quality Guidelines (40 CFR part 1500); and the Natural Resources Conservation Service Guidelines (7 CFR Part 650); the Natural Resources Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement is not being prepared for the Cote Blanche Hydrologic Restoration Project, St. Mary Parish, Louisiana.

FOR FURTHER INFORMATION CONTACT: Donald W. Gohmert, State Conservationist, Natural Resources Conservation Service, 3737 Government Street, Alexandria, Louisiana 71302; telephone (318) 473–7751.

SUPPLEMENTARY INFORMATION: The environmental assessment of the federally assisted action indicates that the project will not cause significant local, regional, or national impacts on the environment. As a result of these findings, Donald W. Gohmert, State Conservationist, has determined that the preparation and review of an environmental impact statement is not needed for this project.

This plan proposes to reduce wetland loss on approximately 30,000 acres of intermediate marsh in St. Mary Parish, Louisiana. Project measures include 1,700 linear feet of passive type, low-level weir structures, and 10,000 linear feet of shoreline stabilization.

The Notice of a Finding of No Significant Impact (FONSI) has been forwarded to the Environmental Protection Agency and to various federal, state, and local agencies and interested parties. A limited number of copies of the FONSI are available to fill single copy requests at the above address. Basic data developed during the environmental assessment are on file and may be reviewed by contacting Donald W. Gohmert.

No administrative action on implementation of the proposal will be taken until 30 days after the date of this publication in the **Federal Register**.

Dated: August 14, 1995.

Donald W. Gohmert,

State Conservationist.

[FR Doc. 95–21072 Filed 8–23–95; 8:45 am]

BILLING CODE 3410–16–M

Commodity Credit Corporation

RIN 0560–AD–95

Conservation Reserve Program Signup and Related Provisions

AGENCY: Commodity Credit Corporation, USDA.

ACTION: Notice.

SUMMARY: The Commodity Credit Corporation (CCC) will be holding the 13th Conservation Reserve Program (CRP) signup to accept bids for 10- through 15-year contracts to replace acreage that was released from enrollment in the CRP under provisions announced in the **Federal Register** on May 8. Consistent with announcements by the Secretary of Agriculture in December 1994 and in April 1995, this signup will target acreage of higher environmental quality. The goal of the 13th signup is to replace approximately 651,342 acres which was released under the aforenoted provisions. The signup will be conducted in accordance with existing regulations at 7 CFR Part 1410. Variations from the 12th CRP signup period, though consistent with the regulations, are discussed in this notice.

DATES: The signup is scheduled for September 11, 1995, through September 22, 1995.

FOR FURTHER INFORMATION CONTACT: LeslieDee Deavers, Consolidated Farm Service Agency (CFSA), USDA, P.O. Box 2415, room 4714, South Building, Washington, DC, 20013–2415, telephone 202–720–9563.

SUPPLEMENTARY INFORMATION: The 13th CRP signup will be held from September 11, 1995, to September 22, 1995, in county CFSA offices. The regulations at 7 CFR Part 1410 apply to this signup.

The 13th CRP signup will be conducted in generally the manner as the 12th CRP signup was conducted but there will be different acreage goals, types of bids, and ranking requirements. The goal of the 13th signup is to replace the approximately 651,342 acres previously released under the "early out" provisions announced in May 1995 by CCC. CCC's goal is to accept acreage that will meet higher environmental and conservation criteria which will provide significant soil erosion, water quality, tree planting, and wildlife benefits. CCC is also encouraging the enrollment of filter strips and riparian buffers. Only the most environmentally beneficial acres as determined on the basis of per dollar of government expense will be selected.

State CFSA committees have been authorized to develop State-specific environmental criteria to supplement the selection process. During the signup process, each applicant will be informed of the maximum rental rate CCC is willing to pay to enroll participants in specific areas and will be informed that the actual rates accepted by CCC may be less than that maximum amount. By bidding below that maximum amount, the likelihood that an offer will be accepted may be increased because it is anticipated that more acreage than that allowed for enrollment will be offered for enrollment by perspective participants.

There are two types of bids: (1) Environmental Priority (EP) bids for field windbreak establishment, grass waterways, shallow water areas for wildlife, filter strips and riparian buffers, and shelterbelt establishment and (2) Standard bids for all other contracts.

All bids will be evaluated based on the anticipated environmental benefits relative to cost. EP bids will receive the highest possible environmental benefits ranking. To encourage enrollments of filterstrips and riparian buffers, CCC will accept bids with rates for land to be

enrolled for those purposes that are up to 10 percent higher than for other comparable land.

Signed at Washington, DC, on August 14, 1995.

Bruce R. Weber,

Acting Executive Vice President, Commodity Credit Corporation

[FR Doc. 95–21075 Filed 8–21–95; 3:08 pm]

BILLING CODE 3410–05–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–843]

Notice of Postponement of Preliminary Determination of Sales at Less Than Fair Value: Bicycles From the People's Republic of China (PRC)

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: August 24, 1995.

FOR FURTHER INFORMATION CONTACT: Shawn Thompson or Kate Johnson, Office of Antidumping Investigations, Import Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, D.C. 20230; telephone (202) 482–1776 or (202) 482–4929, respectively.

Postponement of Final Determination

On April 25, 1995, the Department initiated an antidumping duty investigation of bicycles from the PRC. The notice of initiation stated that we would issue our preliminary determination on or before September 12, 1995 (60 FR 21065, May 1, 1995). On August 7, 1995, we received questionnaire responses from nine Chinese exporters of the merchandise subject to this investigation.

On August 18, 1995, petitioners requested a 20-day postponement of the preliminary determination, until October 2, 1995, pursuant to section 733(c)(1)(A) of the Tariff Act of 1930, as amended (the Act). In addition, petitioners asserted that the Department is legally precluded from postponing the preliminary determination for the additional 30 days allowable under Section 733(c)(1)(B) because to do so would require a finding of cooperation by the respondents. Petitioners stated that, because only three of the original nine respondents are participating in this investigation, the Department cannot reasonably conclude that the respondents are cooperating.

We disagree with petitioners and are postponing the preliminary determination under section 733(c)(1)(B) of the Act for the full 50-days allowable. Not only have we received questionnaire responses from the three largest PRC exporters of subject merchandise but we have also received responses from six additional firms. All of these participating exporters are cooperating. Accordingly, we find that the "parties concerned are cooperating," within the meaning of section 733(c)(1)(B).

Moreover, this investigation is rendered extraordinarily complicated by the large number of foreign producers. Furthermore, the process of identifying all exporters who sold subject merchandise to the United States during the period of investigation caused significant delays in issuing our questionnaire. In addition, it appears that establishing surrogate values for the factors of production will require more time than usual due to the complexity of the product.

For these reasons, pursuant to sections 733(c)(1)(B)(i) (II) and (III) of the Act, we determine that this investigation is extraordinarily complicated and that additional time is necessary to make the preliminary determination in accordance with 733(c)(1)(B)(ii) of the Act. We will make our preliminary determination no later than November 1, 1995.

This notice is published pursuant to section 733(c)(2) of the Act and 19 CFR 353.15(d).

Dated: August 18, 1995.

Barbara R. Stafford,

Deputy Assistant Secretary for Investigations.

[FR Doc. 95–21070 Filed 8–23–95; 8:45 am]

BILLING CODE 3510–DS–P

[A–580–816]

Certain Corrosion-Resistant Carbon Steel Flat Products From Korea: Preliminary Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of preliminary results of antidumping duty administrative review.

SUMMARY: In response to requests by two respondents, the Department of Commerce ("the Department") is conducting an administrative review of the antidumping duty order on certain corrosion-resistant carbon steel flat products from Korea. The review covers two manufacturers/exporters of the subject merchandise to the United States during the period of review ("POR") from February 4, 1993, through July 31, 1994.

We have preliminarily determined that sales have been made below the foreign market value ("FMV"). If these preliminary results are adopted in our final results of administrative review, we will instruct U.S. Customs to assess antidumping duties equal to the difference between the United States price ("USP") and the FMV.

Interested parties are invited to comment on these preliminary results.

EFFECTIVE DATE: August 24, 1995.

FOR FURTHER INFORMATION CONTACT: Alain Letort or Linda Ludwig, Office of Agreements Compliance, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230, telephone (202) 482–3793 or fax (202) 482–1388.

SUPPLEMENTARY INFORMATION:

Applicable Statute and Regulations

Unless otherwise indicated, all citations to the statute and to the Department's regulations are references to the provisions as they existed on December 31, 1994.

Background

On July 9, 1993, the Commerce Department published in the Federal Register (58 FR 37176) the final affirmative antidumping duty determination on certain corrosion-resistant carbon steel flat products from Korea, for which we published an antidumping duty order on August 19, 1993 (58 FR 44159). On August 3, 1994, the Department published the "Notice of Opportunity to Request an Administrative Review" of this order the period February 4, 1993 through July 31, 1994 (59 FR 39543). We receive a request for an administrative review from Dongbu Steel Co., Ltd ("Dongbu"), Union Steel Manufacturing Co., Ltd. ("Union"), Pohang Coated Steel Co., Ltd ("PCS") and Dongkuk International ("Dongkuk"). We initiated the administrative review on September 8, 1994 (59 FR 46391). Subsequently, PCS and Dongkuk made timely requests that they be allowed to withdraw from the administrative review pursuant to 19 CFR 353.22(a)(5). On April 12, 1995, we published a "Notice of Partial Termination of Administrative Review of Antidumping Order" with respect to these respondents (60 FR 18581). The Department is conducting this review in accordance with section 751 of the Tariff Act of 1930, as amended ("the Act").

Scope of the Review

These products include flat-rolled carbon steel products, of rectangular shape, either clad, plated, or coated with corrosion-resistant metals such as zinc, aluminum, or zinc-, aluminum-, nickel- or iron-based alloys, whether or not corrugated or painted, varnished or coated with plastics or other nonmetallic substances in addition to the metallic coating, in coils (whether or not in successively superimposed layers) and of a width of 0.5 inch or greater, or in straight lengths which, if of a thickness less than 4.75 millimeters, are of a width of 0.5 inch or greater and which measures at least 10 times the thickness or if of a thickness of 4.75 millimeters or more are of a width which exceeds 150 millimeters and measures at least twice the thickness, as currently classifiable in the HTS under item numbers 7210.31.0000, 7210.39.0000, 7210.41.0000, 7210.49.0030, 7210.49.0090 7210.60.0000, 7210.70.6030, 7210.70.6060, 7210.70.6090, 7210.90.1000, 7210.90.6000, 7210.90.9000, 7212.21.0000, 7212.29.0000, 7212.30.1030, 7212.30.1090, 7212.30.3000, 7212.30.5000, 7212.40.1000, 7212.40.5000, 7212.50.0000, 7212.60.0000, 7215.90.1000, 7215.90.5000, 7217.12.1000, 7217.13.1000, 7217.19.1000, 7217.19.5000, 7217.22.5000, 7217.23.5000, 7217.29.1000, 7217.29.5000, 7217.32.5000, 7217.33.5000, 7217.39.1000, and 7217.39.5000. Included are flat-rolled products of nonrectangular cross-section where such cross-section is achieved subsequent to the rolling process (*i.e.*, products which have been "worked after rolling")—for example, products which have been bevelled or rounded at the edges. Excluded are flat-rolled steel products either plated or coated with tin, lead, chromium, chromium oxides, both tin and lead ("terne plate"), or both chromium and chromium oxides ("tin-free steel"), whether or not painted, varnished or coated with plastics or other nonmetallic substances in addition to the metallic coating. Also excluded are clad products in straight lengths of 0.1875 inch or more in composite thickness and of a width which exceeds 150 millimeters and measures at least twice the thickness. Also excluded are certain clad stainless flat-rolled products, which are three-layered corrosion-resistant carbon steel flat-rolled products less than 4.75 millimeters in composite thickness that consist of a carbon steel flat-rolled product clad on both sides with stainless steel in a 20%–60%–20% ratio. These HTS item numbers are provided for convenience and Customs purposes. The written description remains dispositive.

The POR is February 4, 1993 through July 31, 1994. This review covers sales of certain corrosion-resistant carbon steel flat products by Dongbu and Union.

United States Price

The Department used purchase price, in accordance with section 772(b) of the Act, when the subject merchandise was sold to unrelated purchasers in the United States. For Union, however, the Department determined, in certain instances, that exporter's sales price ("ESP"), as defined in section 772(c) of the Act, was a more appropriate basis for calculating USP (see below).

We adjusted USP for the Korean value-added tax in accordance with our practice as outlined in various determinations, including Silicomanganese from Venezuela; Final Determination of Sales at Less Than Fair Value, 59 FR 55435 (November 7, 1994).

Dongbu

All of Dongbu's U.S. sales were based on the price to the first unrelated purchaser in the United States. The Department determined that purchase price, as defined in section 772 of the Act, was the appropriate basis for calculating USP. Depending on the channel of trade, we treated the date of either the purchase order, the internal confirmation or the date of the production order as date of sale. We made adjustments to purchase price, where appropriate, for foreign inland freight, foreign brokerage, ocean freight, containerization, U.S. duty and U.S. brokerage and handling.

No other adjustments were claimed or allowed.

Union

All of Union's U.S. sales were based on the price to the first unrelated purchaser in the United States. The Department determined that, in most instances, purchase price, as defined in section 772(b) of the Act, was the appropriate basis for calculating USP. In a very few instances, however, the Department determined that exporter's sales price ("ESP"), as defined in section 772(c) of the Act, was a more appropriate basis for calculating USP. These instances involved either (a) sales where the merchandise was resold after entry into the United States, or (b) sales made prior to importation where the merchandise was further processed by an outside contractor in the United States on a fee-for-service basis. In the latter case, the Department's determination was based on the following facts: (a) Union America ("UA"), Union's sales office in the United States, was the importer of record and took title to the merchandise; (b) UA financed the relevant sales transactions; (c) UA arranged and paid for the further processing; and (d) UA assumed the seller's risk. See the Department's analysis memorandum (for Union) dated August 10, 1995, copies of which, as well as copies of other memoranda referred to in this notice, are available in Room B–099 of the Department's Central Records Unit.

Because quantities were not finalized until the merchandise was actually shipped to the United States, we treated the date of shipment as date of sale (*see* the Department's analysis memorandum referred to above). We made adjustments to purchase price, where appropriate, for cash discounts and rebates, foreign inland freight, foreign brokerage and handling, ocean freight, marine insurance, U.S. duty, U.S. brokerage and handling, U.S. inland freight, and duty drawback. We made adjustments to ESP, where appropriate, for cash discounts and rebates, foreign inland freight, foreign brokerage and handling, ocean freight, marine insurance, U.S. duty, U.S. brokerage and handling, U.S. inland freight, commissions, credit expenses, warranty expenses, indirect selling expenses, further processing in the United States, and duty drawback. Because Union had understated its U.S. credit expenses by not including bank charges therein, we increased Union's U.S. credit expense by the amount of those charges, which we obtained from UA's audited financial statement.

No other adjustments were claimed or allowed.

Foreign Market Value

Based on a comparison of the volume of home-market sales and third-country sales, we determined that Dongbu's and Union's home markets were viable. Therefore, in accordance with section 773(a)(1)(A) of the Act, we based FMV on the packed, delivered price to unrelated purchasers in the home market, using the date of the invoice as the date of sale.

Based on a review of Dongbu's and Union's submissions, the Department determined that only a small percentage of those companies' home-market sales were made to related parties who, in turn, resold the merchandise ("downstream sales"). The Department determined that Dongbu and Union need not report their home-market

downstream sales because of their low volume.

Petitioners alleged that Dongbu and Union sold corrosion-resistant carbon steel flat products in the home market at prices below their cost of production ("COP"). Based on this allegation, the Department determined that it had reasonable grounds to believe or suspect that Dongbu and Union had sold the subject merchandise in the home market at prices below the COP. We therefore initiated a cost investigation, in accordance with section 773(b) of the Act. As a result, we investigated whether Dongbu and Union sold such or similar merchandise in the home market at prices below the COP. In accordance with 19 CFR 353.51(c) we calculated COP for Dongbu and Union as the sum of reported materials, labor, factory overhead, and general expenses, and compared COP to home-market prices, net of price adjustments, discounts and movement expenses.

In accordance with section 773(b) of the Act, in determining whether to disregard home-market sales made at prices below the COP, we examined whether such sales were made in substantial quantities over an extended period of time, and whether such sales were made at prices which permitted recovery of all costs within a reasonable period of time in the normal course of trade.

To satisfy the requirement of section 773(b)(1) that below-cost sales be disregarded only if made in substantial quantities, we applied the following methodology. For each model for which less than 10 percent, by quantity, of the home-market sales during the POR were made at prices below the COP, we included all sales of that model in the computation of FMV. For each model for which 10 percent or more, but less than 90 percent, of the home-market sales during the POR were priced below the COP of the merchandise, we excluded from the calculation of FMV those home-market sales which were priced below the COP, provided that they were made over an extended period of time. For each model for which 90 percent or more of the home-market sales during the POR were priced below the COP and were made over an extended period of time, we disregarded all sales of that model in our calculation and, in accordance with section 773(b) of the Act, we used the constructed value ("CV") of those models, as described below. See, e.g., Mechanical Transfer Presses from Japan; Final Results of Antidumping Duty Administrative Review, 59 FR 9958 (March 2, 1994).

In accordance with section 773(b)(1) of the Act, to determine whether sales below cost had been made over an extended period of time, we compared the number of months in which sales below cost occurred for a particular model to the number of months in which that model was sold. If the model was sold in fewer than three months, we did not disregard below-cost sales unless there were below-cost sales of that model in each month sold. If a model was sold in three or more months, we did not disregard below-cost sales unless there were sales below cost in at least three of the months in which the model was sold. We used CV as the basis for FMV when an insufficient number of home-market sales were made at prices above COP. See Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, from Japan and Tapered Roller Bearings, Four Inches or Less in Outside Diameter, and Components Thereof, from Japan; Final results of Antidumping Duty Administrative Reviews, 58 FR 64720, 64729 (December 8, 1993).

Because Dongbu and Union provided no indication that their below-cost sales of models within the "greater than 90 percent" and the "between 10 and 90 percent" categories were at prices that would permit recovery of all costs within a reasonable period of time and in the normal course of trade, we disregarded those sales within the "10 to 90 percent" category which were made below cost over an extended period of time. In addition, as a result of our COP test for home-market sales of models within the "greater than 90 percent" category, we based FMV on CV for all U.S. sales for which there were insufficient sales of the comparison home-market model at or above COP. Finally, where we found, for certain of Dongbu's and Union's models, home-market sales for which less than 10 percent were made below COP, we used all home-market sales of those models in our comparisons.

We also used CV as FMV for those U.S. sales for which there was no contemporaneous sale of such or similar merchandise in the home market. We calculated CV in accordance with section 773(e) of the Act. We included the cost of materials, labor, and factory overhead in our calculations. Where the general expenses were less than the statutory minimum of 10 percent of the cost of manufacture ("COM"), we calculated general expenses as 10 percent of the COM. Where the actual profits were less than the statutory minimum of 8 percent of the COM plus general expenses, we calculated profit as 8 percent of the sum of COM plus general expenses. Based on our verification of Dongbu's and Union's cost response, we adjusted Dongbu's reported COP and CV to reflect certain adjustments to general and administrative expenses and interest expenses. See the Department's separate cost calculation memoranda for Dongbu and Union, both dated August 10, 1995.

Dongbu

In accordance with section 773 of the Act, for those U.S. models for which we were able to find a home-market such or similar match that had sufficient above-cost sales, we calculated FMV based on the packed, f.o.b., ex-factory, or delivered prices to unrelated purchasers in the home market. We made adjustments, where applicable, for certain rebates tied to specific sales, post-sale inland freight, home-market direct selling expenses, *i.e.*, credit and warranty expenses, and for the Korean value-added tax. We also adjusted FMV for differences in physical characteristics of the merchandise. Finally, we adjusted FMV for differences in packing by deducting home-market packing expenses from, and adding U.S. packing expenses to, FMV.

Union

In accordance with section 773 of the Act, for those U.S. models for which we were able to find a home-market such or similar match that had sufficient above-cost sales, we calculated FMV based on the packed, f.o.b., ex-factory, or delivered prices to unrelated purchasers in the home market. We made adjustments, where applicable, for post-sale inland freight, for home-market direct selling expenses, *i.e.*, credit expenses, and for the Korean value-added tax.

We treated Union's warehousing expense as an indirect selling expense, rather than direct, as Union had claimed, because Union evenly allocated this expense to all home market sales across-the-board, rather than calculating a discrete warehousing expense for each home-market sale.

We also treated Union's pre-sale inland freight as an indirect selling expense, rather than direct, as Union had claimed, pursuant to the decision by the Court of Appeals for the Federal Circuit in *Ad Hoc Committee* v. *United States*, 13 F.3d 398 (Fed. Cir. 1994). The Department considers pre-sale movement expenses as direct selling expenses only if the movement expenses in question are directly related to the home-market sales under consideration. In order to determine whether pre-sale movement expenses

are direct under the facts of a particular case, the Department examines the respondent's pre-sale warehousing expenses, since the pre-sale movement charges incurred in positioning the merchandise at the warehouse are, for analytical purpose, inextricably linked to pre-sale warehousing expenses. If the pre-sale warehousing constitutes an indirect expense, the expense involved in getting the merchandise to the warehouse must also be indirect. conversely, a direct pre-sale warehousing expense necessarily implies a direct pre-sale movement expense. We note that, although pre-sale warehousing expenses in most cases have been found to be indirect selling expenses, these expenses may be deducted from FMV as a circumstance-of-sale adjustment in a particular case if the respondent is able to demonstrate that the expenses are directly related to the sales under consideration. In the instant review, Union did not distinguish between pre- and post-sale warehousing expenses, nor did it demonstrate that these expenses were directly tied to the home-market sales under consideration. The Department, therefore, determined to treat home-market warehousing expenses as indirect selling expenses.

We also adjusted FMV for differences in packing by deducting home-market packing expenses from, and adding U.S. packing expenses to, FMV.

During the verification of Union's responses, the Department was unable to fully verify the accuracy of Union's reported home-market product characteristics, because Union did not retain the relevant information in its records, thereby casting doubt on the accuracy of the model match. It is the Department's preference to calculate antidumping duties on the basis of price-to-price comparisons whenever possible. It is also the Department's preference to use as much of respondent's data as possible. For purposes of this review, therefore, the Department has decided to use Union's model-matching product characteristics, but to apply to all of Union's price-to-price sales comparisons a flat, across-the-board adjustment for differences in physical characteristics of the merchandise ("difmer") of 20 percent as the best information otherwise available ("BIA"). Twenty percent is the maximum difmer allowed between U.S. and home-market models for the purposes of comparison. See the Department's internal memorandum from Joseph A. Spetrini to Susan G. Esserman, dated August 8, 1995.

In a letter dated May 24, 1995, petitioners formally requested that the Department consider Union and Dongkuk Industries Co., Ltd. ("DKI"), which is not a respondent, as a single producer of corrosion-resistant carbon steel flat products. This request to "collapse" Union and DKI was not made until well after the 180-day deadline for the submission of new factual information and after verification had been completed. Because petitioner's request was untimely, and the record evidence to collapse Union and DKI is insufficient, the Department has rejected petitioners' request to consider the issue of collapsing Union and DKI as a single producer of corrosion-resistant carbon steel flat products (*see* the Department's internal memorandum from Joseph A. Spetrini to Susan G. Esserman, dated July 28, 1995).

Preliminary Results of Review

As a result of our comparison of USP to FMV, we preliminarily determine that the following margins exist for the period February 4, 1993, through July 31, 1994:

CERTAIN CORROSION-RESISTANT CARBON STEEL FLAT PRODUCTS

Producer/manufacturer/exporter	Weighted-average margin (percent)
Dongbu	1.74
Union	5.72

Interested parties may request disclosure within 5 days of the date of publication of this notice and may request a hearing within 10 days of publication. Any hearing, if requested, will be held 44 days after the date of publication or the first business day thereafter. Case briefs and/or written comments from interested parties may be submitted no later than 30 days after the date of publication. Rebuttal briefs and rebuttals to written comments, limited to issues raised in those comments, may be filed not later than 37 days after the date of publication of this notice. The Department will publish the final results of this administrative review including the results of its analysis of issues raised in any such written comments or at a hearing.

The Department shall determine, and the Customer Service shall assess, antidumping duties on all appropriate entries. Individual differences between the USP and FMV may vary from the percentages stated above.

Furthermore, the following deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided for by section 751(a)(1) of the Act. A cash deposit of estimated antidumping duties shall be required on shipments of certain corrosion-resistant carbon steel flat products from Korea as follows: (1) The cash deposit rates for the reviewed company will be the rate established in the final results of this review; (2) for previously investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review or the original less-than-fair-value ("LTFV") investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) if neither the exporter nor the manufacturer is a firm covered in this review, the cash deposit rate for this case will be 17.88 percent, which is the "all others" rate for the LTFV investigation. See Final Determination of Sales at Less Than Fair Value: Certain Corrosion-Resistant Carbon Steel Flat Products from Korea, 58 FR 37176 (July 9, 1993).

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR § 353.26 to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This administrative review and this notice are in accordance with section 751(a)(1) of the Act (19 U.S.C. 1675(a)(1)) and 19 CFR § 353.22.

Dated: August 16, 1995.

Susan G. Esserman,

Assistant Secretary for Import Administration.

[FR Doc. 95–21067 Filed 8–23–95; 8:45 am]

BILLING CODE 3510–DS–M

[A–412–810]

Certain Hot-Rolled Lead and Bismuth Carbon Steel Products From the United Kingdom; Final Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of final results of antidumping duty administrative review.

SUMMARY: On February 23, 1995, the Department of Commerce (the Department) published the preliminary results of its 1992–94 administrative review of the antidumping duty order on certain hot-rolled lead and bismuth carbon steel products from the United Kingdom (60 FR 10061). The review covers one manufacturer/exporter of this merchandise, United Engineering Steels Limited (UES). The review period is September 28, 1992, through February 28, 1994. We gave interested parties the opportunity to comment on the preliminary results. Based on our analysis of the comments received, we have adjusted UES's margin for these final results.

EFFECTIVE DATE: August 24, 1995.

FOR FURTHER INFORMATION CONTACT: G. Leon McNeill or Maureen Flannery, Office of Antidumping Compliance, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230, telephone: (202) 482–4733.

SUPPLEMENTARY INFORMATION:

Background

On February 23, 1995, the Department published in the **Federal Register** (60 FR 10061) the preliminary results of its administrative review of the antidumping duty order on certain hot-rolled lead and bismuth carbon steel products from the United Kingdom (58 FR 15324, March 22, 1993). The Department has now completed that administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (the Tariff Act).

Applicable Statutes and Regulations

Unless otherwise stated, all citations to the statute and to the Department's regulations are references to the provisions as they existed on December 31, 1994.

Scope of the Review

The products covered by this review are hot-rolled bars and rods of nonalloy or other alloy steel, whether or not descaled, containing by weight 0.03 percent or more of lead or 0.05 percent of bismuth, in coils or cut lengths, and in numerous shapes and sizes. Excluded from the scope of this review are other alloy steels (as defined by the Harmonized Tariff Schedule of the United States (HTSUS) Chapter 72, note 1 (f)), except steels classified as other alloy steels by reason of containing by weight 0.4 percent or more of lead, or 0.1 percent or more of bismuth, tellurium, or selenium. Also excluded are semi-finished steels and flat-rolled products. Most of the products covered in this review are provided for under subheadings 7213.20.00 and 7214.30.00.00 of the HTSUS. Small quantities of these products may also enter the United States under the following HTSUS subheadings: 7213.31.30.00, 60.00; 7213.39.00.30, 00.60, 00.90; 7214.40.00.10, 00.30, 00.50; 7214.50.00.10, 00.30, 00.50; 7214.60.00.10, 00.30, 00.50; and 7228.30.80.00. HTSUS subheadings are provided for convenience and Customs purposes. They are not determinative of the products subject to the order. The written description remains dispositive.

This review covers sales of the subject merchandise manufactured by UES and entered into the United States during the period September 28, 1992, through February 28, 1994.

Analysis of Comments Received

We gave interested parties an opportunity to comment on the preliminary results as provided by section 353.22(c) of our regulations. At the request of the petitioner, Inland Steel Bar Company, and respondent, UES, we held a public hearing on April 10, 1995. We received case and rebuttal briefs from the petitioner and respondent.

Comment 1: Petitioner claims that the Department failed to adjust for actual antidumping duties UES paid on lead and bismuth steel. It argues that, since the actual dumping duties are paid by UES, the Department should treat the duty as a direct selling expense and make an adjustment for the amount of the actual dumping duties. Petitioner notes that the Department, in previous cases, has not considered estimated dumping duty deposits to be expenses within the meaning of section 772(d)(2)(A) of the Tariff Act because of the possibility that the estimated duties may vary from actual duties that may be assessed. However, it contends that, where UES is paying the actual dumping duties, the statute requires that the Department treat these duties the same way as any other direct selling expense.

UES disagrees with petitioner and cites, as support, Antifriction Bearings (Other Than Tapered Roller Bearings) and Parts Thereof from France, *et. al.* (60 FR 10900, February 28, 1995). UES also notes that, as part of the debate prior to the passage of the Uruguay Round Agreements Act, attempts were made to persuade Congress to change the law to permit the Department to consider dumping duty as a cost, but these attempts did not succeed. UES argues that to deduct the dumping duty from the U.S. price (USP) would be double-counting, because actual duties assessed will offset any price discrimination.

Department's Position: We disagree with petitioner. Antidumping duties are intended to offset the effect of discriminatory pricing between two markets. In this context, making an additional deduction from USP for the same antidumping duties that correct this price discrimination would result in double-counting. Therefore, we have not treated cash deposits of estimated antidumping duties as direct selling expenses. See Color Television Receivers from the Republic of Korea, Final Results of Administrative Review (58 FR 50333, September 27, 1993) and Antifriction Bearings (Other Than Tapered Roller Bearings) and Parts Thereof from France, et al.; Final Results of Antidumping Administrative Reviews (60 FR 10900, February 28, 1995).

Comment 2: Petitioner argues that the Department should use the date of order entry rather than shipment date as the date of sale, as it did in the original investigation. Petitioner argues that UES has offered insufficient reason in this review to justify a change in its date of sale methodology from the original investigation; in fact, petitioner notes, UES has conceded that the sales terms have not changed since the period of investigation (POI). Petitioner contests the analysis of order changes UES provided and the Department attached as an exhibit to its verification report. Petitioner notes that leaded bar is typically produced to order, and thus that the basic terms of sale—including price, quantity, and physical specifications—must generally be fixed prior to manufacturing and shipment. Petitioner contends that, due to the decrease in the value of the British pound during the period of review (POR), UES changed its methodology in order to use the date of shipment as the date of sale, thus benefitting from exchange rate changes which result in lower dumping margins.

UES maintains that, during the POR, more than half the orders placed were amended with respect to their essential terms—price, quantity, or product specifications. UES agrees that it has not changed its policy since the POI. According to UES, there were numerous amendments during the POI, but it lacked the computer capability at that time to analyze and quantify the order amendment type and frequency. Therefore, in the investigation of sales at

less than fair value (LTFV), the Department used the order date as the date of sale. UES states that, since the POI, UES installed a new computer system, able to quantify the number of amendments for each order, and to identify which orders modify essential terms. UES contends that the Department's verifiers thoroughly examined the computer code, confirmed that the program identified only amendments to essential terms, and also examined hard copy orders and amendment documents.

Department's Position: We disagree with petitioner. During the course of verification, the verifying team thoroughly examined computer programs and associated documents, and confirmed that a significant percentage of U.K. orders and U.S. sales were amended subsequent to the original purchase order. *See* Verification Report dated February 22, 1995 at page 4. Therefore, because the essential terms of sale were not final until the date of shipment, the Department has used, for these final results, the date of shipment as the appropriate date of sale.

Comment 3: Petitioner disputes the model match methodology used by the Department. Petitioner claims that in the LTFV investigation, the Department used the variable "CONNUM" as the product identification number for identifying identical products, and the variable "CONSIM" as the product identification number for identifying similar products. Petitioner argues that, in the preliminary results of review, the Department deviated from that methodology in that it did not use similar home market products as the basis for foreign market value (FMV) when a match with an identical product code could not be found. As a result, the Department eliminated most of the comparisons to similar merchandise and instead based FMV on constructed value (CV). Petitioner argues that similar products should be matched on the basis of CONSIM, not the product code.

Department's Position: We disagree with petitioner. Products should be matched by CONNUM, not by CONSIM. In this case, the product code is an internal company code assigned in the normal course of business. The CONNUM, on the other hand, reflects the criteria which the Department has established for purposes of defining identical and similar merchandise. CONSIM is identical to CONNUM, except that the grade designation is less specific than that identified by CONNUM. That is, it ignores "residuals," or trace elements. As we noted in the preliminary results, product differences due to residuals are commercially significant and not incidental, as they are designed into the product. Therefore, CONNUM is the appropriate variable to be used for model matching. However, in the preliminary results of this review, we erred by matching the product by CONNUM and product code. For these final results, we have revised our computer programming language to match the product by CONNUM only.

Comment 4: Petitioner argues that the Department should use identical matches when available, even if quantities differ. It maintains that the Department erroneously matched the U.S. product to a similar U.K. product in the same quantity grouping, rather than to the identical product in a different quantity grouping, thereby allowing the quantity of the sale to take precedence over the similarity of the sale. Petitioner contends that this conflicts with the Department's past practice of giving physical similarity precedence over other matching criteria.

Department's Position: We agree with petitioner, and have revised the computer programming language to match the U.S. product to the identical U.K. product regardless of its quantity grouping before matching it to a similar product.

Comment 5: The petitioner argues that, for the CV calculations, the Department should compute profit exclusive of UES's non-arm's-length related party sales. Petitioner asserts that these prices are essentially transfer prices rather than market prices, and it makes little sense to use the profit on such sales in calculating CV when the sales themselves are excluded from the price-to-price comparisons.

UES contends that, since UES's sales to its related customers were at arm's length, the petitioner's argument is moot. Furthermore, UES asserts that, contrary to the petitioner's argument, related party sales that fail the arm's-length test should not necessarily be excluded from the profit calculation. As support, UES cites Antifriction Bearings (Other Than Tapered Roller Bearings) and Parts Thereof from France, *et al.* (60 FR 10900, February 28, 1995 (AFB Final Results)). According to UES, the essential factor is whether the prices used in calculating CV reflect the market under consideration.

Moreover, UES notes that the petitioner relies on a simplistic analysis showing that UES's related customers, on average, pay a lower per-unit net price. UES asserts, however, that these related customers paid a lower price because they purchased large quantities. UES notes that it provides the same price advantages to high-volume related and unrelated customers. UES contends that this does not represent non-market, uneconomic transfer pricing. On the contrary, UES claims that it accepted lower per-unit profits to achieve higher overall company profitability. Consequently, UES insists these profits fairly reflect the amount usually earned on sales in the market.

Department's Position: We disagree, in part, with both petitioner and UES. As we stated in AFB Final Results, there is no basis for automatically including, for the purposes of calculating profit for CV, sales to related parties that fail the arm's-length test. This is because in doing the arm's-length test we may not adjust for certain expenses that are reflected in the profit calculation. However, related-party sales that fail the arm's-length test can give rise to the possibility that certain elements of value, such as profit, may not fairly reflect an amount usually reflected in sales of the merchandise. We considered whether the amount for profit on UES's sales to related parties was reflective of an amount for profit usually reflected on sales of the merchandise. To do so, we compared profit on sales to related parties that failed the arm's-length test to profit on sales to unrelated parties and arm's-length sales to related parties. Because the profit on non-arm's-length sales to related parties varied significantly from the profit on sales to unrelated parties and arm's-length sales to related parties, we disregarded non-arm's-length related-party sales for the purposes of calculating profit for CV for these final results. See proprietary memorandum from case analyst to file, "Lead and Bismuth Steel from the United Kingdom—Profit Analysis," dated July 3, 1995. See also AFBs Final Results.

Comment 6: The petitioner argues that UES excluded the cost of producing identical products sold in third countries from its submitted cost of production. According to the petitioner, UES did not identify the one U.S. product affected by this error. Therefore, petitioner asserts, the Department should make an adverse inference regarding UES's CV submission. Petitioner urges the Department to increase the cost of all U.S. products by the largest understatement of reported costs for the home market models.

UES contends that, contrary to the petitioner's claim, the cost of production for U.S. products was not materially affected by excluding production costs for third-country sales. UES asserts that the petitioner misunderstood the data reported in certain cost verification exhibits. According to UES, these exhibits reveal

that there were only four products manufactured in more than one mill and sold in both the United Kingdom and third countries. Additionally, UES claims that these documents show that its reported costs of those four products were slightly higher than the costs UES calculated by including the third-country production costs.

Furthermore, UES asserts that the single product mentioned by petitioner would have the same cost with or without including production costs for third-country sales because the product was only manufactured at one of UES's mills. Therefore, UES contends the petitioner's proposed adjustment to UES's costs has no merit.

Department's Position: We agree with UES that petitioner's proposed adjustment has no merit. During verification, UES presented support showing the product in question was only produced in one mill; thus, third-country production costs are irrelevant. Furthermore, the petitioner apparently misunderstood the results of UES's analysis regarding the impact of third-country production. During verification, UES demonstrated that there were only four products manufactured in multiple mills and sold in both the home market and third countries. The impact of weight averaging the production costs for these four products is minimal. Moreover, as respondent noted, its reported costs for the four products were slightly higher than the weighted-average costs it calculated by including the production costs for the third-country sales of these products. Thus, we accepted UES's submission methodology for calculating the cost of production.

Comment 7: Petitioner notes that, at the beginning of verification, UES reported a minor clerical error that increased the costs it reported it had incurred at one of its mills. The petitioner argues that the Department should increase CV for all U.S. products by the amount reported because many U.S. products were produced in that particular mill.

Department's Position: Pursuant to 19 CFR 353.59 (1994), the Department may disregard insignificant adjustments to FMV. For individual adjustments, those which have an *ad valorem* effect of less than 0.33 percent of the FMV are deemed insignificant. Since UES's clerical error was less than 0.33 percent, we have disregarded this adjustment in calculating CV. UES reported its calculation of this clerical error in Cost Verification Exhibit 1.

Comment 8: According to the petitioner, the Department should include the company's 1993 reorganization costs for its steel division in the general and administrative (G&A) expense calculation. Specifically, the petitioner suggests allocating these restructuring costs to UES's steel and forging divisions based on cost of sales.

UES asserts that the Department should exclude the 1993 restructuring costs because these costs reflect an estimate of expenses to be incurred for the company's 1994 reorganization. UES contends the restructuring costs were incurred after the POR and were less than the estimated amount. In addition, UES recorded the actual restructuring expenses by division in its financial accounts as the costs were incurred in 1994. Thus, UES states, these restructuring expenses would be appropriately captured in the next administrative review.

Department's Position: At verification, UES demonstrated that the actual restructuring expenses for each division were incurred after the POR. Therefore, we have not allocated the company level 1993 estimate to each of UES's mills for purposes of this review.

Comment 9: The petitioner contends that part of the closure costs for UES's Templeborough facility should be included in the company's G&A expense calculation. Specifically, the petitioner argues Templeborough closure costs should be allocated to the subject merchandise (leaded bar) using the same methodology the Department applied to the Woodstone mill closure costs.

According to UES, the Department should exclude Templeborough closure costs because the facility did not produce leaded bar and did not have the capability of producing any leaded steel products. UES asserts that, in contrast, its Woodstone mill produced leaded bar; therefore, UES maintains that the Department properly allocated the Woodstone closure costs to the subject merchandise in its preliminary analysis. Furthermore, UES asserts that the Department normally excludes non-operating expenses related solely to entities producing only non-subject merchandise. UES notes it incurred only non-operating expenses in closing its Templeborough facility.

Department's Position: At verification, UES showed that its Templeborough facility did not produce any leaded bar products. We therefore excluded these non-operating costs from our calculation of G&A because UES demonstrated that these closure costs related exclusively to an operation that had produced only non-subject merchandise. See Final Determination of Sales at Less Than Fair Value: Furfuryl Alcohol from South Africa, 60 FR 22550, May 8, 1995.

Comment 10: UES maintains that the Department's determination to exclude home market related-party sales from the price comparison is inappropriate. UES contends that, even if its sales did not satisfy the traditional arm's-length test, other evidence on the record indicates that UES's related-party price are arm's length in nature. UES argues that it performed the Department's traditional test for determining when related-party prices are at arm's length, and the test shows that UES's prices to related customers are on average higher than its prices to unrelated customers. UES contests the Department's determination, stated in the preliminary review results, that "UES's analysis of data from this review fails to provide an accurate assessment of whether its related-party sales were made at arm's length because it did not account for certain rebates and it did not perform its arm's-length test on a model group-by-model group basis." UES argues that it did perform its analysis on a model-by-model basis, exactly as, it asserts, the Department customarily performs the analysis. According to UES, it first calculated the weighted-average price of each product by CONNUM for each related customer and for all unrelated customers together, separately by level of trade. It then compared the average price for each related customer for each product to the average price for that same product to derive a ratio by which the related-customer price was over or under the unrelated price for that particular product. UES explains that it then weight-averaged each customer's ratios to derive an overall ratio for each related customer. Finally, UES weight-averaged all related customers' ratios to yield the overall ratio between related and unrelated customers' prices. To support this explanation, UES has attached to its brief the model-specific output.

UES argues that the Department improperly deducted "Rebate 2" from gross price in performing the arm's-length test, thus skewing the analysis. See UES's proprietary case brief at pages 4–6. It contends that this rebate is available on the same terms to both related and unrelated customers. UES asserts that the varying use of the rebate by different customers is outside of UES's knowledge and control, and does not change the fact that UES negotiates all customers' prices on an arm's-length basis.

UES argues that, even if its sales did not satisfy the traditional arm's-length test, the Department should still confirm its previous determination that UES's prices are market-based and non-discriminatory. UES contends that it

deals with all home market customers on an arm's-length basis, whether related or unrelated. However, UES claims the one overriding determinant of price among customers—which has nothing to do with relatedness—is that UES negotiates lower prices with high-volume customers. UES argues that if the Department identifies any price difference between its large-quantity related customers and its small-quantity unrelated customers, it would be attributed to the fact that UES negotiates lower prices with high-volume customers. UES claims that the same issue arose in the original LTFV investigation, and the Department determined that UES's related party prices were at arm's length. According to UES, it has confirmed to the Department that its policy has not changed since the original LTFV investigation and that it does not discriminate in favor of related customers.

UES notes that, during the POR, it purchased one of its largest customers, Lee Bright Bar (LBB). UES maintains that, if there were price discrimination in favor of related parties, one would expect its prices to LBB to have decreased after the purchase. On the contrary, UES argues, its prices to LBB increased after it became a related party, and even increased at a higher rate than the average for UES's customers in general.

UES asserts that, as further confirmation of its non-discriminatory pricing policy, it has demonstrated that its related prices are equivalent to prices it charged to an unrelated German customer which is comparable in size and purchase volume to UES's related home market customers. UES argues that its sales prices to this unrelated German customer are at or below the weighted-average prices to its related customers in the United Kingdom for the same products in the same months. UES counters petitioner's argument that differences in the U.K. and German markets might account for these price differences by stating that the European Union (EU) is a single, unified market, UES competes directly with German mills, and UES's customers can as freely purchase from European producers as from UES.

Petitioner argues that the Department correctly included Rebate 2 among the items it deducted from gross sales price in performing its arm's-length analysis, in accordance with its policy of using net sales price, after all discounts and rebates have been deducted, in that analysis. Further, petitioner asserts that UES failed to provide any written documentation in support of its claim that all customers are entitled to take advantage of Rebate 2. Petitioner contends that UES is practicing *de facto* price discrimination against unrelated customers through its rebate programs. Petitioner maintains that, even if UES were not intentionally price discriminating against unrelated customers through its rebate program, the terms of Rebate 2 are too onerous to unrelated parties for them to regularly take advantage of this program.

Petitioner challenges what UES has offered as alternate evidence that it does not discriminate in favor of related customers. According to petitioner, UES's related-party profit margin demonstrates that sales to related parties are not made at arm's length. Petitioner argues that sales to a single related customer, LBB, are not representative of sales to all related parties. Petitioner maintains that the Department should disregard UES's claims regarding the German market, since the U.K. market is viable. Furthermore, petitioner asserts that UES failed to provide for the record detailed information, by CONNUM, on all German sales in order to show that the product mix was not responsible for the average price differences. Moreover, petitioner states that, contrary to UES's claim, the EU is not a single market, because significant currency variation occurs between EU member countries. Petitioner argues that UES's claim must be rejected because Congress has specifically prohibited looking at customs unions, such as the UE, as a single country in determining the occurrence of dumping. Petitioner contends that the Department should not make an adjustment to its arm's-length test to take into account differences in sales volumes because the analysis of UES's sales data demonstrates that there were no sales made at different levels of trade and different quantities during the POR.

Department's Position: We disagree with respondent. The information UES originally presented did not indicate that UES had performed the arm's-length test on a model group-by-model group basis. The first time this was mentioned, and the model-specific output submitted to the Department, was in UES's case brief of March 27, 1995. In any event, UES's test was inaccurate since it failed to deduct certain rebates from the sales prices before comparisons were made. UES's argument that we should not deduct rebates prior to the arm's length test is incorrect. Because these rebates are adjustments to price which UES made, we must deduct them from UES's home market prices in order to fairly compare the prices ultimately paid by related and unrelated customers. See Final Determination of Sales at Less Than Fair Value; Antifriction Bearings (Other Than Tapered Roller Bearings) and Parts Thereof From the Federal Republic of Germany (54 FR 19089, 19090, May 3, 1989).

Even if we were to abandon our traditional arm's-length test in this case, there is not sufficient evidence on the record to demonstrate that UES meets an acceptable alternate test. In order to determine whether UES's sales to related home market customers were arm's-length in nature, we conducted a three-pronged analysis. See the proprietary memorandum from case analyst to file concerning UES's related party sales dated July ____, 1995. Based on our analysis, we concluded that UES's home market sales to related parties were not at arm's length. Accordingly, we have not used these sales in our determination of FMV.

Comment 11: UES states that the Department correctly decided that, where possible, it would match U.S. and U.K. sales within two quantity groups: one of 25 tons or more, and one of less than 25 tons. However, UES argues that, in its dumping margin computer program, the Department assigned all U.S. sales to the less-than-25-tons group by inadvertently using the wrong quantity variable.

Department's Position: We agree and have revised the computer programming language accordingly.

Comment 12: UES contends that, instead of using selling and packing expenses from the sales database in its cost of production calculations, the Department erroneously used the average selling and packing expenses from the cost database.

Department's Position: We agree and have revised our calculations accordingly.

Comment 13: UES maintains that the Department erred in failing to adjust invoice quantity by the amount shown in the quantity adjustment field. According to UES, this field shows corrections to invoice quantity which UES issues to its customers to correct invoice errors.

Department's Position: We agree and have made the appropriate revision in our calculations.

Final Results of Review

As a result of this review, we determine that the following weighted-average dumping margin exists for the period September 1, 1992, through February 28, 1994:

Manufacturer/Exporter	Period of review	Margin (percent)
United Engineering Steels Ltd. (UES)	9/28/92–2/28/94	5.05

The Department will instruct the Customs Service to assess antidumping duties on all appropriate entries. Individual differences between USP and FMV may vary from the percentage stated above. The Department will issue appraisement instructions concerning all respondents directly to the Customs Service.

Furthermore, the following deposit requirements will be effective upon publication of these final results of administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption, as provided by section 751(a)(1) of the Tariff Act: (1) The cash deposit rate for the reviewed company will be the rate shown above; (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the original LTFV investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 25.82 percent, the "all others" rate established in the LTFV investigation.

These deposit requirements shall remain in effect until publication of the final results of the next administrative review.

This notice serves as a final reminder to importers of their responsibility under 19 CFR 353.26 to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This notice also serves as a reminder to parties subject to administrative protective orders (APOs) of their responsibility concerning disposition of proprietary information disclosed under APO in accordance with 19 CFR 353.34(d). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This administrative review and notice are in accordance with section 751(a)(1) of the Tariff Act (19 U.S.C. 1675(a)(1) and 19 CFR 353.22.

Dated: August 17, 1995.

Susan G. Esserman,

Assistant Secretary for Import Administration.

[FR Doc. 95–20934 Filed 8–23–95; 8:45 am]

BILLING CODE 3510–DS–M

[C–401–401]

Certain Carbon Steel Products From Sweden; Preliminary Results of Countervailing Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of preliminary results of countervailing duty administrative review.

SUMMARY: The Department of Commerce (the Department) is conducting an administrative review of the countervailing duty order on certain carbon steel products from Sweden. We preliminarily determine the net subsidy to be 2.98 percent ad valorem for the period January 1, 1993 through December 31, 1993. If the final results remain the same as these preliminary results of administrative review, we will instruct the U.S. Customs Service to assess countervailing duties as indicated above. Interested parties are invited to comment on these preliminary results.

EFFECTIVE DATE: August 24, 1995.

FOR FURTHER INFORMATION CONTACT: Stephanie Moore or Christopher Jimenez, Office of Countervailing Compliance, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230; telephone: (202) 482–2786.

SUPPLEMENTARY INFORMATION:

Background

On October 11, 1985, the Department published in the **Federal Register** (50 FR 41547) the countervailing duty order on certain carbon steel products from Sweden. On October 7, 1994, the Department published a notice of "Opportunity to Request an Administrative Review" (59 FR 5166) of this countervailing duty order. We received a timely request for review from SSAB Svenskt Stal AB (SSAB), the sole known producer/exporter of the subject merchandise during the period of review (POR).

We initiated the review, covering the period January 1, 1993 through December 31, 1993, on November 14, 1994 (59 FR 56459). We conducted verification of the questionnaire responses from March 27, 1995 through March 31, 1995. The review covers SSAB and nine programs.

Applicable Statute and Regulations

The Department is conducting this administrative review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act). Unless otherwise indicated, all citations to the GATT Subsidies Code, the U.S. statute, and to the Department's regulations are in reference to the provisions as they existed on December 31, 1994. References to the Department's Countervailing Duties; Notice of Proposed Rulemaking and Request for Public Comments, (54 FR 23366; May 31, 1989) (Proposed Regulations), are provided solely for further explanation of the Department's countervailing duty practice. Although the Department has withdrawn the particular rulemaking proceeding pursuant to which the Proposed Regulations were issued, the subject matter of these regulations is being considered in connection with an ongoing rulemaking proceeding which, among other things, is intended to conform the Department's regulations to the Uruguay Round Agreements Act. See 60 FR 80; Jan. 3, 1995.

Scope of the Review

Imports covered by this review are shipments of certain carbon steel products from Sweden. These products include cold-rolled carbon steel, flat-rolled products, whether or not corrugated or crimped: whether or not pickled, not cut, not pressed and not stamped to non-rectangular shape; not coated or pleated with metal and not clad; over 12 inches in width and of any thickness; whether or not in coils. During the review period, such merchandise was classifiable under the Harmonized Tariff Schedule (HTS) item numbers 7209.11.0000, 7209.12.0000, 7209.13.0000, 7209.21.0000, 7209.22.0000, 7209.23.0000, 7209.24.5000, 7209.31.0000, 7209.32.0000, 7209.33.0000, 7209.34.0000, 7209.41.0000, 7209.43.0000, 7209.44.0000, 7209.90.0000, 7211.30.5000, 7211.41.7000 and 7211.49.5000.

Calculation Methodology for Assessment and Cash Deposit Purposes

Because SSAB is the only manufacturer/exporter of the subject merchandise to the United States, SSAB's net subsidy rate is also the country-wide rate.

Privatization

SSAB was partially privatized twice, in 1987 and in 1989. In the Final Affirmative Countervailing Duty Determinations: Certain Steel Products from Sweden (58 FR 37385; July 9, 1993) (Final Determination), the Department found that SSAB had received countervailable subsidies prior to these partial privatizations. Further, the Department found that a private party purchasing all or part of a government-owned company can repay prior subsidies on behalf of the company as part or all of the sales price (*see* the General Issues Appendix appended to the Final Countervailing Duty Determination; Certain Steel Products from Austria (58 FR 37262; July 9, 1993) (General Issues Appendix)). Therefore, to the extent that a portion of the sales price paid for a privatized company can be reasonably attributed to prior subsidies, that portion of those subsidies will be extinguished.

To calculate the subsidies remaining with SSAB after each partial privatization, we performed the following calculations. We first calculated the net present value (NPV) of the future benefit stream of the subsidies at the time of the sale of the shares. We then multiplied the NPV by the percentage of shares the government retained after the sale to derive the amount of subsidies not affected by privatization. Next, we estimated the portion of the purchase price which represents repayment of prior subsidies in accordance with the methodology described in the "Privatization" section of the General Issues Appendix (58 FR 37259). This amount was then subtracted from the NPV, and the result was divided by the NPV to calculate the ratio representing the amount of subsidies remaining with SSAB after each partial privatization.

With respect to sales of "productive units" by SSAB, we have followed the same methodology used in the Final Determination (58 FR 37385). In accordance with that methodology, a portion of the price paid when a productive unit is sold is allocable to repayment of subsidies received in prior years by the seller of the productive unit. The subsidies allocated to the POR have been reduced for all of the programs, as described above. These subsidies were further adjusted by the asset value of the productive unit. For a further explanation of the Department's methodology regarding "sales of productive units" and these calculations, see the "Restructuring" section of the General Issues Appendix (58 FR 37265).

To calculate the benefit provided to SSAB, we multiplied the benefit calculated for 1993, adjusted for sales of productive units, by the ratio representing the amount of subsidies remaining with SSAB after the partial privatization. We then divided the results by the company's total sales in 1993.

Analysis of Programs

I. Programs Preliminarily Found to Confer Subsidies

(1) Equity Infusion

In 1981, the Government of Sweden (GOS) provided equity capital to SSAB totaling 1,125 million Swedish kronor (MSEK). Simultaneously, Granges, a private company and the only other shareholder at the time, contributed 375 MSEK. To persuade Granges to contribute this equity capital, the GOS guaranteed a specified sum to be paid to Granges in 1991. Because of this arrangement, we determined that the 375 MSEK paid by Granges was an equity infusion provided indirectly by the GOS, through Granges, specifically to SSAB. See, Certain Carbon Steel Products from Sweden; Final Results of Countervailing Duty Administrative Review; (59 FR 6620; February 11, 1994) (Final Results Cold-Rolled) and Final Determination (58 FR 37385).

In the Final Results Cold-Rolled (59 FR 6620) and in the Final Determination (58 FR 37385), we determined that SSAB was unequityworthy in 1981 when it received the equity infusions, and that the two equity infusions are therefore countervailable. There has been no new information or evidence of changed circumstances in this review to warrant reconsideration of this determination.

In accordance with the "Equity" section of the General Issues Appendix, we treated the equity infusions as grants. To calculate the benefit from these equity infusions for the POR, we used the grant methodology as described in the "Allocation" section of the General Issues Appendix (58 FR 37226). Because the Department determined in the Final Determination that the infusions are non-recurring subsidies, we have allocated the subsidies over 15 years, the average useful life of assets in the steel industry, according to the asset classes guidelines of the Internal Revenue Service. As the discount rate, we have used SSAB's company-specific interest rate on fixed-rate long-term loans (see § 355.49 of the Proposed Regulations).

We reduced the benefit from these equity infusions attributable to the POR according to the methodology outlined in the "Privatization" section above. We then divided the result by SSAB's total sales for 1993. On this basis, we preliminarily determine the net subsidy to be 0.82 percent *ad valorem*.

(2) Structural Loans

SSAB received structural loans under three separate pieces of legislation for investment in plant and equipment. The loans were disbursed in installments between 1978 and 1983. All three loans were outstanding during the POR.

According to the terms of the loans, all three structural loans were interest-free for three years from the date of disbursement. After that time, one loan incurred interest at a fixed rate of five percent per annum while the other two loans incurred interest at a variable rate subject to change every five years. The variable interest rate on these two loans is set at the rate of the long-term government bonds plus a 0.25 percent margin. After a five-year grace period, the principal is repaid in 20 equal installments at the end of each calendar year.

In the Final Results Cold-Rolled (59 FR 6620) and in the Final Determination (58 FR 37385), we determined that these loans are countervailable because they were provided specifically to SSAB on terms inconsistent with commercial considerations. There has been no new information or evidence of changed circumstances in this review to warrant reconsideration of this determination.

To calculate the benefit from the fixed-rate structural loan, we employed the long-term loan methodology described in § 355.49(c)(1) of the Proposed Regulations. To calculate the benefits from the two variable-rate loans, we used the variable-rate long-term loan methodology described in § 355.49(d)(1) of the Proposed Regulations. As the discount rate, we used the same benchmark previously established. See, Final Results Cold-Rolled (59 FR 6620) and Final Determination (58 FR 37385).

We reduced the benefit attributable to the POR from the fixed-rate structural loan according to the methodology outlined in the "Privatization" section above. We then aggregated the benefits for the three loans (fixed interest rate and variable interest rate) and divided the results by SSAB's total sales for

1993. On this basis, we preliminarily determine the net subsidy from the three structural loans to be 0.38 percent *ad valorem*.

(3) Forgiven Reconstruction Loans

The GOS provided reconstruction loans to SSAB between 1979 and 1985 to cover operating losses, investment in certain plants and equipment, and for employment promotion purposes. The loans were interest free for three years, after which a fixed interest rate was charged. According to the terms of the loans, up to half of the outstanding amount of the loan can be written off after the second calendar year following the disbursement. The remainder of the loan can be written off entirely at the end of the ninth calendar year after disbursement. Pursuant to the terms of the reconstruction loans, the GOS wrote off large portions of principal and accrued interest on these loans between 1980 and 1990.

In the Final Results Cold-Rolled (59 FR 6620) and in the Final Determination (58 FR 37385), we determined that forgiveness of these loans is countervailable. There has been no new information or evidence of changed circumstances in this review to warrant reconsideration of this determination.

To calculate the benefit, we treated the written-off portions of the reconstruction loans as countervailable grants received in the years the loans were forgiven and calculated the benefit using the grant methodology as described in the "Allocation" section of the General Issues Appendix (58 FR 37225). We reduced the benefits from these grants attributable to the POR according to the methodology outlined in the "Privatization" section above. We then divided the results by SSAB's total sales for 1993. On this basis, we preliminarily determine the net subsidy from the three structural loans to be 1.77 percent *ad valorem*.

(4) Grants for Temporary Employment for Public Works

The GOS provided temporary employment grants to companies and government agencies which hired individuals on a temporary basis to work on public works projects (e.g., construction, road building, repairs). SSAB received such grants between 1979 and 1988.

In the Final Results Cold-Rolled (59 FR 6620) and in the Final Determination; (58 FR 37385), we determined that these grants are countervailable. There has been no new information or evidence of changed circumstances in this review to warrant reconsideration of this determination.

We calculated the net subsidy of the grant received in 1979 using the grant methodology as described in the "Allocation" section of the General Issues Appendix. The amounts received by SSAB under this program in all other years were less than 0.5 percent of the value of the company's total sales in each year. Therefore, those amounts were allocated to the year of receipt. See, "Allocation" section of the General Issues Appendix (37226).

To calculate the benefit for the POR, we reduced the benefit from the 1979 grant according to the methodology outlined in the "Privatization" section above. We then divided the result by SSAB's total sales for 1993. On this basis, we preliminarily determine the net subsidy to be 0.01 percent *ad valorem*.

II. Programs Preliminarily Found Not to Confer Subsidies

Research & Development (R&D) Loans and Grants

The Swedish National Board for Industrial and Technical Development (NUTEK) provides research and development loans and grants to Swedish industries for R&D purposes. One type of R&D loan (industrial development loans) is mostly aimed at "new" industries such as the biotechnical, electronic, and medical industries. Another type of R&D loan (energy efficiency loans) is directed towards big energy consumers.

The loans accrue interest equal to the official "discount" rate plus a premium of 3.75 percent. However, no interest or principal payments are due until the R&D project is completed. If upon completion of a project the company wishes to use the research results for commercial purposes, the loan must be repaid. On the other hand, if the company decides not to utilize the results and, therefore, does not claim proprietary treatment for the results, NUTEK will forgive the loan and the results of the research become publicly available.

SSAB had several R&D loans outstanding during the POR on which it did not make either principal or interest payments. However, we cannot determine whether SSAB has received a countervailable benefit until the research is completed. It is only then that it is known (1) whether the loans are forgiven, and (2) if the loans were not forgiven, whether the accrued interest is less than what would have accrued had the loans been provided at commercial rates. See, Final Results Cold-Rolled (59 FR 6620) and Final Determination (58 FR 37385). Therefore, we will continue to examine the R&D loans in future administrative reviews.

As explained above, NUTEK may forgive R&D loans if the companies receiving them disseminate publicly the results of the research financed by the loans. Although the Department's practice is to treat forgiven R&D loans as grants, if the research results are publicly available, such assistance does not bestow a countervailable benefit. See, Final Results Cold-Rolled (59 FR 6620) and Final Determination (58 FR 37385). During the POR, three loans were forgiven. At verification, we confirmed that the results of these research projects were publicly available. On this basis, we preliminarily determine that this R&D program did not confer countervailable benefits on the export of the subject merchandise to the United States during the POR.

III. Programs Preliminarily Found Not to be Used

We also examined the following programs and preliminarily determine that SSAB did not apply for or receive benefits under them during the POR:

(A) Regional Development Grants
(B) Transportation Grants
(C) Location-of-industry Loans

IV. Program Preliminarily Found to be Terminated

We also examined the following program and preliminarily determine that the program has been officially terminated and there are no residual benefits. See, Memorandum to File dated June 23, 1995 regarding termination of the program, which is on file in the Central Records Unit, Room B–099 of the Department of Commerce.

State Stockpiling Subsidies

Preliminary Results of Review

For the period January 1, 1993 through December 31, 1993, we preliminarily determine the net subsidy to be 2.98 percent *ad valorem*.

If the final results of this review remain the same as these preliminary results, the Department intends to instruct the U.S. Customs Service to assess the following countervailing duties:

All Companies 2.98 percent *ad valorem*

The Department also intends to instruct the U.S. Customs Service to collect a cash deposit of estimated countervailing duties of 2.98 percent of the f.o.b. invoice price on all shipments of the subject merchandise from all manufacturers, producers, and exporters, entered or withdrawn from warehouse, for consumption on or after

the date of publication of the final results of this review.

Parties to the proceeding may request disclosure of the calculation methodology and interested parties may request a hearing not later than 10 days after the date of publication of this notice. Interested parties may submit written arguments in case briefs on these preliminary results within 30 days of the date of publication. Rebuttal briefs, limited to arguments raised in case briefs, may be submitted seven days after the time limit for filing the case brief. Parties who submit written arguments in this proceeding are requested to submit with the argument (1) a statement of the issue and (2) a brief summary of the argument. Any hearing, if requested, will be held seven days after the scheduled date for submission of rebuttal briefs. Copies of case briefs and rebuttal briefs must be served on interested parties in accordance with 19 CFR 355.38(e).

Representatives of parties to the proceeding may request disclosure of proprietary information under administrative protective order no later than 10 days after the representative's client or employer becomes a party to the proceeding, but in no event later than the date the case briefs, under § 355.38(c) of the regulations, are due. The Department will publish the final results of this administrative review including the results of its analysis of issues raised in any case or rebuttal brief or at a hearing.

This administrative review and notice are in accordance with section 751(a)(1) of the Act (19 U.S.C. 1675(a)(1)) and 19 CFR 355.22.

Dated: August 16, 1995.

Susan G. Esserman,

Assistant Secretary for Import Administration.

[FR Doc. 95–21069 Filed 8–23–95; 8:45 am]

BILLING CODE 3510–DS–P

[C–401–804]

Certain Cut-to-Length Carbon Steel Plate From Sweden; Preliminary Results of Countervailing Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of preliminary results of countervailing duty administrative review.

SUMMARY: The Department of Commerce (the Department) is conducting an administrative review of the countervailing duty order on certain cut-to-length carbon steel plate from Sweden. We preliminarily determine the net subsidy to be 2.98 percent ad valorem for the period December 7, 1992 through December 31, 1993. If the final results remain the same as these preliminary results of administrative review, we will instruct the U.S. Customs Service to assess countervailing duties as indicated above. Interested parties are invited to comment on these preliminary results.

EFFECTIVE DATE: August 24, 1995.

FOR FURTHER INFORMATION CONTACT: Stephanie Moore or Christopher Jimenez, Office of Countervailing Compliance, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–2786.

SUPPLEMENTARY INFORMATION:

Background

On August 17, 1993, the Department published in the **Federal Register** (58 FR 43758) the countervailing duty order on certain cut-to-length carbon steel plate from Sweden. On August 3, 1994, the Department published a notice of "Opportunity to Request an Administrative Review" (59 FR 39543) of this countervailing duty order. We received a timely request for review from SSAB Svenskt Stal AB (SSAB), the sole known producer/exporter of the subject merchandise during the period of review (POR).

We initiated the review, covering the period December 7, 1992 through December 31, 1993, on September 8, 1994 (59 FR 46391). We conducted verification of the questionnaire responses from March 27, 1995 through March 31, 1995. The review covers SSAB and ten programs.

Because the POR covers only three weeks in 1992 (December 7 through December 31, 1992), the Department determined that it was appropriate to apply the assessment rate calculated for 1993 to exports made during the three-week period. See, Memorandum for Joseph A. Spetrini from the Steel Team dated October 3, 1994, regarding calculation of the assessment rate in the first administrative reviews of the Certain Steel Countervailing Duty Orders, which is on file in the Central Records Unit, Room B–099 of the Department of Commerce.

Applicable Statute and Regulations

The Department is conducting this administrative review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act). Unless otherwise indicated, all citations to the GATT Subsidies Code, the U.S. statute, and to the Department's regulations are in reference to the provisions as they existed on December 31, 1994. References to the Department's Countervailing Duties; Notice of Proposed Rulemaking and Request for Public Comments, (54 FR 23366, May 31, 1989) (Proposed Regulations), are provided solely for further explanation of the Department's countervailing duty practice. Although the Department has withdrawn the particular rulemaking proceeding pursuant to which the *Proposed Regulations* were issued, the subject matter of these regulations is being considered in connection with an ongoing rulemaking proceeding which, among other things, is intended to conform the Department's regulations to the Uruguay Round Agreements Act. See 60 FR 80, Jan. 3, 1995.

Scope of the Review

Imports covered by this review are shipments of certain cut-to-length carbon steel plate from Sweden. These products include hot-rolled carbon steel universal mill plates (i.e., flat-rolled products rolled on four faces or in a closed box pass, of a width or in a closed box pass, of a width exceeding 150 millimeters but not exceeding 1,250 millimeters and of a thickness of not less than 4 millimeters and of a thickness of not less than 4 millimeters, not in coils and without patterns in relief), of rectangular shape, neither clad, plated nor coated with metal, whether or not painted, varnished, or coated with plastics or other nonmetallic substances; and certain hot-rolled carbon steel flat-rolled products in straight lengths, of rectangular shape, hot rolled, neither clad, plated, nor coated with metal, whether or not painted, varnished, or coated with plastics or other nonmetallic substances, 4.75 millimeters or more in thickness and of a width which exceeds 150 millimeters and measures at least twice the thickness. During the review period, such merchandise was classifiable under the Harmonized Tariff Schedule (HTS) item numbers 7208.31.0000, 7208.32.0000, 7208.33.1000, 7208.33.5000, 7208.41.0000, 7208.42.0000, 7208.43.0000, 7208.90.0000, 7210.70.3000, 7210.90.9000, 7211.11.0000, 7211.12.0000, 7211.21.0000, 7211.22.0045, 7211.90.0000, 7212.40.1000, 7212.40.5000, and 7212.50.0000. Included in this order are flat-rolled products of non-rectangular cross-section where cross-section is achieved subsequent to the rolling process (i.e., products which have been

"worked after rolling")—for example, products which have been beveled or rounded at the edges. Excluded from this order is grade X–70 plate. The HTS item numbers are provided for convenience and customs purposes. The written description remains dispositive.

Calculation Methodology for Assessment and Cash Deposit Purposes

Because SSAB is the only manufacturer/exporter of the subject merchandise to the United States, SSAB's net subsidy rate is also the country-wide rate.

Privatization

SSAB was partially privatized twice, in 1987 and in 1989. In the Final Affirmative Countervailing Duty Determinations: Certain Steel Products from Sweden (58 FR 37385, July 9, 1993) (Final Determination), the Department found that SSAB had received countervailable subsidies prior to these partial privatizations. Further, the Department found that a private party purchasing all or part of a government-owned company can repay prior subsidies on behalf of the company as part or all of the sales price (*see* the General Issues Appendix appended to the Final Countervailing Duty Determination; Certain Steel Products from Austria (58 FR 37262, July 9, 1993) (General Issues Appendix)). Therefore, to the extent that a portion of the sales price paid for a privatized company can be reasonably attributed to prior subsidies, that portion of those subsidies will be extinguished.

To calculate the subsidies remaining with SSAB after each partial privatization, we performed the following calculations. We first calculated the net present value (NPV) of the future benefit stream of the subsidies at the time of the sale of the shares. We then multiplied the NPV by the percentage of shares the government retained after the sale and derived the amount of subsidies not affected by privatization. Next, we estimated the portion of the purchase price which represents repayment of prior subsidies in accordance with the methodology described in the "Privatization" section of the General Issues Appendix (58 FR 37259). This amount was then subtracted from the NPV, and the result was divided by the NPV to calculate the ratio representing the amount of subsidies remaining with SSAB after each partial privatization.

With respect to sales of "productive units" by SSAB, we have followed the same methodology used in the Final Determination (58 FR 37385). In accordance with that methodology, a portion of the price paid when a productive unit is sold is allocable repayment of subsidies received in prior years by the seller of the productive unit. The subsidies allocated to the POR have been reduced for all of the programs, as described above. These subsidies were further adjusted by the asset value of the productive unit. For a further explanation of the Department's methodology regarding "sales of productive units" and these calculations, see the "Restructuring" section of the General Issues Appendix (58 FR 37265).

To calculate the benefit provided to SSAB, we multiplied the benefit calculated for 1993, adjusted for sales of productive units, by the ratio representing the amount of subsidies remaining with SSAB after the partial privatization. We then divided the results by the company's total sales in 1993.

Analysis of Programs

I. Programs Preliminarily Found to Confer Subsidies

(1) Equity Infusion

In 1981, the Government of Sweden (GOS) provided equity capital to SSAB totaling 1,125 million Swedish kronor (MSEK). Simultaneously, Granges, a private company and the only other shareholder at the time, contributed 375 MSEK. To persuade Granges to contribute this equity capital, the GOS guaranteed a specified sum to be paid to Granges in 1991. Because of this arrangement, we determined that the 375 MSEK paid by Granges was an equity infusion provided indirectly by the GOS, through Granges, specifically to SSAB. See, Final Determination (58 FR 37387).

In the Final Determination (58 FR 37385) and in the final determination from a previous investigation of Swedish steel, Final Affirmative Countervailing Duty Determinations; Certain Carbon Steel Products from Sweden (50 FR 33377, August 19, 1985) (Final Certain Carbon Steel Products), we determined that SSAB was unequityworthy in 1981 when it received the equity infusions, and that the two equity infusions are therefore countervailable. There has been no new information or evidence of changed circumstances in this review to warrant reconsideration of this determination.

In accordance with the "Equity" section of the General Issues Appendix, we treated the equity infusions as grants. To calculate the benefit from these equity infusions for the POR, we used the grant methodology as described in the "Allocation" section of the General Issues Appendix (58 FR 37226). Because the Department determined in the Final Determination that the infusions are non-recurring subsidies, we have allocated the subsidies over 15 years, the average useful life of assets in the steel industry, according to the asset guideline classes of the Internal Revenue Service. As the discount rate, we have used SSAB's company-specific interest rate on fixed-rate long-term loans (see § 355.49 of the Proposed Regulations).

We reduced the benefit from these equity infusions attributable to the POR according to the methodology outlined in the "Privatization" section above. We then divided the result by SSAB's total sales for 1993. On this basis, we preliminarily determine the net subsidy to be 0.82 percent *ad valorem*.

(2) Structural Loans

SSAB received structural loans under three separate pieces of legislation for investment in plant and equipment. The loans were disbursed in installments between 1978 and 1983. All three loans were outstanding during the POR.

According to the terms of the loans, all three structural loans were interest-free for three years from the date of disbursement. After that time, one loan incurred interest at a fixed rate of five percent per annum while the other two loans incurred interest at a variable rate subject to change every five years. The variable interest rate on these two loans is set at the rate of the long-term government bonds plus a 0.25 percent margin. After a five-year grace period, the principal is repaid in 20 equal installments at the end of each calendar year.

In the Final Determination (58 FR 37388) and in Final Certain Carbon Steel Products (50 FR 33376), we determined that these loans are countervailable because they were provided specifically to SSAB on terms inconsistent with commercial considerations. There has been no new information or evidence of changed circumstances in this review to warrant reconsideration of this determination.

To calculate the benefit from the fixed-rate structural loan, we employed the long-term loan methodology described in § 355.49(c)(1) of the Proposed Regulations. To calculate the benefits from the two variable-rate loans, we used the variable-rate long-term loan methodology described in § 355.49(d)(1) of the Proposed Regulations. As the discount rate, we used the same benchmark previously established. See, Final Determination (58 FR 37386).

We reduced the benefit attributable to the POR from the fixed-rate structural loan according to the methodology outlined in the "Privatization" section above. We then aggregated the benefits for the three loans (fixed interest rate and variable interest rate) and divided the results by SSAB's total sales for 1993. On this basis, we preliminarily determine the net subsidy from the three structural loans to be 0.38 percent *ad valorem*.

(3) Forgiven Reconstruction Loans

The GOS provided reconstruction loans to SSAB between 1979 and 1985 to cover operating losses, investment in certain plants and equipment, and for employment promotion purposes. The loans were interest free for three years, after which a fixed interest rate was charged. According to the terms of the loans, up to half of the outstanding amount of the loan can be written off after the second calendar year following the disbursement. The remainder of the loan can be written off entirely at the end of the ninth calendar year after disbursement. Pursuant to the terms of the reconstruction loans, the GOS wrote off large portions of principal and accrued interest on these loans between 1980 and 1990.

In the Final Determination (58 FR 37388) and in Final Certain Carbon Steel Products (50 FR 33377), we determined that forgiveness of these loans is countervailable. There has been no new information or evidence of changed circumstances in this review to warrant reconsideration of this determination.

To calculate the benefit, we treated the written-off portions of the reconstruction loans as countervailable grants received in the years the loans were forgiven and calculated the benefit using the grant methodology as described in the "Allocation" section of the General Issues Appendix (58 FR 37225). We reduced the benefits from these grants attributable to the POR according to the methodology outlined in the "Privatization" section above. We then divided the results by SSAB's total sales for 1993. On this basis, we preliminarily determine the net subsidy from the three structural loans to be 1.77 percent *ad valorem*.

(4) Grants for Temporary Employment for Public Works

The GOS provided temporary employment grants to companies and government agencies which hired individuals on a temporary basis to work on public works projects (e.g., construction, road building, repairs). SSAB received such grants between 1979 and 1988.

In the Final Determination (58 FR 37389) and in Final Certain Carbon Steel Products (50 FR 33375), we determined that these grants are countervailable. There has been no new information or evidence of changed circumstances in this review to warrant reconsideration of this determination.

We calculated the net subsidy of the grant received in 1979 using the grant methodology as described in the "Allocation" section of the General Issues Appendix. The amounts received by SSAB under this program in all other years were less than 0.5 percent of the value of the company's total sales in each year. Therefore, those amounts were allocated to the year of receipt. See, "Allocation" section of the General Issues Appendix (37226).

To calculate the benefit for the POR, we reduced the benefit from the 1979 grant according to the methodology outlined in the "Privatization" section above. We then divided the result by SSAB's total sales for 1993. On this basis, we preliminarily determine the net subsidy to be 0.01 percent *ad valorem*.

II. Programs Preliminarily found not to Confer Subsidies

(1) Research & Development (R&D) Loans and Grants

The Swedish National Board for Industrial and Technical Development (NUTEK) provides research and development loans and grants to Swedish industries for R&D purposes. One type of R&D loan (industrial development loans) is mostly aimed at "new" industries such as the biotechnical, electronic, and medical industries. Another type of R&D loan (energy efficiency loans) is directed towards big energy consumers.

The loans accrue interest equal to the official "discount" rate plus a premium of 3.75 percent. However, no interest or principal payments are due until the R&D project is completed. If upon completion of a project the company wishes to use the research results for commercial purposes, the loan must be repaid. On the other hand, if the company decides not to utilize the results and, therefore, does not claim proprietary treatment for the results, NUTEK will forgive the loan and the results of the research become publicly available.

SSAB had several R&D loans outstanding during the POR on which it did not make either principal or interest payments. However, we cannot determine whether SSAB has received a countervailable benefit until the research is completed. It is only then that it is known (1) whether the loans are forgiven, and (2) if the loans were not forgiven, whether the accrued interest is less than what would have accrued had the loans been provided at commercial rates. See, Final Determination (58 FR 37389). Therefore, we will continue to examine the R&D loans in future administrative reviews.

As explained above, NUTEK may forgive R&D loans if the companies receiving them disseminate publicly the results of the research financed by the loans. Although the Department's practice is to treat forgiven R&D loans as grants, if the research results are publicly available, such assistance does not bestow a countervailable benefit. See, Final Determination (58 FR 37391). During the POR, three loans were forgiven. At verification, we confirmed that the results of these research projects were publicly available. On this basis, we preliminarily determine that this R&D program did not confer countervailable benefits on the export of the subject merchandise to the United States during the POR.

(2) Fund for Industry and New Business Research and Development

SSAB reported in its questionnaire responses that SSAB Oxelosund, a subsidiary, received a conditional repayment research and development loan from the Fund for Industry and New Business (the Fund).

The Fund provides project financing to firms with a budget of at least two million Swedish kronor (MSEK), and start-up loans to new "limited" companies. Projects are financed through (1) conditional repayment loans (2) capital in return for royalty (3) project guarantees, and (4) credit guarantees for developing new products, processes and systems, and marketing. The terms and conditions of the financing depend on the type of financing provided.

In October 1992, the Fund approved a 6 MSEK conditional repayment loan for SSAB Oxelosund, a subsidiary of SSAB. Only 3 MSEK of the loan amount was disbursed. Under the terms of the loan, 50 percent of the principal was to be paid at the end of 1994, with the remaining 50 percent to be paid at the end of 1995. The loan accrued interest from the date of disbursement at a rate equal to the Central Bank's "discount" rate plus a 4 percent premium, paid quarterly for the prior quarter.

The Proposed Regulations at § 355.44(b)(5) sets forth the hierarchy for selecting long-term interest rate benchmarks for variable rate loans. We

were unable to use a company-specific rate because SSAB did not obtain any long-term commercial loans during 1992 or 1993, nor did the company issue any bonds. The record does not contain any information on variable interest rates in Sweden during 1992 or 1993. Therefore, as the benchmark, we used the national average long-term fixed interest rate on 10-year industrial bonds in Sweden in 1992 and in 1993. We compared the interest paid by the company with the amount of interest that the company would have paid on a similar loan provided at the benchmark rates. We found that the amount paid by the company was higher than the amount that would have been paid at the commercial benchmark rates. On this basis, we preliminarily determine that this program did not confer a countervailable benefit on the export of the subject merchandise to the United States during the POR. See, Memorandum for the File from Team E dated July 6, 1995 regarding the Fund for Industry and New Business Research and Development Program, which is on file in the Central Records Unit, Room B–099 of the Department of Commerce.

III. Programs Preliminarily Found Not to be Used

We also examined the following programs and preliminarily determine that SSAB did not apply for or receive benefits under them during the POR:

(A) Regional Development Grants
(B) Transportation Grants
(C) Location-of-industry Loans

IV. Program Preliminarily Found to be Terminated

We also examined the following program and preliminarily determine that the program has been officially terminated and there are no residual benefits. *See*, Memorandum to File from Team E dated June 23, 1995 regarding termination of the program, which is on file in the Central Records Unit, Room B–099 of the Department of Commerce.

State Stockpiling Subsidies

Preliminary Results of Review

In accordance with 19 CFR 355.22(b)(1), an administrative review "normally will cover entries or exports of merchandise during the most recently completed reporting year of the government of the affected country." However, because this is the first administrative review of this countervailing duty order, in accordance with 19 CFR 355.22(b)(2), this review covers the period, and the corresponding entries, "from the date of suspension of liquidation * * * to the end of the most recently completed reporting year of the government of the affected country." This period is December 7, 1992 through December 31, 1993.

The Department issued its preliminary affirmative countervailing duty determination in the investigation on December 7, 1992 (57 FR 57793). On March 8, 1993 in accordance with section 705(a)(1) of the Tariff Act of 1930, as amended (the Act), we aligned the final countervailing duty determinations with the final antidumping duty determinations on certain steel products from various countries (58 FR 12935, March 8, 1993).

Under 19 CFR 355.20(c)(1)(ii), and pursuant to article 5.3 of the GATT Subsidies Code, we cannot require suspension of liquidation under these circumstances (i.e., alignment of countervailing and antidumping determinations) for more than 120 days without the issuance of a countervailing duty order. Therefore, the Department instructed the U.S. Customs Service to suspend liquidation of all entries, or withdrawals from warehouse, for consumption of the subject merchandise entered between December 7, 1992, and April 5, 1993, but to discontinue the suspension of liquidation of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after April 6, 1993. The Department reinstated suspension of liquidation and required cash deposits of estimated countervailing duties of entries made on or after August 17, 1993, the date of the publication of the countervailing duty order. Merchandise entered on or after April 6, 1993 and before August 17, 1993 is to be liquidated without regard to countervailing duties.

For the periods December 7, 1992 through April 5, 1993, and August 17, 1993 through December 31, 1993, we preliminarily determine the net subsidy to be 2.98 percent *ad valorem*.

If the final results of this review remain the same as these preliminary results, the Department intends to instruct the U.S. Customs Service to assess the following countervailing duties:

December 7, 1992–April 5, 1993; 2.98 percent *ad valorem*.

April 6, 1993–August 16, 1993; 0 (zero).

August 17, 1993–December 31, 1993; 2.98 percent *ad valorem*.

The Department also intends to instruct the U.S. Customs Service to collect a cash deposit of estimated countervailing duties of 2.98 percent of the f.o.b. invoice price on all shipments of the subject merchandise from all manufacturers, producers, and exporters, entered or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review.

Parties to the proceeding may request disclosure of the calculation methodology and interested parties may request a hearing not later than 10 days after the date of publication of this notice. Interested parties may submit written arguments in case briefs on these preliminary results within 30 days of the date of publication. Rebuttal briefs, limited to arguments raised in case briefs, may be submitted seven days after the time limit for filing the case brief. Parties who submit written arguments in this proceeding are requested to submit with the argument (1) a statement of the issue and (2) a brief summary of the argument. Any hearing, if requested, will be held seven days after the scheduled date for submission of rebuttal briefs. Copies of case briefs and rebuttal briefs must be served on interested parties in accordance with 19 CFR 355.38(e). Representatives of parties to the proceeding may request disclosure of proprietary information under administrative protective order no later than 10 days after the representative's client or employer becomes a party to the proceeding, but in no event later than the date the case briefs, under § 355.38(c), are due. The Department will publish the final results of this administrative review including the results of its analysis of issues raised in any case or rebuttal brief or at a hearing.

This administrative review and notice are in accordance with section 751(a)(1) of the Act (19 U.S.C. 1675(a)(1)) and 19 CFR 355.22.

Dated: August 16, 1995.

Susan G. Esserman,

Assistant Secretary for Import Administration.

[FR Doc. 95–21068 Filed 8–23–95; 8:45 am]

BILLING CODE 3510–DS–P

Export Trade Certificate of Review

ACTION: Notice of Issuance of an Export Trade Certificate of Review, Application No. 95–00003.

SUMMARY: The Department of Commerce has issued an Export Trade Certificate of Review to U.S. Textile Export Co., Inc., t/a TEXPORT, Inc. on August 15, 1995. This notice summarizes the conduct for which certification has been granted.

FOR FURTHER INFORMATION CONTACT: W. Dawn Busby, Director, Office of Export Trading Company Affairs, International Trade Administration, 202–482–5131. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (15 U.S.C. 4001-21) authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. The regulations implementing Title III are found at 15 CFR part 325 (1993).

The Office of Export Trading Company Affairs ("OETCA") is issuing this notice pursuant to 15 CFR 325.6(b), which requires the Department of Commerce to publish a summary of a Certificate in the **Federal Register.** Under section 305 (a) of the Act and 15 CFR 325.11(a), any person aggrieved by the Secretary's determination may, within 30 days of the date of this notice, bring an action in any appropriate district court of the United States to set aside the determination on the ground that the determination is erroneous.

Description of Certified Conduct:

A. Export Trade

1. Products

Broadwoven fabric, cotton (SIC 2211); Broadwoven fabric, man-made fiber (SIC 2221); Broadwoven fabric, wool (SIC 2231); Narrow woven fabric and other small wares (SIC 2258); Finishers of broadwoven fabric of cotton (SIC 2261); Finishers of broadwoven fabrics of man-made fiber (SIC 2262); Nonwoven fabrics (SIC 2297).

2. Export Trade Facilitation Services (As They Relate to the Export of Products and Services)

Export Trade Facilitation Services including advertising and promotional services, market research, purchase or commission studies and reports of foreign markets, legal, accounting, customs brokerage and other services.

B. Export Markets

The export markets include all parts of the world except the United States (the fifty states of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, and the Trust Territory of the Pacific Islands.)

Export Trade Activities and Methods of Operation

1. To engage in Export Trade in the Export Markets, TEXPORT and/or one or more of its Members may:

a. Solicit orders from foreign customers;

b. Arrange for transportation of merchandise sold from Members' plants, warehouses, etc. to customers' premises;

c. Arrange for financing of sales, collect accounts receivable and disburse funds to Members;

d. Arrange for customs clearance and, where applicable and permitted, assist Members in filing claims for drawback of duties paid on imported raw materials;

e. Collaborate with one or more of its Members or on its own, to conduct market research in foreign markets; purchase or commission studies and reports of foreign markets; participate in trade shows and missions; secure and provide advertising and promotional services; engage legal, accounting, customs brokerage and other services required to facilitate TEXPORT's ongoing business activity; and solicit, from private or public sector sources, monetary grants and funding to assist TEXPORT in the conduct of its business;

f. Quote prices to potential customers from Members' price lists, with each member being free to deviate from such prices by whatever amount it sees fit;

g. Confer, from time to time, with one or more of its Members regarding a potential sale with regard to the quantities, price, delivery schedule and other pertinent matters pertaining thereto. Members may agree to share in a sale or submit joint bids. TEXPORT and one or more of its Members may refuse to quote prices for, market or sell Products in Export Markets;

h. Require that active membership in the American Textile Manufacturers Institute be a condition for membership in TEXTPORT, Inc.;

i. Receive a commission on final sales by the Member(s) for whose account the sale was made, the percentage of such commission to be mutually agreed between applicant and Member(s).

2. TEXPORT, Inc. will not divulge the prices or quantities of goods sold for any Member's account to other Members but reserves the right to divulge the total of sales commissions paid by an individual Member during any fiscal year.

3. Members may exchange and discuss the following types of information:

a. Information that is already generally available to the trade or public;

b. Information about sales or marketing efforts in Export Markets; activities and opportunities for sales of Products in Export Markets; pricing in Export Markets; projected demand in Export Markets; customary terms of sale in Export Markets; the types and prices of Products available from competitors for sale in Export Markets; and customer specifications for Products in Export Markets;

c. Information about the export prices, quality, quantity, source, and delivery dates of Products available from Members for export;

d. Information about terms, conditions, and specifications of particular contracts for sale in Export Markets to be considered and/or bid on by TEXPORT Members;

e. Information about joint bidding, selling, or servicing arrangements in Export Markets and allocation of sales resulting therefrom among the Members;

f. Information about expenses specific to exporting to, and distribution and sale in, Export Markets, including, without limitation, transportation, intermodal shipments, insurance, inland freight to port, port storage, commissions, export sales, documentation, financing, customs, duties, and taxes;

g. Information about U.S. and foreign legislation and regulations affecting sales in Export Markets; and information about TEXPORT's or the Members' export operations, including, without limitation, sales and distribution networks established by TEXPORT or the Members in Export Markets, and prior export sales by Members (including prior export price information).

Terms and Conditions of Certificate

(a) Except as provided in paragraphs two and three (f) of Export Trade Activities and Methods of Operation, in engaging in Export Trade Activities and Methods of Operation, neither TEXPORT nor any Member shall intentionally disclose, directly or indirectly, to any other Member any information that is about its or any other Member's costs, production, capacity, inventories, domestic prices, domestic sales, domestic orders, terms of domestic marketing or sale, or U.S. business plans, strategies, or methods, unless (i) such information is already generally available to the trade or public; or (ii) the information disclosed is a necessary term or condition (e.g., price, time required to fill an order, etc.) of an actual or potential bona fide sale and the disclosure is limited to the prospective purchasing Member.

(b) Participation by a Member in any Export Trade Activity or Method of Operation under this Certificate shall be entirely voluntary as to that Member, subject to the honoring of contractual commitments for sales of Products in specific export transactions. A Member may withdraw from coverage under this Certificate at any time by giving written notice to TEXPORT, a copy of which

TEXPORT shall promptly transmit to the Secretary of Commerce and the Attorney General.

(c) TEXPORT and its Members will comply with requests made by the Secretary of Commerce on behalf of the Secretary of Commerce or the Attorney General for information or documents relevant to conduct under this Certificate. The Secretary of Commerce will request such information when either the Attorney General or the Secretary of Commerce believes that the information or documents are required to determine that the Export Trade Activities or Methods of Operation of a person protected by this Certificate of Review continue to comply with the standards of section 303(a) of the Act.

Definitions

1. *Member* means a person who has a membership in TEXPORT, Inc. and who has been certified as a "Member" within the meaning of § 325.2(1) of the regulations set out in Attachment A and incorporated by reference.

A copy of this certificate will be kept in the International Trade Administration's Freedom of Information Records Inspection Facility Room 4102, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230.

EFFECTIVE DATE: August 18, 1995.

Dated: August 18, 1995.

W. Dawn Busby,

Director, Office of Export Trading Company Affairs.

Attachment A

Members (Within the Meaning of Section 325.2(1) of the Regulations)

Arkwright Mills, Spartanburg, SC
Armtex, Inc., Pilot Mountain, NC
Cleyn & Tinker (1989) Inc., Huntingdon, Quebec, Canada
CMI Industries, Inc., Columbia, SC
Copland, Inc., Burlington, NC
Cranston Print Works Company, Cranston, RI
Greenwood Mills, Inc., Greenwood, SC
Hamrick Mills, Gaffney, SC
Inman Mills, Inman, SC
Mayfair Mills, Inc., Arcadia, SC
The New Cherokee Corporation, Spindale, NC
Southern Mills, Inc., Union City, GA
Spartan Mills, Inc., Spartanburg, SC

[FR Doc. 95–21066 Filed 8–23–95; 8:45 am]

BILLING CODE 3510–DR–P

National Oceanic and Atmospheric Administration

Modernization Transition Committee (MTC); Meeting

ACTION: Notice of public meeting.

Date: September 14, 1995 from 8:00 a.m. to 4 p.m.

Place: This meeting will take place at the Portland Hilton Hotel, 921 S.W. Sixth Avenue, Portland, OR.

Status: The meeting will be open to the public. On September 14, 1995, 10:15 a.m. to 11:00 a.m. will be set aside for oral comments or questions from the public. Approximately 50 seats will be available on a first-come first-served basis for the public.

Matters to be Considered: This meeting will cover: A Fire Weather Presentation, a briefing on the status of Department of Commerce review of the NRC Study, consultation on final Consolidation Certifications for WSOs Los Angeles and Galveston, and proposed Consolidation certifications for WSOs Oklahoma City, Phoenix, Tulsa and New Orleans.

Contact Person for More Information: Mr. Nicholas Scheller, National Weather Service, Modernization Staff, 1325 East-West Highway, SSMC2, Silver Spring, Maryland 20910. Telephone: (301) 713–0454.

Dated: August 21, 1995.

Nicholas R. Scheller,

Manager, National Implementation Staff.

[FR Doc. 95–21025 Filed 8–23–95; 8:45 am]

BILLING CODE 3510–12–M

COUNCIL ON ENVIRONMENTAL QUALITY

Review of Climate Change Action Plan

AGENCY: Council on Environmental Quality.

ACTION: Request for public comment; notice of meeting.

SUMMARY: The Council on Environmental Quality (CEQ) is seeking comments from the public as part of its efforts to review and update the Climate Change Action Plan (CCAP). CEQ invites interested parties to provide comments on all aspects of the existing CCAP, and suggestions for its modification, for consideration by the Council as it conducts its biennial review of the plan. Comments should be submitted to CEQ at the address provided below by September 25, 1995.

FOR FURTHER INFORMATION CONTACT: Stephen R. Seidel, Special Coordinator for Climate Change, Council on Environmental Quality, 722 Jackson Place, NW, Washington, D.C. 20503. 202–395–3706.

SUPPLEMENTARY INFORMATION: In October 1993, President Clinton announced this nation's Climate Change Action Plan (CCAP). The CCAP had as its goal to return greenhouse gas emissions to 1990 levels by the year 2000. To accomplish this objective, the plan laid out nearly 50 initiatives that relied extensively on innovative voluntary partnerships between the private sector and government aimed at producing cost-effective reductions in greenhouse gas emissions. It primarily focussed on the creation of market incentives, rather than the imposition of new regulatory measures. The plan was comprehensive in scope. It covered all major greenhouse gases, contained activities in all major sectors emitting these compounds, focussed on both reducing emissions and enhancing sinks, and contained measures aimed at reducing energy demand and expanding alternative sources of supply. Key elements of the plan are being undertaken by the Department of Energy, Department of Transportation, the Department of Agriculture, and the Environmental Protection Agency.

The CCAP also serves as a key element of the U.S. effort to meet its obligation to mitigate climate change under the Framework Convention on Climate Change.

The plan also called for biennial reviews of its implementation to determine what, if any, revisions might be required. The first such review of the plan has recently been initiated with a goal of issuing a report by December of this year. This notice is aimed at soliciting public comment on the plan and its implementation, and any suggestions for its modification.

Comments may address any aspect of the CCAP. The following issues are indicative of those that may be addressed during this review and for which comment is explicitly encouraged:

—To what extent have individual actions under the CCAP resulted in actions to reduce greenhouse gas emissions or to enhance sinks? What modifications in existing actions appear warranted?

—What additional cost-effective opportunities exist to achieve reductions in emissions or enhancements of sinks of greenhouse gases prior to the year 2000?

—What actions, not now included in the plan, might be possible that would achieve significant emission reductions or sink enhancements after the year 2000? How would they be implemented and what would be their likely costs and impacts on reducing greenhouse gas emissions or enhancing sinks?

—To what extent are modifications in the 1990 and 2000 baseline cases

(assuming no action was taken) required to reflect more recent information? What impact will such modifications have on the plan?

—Is the general approach of the action plan, which relies extensively on voluntary measures, appropriate in the near-term or in the period after the year 2000? What other general approaches exist and what would be the advantages and disadvantages of any alternative strategies?

—To what extent are modifications in the existing plan's 1990 and 2000 baseline cases (assuming no action was taken) required to reflect more recent information? What impact will such modifications have on the plan?

Written comments should be submitted in triplicate by September 25, 1995 to the address specified above. Comments will be kept on file and available for public inspection at CEQ's offices. A public meeting to present comments will be held on September 22, 1995 in the Truman Room at 726 Jackson Place, NW, Washington, DC at 9:00 a.m. Parties interested in making presentations should contact the CEQ official listed above ten days prior to the date of the hearing.

Dated: August 21, 1995.

Elisabeth Blaug,

Associate General Counsel, Council on Environmental Quality.

[FR Doc. 95–21024 Filed 8–23–95; 8:45 am]

BILLING CODE 3125–01–M

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

ACTION: Notice of proposed information collection requests.

SUMMARY: The Director, Information Resources Group, invites comments on proposed information collection requests as required by the Paperwork Reduction Act of 1980.

DATES: An expedited review has been requested in accordance with the Act, since allowing for the normal review period would adversely affect the public interest. Approval by the Office of Management and Budget (OMB) has been requested by August 31, 1995.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Dan Chenok, Desk Officer, Department of Education, Office of Management and Budget, 725 17th Street NW., Room 3208, New Executive Office Building, Washington, DC 20503. Requests for copies of the proposed information collection request should be addressed to Patrick J. Sherrill, Department of Education, 600 Independence Avenue, SW., Room 5624, Regional Office Building 3, Washington, DC 20202–4651.

FOR FURTHER INFORMATION CONTACT: Patrick J. Sherrill, (202) 708–9915. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: Section 3517 of the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 3517) requires that the Director of OMB provide interested Federal agencies and persons an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations.

The Director, Information Resources Group, publishes this notice with the attached proposed information collection request prior to submission of this request to OMB. This notice contains the following information: (1) Type of review requested, e.g., expedited; (2) Title; (3) Abstract; (4) Additional Information; (5) Frequency of collection; (6) Affected public; and (7) Reporting and/or Recordkeeping burden. Because an expedited review has been requested, a description of the information to be collected is also included as an attachment to this notice.

Dated: August 17, 1995.

Gloria Parker,

Director, Information Resources Group.

Office of The Secretary

Type of Review: Expedited

Title: Pre-Form Survey of Participants in the 1995 Goals 2000 Teacher Forum

Frequency: One Time

Affected Public: Individual or households; State, Local or Tribal Government

Reporting Burden:
Responses: 119
Burden Hours: 98

Recordkeeping Burden:
Recordkeepers: 0
Burden Hours: 0

Abstract: The survey will be used to gather information on the activities, knowledge, and perceptions of teachers who will participate in the 1995 Goals 2000 Teacher Forum. The results will be used to design the 1995 Forum and the supportive services provided by ED after the Forum. The survey has been only slightly changed from the 1994 Pre-forum Survey of Participants.

[FR Doc. 95–20959 Filed 8–23–95; 8:45 am]

BILLING CODE 4000–01–M

DEPARTMENT OF ENERGY

Floodplain and Wetlands Involvement for the Proposed High Explosives Waste Water Treatment Facility at the Los Alamos National Laboratory

AGENCY: Department of Energy (DOE).

ACTION: Notice of floodplain and wetlands involvement.

SUMMARY: DOE is giving notice of floodplain and wetlands involvement for a proposal to improve its treatment of wastewater from high explosives (HE) research and development activities. The proposed High Explosives Wastewater Treatment Facility (HEWTF) project would focus on greatly reducing the amount of wastewater needing treatment. This would entail extensive process modifications, including installation of new equipment and improvements in existing systems. The thrust of these modifications would be to prevent hazardous chemicals and HE from entering the wastewater stream and to curtail water use in the HE operations. The result would be a reduction in wastewater discharges of approximately 90 percent from the current volume being discharged to wetlands located in the vicinity of the proposed facility in Los Alamos County, New Mexico. Remaining discharges would be primarily from stormwater run-off. In accordance with 10 CFR Part 1022, DOE will prepare a floodplain and wetlands assessment and include it in the Environmental Assessment (EA) being prepared for the proposed action.

DATES: Comments are due to the address below no later than September 8, 1995.

ADDRESSES: Comments should be addressed to:

Elizabeth Withers, Acting NEPA Compliance Officer, Office of Environment and Projects, Department of Energy, Los Alamos Area Office, 528 35th Street, Los Alamos, NM 87544, (505) 667–8690

FOR FURTHER INFORMATION ON THIS PROPOSED ACTION, CONTACT:

Jesus Amezquita, Project Manager, Office of Environment and Projects, Department of Energy, Los Alamos Area Office, 528 35th Street, Los Alamos, NM 87544, (505) 667–2268

FOR FURTHER INFORMATION ON GENERAL DOE FLOODPLAIN/WETLANDS ENVIRONMENTAL REVIEW REQUIREMENTS, CONTACT:

Carol M. Borgstrom, Director, Office of NEPA Policy and Assistance, EH–42, U. S. Department of Energy, 1000 Independence Avenue, SW, Washington, D.C. 20585, (202) 586–4600 or (800) 472–2756

SUPPLEMENTARY INFORMATION:

I. Project Description

DOE proposes to improve its treatment of wastewater from HE research and development activities at the Los Alamos National Laboratory (LANL). The proposed HEWTF project would focus on greatly reducing the amount of HE-contaminated wastewater needing treatment prior to its discharge to the environment. This would entail extensive facility and process modifications, including installation of new equipment and improvements in existing systems. The thrust of these modifications would be to prevent hazardous chemicals and HE from entering the wastewater stream and to curtail water use in the HE operations. The result would be an approximately 90 percent decrease in wastewater volume from the current level of 5,539,700 L/mo (1,463,598 gal./mo) to 535,549 L/mo (138,206 gal./mo). LANL would use two vacuum trucks to transport wastewater from HE processing facilities to one new treatment building.

A new treatment plant would be built to handle all HE wastewater. The proposed location of the treatment plant is on a mesa top in Technical Area (TA) 16. The treated wastewater would be discharged into an existing National Pollutant Discharge Elimination System (NPDES) permitted outfall at TA–16. The number of NPDES outfalls for HE contaminated wastewater would be reduced from 16 to 1. All effluent would meet or exceed effluent quality standards in the recently revised NPDES permit, which took effect on August 1, 1994.

II. Floodplain/Wetland Effects

In 1990, the U.S. Fish and Wildlife Service (USFWS) mapped wetlands at LANL in accordance with the National Wetlands Inventory standards. The USFWS survey identified one wetland area in the project area. This is an engineered pond in TA–16 behind Building 90 and is classified as a "palustrine, unconsolidated shore, seasonally flooded, and diked/impounded (PUSCh) wetland area." The pond received liquid waste sometime between the 1940s and 1980s. It now receives only seasonal rain and snowfall and may dry up for approximately four weeks each year.

In addition to the USFWS-described wetlands, there are 27 NPDES outfalls within the area, 15 of which are classified as HE-contaminated. Of these, eight (05A–052, 05A–053, 05A–054, 05A–058, 05A–061, 05A–069, 05A–071, and 05A–072) support hydrophytic vegetation. These are man-induced wetlands. A man-induced wetland is an area that has developed characteristics of naturally-occurring wetlands due to human activities.

Implementation of the HEWTF project would not involve construction within the boundaries of any wetlands. However, the HEWTF would stop the flow from over one-half of the outfalls in the area and inevitably eliminate some wetland areas. At the same time, it may enhance the wetland at the new treatment facility as a result of a four-fold increase in effluent volume. However, total discharge volume would be reduced.

Cañon del Valle and Water Canyon, both affected by HE wastewater outfalls, contain small floodplains. Floodplains in Los Alamos County have been mapped using the U.S. Army Corps of Engineers' computer-based Flood Hydrograph Package to define the 100-year frequency, 6-hour design storm events. None of the proposed HEWTF falls within this floodplain.

In accordance with DOE regulations for compliance with floodplain and wetlands environmental review requirements (10 CFR Part 1022), DOE will prepare a floodplain and wetlands assessment for this proposed DOE action.

The assessment will be included in the EA being prepared for the proposed project in accordance with the requirements of the National Environmental Policy Act. A floodplain statement of findings will be included in any finding of no significant impact that it issued following the completion of the EA or may be issued separately.

Issued in Los Alamos, New Mexico on August 14, 1995.

Joseph C. Vozella,

Assistant Area Manager for Environment and Projects.

[FR Doc. 95–21062 Filed 8–23–95; 8:45 am]

BILLING CODE 6450–01–P

Noncompetitive Financial Assistance

AGENCY: U.S. Department of Energy (DOE).

ACTION: Notice of intent.

SUMMARY: The U.S. Department of Energy, Idaho Operations Office, announces that it intends to award a noncompetitive financial assistance grant to the Oregon Institute of Technology, Geo-Heat Center (OIT). The purpose of this grant is to provide continued services to state and federal agencies, engineering consultants, planners and developers who request assistance for the development of geothermal direct uses. The award of this noncompetitive assistance is justified under sub-paragraphs (A) and (B) of the DOE Financial Assistance Rules 10 CFR 600.7(b)(2)(i) as follows: (A) The activity to be funded is necessary for the satisfactory completion of research and the continuation of direct use assistance presently being funded by DOE under Grant No. DE–FG07–90ID13040, and for which competition for support would have a significant adverse effect on continuity of the activity; (B) The activity would be conducted by the applicant using its own resources or those donated or provided by third parties; however, DOE support of the activity would enhance the public benefits to be derived.

FOR FURTHER INFORMATION CONTACT:

Carol Bruns, U.S. Department of Energy, Idaho Operations Office, 850 Energy Drive, MS 1221, Idaho Falls, Idaho 83401–1563, (208) 526–1534.

SUPPLEMENTARY INFORMATION: The statutory authority for the proposed award is Public Law 93–40, Geothermal Research, Development, and Demonstration Act of 1974. The overall program objective is to obtain increased utilization of the large direct-heat resource base by providing users with: (1) direct-use geothermal project technical and development assistance, (2) research to aid in resource and technical development problems, and (3) information, educational materials and services to stimulate development. These activities will further advance the knowledge to meet the public need to help reduce dependence upon foreign energy sources and help reduce atmospheric pollution. The anticipated grant will cover an award period of five years with an estimated total cost of $1,600,000.

R. Jeffrey Hoyles,

Director, Procurement Services Division.

[FR Doc. 95–21061 Filed 8–23–95; 8:45 am]

BILLING CODE 6450–01–M

Federal Energy Regulatory Commission

[Docket No. TM96–1–1–000]

Alabama-Tennessee Natural Gas Company; Notice of Filing of Report of Refunds

August 18, 1995.

Take notice that on August 15, 1995, Alabama-Tennessee Natural Gas Company (Alabama-Tennessee), tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1, the following tariff sheet with a proposed effective date of October 1, 1995:

Ninth Revised Sheet No. 4

Alabama-Tennessee states that the purpose of this filing is to reflect a $0.0001 per dekatherm decrease in Alabama-Tennessee's rates under its Annual Charge Adjustment (ACA) clause that results from a corresponding decrease in its annual charge accessed Alabama-Tennessee by the Commission.

Alabama-Tennessee requests any waiver that may be required in order to accept and approve this filing as submitted.

Alabama-Tennessee states that copies of the tariff filing have been served upon the Company's affected customers and interested public bodies.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE, Washington, DC 20426, in accordance with 18 CFR 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before August 25, 1995. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party to the proceeding must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 95–20972 Filed 8–23–95; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. CP95–656–000]

Blue Lake Gas Storage Company; Notice of Application

August 18, 1995.

Take notice that on August 7, 1995, Blue Lake Gas Storage Company (Blue Lake), 500 Renaissance Center, Detroit, Michigan 48423, filed in Docket No. CP95–656–000 an application pursuant to Section 7(c) of the Natural Gas Act for authorization to increase the maximum volume of natural gas stored in its Northern Michigan storage field, all as more fully set forth in the application on file with the Commission and open to public inspection.

Blue Lake proposes to increase the maximum volume of gas authorized to be stored from 50,236 MMcf to 54,119 MMcf. It is stated that the increase would raise the inventory from the volume authorized by the Commission in Docket No. CP91–2704–000 to a level supported by actual operating experience. It is asserted that the increase would allow Blue Lake greater operational flexibility by allowing it to use the maximum storage capacity of the storage field. Blue Lake states that the increase in capacity would not require additional pressure.

Any person desiring to be heard or to make any protest with reference to said application should on or before September 8, 1995, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Blue Lake to appear or be represented at the hearing.

Lois D. Cashell,

Secretary.

[FR Doc. 95–20973 Filed 8–23–95; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. CP95–669–000]

Columbia Gas Transmission Corporation; Notice of Request Under Blanket Authorization

August 18, 1995.

Take notice that on August 7, 1995, Columbia Gas Transmission Corporation (Columbia), 1700 MacCorkle Avenue, S.E. Charleston, West Virginia 25314–1599, filed in Docket No. CP95–669–000 a request pursuant to § 157.205 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205) for authorization to modify an existing point of delivery and reassign and reduce Maximum Daily Delivery Obligations (MDDO) at another existing point to Baltimore Gas & Electric Company (BG&E) for firm Part 284 transportation service to BG&E, in Cecil County, Maryland, under Columbia's blanket certificate issued in Docket No. CP6–240–000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

Columbia states that the MDDO at the Conowingo delivery point would be increased from 1,249 Dth/day to 7,319 Dth/day. It is said that the increased deliveries to BG&E resulting from modifications and the reassignment of MDDO's are estimated to be 2,264 Dth/day and up to 826,360 Dth/annually.

Columbia states further that the estimated cost to modify the Conowingo delivery point would be approximately $182,000 and that Columbia would pay for the cost of the modifications.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to § 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for

authorization pursuant to Section 7 of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 95–20974 Filed 8–23–95; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP88–44–052]

El Paso Natural Gas Company; Notice of Tariff Filing

August 18, 1995.

Take notice that on August 14, 1995, El Paso Natural Gas Company (El Paso), tendered for filing pursuant to Part 154 of the Commission's Regulations Under the Natural Gas Act, and in compliance with the Commission's Order Accepting Tariff Sheets Subject to Conditions, Granting Request for Clarification, and Granting in Part and Denying in Part Rehearing issued July 14, 1995 at Docket Nos. RP88–44–50 and RP88–44–051, certain tariff sheets to its FERC Gas Tariff, Second Revised Volume No. 1–A.

El Paso states that it is modifying Section 4.2(e) to it Capacity Allocation Procedure in compliance with the July 14, 1995 order in which the Commission ordered El Paso to revise its tariff to include provisions giving relief to any firm Shipper when that Shipper (Emergency Shipper) has exhausted all other self-help remedies in times of bona fide emergencies including minimum plant protection. El Paso states that it is modifying Section 4.2(e) to provide that the emergency capacity will be provided at a receipt point which causes the least amount of interruption among its Shippers.

El Paso states that a Shipper with a contract demand shall not be entitled to emergency service in excess of such contract demand. The emergency capacity available to a Shipper with a full requirements contract shall be determined to be that capacity required to serve a verifiable emergency in excess of the quantity initially scheduled by said Shipper. El Paso states that it has added a new Section 4.2(f) to provide a compensation plan to reimburse Shippers who receive less than their scheduled capacity due to emergency service being provided to an Emergency Shipper.

El Paso respectfully requests that the Commission accept the tendered tariff sheets for filing and permit it to become effective on January 4, 1995, the date on which the Commission's July 14, 1995 order made the tariff sheets effective, subject to conditions.

El Paso states that copies of the filing were served upon all of El Paso's interstate pipeline system transportation customers and interested state regulatory commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with § 385.211 of the Commission's Rules and Regulations. All such protests should be filed on or before August 25, 1995. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 95–20975 Filed 8–23–95; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP95–373–001]

National Fuel Gas Supply Corporation; Notice of Compliance Filing

August 18, 1995.

Take notice that on August 15, 1995, National Fuel Gas Supply Corporation (National) tendered for filing as part of its FERC Gas Tariff, Third Revised Volume No. 1, Substitute Fifth Revised Sheet Nos. 237A and 237B, to be effective August 1, 1995.

National states that these tariff sheets are submitted to reflect the recalculation of refunds of Account Nos. 191 and 186-related dollars received from certain of National's former upstream pipeline-suppliers, as required by the Commission's order issued July 31, 1995, in the above-captioned proceeding.

National further states that it is also submitting worksheets to clarify the calculations made in the tariff sheets, and to clarify the interest calculations contained in the filing.

National states that copies of this filing were served upon the company's jurisdictional customers and upon the Regulatory Commissions of the States of New York, Ohio, Pennsylvania, Delaware, Massachusetts, and New Jersey.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). All such protest should be filed on or before August 25, 1995. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 95–20976 Filed 8–23–95; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP95–5–007]

Northwest Pipeline Corporation; Notice of Compliance Filing

August 18, 1995.

Take notice that on August 16, 1995, Northwest Pipeline Corporation (Northwest) tendered for filing as part of its FERC Gas Tariff, Third Revised Volume No. 1, the following tariff sheets with a proposed effective date of November 6, 1994:

Fourth Substitute Original Sheet No. 237–A
Second Revised Sheet No. 237–C

Northwest states that the purpose of this filing is to comply with the Commission's Order Following Technical Conference, Accepting Tariff Subject to Modification, Granting Waiver, and Denying Rehearing as Moot issued on June 23, 1995 in Docket Nos. RP–5–001, RP95–5–002, and RP95–5–004. (Northwest's July 10, 1995 compliance filing in this proceeding was rejected by the Commission.)

Northwest states that it has modified Section 15.6 of the General Terms and Conditions of its tariff to eliminate the language which allows volumization of penalty revenues for crediting to its firm Shippers as directed by the Commission.

Northwest also states that it has modified that tariff language in §§ 15.7 and 15.11 to toll the make-up period for Shipper Imbalances when Northwest is unable to accept a make-up nomination due to "operational conditions". However, it should be noted that Northwest has filed a Request for Rehearing on this issue.

Northwest states that a copy of this filing has been served upon all interveners in Docket No. RP95–5, Northwest's jurisdictional customers, and relevant state regulatory commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, DC 20426, in accordance with § 385.211 of the Commission's Rules of Practice and Procedure. All such protests should be filed on or before August 25, 1995. Protests will be considered by the Commission in

determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 95–20977 Filed 8–23–95; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. CP95–679–000]

Tennessee Gas Pipeline Company; Columbia Gas Transmission Corporation; Notice of Application

August 18, 1995.

Take notice that on August 10, 1995, Tennessee Gas Pipeline Company (Tennessee), P.O. Box 2511, Houston, TX 77252, and Columbia Gas Transmission Corporation (Columbia), 1700 MacCorkle Avenue, WV 25314, filed in Docket No. CP95–679–000 a joint application pursuant to Section 7(b) of the Natural Gas Act for permission and approval to abandon a transportation service provided to Mississippi River Transmission Corporation (MRT) which was authorized in Docket No. CP83–260–000, all as more fully set forth in the application on file with the Commission and open to public inspection.

Tennessee and Columbia, through the Ozark Gas Transmission Corporation, provided the service to MRT. However, Applicants were recently authorized to terminate their contracts with Ozark. As a result, the agreement designated as Rate Schedules T–155 and X–125, respectively, is no longer necessary.

Any person desiring to be heard or to make any protest with reference to said application should on or before September 8, 1995 file with the Federal Energy Regulatory Commission, Washington, DC 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that permission and approval for the proposed abandonment are required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Tennessee and Columbia to appear or be represented at the hearing.

Lois D. Cashell,

Secretary.

[FR Doc. 95–20978 Filed 8–23–95; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. CP94–724–003]

Trailblazer Pipeline Company; Notice of Proposed Changes in FERC Gas Tariff

August 18, 1995.

Take notice that on August 11, 1995, Trailblazer Pipeline Company (Trailblazer) submitted for filing to be part of its FERC Gas Tariff, Third Revised Volume No. 1, First Revised Sheet No. 400, to be effective June 15, 1995.

Trailblazer states that this tariff sheet was filed to reflect the termination of a transportation service previously performed by Trailblazer under Rate Schedule T for Columbia Gas Transmission Corporation (Columbia Gas) pursuant to a service agreement between Trailblazer and Columbia Gas dated October 8, 1982. Trailblazer states that this tariff sheet was submitted in compliance with the Federal Energy Regulatory Commission's (Commission) order issued February 10, 1995 in Docket No. CP94–724–000, which order granted Trailblazer, among other things, authorization to abandon its transportation service for Columbia Gas performed under Trailblazer's Rate Schedule T pursuant to authorization granted Trailblazer in Docket No. CP79–80, as amended.

Trailblazer requested waiver of the Commission's Regulations to the extent necessary to permit First Revised Sheet No. 400 to become effective June 15, 1995, the effective date of a settlement between Trailblazer and Columbia Gas.

Trailblazer states that it sent a copy of this filing to the affected party, Columbia Gas.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with § 385.211. All such motions must be filed on or before August 25, 1995. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make the protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 95–20979 Filed 8–23–95; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. CP88–391–017]

Transcontinental Gas Pipe Line Corporation; Notice of Filing

August 18, 1995.

Take notice that on August 14, 1995 Transcontinental Gas Pipe Line Corporation (Transco) tendered for filing to become part of its FERC Gas Tariff, Third Revised Volume No. 1, certain revised tariff sheets enumerated in Appendix A attached to the filing. The tariff sheets are proposed to be effective September 13, 1995.

Transco states that the purpose of the instant filing is to establish a new Section 13.5 in the General Terms and Conditions (GT&C) of Transco's FERC Gas Tariff in order to describe the compensation rights available to Buyers under the supply curtailment provisions of Section 13 of the GT&C.

Transco states that the instant filing is being made to comply with the Commission's July 14, 1995 Order on Remand in the instant docket directing Transco to file, within 30 days of the date of the order, tariff language describing compensation rights available under certain circumstances to certain sales customers in the event that priority relief is granted under the supply curtailment provisions of Section 13 of the GT&C of Transco's FERC Gas Tariff.

Accordingly, Transco is submitting tariff sheets reflecting a new Section 13.5 in Section 13, Supply Curtailment, of the GT&C of Transco's FERC Gas Tariff. Section 13.5(a) sets forth the circumstances establishing a Buyer's right to compensation. Section 13.5(b)

sets forth Transco's notice obligation in the event priority relief that gives rise to compensation is granted, and the information to be included in Transco's notice. Section 13.5(c) sets forth the compensation plan.

Transco states that it is serving copies of the instant filing on parties to Docket No. CP88–391–014.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E. Washington, D.C. 20426, in accordance with 385.211 of the Commission's Rules and Regulations. All such protests should be filed on or before August 25, 1995. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 95–20980 Filed 8–23–95; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. CP95–683–000]

Transcontinental Gas Pipe Line Corporation and Florida Gas Transmission Company; Notice of Application

August 18, 1995.

Take notice that on August 10, 1995, Transcontinental Gas Pipe Line Corporation (Transco), P.O. Box 1396, Houston, Texas 77251, and Florida Gas Transmission Company (Florida) (Transco and Florida are referred to jointly as Applicants), 1400 Smith Street, P.O. Box 1188, Houston, Texas 77251–1188, filed in Docket No. CP95–683–000 an application pursuant to Section 7(b) of the Natural Gas Act for permission and approval to abandon a jointly owned meter facility,[1] all as more fully set forth in the application on file with the Commission and open to public inspection.

Applicants propose to abandon a certain meter facility by sale to Mobil Oil Exploration & Producing Southeast Inc. (MOEPSI). It is stated that the meter facility is located at the interconnection between MOEPSI's gas treatment facility and Applicants' jointly owned Mobile Bay Lateral (also referred to sometimes as the Onshore Mobile Bay Pipeline) near Coden in Mobile County, Alabama.

Applicants state that the public interest would be served by the requested abandonment because the abandonment would result in the most economically efficient utilization of the meter facility. Specifically, Applicants state that the meter facility is currently classified for rate purposes on Transco's system as a gathering facility, and, therefore, shippers moving gas through Transco's capacity in the meter facility must pay Transco's separately stated gathering charge under its transportation rate schedules. (Florida does not have a separately stated gathering charge for services rendered through the meter facility.) Applicants understand that after the transfer of ownership of the meter facility to MOEPSI, the meter facility would be considered as part of MOEPSI's gas treatment plant operations and MOEPSI would absorb the cost of the meter facility into its current infrastructure charges for the plant. As a result, it is stated, Transco's shippers no longer would incur Transco's separately stated gathering charge for transportation service from the plant, and, because the cost of the meter facility would be absorbed into the plant charges, the producers would not incur any separate charge for MOEPSI's measurement of the gas at the meter facility.

Applicants state that the purchase price to be paid by MOEPSI for the meter facility would be the net book value of the meter facility as of the closing of the purchase and sale.

Any person desiring to be heard or to make any protest with reference to said application should on or before September 8, 1995, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that permission and approval for the proposed abandonment are required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Transco or Florida to appear or be represented at the hearing.

Lois D. Cashell,

Secretary.

[FR Doc. 95–20981 Filed 8–23–95; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. MT95–16–000]

Williams Natural Gas Company; Proposed Changes in FERC Gas Tariff

August 18, 1995.

Take notice that on August 16, 1995 Williams Natural Gas Company (WNG) tendered for filing to become part of its FERC Gas Tariff, Second Revised Volume No. 1, First Revised Sheet Nos. 221 and 222. The proposed effective date of these tariff sheets is September 16, 1995.

WNG states that the purpose for the instant filing is to update Article 8.9, "Relationship with Affiliated Marketing Entities" of the General Terms and Conditions of WNG's FERC Gas Tariff, to reflect the merger with Transco Energy.

WNG states that a copy of its filing was served on all jurisdictional customers and interested state commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with §§ 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before August 25, 1995. Protests will be considered by the Commission in determining the appropriate action to be taken, but will

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[1] It is stated that the meter facility was originally constructed by Transco as part of the Mobile Bay Lateral pursuant to Section 311 of the Natural Gas Policy Act of 1987 and Section 284.3(c) of the Commission's regulations. Further, by order issued October 20, 1992, in Docket No. CP92–405–000 (61 FERC ¶ 61,073 (1992)), the Commission granted Transco certificate authority under Section 7(c) of the Natural Gas Act to operate the Mobile Bay Lateral; and Florida acquired its ownership interest in the facility pursuant to the authorizations granted in Docket Nos. CP92–182, *et al.* See 62 FERC ¶ 61,024 (1993); 63 FERC ¶ 61,093 (1993); and 66 FERC ¶ 61,160 (1994).

not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 95–20982 Filed 8–23–95; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP95–364–001]

Williston Basin Interstate Pipeline Company; Notice of Compliance Filing

August 18, 1995.

Take notice that on August 16, 1995, Williston Basin Interstate Pipeline Company (Williston Basin), submitted workpapers in compliance with the Commission's order issued July 27, 1995, demonstrating that the proposed design of its Rate Schedule ST–1 rates filed June 30, 1995 in Docket No. RP95–364–000 complies with the mitigation requirements of Order No. 636.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20246, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). All such protests should be filed on or before August 25, 1995. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make the protestants parties to the proceeding. Copies of the filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 95–20983 Filed 8–23–95; 8:45 am]

BILLING CODE 6717–01–M

Office of Fossil Energy

[FE Docket No. 95–57–NG]

Conoco Inc.; Order Granting Blanket Authorization to Import and Export Natural Gas From and to Canada and Mexico and Vacating Authorization

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of order.

SUMMARY: The Office of Fossil Energy of the Department of Energy gives notice that it has issued an order on August 14, 1995, granting blanket authorization to Conoco Inc. (Conoco) to import and export natural gas from and to Canada and Mexico. The volume imported and exported would not exceed a combined total of 100 Bcf over a two-year period beginning on the date of the initial import or export delivery, whichever occurs first, after August 26, 1995. As a result, Conoco's current unused authorization to import and export natural gas from and to Canada, and to import liquefied natural gas (LNG) from any foreign country, granted in DOE/FE Opinion and Order No. 824 on July 29, 1993 (1 FE ¶ 70,822), is vacated effective August 27, 1995, because it is no longer needed.

This order is available for inspection and copying in the Office of Fuels Programs Docket Room, 3F–056, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585, (202) 586–9478. The docket room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC on August 14, 1995.

Anthony J. Como,

Director, Office of Coal & Electricity, Office of Fuels Programs, Office of Fossil Energy.

[FR Doc. 95–21063 Filed 8–23–95; 8:45 am]

BILLING CODE 6450–01–P

[FE Docket No. 95–54–NG]

Victoria International, Ltd.; Order Granting Blanket Authorization To Import and Export Natural Gas From and to Canada

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of order.

SUMMARY: The Office of Fossil Energy of the Department of Energy gives notice that it has issued an order granting Victoria International, Ltd. authorization to import and export up to an aggregate of 10 Bcf of natural gas from and to Canada over a two-year term beginning on August 31, 1995.

This order is available for inspection and copying in the Office of Fuels Programs Docket Room, 3F–056, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585, (202) 586–9478. The docket room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, D.C., August 4, 1995.

Clifford P. Tomaszewski,

Director, Office of Natural Gas, Office of Fuels Programs, Office of Fossil Energy.

[FR Doc. 95–21064 Filed 8–23–95; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–5285–1]

Proposed Settlement Under Section 122(h) of the Comprehensive Environmental Response, Compensation and Liability Act, as Amended, 42 U.S.C. 9622(h), Kramer Superfund Site, Elvins, St. Francois County, Missouri

AGENCY: Environmental Protection Agency.

ACTION: Notice of proposed settlement and request for public comment.

SUMMARY: In accordance with Section 122(i) of the Comprehensive Environmental Response, Compensation and Liability Act, as amended by the Superfund Amendments and Reauthorization Act ("CERCLA"), notice is hereby given of a proposed settlement to resolve a claim against Alumax Foils, Inc. and Harvard Industries, Inc. The proposed settlement concerns the federal government's past response costs at the Kramer Superfund Site, Elvins, St. Francois, Missouri. The settlement requires the settling party, Alumax Foils, Inc. to pay $235,000.00 to the Hazardous Substance Superfund, which is in addition to $80,000.00 already paid by Harvard Industries, Inc. pursuant to a previous bankruptcy claim.

For thirty (30) days following the date of publication of this notice, the Agency will receive written comments relating to the settlement. The Agency's response to any comments received will be available for public inspection at the U.S. EPA Region VII office at 726 Minnesota Avenue, Kansas City, Kansas 66101. A copy of the proposed settlement may be obtained from Venessa Cobbs, Regional Hearing Clerk, EPA Region VII, 726 Minnesota Avenue, Kansas City, Kansas 66101, telephone number (913) 551–7630. Comments should reference the "Kramer Superfund Site" and EPA Docket No. VII–90–F–0020 and should be addressed to Ms. Cobbs at the above address.

FOR FURTHER INFORMATION CONTACT: J. Scott Pemberton, Senior Assistant Regional Counsel, EPA Region VII, Office of Regional Counsel, 726 Minnesota Avenue, Kansas City, Kansas 66101, telephone number (913) 551–7276.

Dated: August 16, 1995.

Dennis Grams, P.E.,

Regional Administrator.

[FR Doc. 95–21040 Filed 8–23–95; 8:45 am]

BILLING CODE 6560–50–M

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection Approved by Office of Management and Budget

August 18, 1995.

The Federal Communications Commission (FCC) has received Office of Management and Budget (OMB) approval for the following public information collection pursuant to the Paperwork Reduction Act of 1980, Pub. L. 96–511. You are not required to respond to a collection of information unless it displays a currently valid control number. For further information contact Shoko B. Hair, Federal Communications Commission, (202) 418–1379.

Federal Communications Commission

OMB Control No.: 3060–0677.

Expiration Date: 11/30/95.

Title: 800 Service Providers and Services Investigation.

Estimated Annual Burden: 2000 total annual hours; 80 hours per response; 25 respondents.

Description: The Commission plans to collect information from various long distance carriers and certain 800 service customers to determine whether there is a problem with the "hoarding" of 800 numbers and to evaluate the status of 800 number availability.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 95–21003 Filed 8–23–95; 8:45 am]

BILLING CODE 6712–01–F

[Report No. 2093]

Petition for Reconsideration of Actions in Rulemaking Proceedings

August 21, 1995.

Petition for reconsideration have been filed in the Commission rulemaking proceedings listed in this Public Notice and published pursuant to 47 CFR Section 1.429(e). The full text of these documents are available for viewing and copying in room 239, 1919 M Street NW., Washington, DC, or may be purchased from the Commission's copy contractor ITS, Inc. (202) 857–3800. Opposition to this petition must be filed September 8, 1995. See Section 1.4(b)(1) of the Commission's rules (47 CFR 1.4(b)(1)). Replies to an opposition must be filed within 10 days after the time for filing oppositions has expired.

Subject: Amendment of Section 73.202(b), Table of Allotments, FM Broadcast Stations. (Saltville, Virginia and Jefferson, North Carolina) (MM Docket No. 91–137 and RM–7494)

Number of Petitions Filed: 1.

Subject: Amendment of the Commission's Rules Concerning Maritime Communications. (PR Docket No. 92–257)

Number of Petitions Filed: 1.

Subject: Policies and Rules Concerning Unauthorized Changes of Consumers' Long Distance Carriers. (CC Docket No. 94–129)

Number of Petitions Filed: 6.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 95–21004 Filed 8–23–95; 8:45 am]

BILLING CODE 6712–01–M

FEDERAL DEPOSIT INSURANCE CORPORATION

Privacy Act of 1974; Amendment to an Existing System of Records

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice of amendment to an existing system of records—"Medical Records and Emergency Contact Information System".

SUMMARY: As part of an ongoing examination of the FDIC's systems of records, the "Medical Records and Emergency Contact Information System" has been reviewed for compliance with the Privacy Act of 1974, 5 U.S.C. 552a. Numerous minor amendments have been made that will clarify and/or more accurately describe the following elements in this system of records: System location, categories of records in the system, routine uses of records maintained in the system, storage, safeguards, retention and disposal, and system manager(s) and address.

EFFECTIVE DATE: August 24, 1995.

FOR FURTHER INFORMATION CONTACT: Frederick N. Ottie, Attorney, Office of the Executive Secretary, FDIC, 550–17th Street, NW, Washington, DC 20429, (202) 898–6679.

SUPPLEMENTARY INFORMATION: The FDIC's system of records entitled "Medical Records and Emergency Contact Information System" is being amended to clarify and/or more accurately describe its contents. These modifications update language in the system location and the system manager(s) and address elements to reflect organizational changes within the FDIC. Additionally, since American Red Cross donor cards, Standard Form 78 (Certificate of Medical Examination), and Standard Form 177 (Statement of Physical Ability for Light Duty Work) are no longer contained in this system of records, references to those records are deleted from the following elements in this system of records: categories of records in the system; routine uses of records maintained in the system; storage; and retention and disposal. The language of the storage element is also reworded to indicate that records are now maintained in paper files in manila folders, while records dating from 1986 and earlier are maintained on 8 by 10 cards with a separate emergency contact sheet attached to it. Additionally, the safeguards element is amended to indicate that records are stored in the Health Unit, but not the nurse's office. Lastly, the retention and disposal element is amended to indicate that records are now kept for the duration of the employee's employment with the FDIC and for six years thereafter and then destroyed by shredding.

Accordingly, the FDIC amends the "Medical Records and Emergency Contact Information System" to read as follows:

FDIC 30–64–0017

SYSTEM NAME:

Medical Records and Emergency Contact Information System. (Complete text appears at 47 FR 42168, September 24, 1982).

SYSTEM LOCATION:

Health Unit, Corporate Services Branch, Division of Administration, FDIC: 550–17th Street, NW, Washington, DC 20429 and 3501 North Fairfax Drive, Arlington, Virginia 22226.

* * * * *

CATEGORIES OF RECORDS IN THE SYSTEM:

Medical record of the employee, including the date of visit to the FDIC Health Unit, the diagnosis, and the treatment administered; name and telephone number of the person to contact in the event of an emergency involving the employee.

* * * * *

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

No disclosure (including intra-agency disclosure) of information contained in the medical files is made without the prior written consent of the employee concerned. In the event of an emergency, the emergency contact would be notified.

* * * * *

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Maintained in paper files in manila folders. For records dating from 1986 and earlier, maintained on 8 by 10 cards with a separate emergency contact sheet attached to it.

SAFEGUARDS:

Maintained in lockable metal file cabinets in Health Unit. Only the nurse and substitute nurse are allowed access to the files. The Health Unit is locked whenever the nurse is absent.

RETENTION AND DISPOSAL:

Records are kept for the duration of the employee's employment with FDIC and for six years thereafter, then destroyed by shredding.

SYSTEM MANAGER(S) AND ADDRESS:

Associate Director, Corporate Services Branch, Division of Administration, FDIC, 550–17th Street NW, Washington, DC 20429.

* * * * *

Dated at Washington, DC, this 16th day of August, 1995.

Federal Deposit Insurance Corporation,

Jerry L. Langley,

Executive Secretary.

[FR Doc. 95–20966 Filed 8–23–95; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL EMERGENCY MANAGEMENT AGENCY

[FEMA–1008–DE]

California; Amendment to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of California (FEMA–1008–DR), dated January 17, 1994, and related determinations.

EFFECTIVE DATE: August 11, 1995.

FOR FURTHER INFORMATION CONTACT: Pauline C. Campbell, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–3606.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, effective this date and pursuant to the authority vested in the Director of the Federal Emergency Management Agency under Executive Order 12148, I hereby appoint Kenneth D. Hutchison of the Federal Emergency Management Agency to act as the Federal Coordinating Officer for this declared disaster.

This action terminates my appointment of Patricia Stahlschmidt as Federal Coordinating Officer for this disaster.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance.)

Dated: August 18, 1995.

James L. Witt,

Director.

[FR Doc. 95–21034 Filed 8–23–95; 8:45 am]

BILLING CODE 6718–02–M

[FEMA–1062–DR]

Florida: Amendment to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of Florida, (FEMA–1062–DR), dated August 10, 1995, and related determinations.

EFFECTIVE DATE: August 15, 1995.

FOR FURTHER INFORMATION CONTACT: Pauline C. Campbell, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–3606.

SUPPLEMENTARY INFORMATION: The notice of a major disaster for the State of Florida dated August 10, 1995, is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of August 10, 1995:

The counties of Bay, Brevard, Escambia, Okaloosa, Santa Rosa and Walton for categories C, D, F and G under the Public Assistance program. (already designated for Individual Assistance, Hazard Mitigation Assistance and categories A and E under Public Assistance).

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance.)

Richard W. Krimm,

Associate Director, Response and Recovery Directorate.

[FR Doc. 95–21035 Filed 8–23–95; 8:45 am]

BILLING CODE 6718–02–M

[FEMA–1063–DR]

Vermont; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Vermont (FEMA–1063–DR), dated August 16, 1995, and related determinations.

EFFECTIVE DATE: August 16, 1995.

FOR FURTHER INFORMATION CONTACT: Pauline C. Campbell, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–3606.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated August 16, 1995, the President declared a major disaster under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 *et seq.*), as follows:

I have determined that the damage in certain areas of the State of Vermont, resulting from excessive rain and flooding on August 4–6, 1995, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act ("the Stafford Act"). I, therefore, declare that such a major disaster exists in the State of Vermont.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes, such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Individual Assistance, Public Assistance, and Hazard Mitigation in the designated areas. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance or Hazard Mitigation will be limited to 75 percent of the total eligible costs.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, 42 U.S.C. 5153, shall be for a period not to exceed six months after the date of this declaration.

Notice is hereby given that pursuant to the authority vested in the Director of the Federal Emergency Management Agency under Executive Order 12148, I hereby appoint Alma Armstrong of the Federal Emergency Management Agency to act as the Federal Coordinating Officer for this declared disaster.

I do hereby determine the following areas of the State of Vermont to have been affected adversely by this declared major disaster: The counties of Caledonia, Chittenden, Essex, Lamoille, Orleans, and Washington for Individual Assistance, Public Assistance and Hazard Mitigation Assistance.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance.)

Dated: August 18, 1995.

James L. Witt,

Director.

[FR Doc. 95–21036 Filed 8–23–95; 8:45 am]

BILLING CODE 6718–02–M

FEDERAL RESERVE SYSTEM

Banco Santander, S.A.; FFB Participacoes e Servicos, S.A. Acquisition of Voting Securities of a Bank Holding Company

Banco Santander, S.A., Madrid, Spain, and its wholly owned subsidiary, FFB Participacoes e Servicos, S.A., Funchal, Portugal (together, Applicant), has applied under sections 3 and 4 of the Bank Holding Company Act (12 U.S.C. 1842 and 1843) (BHC Act) and §§ 225.14, 225.21(a) and 225.23(a) of the Board's Regulation Y (12 CFR 225.14, 225.21(a), and 225.23(a)), to acquire approximately 11.4 percent of the outstanding voting shares of First Union Corporation, Charlotte, North Carolina (First Union), and thereby indirectly acquire interests in the following First Union bank and nonbank subsidiaries:

First Union National Bank of Florida, Jacksonville, Florida; First Union National Bank of North Carolina, Charlotte, North Carolina; First Union National Bank of Georgia, Atlanta, Georgia; First Union National Bank of Tennessee, Nashville, Tennessee; First Union National Bank of Maryland, Rockville, Maryland; First Union National Bank of Virginia, Roanoke, Virginia; First Union National Bank of Washington, D.C., Washington, D.C.; First Union National Bank of South Carolina, Greenville, South Carolina; First Union Home Equity Bank, National Association, Charlotte, North Carolina; First Union Capital Markets Corporation, Charlotte, North Carolina; First Union Community Development Corporation, Charlotte, North Carolina; First Union Development Corporation, Charlotte, North Carolina; First Union Export Trading Company, Charlotte, North Carolina; First Union Futures Corporation, Charlotte, North Carolina; First Union Mortgage Corporation, Charlotte, North Carolina, and General Financial Life Insurance Company, Charlotte, North Carolina.

Applicant is not applying to, and will not, acquire control of First Union. Applicant will provide commitments to the Board to ensure that Applicant will not exercise control over First Union. Applicant's acquisition of voting shares of First Union are in consideration for Applicant's ownership interest in First Fidelity Bancorporation, Newark, New Jersey, and Philadelphia, Pennsylvania (First Fidelity). First Union has applied to merge First Fidelity with First Union's direct subsidiary, First Union Corporation of New Jersey, Newark, New Jersey.

Any comments or requests for hearing should be submitted in writing and received by William W. Wiles, Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, not later than September 11, 1995. Any request for a hearing on this proposal must, as required by section 262.3(e) of the Board's Rules of Procedure (12 CFR 262.3(e)), be accompanied by a statement of the reasons why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal. The notice may be inspected at the offices of the Board of Governors or the Federal Reserve Bank of New York.

Board of Governors of the Federal Reserve System, August 18, 1995.

Jennifer J. Johnson,

Deputy Secretary of the Board

[FR. Doc. 95–20999 Filed 8–23–95; 8:45 am]

BILLING CODE 6210–01–F

Andrew Rayford Bounds, Jr. & Mary Lou Bounds; Change in Bank Control Notice

Acquisition of Shares of Banks or Bank Holding Companies

The notificant listed below has applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notice is available for immediate inspection at the Federal Reserve Bank indicated. Once the notice has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for the notice or to the offices of the Board of Governors. Comments must be received not later than September 7, 1995.

A. Federal Reserve Bank of Dallas (Genie D. Short, Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. Andrew Rayford Bounds, Jr. & Mary Lou Bounds, Cleveland, Texas; to jointly acquire an additional 1.41 percent, for a total of 11.87 percent, of the voting shares of First Bancorporation of Cleveland, Cleveland, Texas, and thereby indirectly acquire First Bank & Trust, Cleveland, Texas.

Board of Governors of the Federal Reserve System, August 18, 1995

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 95–20997 Filed 8–23–95; 8:45 am]

BILLING CODE 6210–01–F

Carolina Community Bancshares, Inc.; Formation of, Acquisition by, or Merger of Bank Holding Companies

The company listed in this notice has applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that application or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Comments regarding this application must be received not later than September 18, 1995.

A. Federal Reserve Bank of Richmond (Lloyd W. Bostian, Jr., Senior Vice President) 701 East Byrd Street, Richmond, Virginia 23261:

1. Carolina Community Bancshares, Inc., Latta, South Carolina; to become a bank holding company by acquiring 100 percent of the voting shares of SouthTrust Bank of Dillon County, Latta, South Carolina.

Board of Governors of the Federal Reserve System, August 18, 1995.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 95–20998 Filed 8–23–95; 8:45 am]

BILLING CODE 6210–01–F

Crestar Financial Corporation; Acquisition of Company Engaged in Permissible Nonbanking Activities

The organization listed in this notice has applied under § 225.23(a)(2) or (f) of the Board's Regulation Y (12 CFR 225.23(a)(2) or (f)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than September 7, 1995.

A. Federal Reserve Bank of Richmond (Lloyd W. Bostian, Jr., Senior Vice President) 701 East Byrd Street, Richmond, Virginia 23261:

1. Crestar Financial Corporation, Richmond, Virginia; to acquire Loyola Federal Savings Bank, Baltimore, Maryland, a subsidiary of Loyola Capital Corporation, Baltimore, Maryland, and thereby engage in operating a savings bank pursuant to § 225.25(b)(9) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, August 18, 1995.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 95–20996 Filed 8–23–95; 8:45 am]

BILLING CODE 6210–01–F

Platte Valley Cattle Company, et al.; Notice of Applications to Engage de novo in Permissible Nonbanking Activities

The companies listed in this notice have filed an application under § 225.23(a)(1) of the Board's Regulation Y (12 CFR 225.23(a)(1)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to commence or to engage *de novo*, either directly or through a subsidiary, in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than September 7, 1995.

A. Federal Reserve Bank of Kansas City (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. Platte Valley Cattle Company, Ravenna, Nebraska; to engage *de novo* in the sale of general insurance in a town of less than 5,000 in population, pursuant to § 225.25(b)(8)(iii)(A) of the Board's Regulation Y. These activities will take place in Ravenna, Nebraska, and Pleasanton, Nebraska.

2. BOK Financial Corporation, Tulsa, Oklahoma; to engage *de novo* through its subsidiary, BOKF Leasing Corporation, Tulsa, Oklahoma, in commercial lending pursuant to § 225.25(b)(1) of the Board's Regulation Y, and leasing of real property pursuant to § 225.25(b)(5) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, August 18, 1995.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 95–20994 Filed 8–23–95; 8:45 am]

BILLING CODE 6210–01–F

Western Dakota Holding Company; Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies; Correction

This notice corrects a notice (FR Doc. 95–19984) published on page 41890 of the issue for Monday, August 14, 1995.

Under the Federal Reserve Bank of Minneapolis, the entry for Western Dakota Holding Company, is revised to read as follows:

1. Western Dakota Holding Company, Timber Lake, South Dakota; to become a bank holding company by acquiring 50.02 percent of the voting shares of Dewey County Bank, Timber Lake, South Dakota.

Board of Governors of the Federal Reserve System, August 18, 1995.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 95–20995 Filed 8–23–95; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Agency Information Collection Under OMB Review

Title: Welfare Reform Demonstration Special Application Form.

Description: The purpose of this collection is to obtain the necessary information for accelerated review and approval of proposals that are likely to

assist in promoting the objectives of titles IV–A and D of the Social Security Act.

Respondents: State governments.

Title	No. of respondents	No. of responses per respondent	Average burden per response	Burden
Form	54	1	0.75	40.5

Estimated total annual burden hours: 40.5.

Additional Information

ACF is requesting that OMB grant a 90 day approval for this information collection under procedures for emergency processing. The time period for this request is one day.

Dated: August 15, 1995.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 95–20965 Filed 8–23–95; 8:45 am]

BILLING CODE 4184–01–M

Agency for Health Care Policy and Research

Public Meeting on the Development of Chronic Pain: Headache; Clinical Practice Guideline

The Agency for Health Care Policy and Research (AHCPR) announces a public meeting to receive comments and information pertaining to the development of the AHCPR-sponsored clinical practice guideline on Chronic Pain: Headache. The guideline is being developed for AHCPR by Duke University (Durham, North Carolina) with the assistance of a panel of health care experts and consumers.

A notice announcing that AHCPR was arranging for the development of this clinical practice guideline was published in the **Federal Register** on December 27, 1993 (Vol. 58, No. 246). That notice invited nominations for experts and consumers to serve on the panel that is developing the guideline.

A public meeting to provide an opportunity for interested parties to contribute relevant information and comments, including research findings in areas relevant to the guideline, will be held as follows:

Meeting: Chronic Pain: Headache.
Date: October 31, 1995.
From: 9:00 a.m.—12:00 p.m.
Location: Doubletree Hotel, 300 Army Navy Drive, Arlington, VA 22202–9903.
Phone: (703) 416–4100.
Fax: (703) 416–4126.

Background

The AHCPR is charged, under Title IX of the Public Health Service (PHS) Act, with enhancing the quality, appropriateness, and effectiveness of health care services, and access to such services. The AHCPR accomplishes its goals through the establishment of a broad base of scientific research, and through the promotion of improvements in clinical practice and in the organization, financing, and delivery of health care services. (See 42 U.S.C. 299–299c–6 and 1320–12.)

In keeping with its legislative mandates, AHCPR arranges for the development, periodic review, and update of clinically relevant guidelines that may be used by physicians, nurses, other health care providers, educators, and consumers to assist in determining how diseases, disorders, and other health care conditions can most effectively and appropriately be prevented, diagnosed, treated, and clinically managed. Medical review criteria, standards of quality, and performance measures are then developed based on the guidelines produced.

Section 912 of the Act (42 U.S.C. 299b–1(b)), as amended, requires that the guidelines:

1. Be based on the best available research and professional judgment;
2. Be presented in formats appropriate for use by physicians, nurses, other health care providers, medical educators, medical review organizations, and consumers;
3. Be presented in treatment-specific or condition-specific forms appropriate for use in clinical practice, education programs, and reviewing quality and appropriateness of medical care;
4. Include information on the risks and benefits of alternative strategies for prevention, diagnosis, treatment, and management of the particular health condition(s); and
5. Include information on the costs of alternative strategies for prevention, diagnosis, treatment, and management of the particular health condition(s), where cost information is available and reliable.

Section 914 of the Act (42 U.S.C. 299b–3(a)), as amended, identifies factors to be considered in establishing priorities for guidelines, including the extent to which the guidelines would:

1. Improve methods for disease prevention;
2. Improve methods of diagnosis, treatment, and clinical management, and thereby benefit a significant number of individuals;
3. Reduce clinically significant variations among clinicians in the particular services and procedures utilized in making diagnoses and providing treatment; and
4. Reduce clinically significant variations in the outcomes of health care services and procedures.

Also, in accordance with Title IX of the PHS Act and section 1142 of the Social Security Act, the AHCPR Administrator is to assure that the needs and priorities of the Medicare program are reflected appropriately in the agenda and priorities for development of guidelines and guideline updates.

Arrangements for the October 31, 1995 Public Meeting on Chronic Pain: Headache

Representatives of organizations and other individuals are invited to provide relevant written comments and information, and make a brief (5 minutes or less) oral statement to the panel. Individuals and representatives who would like to attend must register with Ms. Becky Gray, Duke University, at the address set out below by October 10, 1995, and indicate whether they plan to make an oral statement. A written copy of the oral statement, comments, and information should be submitted to Ms. Gray by October 10, 1995. If more requests to make oral statements are received than can be accommodated between 9:00 a.m. and 12:00 p.m. on October 31, 1995, the chairperson will allocate speaking time in a manner that ensures, to the extent possible, that a range of views of health care professionals, consumers, and pharmaceutical and product manufacturers are presented. Those who cannot be granted their requested speaking time because of time constraints are assured that their written comments will be considered when

decisions regarding the AHCPR-sponsored guideline are made.

If sign language interpretation or other reasonable accommodation for a disability is needed, please contact Ms. Gray by October 10, 1995, at the address below.

Registration should be made with, and written materials submitted to: Becky Gray, Duke University, First Union Tower, 2200 West Main Street, Suite 230, Durham, North Carolina 27705, Phone: (919) 286–3399, Fax: (919) 286–5601.

For Additional Information

Additional information on the guideline development process is contained in the AHCPR Program Note, "Clinical Practice Guideline Development," dated August 1993. This document describes AHCPR's activities with respect to clinical practice guidelines including the process and criteria for selecting panels. This document may be obtained from the AHCPR Publications Clearinghouse, P.O. Box 8547, Silver Spring, MD 20907; or call Toll-Free: 1–800–358–9295.

Also, information can be obtained by contacting Douglas B. Kamerow, M.D., M.P.H., Director, Office of the Forum for Quality and Effectiveness in Health Care, Agency for Health Care Policy and Research, Willco Building, 6000 Executive Boulevard, Suite 310, Rockville, MD 20852, Phone 301–594–4015, Fax: 301–594–4027.

Dated: August 18, 1995.

Clifton R. Gaus,

Administrator.

[FR Doc. 95–21000 Filed 8–23–95; 8:45 am]

BILLING CODE 4160–90–M

Centers for Disease Control and Prevention (CDC)

The National Center for Environmental Health (NCEH) of the Centers for Disease Control and Prevention (CDC), Announces the Following Meeting

Name: Annual Meeting of CDC-Funded Childhood Blood Lead Surveillance Cooperative Agreement and Grant Recipients.

Times and Dates: 8:30 a.m.–5 p.m., September 6, 1995; 8:30 a.m.–5 p.m., September 7, 1995; 8:30 a.m.–3 p.m., September 8, 1995.

Place: Terrace Garden Inn-Buckhead, 3405 Lenox Road, NE, Atlanta, Georgia 30326.

Status: Open to the public, limited only by space available.

Purpose: The primary purpose of this meeting is to provide a forum for the recipients of CDC-Funded Childhood Blood Lead Surveillance Cooperative Agreement and Grant funds to review program progress and discuss surveillance issues and concerns.

Matters to be Discussed: Topics will include discussions on CDC childhood lead surveillance activities, CDC Lead Poisoning Prevention Branch and laboratory activities, core variables for laboratory reporting, data use by State health departments to direct prevention activities, data mapping, software demonstrations, and use of bar coding technology to transfer data.

Agenda items are subject to change as priorities dictate.

CONTACT PERSON FOR MORE INFORMATION: Carol A. Pertowski, M.D., Medical Epidemiologist, Surveillance and Programs Branch, Division of Environmental Hazards and Health Effects (F42), NCEH, CDC, 4770 Buford Highway, NE, Atlanta, Georgia 30341–3724, telephone 404/488–7330, FAX 404/488–7330.

Written comments are welcome and should be received by August 31, 1995. Persons wishing to make oral comments at the meeting should notify the contact person in writing or by telephone no later than close of business on August 31, 1995. All requests to make oral comments should contain the name, address, telephone number, and organizational affiliation of the presenter. Depending on the time available and the number of requests to make oral comments, it may be necessary to limit each presenter.

Dated: August 17, 1995.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 95–20992 Filed 8–23–95; 8:45 am]

BILLING CODE 4163–18–M

Food and Drug Administration

[Docket No. 95N–0264]

Drug Export; Bulk Codeine Contin® Granulation (100 milligrams (mg), 150 mg, 200 mg)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the Purdue Frederick Co. has filed an application requesting approval for the export of the human drug Bulk Codeine Contin® granulation to Canada for tablet compression, labeling, and packaging into 100–, 150–, and 200–milligram (mg) controlled release tablets.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: James E. Hamilton, Center for Drug Evaluation and Research (HFD–310), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301–594–3150.

SUPPLEMENTARY INFORMATION: The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the export of drugs that are not currently approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the **Federal Register** within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that The Purdue Frederick Co., 100 Connecticut Ave., Norwalk, CT 06850, has filed an application requesting approval for the export of the human drug Bulk Codeine Contin® granulation to Canada for tablet compression, labeling, and packaging into 100–, 150–, and 200–mg controlled release tablets. Bulk Codeine Contin® granulation is used for the relief of mild to moderate pain requiring the prolonged use of an opioid analgesic preparation. The application was received and filed in the Center for Drug Evaluation and Research on August 2, 1995, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by September 5, 1995, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the

information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Drug Evaluation and Research (21 CFR 5.44).

Dated: August 7, 1995.

Betty L. Jones,

Deputy Director, Office of Compliance, Center for Drug Evaluation and Research.

[FR Doc. 95–20963 Filed 8–23–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95D–0131]

"Point to Consider in the Manufacture and Testing of Therapeutic Products for Human Use Derived From Transgenic Animals (1995);" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a points to consider (PTC) document entitled, "Points to Consider in the Manufacture and Testing of Therapeutic Products for Human Use Derived From Transgenic Animals (1995)." The PTC document is intended to assist manufacturers in the production of safe, pure, potent, and effective therapeutic products for human use that are derived from transgenic animals. The PTC document is also intended to help sponsors assure the quality and consistency of data submitted in connection with an investigational new drug application (IND), product license application (PLA), establishment license application (ELA) or new drug application (NDA).

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the PTC document to the Congressional and Consumer Affairs Branch (HFM–12), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send two self-addressed adhesive labels to assist that office in processing your requests. Persons with access to the INTERNET may request this document from "CBER INFO@A1.CBER.FDA.GOV." The document may also be obtained by calling the CBER FAX Information System at 301–594–1939 from a FAX machine with a touch tone phone attached or built in. Submit written comments on the PTC document to the Dockets Management Branch (HFA–305), 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the PTC document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Timothy Beth, Center for Biologics Evaluation and Research (HFM–635), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a PTC document entitled "Points to Consider in the Manufacture and Testing of Therapeutic Products for Human Use Derived From Transgenic Animals (1995)." The PTC document provides a discussion of issues that should be considered in the development of therapeutic products derived from transgenic animals. A transgenic animal is an animal with an altered genome produced by introduction of deoxyribonucleic acid (DNA) through human intervention. The PTC document addresses issues such as the structure of the gene product, the fidelity of inheritance, the consistency of expression, and the avoidance of contamination by drugs, chemicals, and adventitious agents. Specific topics discussed in the PTC document include: (1) Generation and characterization of the transgene constructs; (2) creation and characterization of the transgenic founder animal; (3) establishment of a reliable and continuous source of transgenic animals; (4) generation and selection of production herds; (5) maintenance of transgenic animals; (6) purification and characterization of the transgenic product; (7) analysis of product quality; and (8) preclinical safety evaluation. The PTC document contains a reference section that lists laws, regulations, guidances, guidelines, PTC's and policies which may be applicable and should be considered when manufacturing therapeutic products for human use from transgenic animals.

As with other PTC documents, FDA does not intend this PTC document to be all-inclusive and cautions that not all information may be applicable to all situations. The PTC document is intended to provide information and does not set forth requirements. The methods and procedures cited in the PTC document are suggestions. FDA anticipates that sponsors and investigators may develop alternative methods and procedures, and discuss them with FDA. FDA may find those alternative methods and procedures acceptable. FDA recognizes that advances will continue in the area of human therapeutic products derived from transgenic animals and that this document may become outdated as those advances occur. The PTC document does not bind FDA and does not create or confer any rights, privileges, or benefits on or for any person, but is intended merely for guidance.

FDA is making available the PTC document in association with its responsibility to regulate drugs, medical devices, and biological products intended for human use. The PTC document is neither a regulation nor a guideline, but is an FDA compilation of information and suggestions on the subject of manufacturing therapeutic products for human use derived from transgenic animals. All applicable Federal laws and regulations must be followed and adhered to when manufacturing therapeutics for human use.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the PTC document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Received comments will be considered in determining whether further revision of the PTC document is warranted.

Dated: August 17, 1995.

William K. Hubbard,

Deputy Commissioner for Policy.

[FR Doc. 95–20964 Filed 8–23–95; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the

meetings and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETINGS: The following advisory committee meetings are announced:

Device Good Manufacturing Practice Advisory Committee

Date, time, and place. September 13 and 14, 1995, 8:30 a.m., Holiday Inn—Gaithersburg, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD. A limited number of overnight accommodations have been reserved at the hotel. Attendees requiring overnight accommodations may contact the hotel at 301–948–8900 and reference the FDA committee meeting block of rooms. Reservations will be confirmed at the group rate based on availability. Attendees with a disability requiring special accommodations should contact Ed Regenstein, Sociometrics, Inc., 301–608–2151. The availability of appropriate accommodations cannot be assured unless prior written notification is received.

Type of meeting and contact person. Open public hearing, September 13, 1995, 8:30 a.m. to 2:30 p.m., unless public participation does not last that long; open committee discussion, 2:30 p.m. to 4:30 p.m.; open committee discussion, September 14, 1995, 8:30 a.m. to 4:30 p.m.; Sharon M. Kalokerinos, Center for Devices and Radiological Health (HFZ–331), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4613, ext. 139, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Device Good Manufacturing Practice Advisory Committee, code 12398.

General function of the committee. The committee reviews proposed regulations for good manufacturing practices governing the methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of devices, and makes recommendations on the feasibility and reasonableness of the proposed regulations.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before August 30, 1995, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. The committee will consider the tentative final rule on quality systems which sets forth requirements for current good manufacturing practices to include methods used in, and the facilities and controls used for the design, purchasing, manufacturing, packaging, labeling, storage, installation, and servicing of all finished medical devices intended for human use. This document was made available through a Notice of Availability published on July 24, 1995 (60 FR 37856), and copies can be obtained from the Division of Small Manufacturers Assistance (HFZ–220), Food and Drug Administration, 1350 Piccard Dr. Rockville, MD 20850.

Peripheral and Central Nervous System Drugs Advisory Committee

Date, time, and place. September 18, 1995, 8:30 a.m., Parklawn Bldg., conference rooms G through J, 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open public hearing, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 5 p.m.; Michael A. Bernstein, Center for Drug Evaluation and Research (HFD–120), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2775, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Peripheral and Central Nervous System Drugs Advisory Committee, code 12543.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in neurological disease.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before September 11, 1995, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. The committee will discuss the safety and effectiveness of Rilutek® (riluzole), new drug application (NDA) 20–599, Rhone-Poulenc Rorer Pharmaceuticals, Inc., for use in the treatment of Amyotrophic Lateral Sclerosis (ALS).

Pulmonary-Allergy Drugs Advisory Committee

Date, time, and place. September 25, 1995, 8 a.m., Parklawn Bldg., conference rooms G through J, 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open public hearing, 8 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 5 p.m.; Leander B. Madoo, Center for Drug Evaluation and Research (HFD–9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4695, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Pulmonary-Allergy Drugs Advisory Committee, code 12545.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the treatment of pulmonary disease and diseases with allergic and/or immunologic mechanisms.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before September 25, 1995, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. The committee will discuss two NDA's: (1)

NDA 20–548, Flovent™ Inhalation Aerosol (a metered-dose inhaler formulation of fluticasone propionate), and (2) NDA 20–549, Flovent™ Inhalation via Diskhaler (a dry powder formulation of fluticasone propionate). Both NDA's are indicated for the maintenance treatment of bronchial asthma and for treatment of patients requiring oral corticosteroid therapy for asthma who may be able to significantly reduce or eliminate their requirement for oral corticosteroids over time. The sponsor for both NDA's is Glaxo Welcome.

Endocrinologic and Metabolic Drugs Advisory Committee

Date, time, and place. September 28, 1995, 8 a.m., Parklawn Bldg., conference rooms G through J, 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open public hearing, 8 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 5 p.m.; Kathleen R. Reedy, Center for Drug Evaluation and Research, Advisors and Consultants Staff (HFD–9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Endocrinologic and Metabolic Drugs Advisory Committee, code 12536.

General function of committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in endocrine and metabolic disorders.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before September 21, 1995, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. The committee will hear presentations and discuss data submitted regarding the safety and efficacy of dexfenfluramine hydrochloride, NDA 20–344, Interneuron Pharmaceuticals, Inc., for an obesity indication..

Joint Meeting of the Drug Abuse Advisory Committee and the Endocrinologic and Metabolic Drugs Advisory Committee

Date, time, and place. September 29, 1995, 9 a.m., Parklawn Bldg., conference rooms G through J, 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open public hearing, 9 a.m. to 10 a.m., unless public participation does not last that long; open committee discussion, 10 a.m. to 5 p.m.; Stephen P. Pollitt or Kathleen R. Reedy, Center for Drug Evaluation and Research (HFD–9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Drug Abuse Advisory Committee, code 12535.

General function of the committee. The Drug Abuse Advisory Committee advises on the scientific and medical evaluation of information gathered by the Department of Health and Human Services and the Department of Justice on the safety, efficacy, and abuse potential of drugs, and recommends actions to be taken on the marketing, investigation, and control of such drugs. The Endocrinologic and Metabolic Drugs Advisory Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in endocrine and metabolic disorders.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before September 18, 1995, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. The committees will discuss the petition to remove from the Controlled Substance Act, Fenfluramine and its isomers, Fenfluramine, NDA 16–618, Wyeth-Ayerst, and Dexfenfluramine, NDA 20–344, Interneuron Pharmaceuticals Inc.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this **Federal Register** notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr.,

Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: August 17, 1995.

Linda A. Suydam,

Interim Deputy Commissioner for Operations.

[FR Doc. 95–21001 Filed 8–23–95; 8:45 am]

BILLING CODE 4160–01–F

Pesticide Residue Monitoring Data Base for Fiscal Year 1994; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of Fiscal Year (FY) 1994 pesticide residue monitoring data on computer diskettes. This is the third annual comprehensive compilation and public release of FDA monitoring data for pesticide residues in foods. The agency is making the information available on computer diskettes to facilitate its dissemination to interested persons.

ADDRESSES: Pesticide residue monitoring data on computer diskettes may be ordered from the National Technical Information Service (NTIS), U.S. Department of Commerce, 5285 Port Royal Rd., Springfield VA 22161. Orders must reference NTIS order number PB95–503132 and include a payment of $50.00 for each copy of the data base. In addition, there is a handling fee of $4.00 for one copy of the data base, $6.00 for two copies, and $8.00 for three or more copies. Payment may be made by check, money order, charge card (American Express, VISA, or MasterCard), or by billing arrangements made with NTIS. Charge card orders must include the charge account number and expiration date. For telephone orders or further information on placing an order call NTIS at 703–487–4650.

FOR FURTHER INFORMATION CONTACT: Marcia G. Houston, Center for Food Safety and Applied Nutrition (HFS–308), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4152.

SUPPLEMENTARY INFORMATION: FDA is making available its FY 94 pesticide residue monitoring data as a set of three personal computer diskettes. The data base includes FDA pesticide monitoring coverage and findings for FY 94 by country/food product/pesticide combination. The data base is accompanied by a search program and report formats, written in dBase III+. Each year FDA receives numerous requests for these data. FDA has determined that it will facilitate dissemination of these data to interested persons if the agency provides for their general availability in a standardized diskette. A user's manual is provided that contains installation instructions and describes the structure and content of the data base.

Dated: August 16, 1995.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 95–20961 Filed 8–23–95; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

Notice of Meeting

Notice is hereby given of the meeting of the NIH AIDS Research Program Evaluation Working Group on September 13, 1995, at the Omni Shoreham Hotel, 2500 Calvert Street NW., Washington, DC, from 8:30 am to 5 pm. The meeting will be open to the public from 10:30 am to 5 pm with attendance limited to space available.

The purpose of the meeting is to review the status of each of the six Area Review Panels through presentations from the Area Review Panel Chairs and to obtain input from the infected and affected community. The NIH AIDS Research Program Evaluation Working Group will develop recommendations to be made to the Office of AIDS Research Advisory Council that address the overall NIH AIDS research initiative, both intramural and extramural, and identify long-range goals in the relevant areas of science. These recommendations will provide the framework for future planning and budget development of the NIH AIDS research program.

The 10:30 am to 12:30 pm session of the meeting will be for presentations from designated participants. The 1 pm to 5 pm session will be for public presentations. Those desiring to make formal presentations at the public session should notify Dr. Robert Eisinger, Office of AIDS Research, National Institutes of Health, 31 Center Drive, MSC 2340, Building 31, room 4B62, Bethesda, MD 20892–2340, (301) 402–8655 before September 8, 1995 and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments. Interested persons may present data, information, or views in writing on issues pending before the Working Group.

There will be a closed session from 8:30 am to 10:30 am to update the Working Group members on privileged information from the Area Review Panels on institute and center grant and contract portfolios.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Dr. Eisinger in advance of the meeting.

Dated: August 18, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95–20987 Filed 8–24–95; 8:45 am]

BILLING CODE 4140–01–M

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Prevention; Notice of Meetings

Pursuant to Public Law 92–463, notice is hereby given of the meetings of the Center for Substance Abuse Prevention (CSAP) Drug Testing Advisory Board and the Center for Substance Abuse Prevention (CSAP) National Advisory Council in September 1995.

The meeting of the CSAP Drug Testing Advisory Board will include discussion of announcements and reports of administrative, legislative, and program developments. It will also include reviews of sensitive National Laboratory Certification Program (NLCP) internal operating procedures and program development issues. Therefore, a portion of this meeting will be closed to the public as determined by the Administrator, SAMHSA, in accordance with 5 U.S.C. 552b(c)(2), (4), and (6) and 5 U.S.C. Appendix 2, section 10(d).

Committee Name: Drug Testing Advisory Board.

Meeting Date(s): September 20, 1995.

Place: DoubleTree Hotel, 1750 Rockville Pike, Rockville, Maryland 20857.

Open: September 20, 1995, 8:30 a.m.–10:00 a.m.

Closed: September 20, 1995, 10:00 a.m.–Adjournment.

Contact: Donna M. Bush, Ph.D.; Parklawn Building, room 13A–54; Telephone: (301) 443–6014.

The September 21 meeting of the CSAP National Advisory Council will include the review of applications for Federal assistance and individual contract proposals; therefore, portions of this meeting will be closed to the public as determined by the Administrator, SAMHSA, in accordance with 5 U.S.C. 552b(c)(3), (4) and (6) and 5 U.S.C. app. 2 10(d). On September 22, additional agenda items will include a presentation from the National Association of State Alcohol and Drug Abuse Directors, discussions of administrative matters and announcements, and reports by workgroups of the SAMHSA National Advisory Council and the CSAP National Advisory Council.

Substantive program information may be obtained from the contact whose name, room number, and telephone number is listed below.

Committee Name: Center for Substance Abuse Prevention National Advisory Council.

Meeting Date(s): September 21–22, 1995.

Place: Bethesda Marriott Residence Inn, 7335 Wisconsin Avenue, Bethesda, Maryland 20814.

Closed: September 21, 1995, 8:30 a.m.–3:30 p.m.

Open: September 22, 1995, 8:30 a.m.–4:00 p.m.

Contact: Yuth Nimit, Ph.D.; Rockwall II Building, Suite 7A–140; Telephone: (301) 443–8455.

A summary of these meetings and rosters of committee members may be obtained from: Ms. Vera Hunter, Acting Committee Management Officer, CSAP, Rockwall II Building, Suite 7A–140, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone: (301) 443–9542.

Dated: August 18, 1995.

Jeri Lipov,

Committee Management Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 95–20940 Filed 8–23–95; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Availability of an Environmental Assessment and Receipt of an Application for an Incidental Take Permit for the Lake Mathews Multiple Species Habitat Conservation Plan, Western Riverside County, California

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability.

SUMMARY: The Southern California Metropolitan Water District (MWD) (applicant) has applied to the Fish and Wildlife Service (Service) for a 50-year Incidental Take Permit pursuant to section 10(a)(1)(B) of the Endangered Species Act of 1973, as amended (Act). The proposed permit would authorize take of five currently listed wildlife species, including the endangered Stephens' kangaroo rat (*Dipodomys stephensi*) (SKR), the endangered bald eagle (*Haliaeetus leucocephela*), the threatened coastal California gnatcatcher (*Polioptila californica californica*), the endangered least Bell's vireo (*Vireo bellii pusillus*), and the endangered southwestern willow flycatcher (*Empidonax traillii extimus*), in western Riverside County, California. In addition, the applicant is seeking authorizations and assurances for 60 other target species (including one currently listed plant species, and 59 plant and animal species not currently listed) that occur within the plan area. This notice opens the comment period on the joint Environmental Assessment/Mitigated Negative Declaration (EA/MND), and permit application package, which includes the Lake Mathews Multiple Species Habitat Conservation Plan and Natural Community Conservation Plan (Plan) and Implementing Agreements (IA). All comments received, including names and addresses, will become part of the administrative record and may be made available to the public.

DATES: Written comments on the Plan, the EA/MND, or the IA should be received on or before September 25, 1995.

ADDRESSES: Comments should be addressed to Mr. Gail Kobetich, Field Supervisor, U.S. Fish and Wildlife Service, 2730 Loker Avenue West, Carlsbad, California 92008. Written comments may also be sent by facsimile to (619) 431–9618. Please refer to permit number PRT–805839 when submitting comments.

FOR FURTHER INFORMATION CONTACT: Jeff Newman, U.S. Fish and Wildlife Service, Carlsbad Field Office, 2730 Loker Ave. West, Carlsbad, California 92008 at (619) 431–9440.

SUPPLEMENTARY INFORMATION:

Availability of Documents

Individuals wishing copies of the documents should immediately contact the Service's Carlsbad Field Office at the above referenced address, or by telephone at (619) 431–9440. Documents will also be available for public inspection, by appointment, during normal business hours at the above address.

Background Information

Listed species are protected pursuant to section 9 of the Act against "take", that is, no one may harass, harm, pursue, hunt, shoot, wound, kill, trap, capture or collect the species, or attempt to engage in such conduct (16 USC 1538). The Service, however, may issue permits to conduct activities involving endangered species under certain circumstances, including carrying out scientific purposes, enhancing the propagation or survival of the species, or incidentally taking the species in connection with otherwise lawful activities. Regulations governing permits for endangered and threatened species are at 50 CFR 17.22 and 17.32. The proposed takings are incidental to otherwise lawful activities in association with the implementation of the Plan, a joint conservation effort initiated by the applicant (a 27-member public entity that delivers water from the California and Colorado River Aqueducts to cities and communities within a 5,125-square-mile service area in southern California) and the Riverside County Habitat Conservation Agency (RCHCA), in cooperation with the Service and the California Department of Fish and Game (CDFG).

Implementation of the proposed Plan could directly or indirectly affect individuals of five currently listed animal species (identified above). In addition, one listed plant species, slender-horned spineflower (*Dodecahema leptoceras*), is also known to occur in the vicinity of Lake Mathews. Although no incidental take authorization is required for listed plant species, impacts to these species must be addressed in the intra-Service consultation required pursuant to section 7(a) of the Act. The Plan establishes and provides management for a 5,110-acre multiple species reserve on the applicant's properties in western Riverside County (the Plan Area). The Multiple Species Reserve consists of a 2,545-acre mitigation bank adjacent to an existing 2,565-acre State Ecological Reserve. The mitigation bank provides mitigation for the applicant's ongoing and future operations, maintenance activities, and capital construction projects at Lake Mathews (totaling approximately 618 acres). Future MWD projects outside the Plan Area can use additional credits remaining in the mitigation bank pursuant to the Mitigation Banking Agreement in Volume 3 of the application package. The RCHCA will receive habitat credit for the 1,269.3 acres of occupied SKR habitat within the Plan Area under the SKR Short-term Habitat Conservation

Plan. Any use by the RCHCA of the 1,269.3 acres as mitigation for effects other than take of SKR would be contingent on Service and CDFG approval of a multiple species plan.

The EA/MND considers the proposed project and no action alternatives in detail. In addition, two other alternatives were considered but were not selected for detailed analysis. These alternatives considered avoiding take of listed species at Lake Mathews, and a modified project that would apply only to projects and activities on MWD's Lake Mathews properties (and would not extend to projects outside the Plan Area).

The proposed Federal action would authorize the incidental take of 65 target species, including habitat modification, during ongoing and future projects and activities described in the Plan. The applicant has requested the issuance of permits that would authorize the incidental take of the five listed wildlife species identified previously in this notice. In addition, the applicant seeks Federal pre-listing assurances for 59 other plant and animal target species which are currently not listed as threatened or endangered but could become listed in the future. These pre-listing assurances are agreements in principle that the Service would modify the permits and authorize incidental take for any of these species should they become listed in the future. These assurances are given on the condition that avoidance, minimization, and reserve management measures identified in the Plan are implemented.

Mitigation pursuant to these authorizations and assurances will be accomplished on a habitat basis rather than on a species-by-species basis. Habitat occupied by multiple species in the Mitigation Bank may be used to mitigate for multiple species affected by activities or projects initiated by the applicant. If a project affects several species, which at some point during their respective life cycles occupy a single habitat type and these species also occur in the Mitigation Bank area, then mitigation for these species may be accomplished on a habitat-by-habitat basis rather than on a species-by-species basis.

This notice is provided pursuant to section 10(c) of the Act and National Environmental Policy Act of 1969 (NEPA) regulations (40 CFR 1506.6). The joint EA/MND meets both NEPA requirements and the requirements of the state of California pursuant to the California Environmental Quality Act (CEQA). Both NEPA, at 40 CFR 1506.6, and the CEQA Guidelines at Section 15222, provide for joint planning processes and environmental assessment documents. The Service will evaluate the application, associated documents, and comments submitted thereon to determine whether the application meets the requirements of NEPA regulations and section 10(a) of the Act. If it is determined that the requirements are met, a permit will be issued for the incidental take of the listed species, and pre-listing agreements provided for the other target species. The final NEPA and permit determination will be made no sooner than 30 days from the date of this notice.

Dated: August 18, 1995.

Thomas Dwyer,

Deputy Regional Director, Region 1, Portland, Oregon.

[FR Doc. 95–20993 Filed 8–23–95; 8:45 am]

BILLING CODE 4310–55–P

Bureau of Land Management

[CA–060–5101–10–B016,CACA 27497]

Notice of Availability of the Supplemental Final Cajon Pipeline Environmental Impact Statement

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In accordance with Section 202 of the National Environmental Policy Act of 1969, the Bureau of Land Management, California Desert District, has prepared a Supplemental Final Environmental Impact Statement (EIS) for a proposed revision to the previously approved Cajon Pipeline Project. This Supplemental Final EIS describes the Project and summarizes the impacts, as previously approved, and analyzes the changes in those impacts resulting from the proposed revisions to the Project. This Project, as revised, will traverse both Federal and private lands in San Bernardino County, California.

DATES: Written comments will be accepted until September 25, 1995.

ADDRESSES: Written comments should be sent to the District Manager, Bureau of Land Management, 6221 Box Springs Blvd., Riverside, CA 92507–0714, ATTN: Cajon Pipeline Project.

FOR FURTHER INFORMATION CONTACT: Stephen L. Johnson, Special Projects Manager, California Desert District Office, 6221 Box Springs Blvd, Riverside, CA 92507–0714; phone (909) 697–5233.

SUPPLEMENTARY INFORMATION: Discoveries in the Santa Barbara Channel off the coast of California along the Outer Continental Shelf (OCS) and on-shore through thermal enhanced oil recovery in the San Joaquin Valley (SJV) have yielded significant new reserves of heavy, high sulphur crude oil. As a result of these discoveries and the desire of producers to transport this heavy crude to the Los Angeles Basin refineries, a heated pipeline system capable of handling this crude in its "neat" state is being considered. Existing pipelines do not have the capacity to handle the anticipated volume. In addition, heavy crude requires the addition of heat to allow it to be efficiently pumped through pipelines, and no heated common carrier pipeline exists today into the Los Angeles Basin.

To connect the producers and refiners, the Cajon Pipeline Company has been granted a permit to build a 142-mile-long, 20-inch diameter insulated buried pipeline from 12-Gauge Lake (27 miles west of Barstow), California, to the Los Angeles crude oil terminals in Carson and Long Beach. The Final EIS (June, 1993) for the Cajon Pipeline Project includes an analysis of the environmental impacts of the proposed pipeline system during construction and operation. The Cajon Pipeline Company is now intending to amend the approved project by constructing a much shorter pipeline. Following the original route from 12-Gauge Lake to the City of Adelanto. Within the vicinity of Adelanto two minor realignments are proposed to provide increased separation between the pipeline and two new schools; Adelanto Middle School and Quail Valley Middle School. The remainder follows the original route through the Cajon Pass and on into the Los Angeles Basin but the Cajon Pipeline Company now proposes to terminate their pipeline in the City of Rancho Cucamonga. This would be Company now proposes to terminate their pipeline in the City of Rancho Cucamonga. This would be with a tie-in to the existing Edison Pipeline and Terminal Company's (EPTC) system at Edison's Etiwanda Generating System and from there the existing EPTC Pipeline would be used to transport the crude oil to the various refineries and terminals near the coast.

This Supplemental Final Environmental Impact Statement (EIS) for the proposed evaluating those changes to the Cajon Pipeline Project has been prepared in compliance with the National Environmental Policy Act (NEPA). The Bureau of Land Management's preferred alternative is to accept the proposed changes to the approved Project, as proposed and

described in the Supplemental Final EIS.

Since the Final EIS was completed in June of 1993, Executive Order 12898, entitled Executive Order on Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, has been issued. In compliance with Executive Order 12898 a section entitled Environmental Justice has now been added and included in the Supplemental Final EIS for the Cajon Pipeline Project.

Dated: August 17, 1995.

Henri R. Bisson,

District Manager.

[FR Doc. 95–20958 Filed 8–23–95; 8:45 am]

BILLING CODE 4310–40–M

[AZ–040–1430–01; AZA 29226]

Notice of Proposed Sale of Lands in Greenlee County, Arizona

AGENCY: Bureau of Land Management.

ACTION: Notice.

SUMMARY: Notice is hereby given that the following land has been found suitable for direct sale under section 203 of the Federal Land Policy and Management Act of 1976 (90 Stat. 2760, 43 U.S.C. 1713) at not less than fair market value. The land will not be offered for sale until at least 60 days after the date of this notice.

Gila and Salt River Meridian, Arizona

T. 7 S., R. 31 E.,
Sec. 34, S½NW¼NE¼SE¼.
Containing 5 acres, more or less.

The land described is hereby segregated from appropriation under the public land laws, including the mining laws, pending disposition of this action or 270 days from the date of publication of this notice, whichever occurs first.

This land is being offered by direct sale to Greenlee County to be used as a solid waste transfer station site. It has been determined that the subject parcel contains no known mineral values, therefore, mineral interest may be conveyed simultaneously. Acceptance of the direct sale offer will qualify the purchaser to make application for conveyance of those mineral interests.

The patent, when issued, will contain certain reservations to the United States. Detailed information concerning reservations as well as specific conditions of the sale are available for review at the Bureau of Land Management, Safford District Office, 711 14th Avenue, Safford, Arizona 85546.

For a period of 45 days from the date of publication of this notice in the **Federal Register**, interested parties may submit comments to the District Manager, Safford District, at the above address. In the absence of timely objections, this proposal shall become the final determination of the Department of the Interior.

Dated: August 17, 1995.

Frank L. Rowley,

Acting District Manager.

[FR Doc. 95–21076 Filed 8–23–95; 8:45 am]

BILLING CODE 4310–32–M

[AZ–026–05–5440–10–A132; AZA–29170]

Realty Action; Noncompetitive Sale of Public Lands in Pima County, Arizona

AGENCY: Bureau of Land Management (BLM), Interior.

ACTION: Notice.

SUMMARY: The following land is being considered for direct sale under section 203 of the Federal Land Policy and Management Act of 1976 (90 Stat. 2750, 43 U.S.C. 1713), at not less than fair market value to the Hia-Ced O'Odham Alliance. The land will not be offered for sale until at least 60 days after publication of this notice.

Gila and Salt River Meridian, Arizona

T. 12 S., R. 6 W.,
Sec. 33, SE¼SW¼NE¼, NE¼NW¼SE¼.
Containing 20 acres.

FOR FURTHER INFORMATION CONTACT: Frank Daniels of the Phoenix District Office, U.S. Bureau of Land Management, 2015 West Deer Valley Road, Phoenix, Arizona 85027, (602) 780–8090.

SUPPLEMENTARY INFORMATION: If it is determined that there are no known mineral values, the mineral interests shall be determined suitable for sale under section 209 of the Federal Land Policy and Management Act of 1976 and may be conveyed simultaneously. Acceptance of the direct sale offer will qualify the purchaser to make application for conveyance of those mineral interests.

The patent, when issued, will contain a reservation to the United States for rights-of-way for ditches and canals. Also to be reserved to the United States will be that portion of the Chico Shunie Road that is located within the 20 acre parcel.

For a period of 45 days from the date of publication of this notice in the **Federal Register**, interested parties may submit comments to the District Manager, Phoenix District, at the above address. In the absence of timely objections, this proposal shall become the final determination of the Department of the Interior.

Dated: August 17, 1995.

G.L. Cheniae,

District Manager, Phoenix District Office.

[FR Doc. 95–21078 Filed 8–23–95; 8:45 am]

BILLING CODE 4310–32–P

[OR–030–1610–00–G5–197]

Intent to Prepare a Resource Management Plan for the Andrews, Malheur, and Jordan Resource Areas, Oregon

AGENCY: Bureau of Land Management, Interior.

ACTION: Opportunity for Public Comment—Notice of Intent to Prepare a Resource Management Plan (RMP) for the Andrews, Malheur, and Jordan Resource Areas of the Burns and Vale Districts, Oregon.

SUMMARY: In accordance with 43 CFR 1601.3–1, notice is hereby given that the Bureau of Land Management, Burns and Vale Districts, Oregon, intend to prepare an RMP for the Andrews, Malheur, and Jordan Resource Areas. The RMP will include 1.7 million acres of public land in the Andrews Resource Area, 1.9 million acres of public land in the Malheur Resource Area, and 2.8 million acres of public land in the Jordan Resource Area. The subject area is located in southeastern Oregon in portions of Harney, Malheur, and Grant Counties.

The purpose of the RMP is to update land use planning decisions in the Andrews, Northern Malheur (Malheur), and Southern Malheur (Jordan) Management Framework Plans (MFPs) to be consistent with current conditions and trends, as required by the Federal Land Policy and Management Act (FLPMA) of October 21, 1976 (43 U.S.C. 1701).

DATES: Comments are due by November 3, 1995.

FOR FURTHER INFORMATION CONTACT:

Gary D. Cooper, Team Leader, Vale District Office, 100 Oregon Street, Vale, Oregon 97918 (Telephone 503–473–3144)

Glenn T. Patterson, Burns District Office, HC 74–12533 Hwy 20 West, Hines, Oregon 97738 (Telephone 503–573–4400)

SUPPLEMENTARY INFORMATION: Issues proposed to be included in the RMP include: (1) Vegetation Management; (2) Land Tenure and Access; (3) Utility Corridors; (4) Fire Management; (5) Special Management Areas; and, (6)

Recreation Management. All issues will be considered in relationship to each other under ecosystem management.

Resource management programs to be represented on the interdisciplinary team preparing the RMP and Environmental Impact Statement (EIS) include: Wildlife, fisheries, riparian, wild horses, recreation, wilderness, cultural, watershed, minerals, lands and realty, range, botanical, threatened and endangered plants and animals, fire management, socioeconomics, and land use planning. Guidelines developed by the Interim Columbia Basin Ecosystem Management Plan will be considered in preparing this RMP.

More detailed information on issues, planning criteria, and preliminary management alternatives is available at the Burns and Vale District Offices and has also been mailed to known interested individuals and parties. Public meetings will be held to discuss preliminary issues and planning criteria for the RMP and associated EIS. The comment period on issues will close November 3, 1995. Dates, times, and location of meetings will be announced through local media and mailing information to interested parties. Other public participation activities will include a 90-day review of the draft RMP/EIS and public meetings to receive comments and answer questions.

Planning documents will be available for inspection at the Burns and Vale District Offices during normal working hours.

Dated: August 14, 1995.

James E. May,

District Manager, Vale.

Jerome A. Petzold,

Assistant District Manager for Operations, Burns.

[FR Doc. 95–21071 Filed 8–23–95; 8:45 am]

BILLING CODE 4310–33–M

[AZ–050–05–1231–00; 8371]

Arizona: Long-Term Visitor Area Program for 1995–1996 and Subsequent Use Seasons; Revision to Existing Supplementary Rules, Yuma District, Arizona, and California Desert District, California, and Revision of Long-Term Visitor Area Boundaries Within the California Desert District, El Centro Resource Area

AGENCY: Bureau of Land Management, Interior.

ACTION: Publication of supplementary rules and revision of Long-Term Visitor Area boundaries within the California Desert District, El Centro Resource Area.

SUMMARY: The Bureau of Land Management (BLM) Yuma District and California Desert District announce revisions to the Long-Term Visitor Area (LTVA) Program. The program, which was instituted in 1983, established designated Long-Term Visitor Areas and identified an annual long-term use season from September 15 to April 15. During the long-term use season, visitors who wish to camp on public lands in one location for extended periods must stay in the designated LTVAs and purchase an LTVA permit.

EFFECTIVE DATE: September 15, 1995.

FOR FURTHER INFORMATION CONTACT: Mark Lowans, Outdoor Recreation Planner, Yuma Resource Area, 3150 Winsor Avenue, Yuma, Arizona 85365, telephone (520) 726–6300; or John Butz, Outdoor Recreation Planner, California Desert District, 6221 Box Springs Boulevard, Riverside, California 92507–0714, telephone (909) 697–5394.

SUPPLEMENTARY INFORMATION: The purpose of the Long-Term Visitor Area program is to provide areas for long-term winter camping use. The sites designated as Long-Term Visitor Areas are, in most cases, the traditional use areas of long-term visitors. Designated sites were selected using criteria developed during the land management planning process, and environmental assessments were completed for each site location.

The program was established to safely and properly accommodate the increasing demand for long-term winter visitation and to provide natural resource protection through improved management of this use. The designation of long-term visitor areas assures that specific locations are available for long-term use year after year, and that inappropriate areas are not used for extended periods.

Visitors may camp without an LTVA permit outside of LTVAs, on public lands not otherwise posted or closed to camping, for up to 14 days in any 28-day period.

Authority for the designation of LTVAs is contained in Title 43, Code of Federal Regulations, Subpart 8372, Sections 0–3 and 0–5(g). Authority for the establishment of a Long-Term Visitor Area program is contained in Title 43, Code of Federal Regulations, Subpart 8372, Section 1, and for the payment of fees in Title 36, Code of Federal Regulations, Subpart 71.

The Authority for establishing supplementary rules is contained in Title 43, Subpart 8365, Section 1–6. The LTVA supplementary rules have been developed to meet the goals of individual resource management plans. These rules will be available in each local office having jurisdiction over the lands, sites, or facilities affected, and will be posted near and/or within the lands, sites, or facilities affected. Violations of supplementary rules are punishable by a fine not to exceed $100,000 and/or imprisonment not to exceed 12 months.

The following are the supplemental rules for the designated LTVAs and are in addition to rules of conduct set forth in Title 43, Code of Federal Regulations, Subpart 8365, Section 1–6.

The following supplemental rules apply year-long to all public land users who enter the LTVAs.

1. The Permit. A permit is required to camp in a designated LTVA between September 15 and April 15. The permit authorizes the permittee to camp within any designated LTVA using those camping or dwelling unit(s) indicated on the permit between the period from September 15 to April 15. There are two types of permits: Long-term and short-visit. The long-term permit fee is $50.00, U.S. funds only, for the entire season and any part of the season. The short-visit permit is $10.00 for seven (7) consecutive days. The short-visit permit may be renewed an unlimited number of times for the cost of $10.00 for seven consecutive days. *No refunds are made on permit fees.*

2. The Permit. To be valid, the short-visit permit or long-term permit decal must be affixed at the time of purchase, with the adhesive backing, to the bottom right hand corner of the windshield of all transportation vehicles and in a clearly visible location on all camping units. A maximum of two (2) secondary vehicles are permitted.

3. Permit Transfers. If you sell, trade, or exchange camping vehicles during the use season, remove the permit from your old vehicle before turning it over to the new owner. Present your permit to a BLM officer authorized to sell permits, or a BLM office which administers an LTVA. The permit will be revised to cover the new camping unit or you will receive a replacement permit for your new vehicle at no cost. The permit may not be reassigned or transferred by the permittee.

4. Permit Revocation. An authorized BLM officer may revoke, without reimbursement, any LTVA permit issued to any person when the permittee violates any BLM rule or regulation, or when the permittee, permittee's family, or guests conduct is inconsistent with the goals of BLM's LTVA Program. Failure to return any LTVA permit to any authorized BLM officer upon demand is a violation of this supplemental rule. Any permittee

whose permit is revoked must remove all property and leave the LTVA system within 12 hours of notice. The revoked permittee will not be allowed into any other LTVA in Arizona or California for the remainder of the LTVA season.

5. Unoccupied Camping Units. Camping or dwelling unit(s) must not be left unoccupied within any LTVA for periods of greater than 5 days unless approved in advance by an authorized BLM officer.

6. Parking. For your safety and privacy, maintain a minimum of 15 feet of space between dwelling units.

7. Removal of Wheels and Campers. Campers, trailers, and other dwelling units must remain mobile. Wheels must remain on all wheeled vehicles. Pickup campers may be set on jacks manufactured for that purpose.

8. Quiet Hours. Quiet hours are from 10 p.m. to 6 a.m. in accordance with applicable state time zone standards.

9. Noise. Operation of audio devices or motorized equipment, including generators, in a manner that makes unreasonable noise that disturbs other visitors is prohibited. Within La Posa and Imperial Dam LTVAs, amplified music is allowed only in locations designated by BLM or when approved in advance by an authorized BLM officer.

10. Access. Do not block roads or trails commonly in public use with your parked vehicles, stones, wooden barricades, or by any other means.

11. Structures and Landscaping. Fixed structures of any type are restricted and must conform to posted policies. This includes, but is not limited to fences, dog runs, storage units, and windbreaks. Alterations to the natural landscape are not allowed. Painting rocks or defacing or damaging any natural or archaeological feature is prohibited.

12. Livestock. Boarding of livestock (horses, cattle, sheep, goats, etc.) within LTVA boundaries is permitted only when approved in advance by an authorized BLM officer.

13. Pets. Pets must be kept on a leash at all times. Keep an eye on your pets. Unattended and unwatched pets may fall prey to coyotes or other desert predators. Pet owners are responsible for cleanup and sanitary disposal of pet waste.

14. Cultural Resources. Do not disturb any archaeological or historical values including, but not limited to, petroglyphs, ruins, historic buildings, and artifacts that may occur on public lands.

15. Trash. Place all trash in designated receptacles. Public trash facilities are shown in the LTVA brochure. Depositing trash or holding-tank sewage in vault toilets is prohibited. An LTVA permit is required for trash disposal within all LTVA campgrounds except for the Imperial Dam and Mule Mountain LTVAs.

16. Dumping. Absolutely no dumping of sewage, gray water, or garbage on the ground. This includes motor oil and any other waste products. The changing of motor oil, vehicular fluids, or disposal and possession of these used substances within an LTVA is strictly prohibited. Federal, state, and county sanitation laws and county ordinances specifically prohibit these practices. Sanitary dump station locations are shown in the LTVA brochure. LTVA permits are required for dumping within all LTVA campgrounds except for the Imperial Dam and Midland LTVAs.

17. Self-Contained Vehicles. In Pilot Knob, Dunes Vista, Midland, Tamarisk, and Hot Springs LTVAs, camping is restricted to self-contained camping units only. Self-contained units must have a permanent affixed waste water holding tank of 10-gallon minimum capacity. Port-a-potty systems, or systems which utilize portable holding tanks, or permanent holding tanks of less than 10-gallon capacity are not considered to be self-contained. The La Posa, Imperial Dam, and Mule Mountain LTVAs are restricted to self-contained camping units, except within 500 feet of a vault or restroom.

18. Campfires. Campfires are permitted in LTVAs subject to all local, state and federal regulations. Comply with posted rules.

19. Wood Collection. No wood collection is permitted within the boundaries of Mule Mountain, Imperial Dam, and La Posa LTVAs. In permitted wood collection areas, only dead, down, and detached wood may be collected for firewood or hobby purposes. Collection and possession of ironwood is regulated to three pieces, not to exceed 10 pounds total in weight. A maximum of 1 cubic yard (3'×3'×3') natural firewood will be allowed per individual or group campfire at any one time. Please contact the nearest BLM office for current regulations concerning firewood collection.

20. Speed Limit. The speed limit in LTVAs is 15 m.p.h. or as otherwise posted.

21. Off-Highway Vehicle Use. Motorized play is prohibited. Motorized vehicles should be used in LTVAs only for access to and from campsites.

22. Vehicle Use. It is prohibited to operate any vehicle in violation of state or local laws and regulations relating to use, standards, registration, operation, and inspection.

23. Firearms. The discharge or use of firearms or weapons is prohibited inside or within ½ mile of the LTVAs.

24. Vending Permits. Any commercial activity requires a vending permit. Please contact the nearest BLM office for information on vending or concession permits.

25. Aircraft Use. Landing or taking off of aircraft, including ultralights and hot air ballons, is prohibited in LTVAs.

26. Perimeter Camping. No camping is allowed within 1 mile of the Hot Spring, Tamarisk, and Pilot Knob LTVA boundaries.

27. Hot Spring LTVA. Food, beverages, glass containers, soap, and pets are prohibited within the fenced-in area at the Hot Springs Spa.

28. Mule Mountain LTVA. All camping within Wiley's Well and Coon Hollow campgrounds is restricted to designated sites only and is limited to one (1) camping or dwelling unit per site.

29. Imperial Dam and La Posa LTVAS. Overnight occupancy is prohibited in desert washes in Imperial Dam and La Posa LTVAs.

30. La Posa LTVA. Access to La Posa LTVA is restricted to legal access roads along U.S. Highway 95. Construction and use of other access points are prohibited. This includes removal and modification of barricades such as fences, ditches, and berms.

31. Posted Rules. Observe all posted rules. Individual LTVAs may have additional specific rules. If posted rules differ from these supplemental rules, the posted rules take precedence.

32. Other Laws. LTVA permit holders are required to observe all Federal, state, and local laws and regulations applicable to the LTVA and shall keep the LTVA and, specifically, their campsite, in a neat, orderly, and sanitary condition.

33. Length of Stay. Length of stay in an LTVA between April 16 and September 14 is limited to 14 days in a 28-day period. After the 14th day of occupation, campers must move outside of a 25-mile radius of the previous location.

The following are the revised boundaries for the LTVAs located within the California Desert District, El Centro Resource Area.

Dunes Vista LTVA

San Bernardino Base Meridian

T. 16 S., R. 20 E.,
Sec. 14, S½SW¼SE¼SW¼, SW¼SE¼SE¼SW¼, E½SE¼SE¼SW¼SW¼.
Sec. 23, NW¼NE¼NE¼NW¼, N½NW¼NE¼NW¼, W½NE¼NE¼NE¼NW¼.

17.5 Acres.

Tamarisk LTVA

San Bernardino Base Meridian

T. 17 S., R. 18 E.,
Sec. 4., NW¼NW¼NE¼, W½NE¼NW¼NE¼.

15 Acres.

Pilot Knob LTVA

San Bernardino Base Meridian

T. 16 S., R. 21 E.,
Sec. 28., NE¼.

160 Acres.

Hot Springs LTVA

San Bernardino Base Meridian

T. 16 S., R. 16 E.,
Sec. 12., W½NW¼NE¼, SW¼NE¼, NE¼NW¼, E½SE¼NW¼, W½SE¼.
Sec. 13., E½SW¼NW¼NE¼, S½SE¼NW¼NE¼, SW¼NE¼, W½SE¼NE¼, W½NE¼SE¼, E½NW¼SE¼, E½W½NW¼SE¼, N½SW¼SE¼, NW¼SE¼SE¼.

355 Acres.

This notice is published under the authority of Title 43, Code of Federal Regulations, Subpart 8365, Section 1–6.

Ed Hastey,

State Director, California.

Michael R. Ford,

Acting State Director, Arizona.

[FR Doc. 95–21074 Filed 8–23–95; 8:45 am]

BILLING CODE 4310–32–P

[CO–956–95–1420–00]

Colorado: Filing of Plats of Survey

August 17, 1995.

The plats of survey of the following described land are officially filed in the Colorado State Office, Bureau of Land Management, Lakewood, Colorado, effective 10 a.m. on August 17, 1995.

The field notes describing the remonumentation of certain original corner points in Township 5 North, Range 92 West, of the Sixth Principal Meridian, Colorado, as provided for in the Special Instructions, Group No. 750, dated July 16, 1982, "Investigation of Physical Evidence of Corner Positions and Accessories when Needed", was accepted August 4, 1995.

The field notes describing the remonumentation of certain original corner points in Township 9 North, Range 98 West, of the Sixth Principal Meridian, Colorado, as provided for in the Special Instructions, Group No. 750, dated July 16, 1982, "Investigation of Physical Evidence of Corner Positions and Accessories when Needed", was accepted August 4, 1995.

The field notes describing the remonumentation of certain original corner points in Township 4 North, Range 101 West, of the Sixth Principal Meridian, Colorado, as provided for in the Special Instructions, Group No. 750, dated July 16, 1982, "Investigation of Physical Evidence of Corner Positions and Accessories when Needed", was accepted August 4, 1995.

The plat representing the dependent resurvey of a portion of the east boundary of Township 7 South, Range 89 West (Eleventh Guide Meridian West), portions of the south, east, and north boundaries, portions of the sectional correction line and sectional guide meridian, a portion of the subdivisional lines, a portion of Tract 37, and portions of certain private land claims, and the subdivision of certain sections, Township 7 South, Range 88 West, Sixth Principal Meridian, Group 794, Colorado, was accepted June 30, 1995.

The plat representing metes-and-bounds survey in certain sections and in Tract 49, Township 43 North, Range 10 West, New Mexico Principal Meridian, Group 799, Colorado, was accepted July 21, 1995.

These surveys were executed to meet certain administrative needs of this Bureau.

The plat representing the dependent resurvey of a portion of the north boundary of the Southern Ute Indian Reservation, a portion of the south boundary, the west boundary, a portion of the subdivisional lines, and the survey of the subdivision of certain sections of Township 34 North, Range 13 West, South of the Ute Line, New Mexico Principal Meridian, Group 1024, Colorado, was accepted July 12, 1995.

This survey was executed to meet certain administrative needs of the Southern Ute Indian Reservation and the Bureau of Reclamation.

The plat representing the dependent resurvey of a portion of the west boundary of Township 33 North, Range 13 West, the east boundary of Township 33 North, Range 15 West, and the south boundary of Township 34 North, Range 14 West, and the survey of the subdivisional lines of Township 33 North, Range 14 West, New Mexico Principal Meridian, Group 1029, Colorado, was accepted July 27, 1995.

This survey was executed to meet certain administrative needs of the Ute Mountain Ute Tribe.

The plat representing the dependent resurvey of certain subdivisional lines and the subdivision of sections 23 and 24, in Township 42 North, Range 10 West, of the New Mexico Principal Meridian, Group 1068, Colorado, was accepted July 27, 1995.

This survey was executed to meet certain administrative needs of the U.S. Forest Service.

The plat representing the dependent resurvey of a portion of the east boundary Township 12 North, Range 91 West, a portion of the subdivisional lines, the subdivision of sections 24 and 25, and a Traverse of the center-line of Moffat County Road 101, as constructed in Sections 24 and 25, Township 12 North, Range 91 West, Sixth Principal Meridian, Group 1088, Colorado, was accepted July 28, 1995.

The supplemental plat depicting the correct boundary of lot 13 and eliminating lots 5 and 6 in section 14 and eliminating lot 8 in section 13, Township 1 North, Range 3 West, Ute Principal Meridian, Colorado, was approved July 21, 1995.

The supplemental plat creating lot 20 from cancelled Mineral Survey No. 52B, Plata Verde Mill Site, Township 22 South, Range 72 West, Sixth Principal Meridian, Colorado, was approved July 28, 1995.

These surveys were executed to meet certain administrative needs of this Bureau.

Darryl A. Wilson,

Chief Cadastral Surveyor for Colorado.

[FR Doc. 95–21077 Filed 8–23–95; 8:45 am]

BILLING CODE 4310–JB–P

Minerals Management Service

Environmental Documents Prepared for Proposed Oil and Gas Operations on the Gulf of Mexico Outer Continental Shelf (OCS)

AGENCY: Minerals Management Service, Interior.

ACTION: Publication of revised Outer Continental Shelf protraction diagrams.

SUMMARY: Notice is hereby given that effective with this publication, the following OCS Official Protraction Diagrams, last revised on the date indicated, are on file and available for information only, in the Gulf of Mexico OCS Regional Office, New Orleans, Louisiana. In accordance with Title 43, Code of Federal Regulations, these Official Protraction Diagrams are the basic record for the description of mineral and oil and gas lease sales in the geographic areas they represent.

REVISED MAPS [1]

Description	Latest revision date
Georgetown, NI 17–09	July 5, 1995.
Savannah, NI 17–11	July 5, 1995.

REVISED MAPS [1]—Continued

Description	Latest revision date
James Island, NI 17–12 ...	July 5, 1995.

[1] Changes consist of adjustments to conform to the North American Datum of 1983.

FOR FURTHER INFORMATION CONTACT: Copies of these Official Protraction Diagrams may be purchased for $2.00 each from the Public Information Unit (MS 5034), Minerals Management Service, Gulf of Mexico OCS Region, 1201 Elmwood Park Boulevard, New Orleans, Louisiana 70123–2394 or by telephone at (504) 736–2519.

SUPPLEMENTARY INFORMATION: Technical comments or questions pertaining to these maps should be directed to the Office of Leasing and Environment, Supervisor, Sales and Support Unit at (504) 736–2768.

Dated: August 16, 1995.

Chris C. Oynes,

Regional Director, Gulf of Mexico OCS Region.

[FR Doc. 95–21079 Filed 8–23–95; 8:45 am]

BILLING CODE 4310–MR–M

National Park Service

Draft Environmental Impact Statement and General Management Plan for Independence National Historical Park, Pennsylvania

AGENCY: National Park Service, Interior.

ACTION: Notice of availability of draft environmental impact statement.

SUMMARY: This notice announces the availability of a Draft Environmental Impact Statement (DEIS) and General Management Plan for Independence National Historical Park, Pennsylvania.

DATES: Written comments on the DEIS should be received no later than October 20, 1995.

ADDRESSES: Written comments should be submitted to: Superintendent, Independence National Historical Park, 313 Walnut Street, Philadelphia, PA 19106.

SUPPLEMENTARY INFORMATION: The DEIS describes and analyzes six alternatives for future management of Independence National Historical Park. Alternative A (the no-action alternative) would minimally meet the requirements of the park's enabling legislation. Some small scale physical actions would be undertaken, but no significant development would occur and no structures would be removed. Alternative B would fulfill the original mission of the park by concentrating on the park's historic sites while the focus would be on the 1775–1800 period of significance. The park landscape would be used as a commemorative setting for the park resources. Primary interpretation would occur at each site rather than at visitor centers. Alternative C would concentrate on the evolution of democracy. Cooperative ventures would expand the methods and scope of interpretation. A new information and orientation center would be constructed. Alternative D would build on the synergy of the park with historic neighborhoods and cooperating institutions. The National Park Service and the city would work cooperatively to strengthen the perception of the park as a focal point of the Old Philadelphia District. A jointly operated regional visitor center would be constructed. Alternative E (preferred action), similar to Alternative D, would provide space for the National Constitution Center on Independence Mall. Also, under this alternative, no underground parking would be developed. Alternative F is similar to both Alternatives D and E in its emphasis on historical and physical links with the city and region and the use of Independence Mall for arrival and orientation. It differs in the arrangement of development on Independence Mall, the location of the National Constitution Center, and the placement of the Liberty Bell.

Dated: August 16, 1995.

Warren D. Beach,

Associate Field Director, NEFA.

[FR Doc. 95–21085 Filed 8–23–95; 8:45 am]

BILLING CODE 4310–70–M

Draft Environmental Impact Statement and General Management Plan for Independence National Historical Park, Pennsylvania

AGENCY: National Park Service, Interior.

ACTION: Notice of public meetings.

SUMMARY: This notice announces public meetings concerning the General Management Plant and Draft Environmental Impact Statement for Independence National Historical Park, Pennsylvania.

DATES: The public meetings will be held on Thursday, October 5, 1995, from 7 pm to 9 pm and on Friday, October 6, 1995, from 1 pm to 3 pm.

LOCATION: The meetings will be held at Independence National Historical Park Visitor Center, Philadelphia, Pennsylvania, located at 3rd and Chestnut Streets.

ADDRESSES: Inquiries regarding the meetings, dates, General Management Plan, and Draft Environmental Impact Statement should be submitted to the Superintendent, Independence National Historical Park, 313 Walnut Street, Philadelphia, PA 19106, telephone (215) 597–0060.

SUPPLEMENTARY INFORMATION: The purpose of these meetings will be to obtain comments from the public on the Draft Environmental Impact Statement/ General Management Plan for Independence National Historical Park released in August 1995.

Dated: August 16, 1995.

Warren D. Beach,

Associate Field Director, NEFA.

[FR Doc. 95–21086 Filed 8–23–95; 8:45 am]

BILLING CODE 4310–70–M

Availability of Final Wallowa River 2(a)(ii) Wild and Scenic River Study Report, Oregon

AGENCY: National Park Service, Interior.

ACTION: Publication of final report and recommendation.

SUMMARY: The National Park Service is publishing the final study report on designating the Wallowa River, Oregon, into the National Wild and Scenic Rivers System. The National Park Service has found that the lower Wallowa River is eligible for the national system and is recommending to Department of the Interior Secretary Bruce Babbitt that the river be designated.

ADDRESSES: Copies of the final report are available from: Dan Haas, National Park Service, 909 First Avenue, Seattle, Washington 98104–1060, telephone (206) 220–4120; and Steve Davis, U.S. Forest Service, Wallowa-Whitman National Forest, 1550 Dewey Avenue, Baker City, Oregon 97814, telephone (503) 523–6391.

FOR FURTHER INFORMATION CONTACT: Dan Haas, National Park Service, 909 First Avenue, Seattle, Washington 98104–1060, (206) 220–4120.

SUPPLEMENTARY INFORMATION: On December 29, 1994, Oregon Governor Barbara Roberts petitioned the Secretary of the Interior to add a 10-mile reach of the Wallowa River to the National Wild and Scenic Rivers System. The section of river under consideration extends from the confluence of the Wallowa and Minam Rivers in the hamlet of Minam (river mile 10.0) downstream to the confluence of the Wallowa and Grande Ronde Rivers (river mile 0.0). Under section 2(a)(ii) of the National Wild and Scenic Rivers Act (P.L. 90–542, as amended), the Secretary has the authority to add a river to the national system at the request of a state, provided

the state has met certain conditions and the river meets eligibility criteria.

These preconditions are:

(1) The river is already designated into a state river protection system.

(2) The state has the ability to manage the river at no cost to the federal government, except for those lands managed by a federal agency.

(3) The river has resources of regional or national significance and is free-flowing as defined by the Departments of the Interior and Agriculture.

(4) The state has adequate mechanisms in place to protect the resources for which the river is eligible in the first place.

Upon the request of a state governor to the Secretary, the National Park Service, acting for the Secretary, undertakes an evaluation of the state's request. The National Park Service requested the assistance of the U.S. Forest Service (USFS) and the Bureau of Land Management (BLM) in the preparation of the report. This was done for two reasons: (1) The BLM currently administers 41% of the area under consideration; and (2) the USFS recently completed a wild and scenic assessment—and an environmental impact statement on the impacts of designation—at the request of Congress through the 1988 Oregon Omnibus Rivers Act. The National Park Service acted as a cooperating agency in the preparation of the USFS report. In addition, the BLM and USFS have an adopted river management plan in place for the Wallowa River. Both the BLM and the USFS acted as cooperating agencies in this assessment on behalf of the state.

Under the 1988 Oregon Omnibus Rivers Act, the USFS was directed to study the Wallowa River for possible inclusion into the National Wild and Scenic Rivers System. In September of 1994, the USFS released their final study and environmental impact statement (EIS). In the EIS, the preferred alternative was identified as wild and scenic river designation through section 2(a)(ii) of the Wild and Scenic Rivers Act. This would permanently protect the nationally significant resources of the Wallowa River, while leaving the river in state management and having the least impact to area residents. Following the release of the EIS, Governor Roberts, acting on the recommendations of the USFS, petitioned Secretary Babbitt to designate the Wallowa River through section 2(a)(ii). As the agency responsible for section 2(a)(ii) determinations, the National Park Service undertook an assessment of the river and the state of Oregon's petition.

As a result of the assessment, the National Park Service has concluded that the state of Oregon has met all requirements to include the Wallowa River in the national system and the river itself meets all eligibility criteria. The National Park Service is recommending that the Secretary designate the Wallowa as a National Recreational River.

Dated: August 18, 1995.

William C. Walters,

Deputy Field Director, Pacific West Field Area, National Park Service.

[FR Doc. 95–21088 Filed 8–23–95; 8:45 am]

BILLING CODE 4310–70–P

INTERSTATE COMMERCE COMMISSION

[Finance Docket No. 32703]

The Kansas City Southern Railway Company; Trackage Rights Exemption; Dallas Area Rapid Transit Property Acquisition Corporation and the Atchison, Topeka & Santa Fe Railway Company

Dallas Area Rapid Transit Property Acquisition Corporation (DART) has agreed to grant overhead trackage rights to The Kansas City Southern Railway Company (KCS) over 15 miles of rail line beginning at the connection of The Atchinson, Topeka and Santa Fe Railway Company (Santa Fe) and DART's rail lien at Santa Fe's milepost 77.35, at or near Wylie, TX, then westerly to the connection at Santa Fe's and DART's rail lien at milepost 73.35, near Renner, TX. In conjunction with the above agreement, Santa Fe has also agreed to grant overhead trackage rights to KCS over 21 miles of rail line between Santa Fe's milepost 385.6 at Dalton Junction, TX, and milepost 364.6 at Santa Fe's new rail yard facility at or near Alliance, TX. The trackage rights were to become effective on August 10, 1995.

This notice is filed under 49 CFR 1180.2(d)(7). If the notice contains false or misleading information, the exemption is void *ab initio*. Petitions to revoke the exemption under 49 U.S.C. 10505(d) may be filed at any time. The filing of a petition to revoke will not stay the transaction. Pleadings must be filed with the Commission and served on: (1) Lonnie E. Blaydes, Jr., Director, Dallas Area Rapid Transit Property Acquisition Corporation, P.O. Box 660163, Dallas, TX 75266–7210; (2) Richard E. Weicher, Esq., General Counsel, The Atchison, Topeka and Santa Fe Railway Company, 1700 East Golf Road, Schaumburg, IL 60173; (3) Robert K. Dreiling, Esq., Assistant General Counsel, The Kansas City Southern Railway Company, 114 West Eleventh St., Kansas City, MO 64105; and (4) William A. Mullins, Esq., Troutman Sanders, 601 Pennsylvania Ave., N.W., Suite 640, Washington, DC 20004–2608.

As a condition to use of this exemption, any employees adversely affected by the trackage rights will be protected pursuant to *Norfolk and Western Ry, Co.—Trackage Rights—BN*, 354 I.C.C. 605 (1978), as modified in *Mendocino Coast Ry., Inc.—Lease and Operate*, 360 I.C.C. 653 (1980).

Decided: August 18, 1995.

By the Commission, Julia M. Farr, Acting Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 95–21060 Filed 8–23–95; 8:45 am]

BILLING CODE 7035–01–M

DEPARTMENT OF JUSTICE

Lodging of Consent Decrees Pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act

Notice is hereby given that two proposed consent decrees in *United States* v. *Velsicol Chemical Corporation, et al.*, Civil Action No. 92–2214–FBRO (W.D. Tenn.), where lodged on August 15, 1995 with the United States District Court for the Western District of Tennessee. The proposed consent decrees settle an action brought under Section 107 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, 42 U.S.C. 9607, as amended, against Velsicol Chemical Corporation, the City of Memphis, and The Procter & Gamble Cellulose Corporation for recovery of costs incurred by the United States in responding to the release and threatened release of hazardous substances at the North Hollywood Landfill located in Memphis, Shelby County, Tennessee.

The proposed consent decree with Velsicol Chemical Corporation and the City of Memphis, Tennessee provides that those entities will collectively pay $1,595,000 to resolve their liability to the United States for past costs incurred at the North Hollywood Landfill. The proposed consent decree with The Procter & Gamble Cellulose Corporation provides for a payment of $300,000 to resolve The Procter & Gamble Cellulose Corporation's liability with the United States for costs incurred at the North Hollywood Landfill. The proposed

consent decree with The Procter & Gamble Cellulose Corporation includes a covenant not to sue by the United States under Sections 106 and 107 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, 42 U.S.C. 9606 and 9607, and under Section 7003 of the Resource Conservation and Recovery Act ("RCRA"), 42 U.S.C. 6973.

The Department of Justice will receive, for a period of thirty (30) days from the date of this publication, comments relating to the two proposed consent decrees. With respect to the consent decree with The Procter & Gamble Cellulose Corporation, commenters may request an opportunity for a public meeting in the affected area, in accordance with section 7003(d) of RCRA. Comments should be addressed to the Assistant Attorney General for the Environment and Natural Resources Division, Department of Justice, Washington, DC 20530, and should refer to the *United States* v. *Velsicol Chemical Corporation, et al.*, DOJ Ref. #90–11–2–629A.

The proposed consent decrees may be examined at the office of the United States Attorney, Western district of Tennessee, 1026 Federal Office Building, 167 N. Main Street, Memphis, Tennessee 38103; the Region IV Office of the Environmental Protection Agency, 345 Courtland Street NE., Atlanta, Georgia 30365; and at the Consent Decree Library, 1120 G Street NW., 4th Floor, Washington, DC 20005, (202) 624–0892. A copy of the proposed consent decrees may be obtained in person or by mail from the Consent Decree Library, 1120 G Street NW., 4th Floor, Washington, DC 20005. In requesting copies please refer to the referenced case and enclose a check in the amount of $9.00 (25 cents per page reproduction costs), payable to the Consent Decree Library.

Bruce S. Gelber,

Acting Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 95–21080 Filed 8–23–95; 8:45 am]

BILLING CODE 4410–01–M

Lodging of Consent Decree Pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act of 1980

Notice is hereby given that on July 19, 1995, a proposed Consent Decree in *United States* v. *Alaskan Battery Enterprises, Inc.*, Civil Action No. A92–606 (D. Alaska), was lodged with the United States District Court for the District of Alaska. This Consent Decree resolves the United States' claims in this action against K & K Recycling, Inc. regarding its liability under sections 107(a) and 113(g) of CERCLA, 42 U.S.C. 9607(a) and 9613(g), for response costs incurred by the United States in connection with the Alaskan Battery Enterprises Superfund Site in Fairbanks, Alaska. The Decree also resolves the liability of the Defense Reutilization and Marketing Service ("DRMS") and the Army & Air Force Exchange Service ("AAFES"), counterclaim defendants in this matter.

The Decree requires, *inter alia*, that K & K Recycling, Inc. reimburse the United States' response costs in the amount of $100,000 plus interest through the date of payment. The DRMS and AAFES are required under this Decree to reimburse the United States' response costs in the amounts $1,169,528.00 and $636,671.00 plus prejudgment interest from May 1, 1994 through the date of payment, respectively. K & K Recycling, Inc. is obligated, ten days after entry of the Decree, to stipulate to the dismissal with prejudice of its counterclaims against the United States; the United States is obligated, ten days after all payments have been received, to dismiss its claims against K & K Recycling, Inc. with prejudice. The Decree provides to K & K Recycling, Inc., DRMS, and AAFES the contribution protection afforded by section 113(f)(2) of CERCLA, 42 U.S.C. 9613(f)(2). The Decree also contains a reopener that permits the United States, in certain situations, to institute additional proceedings to require that these defendants perform further response actions or to reimburse the United States for additional costs of response.

The Department of Justice will receive comments relating to the proposed Consent Decree for a period of thirty (30) days from the date of this publication. Comments should be addressed to the Assistant Attorney General of the Environment and Natural Resources Division, Department of Justice, Washington, D.C. 20530, and should refer to *United States* v. *Alaskan Battery Enterprises, Inc.*, D.J. No. 90–11–3–726A.

The proposed Consent Decree may be examined at the Office of the United States Attorney for the District of Alaska, Room 253, Federal Building and U.S. Courthouse, 222 West Seventh Avenue, Anchorage, Alaska 99513–7567; the Region 10 Office of the Environmental Protection Agency, 1200 Sixth Avenue, Seattle, Washington 98101; and at the Consent Decree Library, 1120 G Street NW, 4th Floor, Washington, DC 20005 (Tel: 202–624–0892). A copy of the proposed Consent Decree may be obtained in person or by mail from the Consent Decree Library, 1120 G Street NW, 4th Floor, Washington, DC 20005. In requesting a copy, please enclose a check in the amount of $6.50 (25 cents per page reproduction cost) payable to Consent Decree Library.

Bruce Gelber,

Acting Chief, Environmental Enforcement Section, Environment & Natural Resources Division.

[FR Doc. 95–21081 Filed 8–23–95; 8:45 am]

BILLING CODE 4410–01–M

Lodging of Consent Decree Pursuant to CERCLA

Notice is hereby given that a proposed consent decree in *United States* v. *City of Marianna, Florida*, Case No. 94–50092/RV was lodged on August 9, 1995, with the United States District Court for the Northern District of Florida, Panama City Division. The consent decree settles a claim for reimbursement of response costs brought against the City of Marianna under section 107(a) of the Comprehensive Environmental Response, Compensation, and Recovery Act of 1980, as amended, 42 U.S.C. 9607(a), in response to the release or threatened release of hazardous substances into the environment from a three-acre facility located at the City of Marianna Municipal Airport Industrial Park, and counterclaims brought by the City of Marianna, Florida against the United States. Under the consent decree, the City of Marianna agrees to reimburse the United States $500,000 plus interest within three years of the date on which the consent decree is entered by the Court and the defendants agree to dismiss the counterclaims.

The Department of Justice will receive, for a period of thirty (30) days from the date of this publication, comments relating to the proposed consent decree. Comments should be addressed to the Assistant Attorney General for the Environment and Natural Resources Division, Department of Justice, Washington, DC 20530, and should refer to *United States* v. *City of Marianna, Florida*, DOJ Ref. # 90–11–3–774.

The proposed consent decree may be examined at the office of the United States Attorney, Northern District of Florida, Panama City Division, 114 East Gregory Street, Pensacola, Florida 32501; the Region IV Office of the United States Environmental Protection Agency, 345 Courtland Street, NE

Atlanta, Georgia 30365; and at the Consent Decree Library, 1120 G Street NW., 4th Floor, Washington, DC 20005, (202) 624–0892. A copy of the proposed consent decree may be obtained in person or by mail from the Consent Decree Library, 1120 G Street NW., 4th Floor, Washington, DC 20005. In requesting a copy please refer to the referenced case and enclose a check in the amount of $4.00 (25 cents per page reproduction costs), payable to the Consent Decree Library.

Bruce Gelber,

Acting Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 95–21082 Filed 8–23–95; 8:45 am]

BILLING CODE 4410–01–M

Antitrust Division

United States v. Sprint Corporation and Joint Venture Co.; Proposed Final Judgment and Competitive Impact Statement

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h), that a proposed Final Judgment, Stipulation and Competitive Impact Statement have been filed with the United States District Court for the District of Columbia in *United States* v. *Sprint Corporation and Joint Venture Co.*, Civil Action No. 95–1304. The proposed Final Judgment is subject to approval by the Court after the expiration of the statutory 60-day public comment period and compliance with the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h).

The Complaint alleges that the proposed sale of 20% of the voting shares of Sprint Corporation ("Sprint") to France Telecom ("FT") and Deutsche Telekom A.G. ("DT"), and the proposed formation of a joint venture among Sprint, FT and DT to provide certain international telecommunications services, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, in the markets for international telecommunications services between the United States and France and the United States and Germany, and in the markets for seamless international telecommunications services.

Under the proposed consents decree, Sprint and the joint venture are subject to various restrictions affecting their relationship with FT and DT. These restrictions operate in two distinct phases, lessening over time as competition develops in France and Germany.

During the first phase, while DT and FT still have monopoly rights in Germany and France and competitors have not been licensed, the relationship that Sprint and the joint venture have with DT and FT will be subject to close oversight. Sprint and the joint venture may not acquire ownership or control of certain types of facilities from FT and DT, may not provide services in which FT or DT have special rights except in limited, non-exclusive circumstances, and may not benefit from discriminatory treatment, disproportionate allocation of international traffic, or cross-subsidization by FT and DT. In addition, access to the French and German public switched networks and public data networks cannot be limited in such a way as to exclude competitors of Sprint and the joint venture.

During both the first phase and the second phase, after FT and DT face licensed competitors in all areas of services and facilities in France and Germany, Sprint and the joint venture must make detailed information on their relationships with FT and DT available to competitors, will be precluded from receiving competitively sensitive information that FT and DT obtain from the competitors of Sprint and the joint venture, and may not offer particular services between the United States and France and Germany unless other United States providers also have or can readily obtain licenses from the French and Germany governments to offer the same services. These provisions of the decree will remain in effect for five years beyond the end of the first phase.

Public comment is invited within the statutory 60-day comment period. Such comments, and the responses thereto, will be published in the **Federal Register** and filed with the Court. Comments should be directed to Donald Russell, Chief, Telecommunications Task Force, Antitrust Division, Room 89104, 555 Fourth Street, N.W., Washington, D.C. 20001 (202–514–5621).

Copies of the Complaint, proposed Final Judgment and Competitive Impact Statement are available for inspection in Room 207 of the U.S. Department of Justice, Antitrust Division, 325 7th Street, N.W., Washington, D.C. 20530. (telephone: (202) 514–2481), and at the office of the Clerk of the United States District Court for the District of Columbia, Third Street and Constitution Avenue, N.W., Washington, D.C. 20001. Copies of any of these materials may be obtained upon request and payment of a copying fee.

Constance K. Robinson,

Director of Operations, Antitrust Division.

In the matter of United States of America, Plaintiff, v. Sprint Corporation and Joint Venture Company, Defendants.

[Civil Action No. 1:95CV01304]

Filed: July 13, 1995.

Stipulation

It is stipulated and agreed by and between the undersigned parties, by their respective attorneys, that:

1. The Court has jurisdiction over the subject matter of this action and over each of the parties hereto and venue of this action is proper in the District of Columbia. Defendants are hereby estopped from contesting the entry or enforceability of the Final Judgment on the ground that the Court lacks venue or jurisdiction over the subject matter of the action or over any defendant. For purposes of this stipulation defendant Joint Venture Company and any reference to Joint Venture Company herein, shall be understood to have the same meaning as the term "Joint Venture Company" in the attached proposed Final Judgment.

2. The parties consent that a Final Judgment in the form hereto attached may be filed and entered by the Court, upon the motion of any party or upon the Court's own motion, at any time after compliance with the requirements of the Antitrust Procedures and Penalties Act (15 U.S.C. 16), and without further notice to any party or other proceedings, provided that plaintiff has not withdrawn its consent. Plaintiff may withdraw its consent to entry of the Final Judgment at any time before it is entered, by serving notice on the defendants and by filing that notice with the Court.

3. Pending entry of the Final Judgment, defendants shall abide by and comply with the provisions of the Final Judgment following consummation of the Investment Agreement dated June 22, 1995 (and related agreements), the Joint Venture Agreement dated June 22, 1995 (and related agreements), or any similar arrangement between any defendant and France Télécom ("FT") or Deutsche Telekom A.G. ("DT"). This obligation shall not be affected by the timing of execution of any agreements between defendants and FT or DT to provide to Sprint and Joint Venture Co. information needed for compliance with the requirements of Sections II.A.1–7 or III of the Final Judgment. Any such agreements, which shall be executed prior to the entry of the Final Judgment, shall be consistent with Section II.B of

the Final Judgment and shall be provided to the Department of Justice upon execution.

4. The agreements governing disclosure to United States international telecommunications providers ("providers"), referred to in Section V.F. of the Final Judgment, will provide that: (1) Non-public information received from the Department of Justice is intended for use to complain to, or provide information to, any government authorities in the United States or France or Germany, and to identify and evaluate internally any conduct that may be made the subject of such a complaint or provision of information, but may not be used for commercial purposes; (2) such information may not be disclosed to persons other than officers, directors, employees, agents, or contractors of the provider, for permissible purposes under (1), and to government authorities in the United States or France or Germany (including, but not limited to, the Federal Communications Commission, Direction Générale des Postes et Télécommunications, and the Bundesministerium für Post und Telekommunikation); (3) all persons to whom the information is disclosed will be advised of the limitations on use and disclosure of the information; and (4) if unauthorized use or disclosure occurs, the Department of Justice may, in its sole discretion, revoke or otherwise limit the provider's further access to such information. Plaintiff, in its discretion, may add further conditions to such agreements. Any actions taken by the Department to redress unauthorized use or disclosure will not diminish or create any ability in Sprint or Joint Venture Co. to pursue separately against persons receiving such information from the Department any legal remedies for unauthorized use or disclosure.

5. FT and DT have reached an agreement with Infonet Services Corporation ("Infonet") as of June 20, 1995, requiring FT and DT to divest part of their shareholdings in Infonet by August 3, 1995 (the "Initial Tranche") and to divest fully their remaining shareholdings in Infonet (the "Second Tranche") forty-five days after the earlier of (1) the date as of which FT or DT directly or indirectly acquire any of the securities of Sprint, or (2) six months after all approvals necessary for the investment by FT and DT in Sprint and the consummation of the joint venture between FT, DT and Sprint have been received from the plaintiff, the Federal Communications Commission, the Commission of the European Communities and the Cartel Office of the Federal Republic of Germany. Infonet is a company that competes with Sprint in providing some types of telecommunications and enhanced telecommunications services and would compete with some of the planned telecommunications and enhanced telecommunications services of Joint Venture Co. Due to this competition between Sprint and Infonet, the United States has indicated that it has competitive concerns about FT and DT having ownership interests in both Sprint and Infonet and representation on the boards of directors of both companies. Sprint will not issue any equity of itself to be acquired by FT or DT, or acquire an ownership interest in or contribute assets to form Joint Venture Co., until FT and DT have each completed the divestiture of their Infonet shares in the Initial Tranche. In addition, until the complete divestiture of FT and DT shareholdings in Infonet is accomplished pursuant to the above referenced agreement, Sprint and Joint Venture Co. shall (a) be maintained as separate and independent businesses with their assets (including proprietary technology, customer base, management, operations and books and records) separate, distinct and apart from those of Infonet; and (b) take all steps necessary to assure that no proprietary business or financial information specific to Infonet is transferred, or otherwise becomes available to Sprint or Joint Venture Co., or is used by Sprint or Joint Venture Co. to compete with Infonet. Moreover, Sprint will not allow any director appointed by FT and DT to serve on the Sprint Board of Directors for such period as any director appointed by FT or DT is serving on the Infonet Board of Directors and exercises any voting rights in connection therewith, and if any director appointed by FT or DT serves on the Infonet Board of Directors, regardless of whether such director exercises any voting rights, for more than 45 days after the occurrence of the first of either of the following events: (i) FT or DT has acquired directly or indirectly any of Sprint's securities, or (ii) FT or DT has appointed any director to the Sprint Board of Directors, Sprint will remove all FT or DT appointed directors from the Sprint board.

6. Joint Venture Co. is necessary as a defendant in this action, together with Sprint, for the relief specified in the proposed Final Judgment to be effective. Until it has been demonstrated to the satisfaction of the plaintiff, such satisfaction being confirmed in writing, that Joint Venture Co. (i) has been created as a legal entity, (ii) is subject to suit and is within the reach of the jurisdiction of the United States courts, and (iii) will have full authority and power to carry out all of the obligations imposed upon it by the proposed Final Judgment as those obligations take effect, and Joint Venture Co. has consented to and executed this Stipulation on the same terms as Sprint, without reservation or qualification, Sprint agrees that it will not issue any equity of itself to be acquired by FT or DT, until Joint Venture Co. has been formed and made a party to this stipulation. Sprint will not permit Joint Venture Co. to do any business until the conditions in this paragraph pertaining to Joint Venture Co. are satisfied. If for any reason the conditions pertaining to Joint Venture Co. in this paragraph are not satisfied, plaintiff shall be under no obligation to move for entry of the Final Judgment and may withdraw its consent to entry of the Final Judgment, and defendants shall not move for entry of the Final Judgment.

7. In the event plaintiff withdraws its consent to entry of the proposed Final Judgment or if the proposed Final Judgment is not entered pursuant to this Stipulation, this Stipulation shall be of no effect whatsoever and its making shall be without prejudice to any party in this or any other proceeding, except that if the Court decides not to enter the Final Judgment, and the defendants and FT and DT have consummated pursuant to paragraph 3 of this Stipulation, defendants shall abide by and comply with the terms of the Final Judgment until the conclusion of this action, unless the parties otherwise agree or the Court otherwise orders.

8. The Stipulation and the Final Judgment to which it relates are for settlement purposes only and do not constitute an admission by defendants in this or any other proceedings that Section 7 of the Clayton Act, 15 U.S.C. 18, as amended, or any other provision of law, has been violated.

9. If the transactions contemplated by the Investment Agreement and Joint Venture Agreement are not consummated in any form, and Sprint, FT and DT withdraw their notifications under the Hart-Scott-Rodino Antitrust Improvements Act, then this Stipulation shall be null and void, and the parties shall be under no obligation to enter into or be bound by the proposed Final Judgment.

Dated: July 13, 1995.

For Plaintiff United States of America:
Anne K. Bingaman,
Assistant Attorney General.
Steven C. Sunshine,
Deputy Assistant Attorney General.
Constance K. Robinson,
Director of Operations, U.S. Department of Justice Antitrust Division.
Donald J. Russell,
Chief, Telecommunications Task Force.
Nancy M. Goodman,
Assistant Chief, Telecommunications Task Force.
Carl Willner,
D.C. Bar #412841.
Susanna M. Zwerling,
D.C. Bar #435774.
Michael J. Hirrel,
Joyce B. Hundley,
Attorneys, Telecommunications Task Force.
Phillip H. Warren,
Attorney, San Francisco Field Office.
U.S. Department of Justice,
Antitrust Division.
For Defendant Sprint Corporation:
King & Spalding
By:
Kevin R. Sullivan,
D.C. Bar #411718.
J. Richard Devlin,
Executive Vice President and General Counsel, Sprint Corporation.

STIPULATION APPROVED FOR FILING

Done this _____ day of _____, 1995.

_____
UNITED STATES DISTRICT JUDGE

Disclosure Pursuant to Rule 108(k)

Pursuant to Rule 108(k) of the Local Rules of this Court, the following is a list of all individuals entitled to be notified of the entry of the foregoing Stipulation and of the entry of the proposed Final Judgment:

Kevin U. Sullivan, Esquire, King & Spalding, 1730 Pennsylvania Avenue, NW., Washington, DC 20006
Counsel for Defendant Sprint
and
Carl Willner, Esquire, Attorney, Telecommunications Task Force, Antitrust Division, U.S. Department of Justice, 555 4th St. NW., Washington, DC 20001
Counsel for Plaintiff the United States

In the matter of: United States of America, Plaintiff, v. Sprint Corporation and Joint Venture Co., Defendants.

[Civil Action No. 1:95CV01304]

Filed: July 13, 1995.

Final Judgment

Whereas, plaintiff, United States of America, filed its Complaint on July 13, 1995.

And whereas, plaintiff and defendants, by their respective attorneys, have consented to the entry of this Final Judgment without trial or adjudication on any issue of fact or law,

And whereas, defendants have further consented after any consummation as defined in the Stipulation entered into by defendants and the United States on July 13, 1995, to be bound by the provisions of this Final Judgment pending its approval by the Court,

And whereas, plaintiff the United States believes that entry of this Final Judgment is necessary to protect competition in the United States telecommunications and enhanced telecommunications markets,

Therefore, it is hereby *ordered, adjudged,* and *decreed:*

I

Jurisdiction

This Court has jurisdiction of the subject matter of this action and of each of the parties consenting to this Final Judgment. The Complaint states a claim upon which relief may be granted against the defendants under Section 7 of the Clayton Act, 15 U.S.C. § 18, as amended.

II

Substantive Restrictions and Obligations

Reporting and Disclosure Requirements

A. Sprint or Joint Venture Co. shall not offer, supply, distribute, or otherwise provide in the United States any telecommunications or enhanced telecommunications service that makes use of telecommunications services provided by FT in France or between the United States and France, or DT in Germany or between the United States and Germany, unless the following information is disclosed in the United States by Sprint or Joint Venture Co., or such disclosure is expressly waived, in whole or in part, by plaintiff through written notice to defendants and the Court:

1. By Joint Venture Co., within 30 days following any agreement or change to an agreement—The prices, terms and conditions, including any applicable discounts, on which FT or DT Products and Services are provided by FT to Joint Venture Co. in France or by DT to Joint Venture Co. in Germany pursuant to interconnection agreements;

2. By Joint Venture Co., within 30 days following any agreement or change to any agreement, or the provision of service absent any specific agreement—The prices, terms, and conditions, including any applicable discounts, on which FT or DT Products and Services are provided by FT to Joint Venture Co. in France or by DT to Joint Venture Co. in Germany for use by Joint Venture Co. in the supply of telecommunications or enhanced telecommunications services between the United States and France or between the United States and Germany or are provided by FT in France or DT in Germany in conjunction with such Joint Venture Co. services where FT or DT is acting as the distributor for Joint Venture Co.;

3. By Sprint, with respect to international switched telecommunications or enhanced telecommunications services jointly provided by FT and Sprint, or DT and Sprint, on a correspondent basis between the United States and France or between the United States and Germany, and to the extent not already disclosed publicly pursuant to the rules and regulations of the Federal Communications Commission, or otherwise to the corporations referred to in Section V.F:

(i) Within 30 days following any agreement or change to an agreement, or the provision of service absent any specific agreement, the accounting and settlement rates and other terms and conditions for the provision of each such service, including the methodology by which proportionate return of traffic is calculated; and

(ii) On an annual basis, for any such services for which more than one accounting and settlement rate may be applicable (e.g., rates for peak and off-peak services), or services with different accounting and settlement rates which are pooled or otherwise combined for calculating proportionate returns, if other United States international telecommunications providers do not have or receive data sufficient to determine whether they are receiving their appropriate share of return traffic in each accounting rate category (e.g., the total volumes of United States traffic to FT and DT, and total volumes of FT and DT traffic to the United States, for each type of traffic with a different accounting rate), Sprint's minutes of traffic to and from FT and DT in each accounting rate category and any other applicable measure of traffic volume;

4. By Joint Venture Co., on a semiannual basis-Schedules of FT or DT Products and Services provided by FT to Joint Venture Co. in France and DT to Joint Venture Co. in Germany for use by Joint Venture Co. in the supply of telecommunications or enhanced telecommunications services between the United States and France or Germany or provided by FT in France or DT in Germany in conjunction with such Joint Venture Co. services where

FT or DT is acting as the distributor for Joint Venture Co., showing:

(i) The types of circuits (including capacity) and telecommunications services provided;

(ii) The actual average time intervals between order and delivery of circuits (separately indicating average intervals for analog circuits, digital circuits up to 2 megabits, and digital circuits 2 megabits and larger) and telecommunications services; and

(iii) The number of outages and actual average time intervals between fault report and restoration of service for circuits (separately indicating average intervals for analog and for digital circuits) and telecommunications services; but excluding the identities of individual customers of FT, DT, Sprint, or Joint Venture Co. or the location of circuits or telecommunications services dedicated to the use of such customers;

5. By Sprint—Schedules showing:

(i) On a semiannual basis, separately for analog international private line circuits ("IPLCs") and for digital IPLCs jointly provided by FT or DT and Sprint between the United States and France or Germany, the actual average time intervals between order and delivery by FT or DT;

(ii) On an annual basis, separately for analog IPLCs and for digital IPLCs jointly provided by FT and Sprint between the United States and France, and by DT and Sprint between the United States and Germany, the number of outages and actual average time intervals between fault report and restoration of service, for any outages that occurred in the international facility, in the cablehead or earth station outside the United States, indicating separately the number of outages and actual average time intervals to restoration of service in each such area; and

(iii) On a semiannual basis, for circuits used to provide international switched telecommunications services or enhanced telecommunications services on a correspondence basis between the United States and France or Germany, the average number of circuit equivalents available to Sprint and the percentage of calls that failed to complete during the busy hour.

6. By Sprint and Joint Venture Co., within 30 days of receipt, any information from FT or DT relating to a Network Change. For purposes of this Section II.A6, a Network Change is any material change or decision relating to the design of, technical standards used in, or points of interconnection to, the FT or DT public switched telephone networks ("FT/DT PSTNs") that would materially affect the terms or conditions on which Sprint, Joint Venture Co. or any other person are able to have access to, or intercorrect with, the FT/DT PSTNs for telecommunications or enhanced telecommunications services within France or Germany or between the United States and France or the United States and Germany.

7. By Sprint and Joint Venture Co., within 30 days of receipt of any information from FT or DT, or otherwise learning of any discount or more favorable term—Any discounts or favorable terms offered by FT or DT to a customer of FT or DT, for FT or DT Products and Services, that is conditioned on Sprint or Joint Venture Co. being selected as the United States provider of telecommunications products or services for such customer.

The obligations of Section II.A shall not extend to the disclosure of intellectual property or other proprietary information of the defendants, FT or DT that has been maintained as confidential by its owner, except to the extent that it is of a type expressly required to be disclosed herein, or is necessary for United States international telecommunications providers to interconnect with the FT/DT PSTNs, or for United States international telecommunications providers to use FT's or DT's international telecommunication or enhanced telecommunications correspondent services.

Restrictions on Sharing of Information Obtained by FT and DT

B. Sprint and Joint Venture Co. shall not receive or seek to receive from FT or DT, or from any persons designated by FT or DT to sit on the Board of Directors of Sprint:

1. Any information that is identified as proprietary by United States telecommunications or enhanced telecommunications service providers (and maintained as confidential by them) and is obtained by FT or DT from such providers as the results of FT's or DT's provision of interconnection or other telecommunications services to them in France or Germany;

2. Any confidential, non-public information obtained by FT or DT as a result of their correspondent relationships or agreements to connect international half-circuits with other United States international telecommunications or enhanced telecommunications service providers, except to the extent necessary for Sprint to comply with its obligations under Section II.A3(ii) concerning disclosure of the total volume of traffic (but not the individual traffic volumes for other providers) received by FT or DT from the United States and sent by FT or DT to the United States that is subject to the Proportionate Return Commitment, or under Section II.A.5 (but not including individual information on other providers); and

3. Any non-public information about the future prices or pricing plans of any provider of international telecommunications services between the United States and France or the United States and Germany with which Sprint competes in the provision of such services.

Further, Sprint and Joint Venture Co. may not employ any personnel who (i) are at the same time employed by FT or DT and have access to any types of information that Sprint and Joint Venture Co. are not permitted to receive from FT or DT under this Section II.B, or (ii) are employed by the Joint Venture or by Sprint, and have been employed by FT or DT within the preceding six months, and had received within that time any of the types of information that Sprint and Joint Venture Co. are not permitted to receive under this Section II.B.

Ability of Competitors to Obtain Licenses and Authorizations for Entry

C. Sprint and Joint Venture Co. shall not offer (directly or through FT or DT), and shall not provide facilities to FT or DT enabling FT or DT to offer, any particular international telecommunications or enhanced telecommunications service between the United States and France or Germany, unless:

1. Offering such a service between the United States and France does not require a license in France and offering such service between the United States and Germany does not require a license in Germany; or

2. If a class license is required to offer such a service in France or Germany, such a license is in effect for other United States international telecommunications providers not affiliated with FT, DT, Sprint or Joint Venture Co. in France and in Germany; or

3. If an individual license is required in France or Germany to offer such a service, established licensing procedures are in effect as of the time of the offering of the service by which other United States international telecommunications providers are also able to secure such a license, and (i) one or more United States international telecommunications providers other than FT, DT, Sprint or Joint Venture Co. and unaffiliated with FT, DT, Sprint or Joint Venture Co. have secured such a license in France and in Germany, or (ii)

if Sprint or Joint Venture Co. or FT or DT is the first provider to seek a license to offer such a service, other United States international telecommunications providers are also able to secure such a license within a reasonable time and in no event longer than the time it took Sprint, Joint Venture Co., FT or DT to obtain such a license, after having applied for such a license, unless the additional time required is attributable to delay caused by the applicant.

This Section II.C. shall operate separately for France and Germany. It shall not restrict Sprint or Joint Venture Co. from providing existing correspondent services to France or Germany pursuant to bilateral agreements with FT or DT that have also been made available to other United States international telecommunications providers. "License," for purposes of this Section II.C., means any form of authorization, whether or not formally characterized as a license, that must be obtained from a governmental body in order to offer a telecommunications or enhanced telecommunications service.

III

Obligations While Phase I of This Final Judgment Is in Effect Prior to Authorization of Facilities-Based Competition in France and Germany

Scope of Activities of the Joint Venture

A. Joint Venture Co. and Sprint will not acquire an ownership interest in, or control over, (i) any facilities in France or Germany that are legally reserved to FT or DT, or (ii) any international half circuits terminating in France or Germany that are used for telecommunications service between the United States and France or the United States and Germany, except to the extent that, and in no greater than the aggregate quantity that, other providers unaffiliated with FT, DT, Sprint or Joint Venture Co. actually own and control such international half-circuits, or plaintiff and defendants agree that meaningful competition exists to such international half-circuits provided by FT or DT. "Control" for purposes of Section III.A and B shall not include publicly available leases or other publicly available uses of such facilities.

B. Joint Venture Co. and Sprint will not acquire an ownership interest in, or control over, the Public Data Networks.

C. Joint Venture Co. and Sprint may provide FT or DT Products and Services only pursuant to a sales agency or resale agreement, and provided that (i) such agreements are not exclusive, and (ii) other United States international telecommunications providers are able to obtain FT or DT Products and Services directly from FT or DT on a nondiscriminatory basis; provided, however, that such FT or DT Products and Services may be used by Joint Venture Co. and Sprint as inputs to their products and services to end users pursuant to the requirements of this Final Judgment.

Conduct of the Joint Venture and Sprint

D. 1. Sprint and Joint Venture Co. shall not purchase, acquire or accept from FT or DT any FT or DT Products and Services on any discriminatory basis for use in the offer, supply, distribution or other provision by Sprint or Joint Venture Co. of any telecommunications or enhanced telecommunications service in the United States or between the United States and France or the United States and Germany.

For purposes of this Section III.D, "discriminatory basis" shall mean terms more favorable to Sprint or Joint Venture Co. than are made available to other similarly situated United States international telecommunications providers with respect to:

(i) The prices (including but not limited to accounting and settlement rates and division of settlements) of any FT or DT Products and Services, whether or not purchased, acquired or accepted from FT or DT alone or bundled with any other product or service of FT or DT;

(ii) The availability of volume or other discounts, or material differences in non-price terms of service, including offers that while not restricted to Sprint or Joint Venture Co. on their face are available to Sprint or Joint Venture Co. but would not reasonably be available to any United States international telecommunications providers not affiliated with FT or DT, Sprint or Joint Venture Co.;

(iii) Material differences in the type or quality of any FT or DT Products and Services, including but not limited to availability of leased lines and international half-circuits of the same type and capacity (including the average provisioning times, number of outages, and time intervals between fault report and restoration of service), and, for switched services, percentage of circuit equivalents available during the busy hour and percentages of calls blocked;

(iv) Interconnection with the FT/DT PSTNs, including interconnection at no less advantageous points in the network, and comparable availability of numbers to the extent that FT and DT have responsibility for number assignments; and

(v) Terms of operating agreements for correspondent services and connection of international half-circuits.

Persons that are "similarly situated" shall mean United States international telecommunications providers (including their subsidiaries and affiliates) that are generally comparable to Sprint and Joint Venture Co. with respect to the volume or type of FT or DT Products and Services purchased, acquired or accepted from FT and DT, provided that volume and type are relevant distinctions in establishing service conditions. If defendants seek to rebut a claim of discrimination by establishing the existence of a justification of costs, defendants shall have the burden of proof to establish such justification. Defendants shall make available to plaintiff all information that was available to them, whether possessed by them or obtained from FT or DT, in considering the relevance of such distinctions.

2. Sprint and Joint Venture Co. may not benefit from any discount or more favorable term offered by FT or DT to any customer for FT or DT Products or Services, that is conditioned on Sprint or Joint Venture Co. being selected as the United States provider of a telecommunications or enhanced telecommunications service.

E. Sprint shall not accept any correspondent telecommunications traffic from France or Germany, from FT or DT respectively, other than in a manner consistent with their Proportionate Return Commitment and the policies of the Federal Communications Commission concerning proportionate return. Sprint shall not accept or benefit from any alteration in the methodology (including assignment of new services to proportionate return categories) by which FT or DT allocate proportionate return traffic among United States international telecommunications providers with whom they have operating agreements if inconsistent with the policies of the Federal Communications Commission with respect to Sprint, FT, and DT, or the change in methodology has the effect of substantially favoring Sprint with respect to all other United States international telecommunications providers, either in the value of traffic (if types of minutes with different accounting rates are pooled for purposes of calculating proportionate return) or volume. In order to implement these requirements:

1. Sprint and Joint Venture Co. shall disclose on a quarterly basis the volume of correspondent telecommunications

traffic received by Sprint or Joint Venture Co. from France through FT or from Germany through DT, respectively (either in the form of reports received from FT or DT or from its own records, if no such reports are received or Sprint has reason to believe they are not accurate), and the volume of correspondent telecommunications traffic sent by Sprint to FT or DT from the United States (either in the form of its reports to FT or DT or from its own records, if no such reports are made), separately showing the volume of traffic in each accounting rate category, where types of correspondent traffic that have different accounting rates have been pooled for calculation of proportionate return, and also separately showing what volume of correspondent traffic has been counted for purposes of proportionate return and what has been excluded.

2. If plaintiff believes that, in any quarterly period, Sprint has accepted correspondent telecommunications traffic in a manner inconsistent with the Proportionate Return Commitment or the policies of the Federal Communications Commission concerning proportionate return, or has benefited from an alteration of the methodology of proportionate return calculation in its favor, then it shall notify Sprint of such belief and the reasons therefor, and may also bring this notification and the supporting information to the attention of the Federal Communications Commission. Within 90 days after receipt of such notification, Sprint shall respond in writing thereto and take all necessary measures to ensure that its conduct complies with its obligations under Section III.E.

F. In order to ensure that the activities of Joint Venture Co. and Sprint are not subsidized by FT and DT during Phase I of this Final Judgment:

1. Joint Venture Co. shall be established and operated as a distinct entity separate from FT and DT until Phase II takes effect for both France and Germany;

2. Joint Venture Co. and Sprint shall obtain their own debt financing on their own credit, provided that Sprint, FT and DT:

(i) May make capital contributions or commercially reasonable loans to Joint Venture Co. as required to enable Joint Venture Co. to conduct the venture business;

(ii) May pledge their venture interests in Joint Venture Co. in connection with nonrecourse financings for Joint Venture Co.; and

(iii) May guarantee any indebtedness of Joint Venture Co., provided that Sprint, FT and DT may only make payments pursuant to any such guarantee following a default by Joint Venture Co. in respect of such indebtedness;

3. Joint Venture Co. and Sprint shall maintain accounting systems and records separate from FT and DT, that identify, individually, payments or transfers to or from FT and DT relating to the purchase, acquisition or acceptance of any FT or DT Products and Services, and the Joint Venture services for which such FT or DT Products or Services are used. Such accounting systems and records of Joint Venture Co. will be made available pursuant to the visitorial provisions of Section VI;

4. Joint Venture Co. and Sprint may not allocate directly or indirectly any part of their operating expenses, costs, depreciation, or other expenses of their businesses to any parts of FT or DT's business units responsible for FT or DT Products and Services (including without limitation the proportionate costs based on work actually performed that are attributable to shared employees or sales or marketing of Sprint or Joint Venture Co. products and services by FT or DT employees), provided, however, that nothing herein shall prevent Sprint and Joint Venture Co. from charging FT and DT for products and services provided to them by Sprint or Joint Venture Co., on the basis of prices charged to third parties (in the case of products or services sold to third parties in commercial quantities) or full cost reimbursement or other arm's length pricing method (in the case of products and services not sold to third parties in commercial quantities); and

5. Joint Venture Co. and Sprint will not receive any material subsidy (including forgiveness of debt) directly or indirectly from FT or DT, or any investment or payment from FT or DT that is not recorded in the books of Joint Venture Co. or Sprint as an investment in debt or equity.

G. 1. Sprint may not offer, supply, distribute or otherwise provide any correspondent telecommunications or correspondent enhanced telecommunications service between the United States and France or Germany pursuant to any operating agreement with FT or DT, unless with respect to such service, at least one other United States international telecommunications provider has also obtained an operating agreement with FT and DT for the provision of such service between the United States and France and Germany. This provision will operate separately for France and for Germany.

2. If a licensed United States international telecommunications provider has requested but has not received an operating agreement with FT or DT for the provision of IDDD voice service or any other services that make use of the FT/DT PSTNs, then Sprint shall offer to carry the correspondent traffic of such United States international telecommunications provider between the United States and the countries for which an operating agreement has been requested, France or Germany, at rates and on terms and conditions that are commercially competitive to those on which other United States international telecommunications providers that have operating agreements are able to provide service, and at rate schedules to be updated on at least an annual basis (and filed with the FCC, as required) which reflect the estimated value of any adjustments in proportionate return traffic that may be received by Sprint from France or from Germany as a result of the traffic originated by United States international telecommunications providers whose traffic is being carried over Sprint's facilities.

H. Sprint or Joint Venture Co. shall not offer, supply, distribute, or otherwise provide in the United States any telecommunications or enhanced telecommunications service that makes use of FT or DT Products and Services, if, with respect to such FT or DT Products and Services, (1) FT or DT have established any proprietary or nonstandardized interface or protocol used by Sprint and Joint Venture Co. to obtain access to such products or services, and (2) FT or DT no longer continue to provide on a basis consistent with previous operations, a non-proprietary or standardized interface or protocol used to obtain access to such FT or DT Products or Services.

I. Sprint or Joint Venture Co. shall not offer, supply, distribute, or otherwise provide in the United States any data telecommunications or enhanced telecommunications service that makes use of the Public Data Networks to complete data telecommunications in France or Germany, unless the Public Data Networks that are based on the X.25 or any other protocol, continue to be available to all other United States international telecommunications providers on nondiscriminatory terms to complete data telecommunications between the United States and France and between the United States and Germany, and within France and Germany for traffic originating within the United States, France or Germany, using the X.75 standard protocol for

interconnection between data networks, or any generally accepted standard network interconnecton protocol that may modify or replace the X.75 standard. If these requirements are met, Joint Venture Co. and Sprint may also offer data telecommunications services other than those based on the X.25/X.75 protocols using the Public Data Networks.

IV

Applicability and Effect

The provisions of this Final Judgment shall be binding upon defendants, their affiliates, subsidiaries, successors and assigns (except for any Sprint business that is subsequently spun-off or otherwise divested and in which neither FT nor DT have any ownership interest), officers, agents, servants, employees and attorneys. Defendants shall cooperate with the United States Department of Justice in ensuring that the provisions of this Final Judgment are carried out. Neither this Final Judgment nor any of its terms or provisions shall constitute any evidence against, an admission by, or an estoppel against the defendants. The effective date of this Final Judgment shall be the date upon which it is entered.

V

Definitions

For the purposes of this Final Judgment:

A. "Affiliate" and "subsidiary" means any entity in which a person has equity ownership, or managerial or operational control, directly or indirectly through one or more intermediaries, *provided that* these terms, when used in connection with Sprint do not include Joint Venture Co., Atlas, FT or DT; when used in connection with FT do not include Joint Venture Co., Sprint or DT but do include Atlas; when used in connection with DT do not include Joint Venture Co., Sprint, or FT but do include Atlas; and when used in connection with Joint Venture Co. do not include Sprint, Atlas, FT or DT (but do include all entities which Joint Venture Co. controls, or which are jointly controlled by Sprint, FT and DT). Atlas, FT and DT shall not be deemed to be persons in active concert or participation with Joint Venture Co. or Sprint for purposes of this Final Judgment. Affiliates and subsidiaries of Sprint and Joint Venture Co. that are not controlled by Sprint or Joint Venture Co. do not have substantive compliance obligations under Sections II and III of this Final Judgment.

B. "Atlas" means a joint venture identified in an agreement entered into between FT and DT on December 15, 1994, as amended, formed, or to be formed, by FT and DT to provide certain telecommunications services in Europe, regardless of the name that entity may subsequently have, or the percentages of ownership of FT or DT or the services or geographic areas in which that joint venture may operate, and any subsidiary, affiliate, predecessor, successor or assign of that joint venture, or any other entity jointly owned by FT and DT and having substantially similar purposes.

C. "Control" means, with respect to any entity's relationship to another entity, any of the following, unless another standard of control is specified in a provision of this Final Judgment:

(1) ownership, directly or indirectly, by such entity of equity or other ownership interest entitling it to exercise in the aggregate 50% or more of the voting power of the entity in question;

(2) the possession by such entity of the power, directly or indirectly, to elect 50% or more of the board of directors (or equivalent governing body) of the entity in question;

(3) the ability to direct or cause the direction of the management, operations, or policies of the entity in question, provided, however, that any party's obligations under the Joint Venture Agreement in the form entered into on June 22, 1995 (exclusive of any subsequent amendments) shall not constitute control under Section V.C. Where more than one entity exercises joint control over an entity, each shall be deemed to have control.

D. "Correspondent" means a bilaterally negotiated arrangement between a provider of telecommunications services in the United States and a provider of telecommunications services in France, or between a provider of telecommunications services in the United States and a provider of telecommunications services in Germany, by which each party undertakes to terminate in its country through its public switched network or its public data network traffic originated by the other party, for provision of an international telecommunications or such enhanced telecommunications service. A service managed by Joint Venture Co., and provided without correspondent relationships with any other provider, shall not be deemed to constitute a correspondent service.

E. "Defendant" or "defendants" means Sprint and Joint Venture Co.

F. "Disclose," for purposes of Section II.A.1–7 and III.E, means disclosure to the United States Department of Justice Antitrust Division, which may further disclose such information to any United States international telecommunications provider that directly or through a subsidiary or affiliate (i) holds or has applied for a license from either the United States Federal Communications Commission or the French Direction Générale des Postes et Télécommunications ("DGPT"), or successors in responsibility to such agencies, to provide international telecommunications or enhanced telecommunications services between the United States and France, or actually provides telecommunications or enhanced telecommunications services between the United States and France, for services where no license is required, or (ii) holds or has applied for a license from either the United States Federal Communications Commission or the German Bundesministerium für Post und Telekommunication ("BMPT"), or successors in responsibility to such agencies, to provide international telecommunications services or enhanced telecommunications services between the United States and Germany, or actually provides telecommunications or enhanced telecommunications services between the United States and Germany, for services where no license is required. Disclosure by the Department of Justice to any provider described above shall be made only upon agreement by such provider, in the form prescribed in the Stipulation entered into by defendants and the United States on July 13, 1995, not to disclose any non-public information to any other person, apart from governmental authorities in the United States, France or Germany. Where Joint Venture Co. is required to disclose in Section II.A particular telecommunications services provided, this shall include disclosure of the identify of each of the services, and reasonable detail about each of the services to the extent not already published elsewhere, but shall not require disclosure of underlying facilities used to provide a particular service that is offered on a unitary basis, except to the extent necessary to identify the service and the means of interconnection with the service.

G. "DT" means Deutsche Telekom A.G., and any entity controlled by DT, provided that DT does not include Joint Venture Co., FT, or Sprint, but does include Atlas.

H. "Enhanced telecommunications service" means any telecommunications service that involves as an integral part of the service the provision of features or capabilities that are additional to the

conveyance (including switching) of the information transmitted. Although enhanced telecommunications services use telecommunications services for conveyance, their additional features or capabilities do not lose their enhanced status as a result.

I. "Facility" means: (i) Any line, trunk, wire, cable, tube, pipe, satellite, earth station, antenna or other means that is directly used or designed or adapted for use in the conveyance, transmission, origination or reception of a telecommunications or enhanced telecommunications service; (ii) any switch, multiplexer or other equipment or apparatus that is directly used or designed or adapted for use in connection with the conveyance, transmission, origination, reception, switching, signaling, modulation, amplification, routing, collection, storage, forwarding, transformation, translation, conversion, delivery or other provision of any telecommunications or enhanced telecommunications service, and (iii) any structure, conduit, pole, or other thing in, on, by or from which any facility as described in (i) or (ii) is or may be installed, supported, carried or suspended.

J. "France" means the Republic of France, excluding its overseas departments and territories for which traffic is reported separately to the Federal Communications Commission.

K. "FT" means France Télécom, and any entity controlled by FT, provided that FT does not include Joint Venture Co., DT, or Sprint, but does include Atlas and Transpac.

L. "FT or DT Products and Services" shall mean any of the following telecommunications or enhanced telecommunications services or facilities in France or Germany, or between the United States and France or the United States and Germany, provided by FT or DT, regardless of whether such services or facilities are considered to be reserved exclusively to FT or DT under the national law of France or Germany:

(i) Correspondent services (but not including enhanced telecommunications services provided by Atlas, unless Atlas is acting as a reseller or sales agent of such services or the services involve interconnection to the Public Data Networks);

(ii) Dedicated or switched transit services;

(iii) Leased lines or international half circuits between the United States and France or between the United States and Germany (including leased lines or international half circuits that may be provided with additional quality, provisioning or maintenance guarantees or alternate routing features), unless plaintiff and defendants agree that meaningful competition exists to such leased lines or international half-circuits provided by DT or FT; or

(iv) Interconnection to the FT/DT PSTNs, including access to customers using ISDN services.

M. "Germany" means the Federal Republic of Germany.

N. "Interconnection," "interconnect" and "interconnection agreement" mean interconnection under the FT Schedule of Obligations ("Cahier des Charges") (or any subsequent or other condition governing interconnection with FT that may be imposed by government authorities in France), and under the Telecommunications Installation Act ("Fernmeldeanlagengesetz") (or any subsequent or other condition governing interconnection with DT that may be imposed by government authorities in Germany), or access to the FT or DT public switched telephone networks that may be obtained outside the terms of such legal obligations.

O. "Joint Venture Co." means the entities referred to in the Joint Venture Agreement entered into by Sprint, FT and DT on June 22, 1995, as the GBN Parent Entity, the ROW Parent Entity, and the ROE Parent Entity (including the governing boards or bodies of such entities) to be formed in accordance with Sections 4.2, 5.2 and 6.2 of the Joint Venture Agreement, and each other entity to be formed pursuant to the terms of the Joint Venture Agreement (including the Global Venture Board, Global Venture Committee and Global Venture Office to be formed in accordance with Section 3.1–3.10 of the Joint Venture Agreement), regardless of the name under which these entities may subsequently do business, or any other entity jointly owned by Sprint, FT and DT and having among its purposes substantially the same purposes as described for the Joint Venture or any of these entities in the Joint Venture Agreement, and any predecessor (whether the predecessor is jointly owned by Sprint, FT and DT or separately owned by any one of them and any one of them formed to conduct the Joint Venture Co. business), successor, or assign of such entities, or any entity controlled by any of these entities. Atlas, FT, DT and Sprint shall not be deemed to be a Joint Venture Co. The individual members of the Global Venture Board, Global Venture Committee and Global Venture Office, are not personally defendants, but are responsible in their official capacities as members of such entities for ensuring compliance of Joint Venture Co. with this Final Judgment, and responding to requests for documents and information under Section VI, in the same manner as any officer of a defendant.

P. "Phase I" means that period of time after the entry of this Final Judgment and before the conditions in Phase II have been met.

Q. "Phase II" means that time that begins when the national governments of France and Germany have:

(1) Removed all of the legal prohibitions on provision of the following services and facilities by entities other than FT and DT and their subsidiaries and affiliates—

(i) The construction, ownership or control of both domestic and international telecommunications facilities, and use of such facilities to provide any telecommunications or enhanced telecommunications services, and

(ii) The provision of public switched domestic and international voice services; and

(2) Issued one or more licenses or other necessary authorizations, to entities other than FT, DT, Sprint or Joint Venture Co. and unaffiliated with FT, DT, Sprint or Joint Venture Co., for—

(i) The construction or ownership, and control, of both (a) domestic telecommunications facilities to serve territory in which one-half or more of the national populations of France and Germany reside, and (b) international telecommunications facilities capable of being used to provide a competitive facilities-based alternative, directly or indirectly, between France and Germany and the United States, and

(ii) The provision of public switched domestic long distance voice services, without any limitation on geographic scope or types of services offered, and international voice service between the United States and France and Germany.

Unless otherwise noted in this Final Judgment, Phase II applies separately to France and Germany, and shall commence with respect to services and facilities between the United States and a country when the conditions are met for that country, even if they are not met in the other country.

R. "Proportionate Return Commitment" means the commitment of each of FT and DT to transmit correspondent voice telecommunications services traffic to the United States, to licensed U.S. international telecommunications carriers holding operating agreements for such services with FT and DT, in the same proportions as the correspondent voice telecommunications traffic from

the United States to France or Germany that FT and DT, respectively, receive from such U.S. carriers. If the Federal Communications Commission adopts proportionate return policies that are made specifically applicable to the relationship between Sprint, FT and DT and that conflict with this Proportionate Return Commitment, the Proportionate Return Commitment shall be modified to be consistent with such policies.

S. "Public Data Network" means either or both of the public data network operated by Transpac in France and the public data network in Germany operated under the "Datex" designation (Datex-P, Datex-J, and the Datex-L service) as of the signing of the Stipulation to enter this Final Judgment, whether such networks are held by FT, DT, Atlas, or any subsidiary or affiliate of FT or DT now or in the future.

T. "Sprint" means Sprint Corporation, and any entity controlled by Sprint. Sprint does not include Joint Venture Co., Atlas, FT, or DT, or any FT or DT employees who may serve on Sprint's Board of Directors.

U. "Telecommunications service" means the conveyance, by electrical, magnetic, electromagnetic, electromechanical or electrochemical means (including fiber-optics), of information consisting of:

—Speech, music and other sounds;
—Visual images;
—Signals serving for the impartation (whether as between persons and persons, things and things or persons and things) of any matter, including but not limited to data, otherwise than in the form of sounds or visual images;
—Signals serving for the actuation or control of machinery or apparatus; or
—Translation or conversion that does not alter the form or content of information as received from that which is originally sent.

For these purposes "convey" and "conveyance" include transmission, switching, and receiving, and cognate expressions shall be construed accordingly. A telecommunications service includes all facilities used in providing such service, and the installation, maintenance, repair, adjustment, replacement and removal of any such facilities. A service that is considered a "telecommunications service" under this definition retains that status when it is used to provide an enhanced telecommunications service, or when used in combination with equipment, facilities or other services.

V. "United States" means the fifty states, the District of Columbia, and all territories, dependencies, or possessions of the United States.

W. "United States international telecommunications providers" means any person or entity actually providing international telecommunications services or enhanced telecommunications services to providers or users in the United States, and that is incorporated in the United States, or that is ultimately controlled by United States persons within the meaning of 16 C.F.R. 801.1., including its subsidiaries and affiliates, or any provider of telecommunications services with which such a United States international telecommunications provider is affiliated. For purposes of this definition, an affiliate shall mean any entity in which a person or entity has a direct or indirect equity interest or whose equity is owned directly or indirectly by a person or entity in the amount of 10% or more.

VI

Visitorial and Compliance Provisions

A. Sprint and Joint Venture Co. each agree to maintain sufficient records and documents to demonstrate compliance with the requirements of this Final Judgment.

B. For the purposes of determining or securing compliance of defendants with this Final Judgment, duly authorized representatives of the plaintiff, upon written request of the Attorney General or the Assistant Attorney General in charge of the Antitrust Division, and on reasonable notice to the relevant defendant, shall have access without restraint or interference to Sprint and to Joint Venture Co. in the United States:

1. during their office hours to inspect and copy all records and documents in their possession or control relating to any matters contained in this Final Judgment; and

2. to interview or take sworn testimony from their officers, directors, employees, trustees, or agents, who may have counsel present, relating to any matter contained in this Final Judgment; provided, however, that Joint Venture Co. officers who are or were employees of FT or DT shall be required to produce information only concerning Joint Venture Co., and that Joint Venture Co. or Sprint directors who are or were employees of FT or DT shall be required to produce only Joint Venture Co. and Sprint documents and to provide information only concerning Joint Venture Co. and Sprint.

C. Joint Venture Co. consents to make available to duly authorized representatives of the plaintiff, for the purposes of determining whether defendants have complied with the requirements of this Final Judgment and to secure their compliance:

1. at the premises of the Antitrust Division in Washington, D.C., within sixty days of receipt of written request by the Attorney General or Assistant Attorney General in charge of the Antitrust Division, records and documents in the possession or control of Joint Venture Co.; and

2. for interviews or sworn testimony, in the United States if requested by plaintiff but subject to their reasonable convenience, officers, directors, employees, trustees or agents, who may have counsel present;

provided, however, that Joint Venture Co. officers who are or were employees of FT or DT shall be required to produce information only concerning Joint Venture Co., and Joint Venture Co. directors who are or were employees of FT or DT shall be required to produce only Joint Venture Co. documents and to provide information only concerning Joint Venture Co.

D. Upon the written request of the Attorney General or the Assistant Attorney General in charge of the Antitrust Division, a defendant shall submit written reports, under oath if requested, relating to any of the matters contained in this decree.

E. No information or documents obtained by the means provided in this Section VI shall be divulged by the plaintiff to any person other than the United States Department of Justice, the Federal Communications Commission, and their employees, agents and contractors, except in the course of legal proceedings to which the United States is a party, or for the purpose of securing compliance with this decree, or for identifying to the DGPT or other appropriate French regulatory agencies conduct by defendants or FT that may violate French law or regulations or FT's license to operate its French public telecommunications system (but no documents received from defendants pursuant to this Section VI shall be disclosed to French authorities by the Department of Justice), or for identifying to the BMPT or other appropriate German regulatory agencies conduct by defendants or DT that may violate German law or regulations or DT's license to operate its German public telecommunications system (but no documents received from defendants pursuant to this Section VI shall be disclosed to German authorities by the Department of Justice), or as otherwise required by law. Prior to divulging any documents, interviews or sworn testimony obtained pursuant to this Section VI to the Federal Communications Commission, or any French or German regulatory agencies, plaintiff will obtain assurances that such materials are protected from

disclosure to third parties to the extent permitted by law.

VII

Retention of Jurisdiction

Jurisdiction is retained by this Court for the purposes of enabling any of the parties to this Final Judgment to apply to this Court at any time for such further orders or directions as may be necessary or appropriate to carry out or construe this decree, to modify or terminate any of its provisions, to enforce compliance, and to punish any violations of its provisions.

VIII

Modification

A. Any party to this Final Judgment may seek modification of its substantive terms and obligations and other parties to the Final Judgment shall have an opportunity to respond to such a motion. If the motion is contested by another party, it shall only be granted if the movant makes a clear showing that (i) a significant change in circumstances or significant new event subsequent to the entry of the Final Judgment requires modification of the Final Judgment to avoid substantial harm to competition or consumers in the United States, or to avoid substantial hardship to defendants, and (ii) the proposed modification is (a) in the public interest, (b) suitably tailored to the changed circumstances or new events and would not result in serious hardship to any defendant, and (c) consistent with the purposes of the antitrust laws of the United States and with the telecommunications regulatory regimes of the United States, France and Germany. If a motion to modify this Final Judgment is not contested by any party, it shall be granted if the proposed modification is within the reaches of the public interest.

B. Neither the absence of specific reference to a particular event in the Final Judgment nor the foreseeability of such an event at the time this Final Judgment was entered, shall preclude this Court's consideration of any modification request. This standard for obtaining contested modifications shall not require the United States to initiate a separate antitrust action before seeking modifications. The same standard shall apply to any party seeking modification of this Final Judgment. Where modifications of the Final Judgment are sought, the provisions of Section VI of this Final Judgment may be invoked to obtain any information or documents needed to evaluate the proposed modification prior to decision by the Court.

C. In addition to VIII.A and VIII.B, it is not the intent of the parties that Sprint should be competitively disadvantaged in such a way as to harm competition. If defendants believe that changed circumstances have caused any terms of the Final Judgment to operate in a way that is harmful to competition, they may present to plaintiff the reasons therefore and any supporting evidence, and if plaintiff in its sole discretion agrees that modification of the Final Judgment is appropriate, a request for modification shall be presented to the Court.

IX

Sanctions

Nothing in this Final Judgment shall prevent the United States from seeking, or this Court from imposing, against defendants or any other person, any relief available under any applicable provision of law.

X

Further Provisions

A. The entry of this Final Judgment is in the public interest.

B. The substantive restrictions and obligations of this Final Judgment shall be removed five years from the date that Phase II of this Final Judgment has taken effect with respect to both France and Germany, unless this Final Judgment has been previously terminated. The substantive obligations of Section III of this Final Judgment shall be removed on the date that Phase I of this Final Judgment ends, separately with respect to France and with respect to Germany, unless otherwise specified in this Final Judgment.

Dated:

United States District Judge

In the matter of United States of America, Plaintiff, v. Sprint Corporation and Joint Venture Co., Defendants.

[Civil Action No. 95 CV 1304]

Filed: July 13, 1995.

Competitive Impact Statement

The United States, pursuant to section 2(b) of the Antitrust Procedures and Penalties Act ("APPA" or "Tunney Act"), 15 U.S.C. 16 (b)–(h), files this Competitive Impact Statement relating to the proposed Final Judgment submitted for entry in this civil antitrust proceeding.

I

Nature and Purpose of the Proceeding

On July 13, 1995, the United States filed a civil antitrust complaint under Section 15 of the Clayton Act, as amended, 15 U.S.C. 25, alleging that the proposed acquisition of a total of 20% of the stock of Sprint Corporation ("Sprint") by France Télécom ("FT") and Deutsche Telekom A.G. ("DT"), and the proposed formation of a joint venture between Sprint, FT and DT to provide international telecommunications services, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, by lessening competition in the markets for international telecommunications services between the United States and France and Germany, and for seamless international telecommunications services, thereby depriving United States consumers of the benefits of competition—lower prices and higher quality services. Defendants are Sprint and Joint Venture Co., a term collectively designating the entities which will become the joint venture of Sprint, FT and DT upon consummation of the agreements between them. The Complaint seeks injunctive and other relief.

The United States and Sprint have stipulated to the entry of a proposed Final Judgment, after compliance with the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h). Joint Venture Co. will also enter into this stipulation once it has been formed and satisfied other preconditions stated in the stipulation. Entry of the proposed Final Judgment would terminate this action, except that the Court would retain jurisdiction to construe, modify, and enforce the proposed Final Judgment and to punish violations of the Judgment. The United States and Sprint have stipulated, and Joint Venture Co. will also stipulate, that the defendants will abide by the terms of the proposed Final Judgment after consummation of the transactions between them, pending entry of the Final Judgment by the Court, permitting the transactions to go forward prior to completion of the Tunney Act procedures. Should the Court decline to enter the Final Judgment, Sprint has also committed in the stipulation, and Joint Venture Co. will commit, to abide by the terms of the Final Judgment until the conclusion of this action.

II

Events Giving Rise to the Alleged Violation

A. The Proposed Transactions

On June 22, 1995, Sprint, FT and DT entered into a Joint Venture Agreement, providing for the formation of an international joint venture to provide various types of international telecommunications and enhanced

telecommunications services. In addition, FT and DT entered into an Investment Agreement with Sprint on July 31, 1995, entitling FT and DT to acquire a total of up tr 20% of the voting equity in Sprint for a variable price that could be as high as approximately $4.2 billion. As a result of the acquisition of Sprint's equity, FT and DT would also acquire special shareholder rights, including the right to appoint directors to a number of seats on Sprint's Board of Directors in proportion to their ownership interest (a 20% investment would give FT and DT three of the fifteen seats on Sprint's Board of Directors), with a minimum of two directors. These agreements finalize transactions that have been contemplated since June 1994, when Sprint, FT and DT entered into a Memorandum of Understanding concerning the creation of the joint venture and the acquisition of equity in Sprint.

Consummation of the Joint Venture Agreement between Sprint, FT and DT will establish Joint Venture Co., a group of related entities that will engage in the joint venture business, including the offering of (i) international data, voice and video business services for multinational corporations and business customers, (ii) international consumer services based on card services for travelers and (iii) carrier's carrier services including transport services for other carriers. In forming the joint venture, each of the parties will contribute most of their existing operations outside their respective home countries to Joint Venture Co., and will make capital contributions, for a total value of approximately $1 billion. FT and DT intend to hold and manage their interests in Joint Venture Co. together through their own joint venture, known as Atlas, which when formed will be owned 50% by DT and 50% by FT. Sprint, DT, and FT will have equal representation on Joint Venture Co.'s Global Venture Board, which will determine the strategic direction and oversee operations of Joint Venture Co. The international telecommunications facilities of Joint Venture Co., including switches, other transmission equipment, computer hardware and software, and leased lines, will form an international "backbone" network used to carry the joint venture's services. This backbone network will be owned 50% by Sprint and 50% by DT and FT through Atlas. The Joint Venture Co. entity responsible for worldwide activities outside the United States and Europe (the "Rest of World" or "ROW" entity) will have the same 50–50 ownership structure as the backbone network. The Joint Venture Co. entity responsible for activities in Europe but outside of France and Germany (the "Rest of Europe" or "ROE" entity), however, will be owned 33⅓% by Sprint and 66⅔% by DT and FT through Atlas.

Sprint will have the exclusive right to provide Joint Venture Co. services in the United States, its home country, and FT and DT are to refrain from competing with Sprint in the United States in the joint venture's services and certain other telecommunications services. Similarly, Sprint is to refrain from competing with FT and DT in their home countries, France and Germany. Moreover, none of the owners of Joint Venture Co. will compete with Joint Venture Co. Therefore, FT's and DT's direct participation in the areas of business in which Joint Venture Co. is engaged will be limited to their ownership interests in the joint venture entities and sales of the joint venture services, and they generally will only be able to participate directly in United States telecommunications markets through their ownership interests in Sprint.

B. The Parties to the Transaction and the Relevant Markets

1. The Parties

This transaction is a strategic alliance between three of the largest telecommunications carriers in the world, creating vertical affiliation between a major U.S. long distance carrier and two of the largest foreign telecommunications monopolies. Together, DT, FT and Sprint had approximately $85 billion in revenues in 1994, considerably more than AT&T Corporation ("AT&T"), the largest carrier worldwide,[1] and more than twice as much as the total revenues of British Telecommunications plc ("BT") and MCI Communications Corporation ("MCI"), the partners in the Concert strategic alliance consummated in 1994.[2] The United States, where Sprint's principal network is located, is by far the most important location for multinational customers of telecommunications services in the world. The home countries of the other two partners, France and Germany, are also key locations for multinational customers, matched in significance by only a handful of other countries.[3] To illustrate, more multinational companies have their headquarters located in either France or Germany, in combination, than in any single country other than the United States or the United Kingdom. FT and DT are the government-owned dominant telecommunications carriers in their home countries, where they have monopolies over public switched voice services and transmission infrastructure, representing more than 75% of all telecommunications revenues, and market power in other key services such as public data networks.

Sprint is one of the three principal domestic long distance and international telecommunications carriers in the United States. It provides long distance telecommunications and enhanced telecommunications products and services in the United States and international telecommunications and enhanced telecommunications products and services between the U.S. and other nations, including France and Germany. Sprint's 1994 revenues were more than $12.6 billion, about half of which came from domestic and international long distance services. Sprint's principal long distance domestic and international competitors in the United States are AT&T, the largest carrier, and MCI, the second largest carrier. These three carriers provide over 80% of domestic long distance service in the United States and almost all international voice telecommunications services originating in the United States; Sprint's market share in both domestic and international U.S. voice traffic is about 10%. Sprint, MCI and AT&T are also among the most important providers of international enhanced telecommunications services and data services in the United States, directly or through subsidiaries and affiliates (such

[1] A large part of the revenues of AT&T do not even come from telecommunications services markets, but from equipment manufacturing and other businesses. Thus, the eggregete competitive significence of the parties to this alliance, all of which derive the great bulk of their revenues from telecommunicetions services markets, is even larger relative to AT&T elone than a comparison of total revenues would suggest.

[2] In June 1994, the United States filed a suit and entered into e proposed consent decree with MCI end the joint venture being established by BT and MCI to provide international telecommunicetions and enhanced telecommunications services, now called Concert. The decree was epproved by this Court in September 1994.

[3] Only the United States, the United Kingdom and Japan surpess Germeny or France in numbers of headquarters of multinational corporations, though several other countries, including Switzerland, Sweden, Canada, the Netherlands, and Australia, elso have e substantiel number of multinational heedquarters. Only in the United Stetes and the United Kingdom heve more multinationel companies located their operetions than in Germany or France, though there are e number of other countries, including Japan, Caneda, the Netherlands, Austrelie, Switzerland, Italy, Belgium, and Spain, where many multinationel compenies have located their operations. The countries identified here are not the only ones where multinational corporations heve a significant presence.

as the Concert joint venture between MCI and BT). Sprint is one of the largest providers of domestic and international data telecommunications services in the United States. For these types of services, Sprint's market share is generally much larger than its share of voice services. Indeed, for some data services Sprint is larger than any of the other U.S. international carriers in terms of revenues.[4]

FT is owned by the government of France, and is the fourth largest provider of telecommunications services in the world. Its consolidated annual revenues in 1994 were 142.6 billion FF (approximately $28.5 billion) and its net income for 1994 was 9.9 billion FF (approximately $2.1 billion). FT provides local, long distance, and enhanced telecommunications services in France, and international and enhanced telecommunications services between France and other countries, including the U.S. and Germany. FT owns and operates the French public switched network, with about 32 million telephone access lines in service. FT is the state authorized monopoly provider of all public switched voice service, as well as all transmission facilities for domestic and international telecommunications in France. FT also has market power in the provision of public data network services in France, even though that area has been legally opened to competition since 1993.

DT is the second or third largest telecommunications company in the world, and Europe's largest telecommunications carrier. Its 1994 revenues were 61.2 billion DM (approximately $44 billion). DT provides local, long distance, and enhanced telecommunications services in Germany, as well as international and enhanced telecommunications services between Germany and other countries, including the U.S. and France. Pursuant to a German telecommunications law enacted in 1994, DT became a private corporation on January 1, 1995, but the German government remains DT's sole shareholder. Sale of DT's shares to the public will not begin until sometime in 1996, and the German government is expected to hold a majority of DT's shares through 1999. DT owns and operates the German public switched network, with more than 37 million telephone access lines in service, and 87,000 kilometers of fiber optic lines installed, representing over a third of its total network. DT is the state authorized monopoly provider of all public switched voice service, as well as all transmission facilities for domestic and international telecommunications in Germany. DT also has market power in the provision of public data network services in Germany, even though this area of business has been legally opened to competition since 1990.

[4] International data services are also offered by some companies that are not voice carriers, such as Infonet Services Corporation.

2. The Product and Geographic Markets

Broadly speaking, there are two types of markets of concern under the antitrust laws of the United States that are affected by the vertical relationships created in this transaction: the markets for international telecommunications services (including enhanced telecommunications services) between the United States and France and the United States and Germany, and the emerging markets for seamless international telecommunications (including enhanced telecommunications) services.[5] These broad markets may further encompass multiple distinct product markets. The various types of data telecommunications services, for example, are distinct from voice services in important respects, from the perspective of both consumers and service providers. For purposes of analyzing the vertical effects of this transaction, however, it is not necessary to distinguish between individual telecommunication services, since the monopoly power of DT and FT affects all of the possible markets at issue.

US-France and US-Germany international telecommunications services are used by individuals and companies in the US to exchange voice, data and video messages with individuals and companies in France and Germany. These services typically are provided on a correspondent basis, meaning that telecommunications providers in different countries agree to interconnect their facilities and services in order to permit international traffic to be completed.[6] Correspondent relationships are established between international telecommunications carriers by entering into commercially negotiated operating agreements, and separate operating agreements often exist for distinct types of services and facilities. According to Federal Communications Commission data for 1993, the most recent year available, all U.S. international carriers received $600,869,527 in total revenues from traffic to Germany billed in the United States, and $261,896,962 in total revenues from traffic to France billed in the United States, for the standard type of switched voice telephone service provided under the correspondent system.[7] France and Germany are among the most important destinations for U.S. international switched voice traffic, and in 1993 France and Germany in combination accounted for over 13% of total international billed revenues of all U.S. international carriers for switched voice service, a share surpassed only by Canada and Mexico.[8] No close substitute exists for international telecommunications and enhanced telecommunications services between the U.S. and France or the U.S. and Germany. In order to compete effectively in providing international telecommunications services between the U.S. and France and the U.S. and Germany, U.S. providers must have nondiscriminatory access to FT's and DT's facilities and services in France and Germany to terminate traffic from the U.S., and to receive traffic from France and Germany.

Seamless international telecommunications services are an

[5] Other markets not within the scope of U.S. antitrust review, including markets for various types of telecommunications and enhanced telecommunications services in Europe, are also effected by this transaction. Issues involving those markets are being considered separetely by the competition authorities of the European Union in e pending investigetion.

[6] Internetional correspondent telecommunications services primarily consist of the basic switched voice telephone call (which is known either es Internationel Direct Diel ("IDDD") or Internationel Message Telephone Service ("IMTS")), and Internetional Private Line Service ("IPLS"). They also include certain other switched telecommunications and enhanced telecommunications services.

"Switched" traffic mekes use of switching facilities and common lines. Consumers typically obtain switched correspondent services from the provider in the country where a call originates, and calls are handed off to the provider in the other country without direct customer involvement. IPLS consists of circuits dedicated to the use of e single customer, end the providers of IPLS in eech country typically sell their "half" of the circuit to the user separetely. Switched services constitute the great majority of international telecommunications services in terms of both treffic and revenues.

[7] Federal Communications Commission, Common Carrier Bureau, Industry Analysis Division, 1993 Section 43.61 Internetionel Telecommunicetions Dete, International Treffic Date for All U.S. Points, Teble A1 (Nov. 1994) (hereinafter 1993 Internetionel Telecommunications Data). The revenue retained by U.S. international carriers from amounts billed to customers is greatly reduced, in the case of France and Germany by nearly half, due to peyouts to the foreign carriers for delivering treffic, but et the same time revenues of U.S. carriers are eugmented by peyments from the foreign carriers for delivering traffic that is billed in the foreign countries. In the case of Germany, amounts paid out by ell U.S. carriers for IMTS service to DT were $263,923,146, and amounts received from DT were $119,430,422, in 1993. For France, amounts paid out by all U.S. carriers for IMTS service to FT were $105,449,969, end amounts received from FT were $76,536,312, in 1993. *Id.*

[8] *Id.*

emerging area of international telecommunications, developing in response to the limitations of the traditional correspondent system, over which the great majority of international telecommunications traffic is still carried. Seamless services represent an important market for the evolution of international telecommunications. Seamless international telecommunications services would be made available by a single provider using an integrated international network of owned or leased facilities, and would have the same quality, features, characteristics, and capabilities wherever they are provided, making them significantly superior to ordinary correspondent telecommunications services for many customers, particularly multinational corporations and other large users of international telecommunications. These services could overcome many of the inadequacies and differences in standards that now exist in various national telecommunications systems, and they could offer scale economies by comparison with private networks individually organized by users.

Some types of international telecommunications services, such as data services, already are being offered between some countries in a seamless fashion, as well as through the correspondent system. However, creating seamless international networks that reach a large number of countries with a wide range of services will require a major commitment of resources and expertise that few firms can supply. While the providers of seamless services aim eventually to have a global reach, today there remain many differences between particular countries affecting both the legality and the technical feasibility of offering seamless services. Other participants in this market include the Concert alliance of BT and MCI, and AT&T's international partnerships, including Worldpartners (a non-exclusive partnership with several foreign providers including Japan's KDD) and Uniworld (an alliance with the national or principal telecommunications providers in Switzerland, Sweden, Spain and the Netherlands). Though the BT–MCI alliance and AT&T's partnerships share a general interest in the emerging market for seamless international telecommunications services, these other transactions are structured in somewhat different ways and vary in their degrees of exclusivity and investment.

Where available, seamless international telecommunications services will be used by multinational corporations and other users of international telecommunications services in the U.S. to exchange voice, data and video messages with corporate offices, vendors, operations and persons in France and Germany as well as in other countries. Other types of international telecommunications and enhanced telecommunications services provided through the correspondent system are not likely to be close substitutes for seamless international telecommunications services as they fully emerge. Existing services often lack international standardization or advanced features that customers are expected to prefer, and may require that customers deal with multiple providers. To compete effectively in seamless international telecommunications services, providers must have nondiscriminatory access to the U.S., France and Germany. All of these countries are key locations for multinational customers. In combination, the United States, France and Germany have nearly half of all headquarters of multinational corporations, and most potential customers of these services need telecommunications services into and out of the U.S., France and Germany.

3. Monopoly Power of FT and DT

FT and DT occupy very similar market positions in their home countries, as both are the government-owned dominant providers of telecommunications services and continue to exercise extensive legal monopoly rights, making competitors dependent on FT and DT even in those areas of service that have been opened to competition. Access to FT's and DT's public switched network and transmission infrastructure is necessary for international telecommunications and enhanced telecommunications services that originate or terminate in France and Germany. FT's and DT's legal monopolies in the provision of public switched voice telecommunications services and transmission infrastructure together account for over 75% of all telecommunications revenues in France and in Germany. Virtually all international telecommunications traffic between the U.S. and France and between the U.S. and Germany originates or terminates over FT's or DT's public switched networks, their transmission infrastructure, or both.

FT currently has a monopoly in the provision of both domestic leased lines in France and international half-circuits terminating in France, and DT has a similar monopoly in the provision of domestic leased lines in Germany and international half-circuits terminating in Germany.[9] Third party service providers that want to offer data or value added services between France and the United States, or between Germany and the United States, must obtain their transatlantic half-circuits terminating in France from FT[10] and in Germany from DT. FT's domestic leased lines in France and DT's domestic leased lines in Germany are essential inputs for many services that are open to competition in those countries, such as data services and corporate networks serving closed user groups. A very large portion of the costs of competitors of FT and DT, both in domestic telecommunications and enhanced telecommunications services in France and Germany and international telecommunications and enhanced telecommunications services originating or terminating in France and Germany, are the costs of obtaining transmission infrastructure from FT and DT.

No other facilities outside of FT's or DT's control that are permitted today to be used for transmission of some types of telecommunications services in France and Germany, including satellite "Very Small Aperture Terminal" (VSAT) earth stations and cable TV infrastructure, are effective substitutes for FT's and DT's point-to-point leased lines for most telecommunications traffic, due to technical or economic limitations, lack of sufficient geographic scope or other factors. Indeed, unlike the U.S. and U.K., where cable television infrastructure is owned by independent providers and substantial penetration exists, in France a significant share of the cable infrastructure is owned by FT and penetration is low overall, while in Germany all of the cable infrastructure is owned by DT. Although some competition to the FT and DT public switched voice services and network would likely emerge were all legal restrictions on competition lifted, replication of the entire public switched network would be prohibitively expensive for any new entrant. Accordingly, any provider of telecommunications or enhanced telecommunications services, or

[9] DT also offers a managed leased line service referred to as DDV that is used by it and its competitors for transmission in much the same way as the monopoly leased line service. DDV, however, has better management and diagnostic facilities, back-up routing and service guarantees. Though DT's DDV service has been classified nominally as "competitive" under German law, DT effectively has a monopoly over this transmission infrastructure as well, since there is virtually no competition for DDV service.

[10] FT markets such facilities through its wholly owned subsidiary France Cables et Radio ("FCR").

seamless international telecommunications services, whether in the U.S., France, Germany or elsewhere, is and will continue to be dependent to some extent for the foreseeable future on FT for origination and termination of telecommunications between France and anywhere else, and on DT for origination and termination of telecommunications between Germany and anywhere else.

FT has a dominant market position and market power in France, and DT has a dominant position and market power in Germany, in providing public data network services. These are services that are offered to the general public, rather than to an exclusive user or limited group, to carry data telecommunications through a network of transmission lines and nodes, the points of interconnection with the network. FT's and DT's continuing market power in their home countries in public data network services, which are legally open to competition,[11] is reinforced by their continuing monopolies over the transmission infrastructure used by their own data networks as well as those of their competitors. In addition, the German competition authority, the Federal Cartel Office, has found that DT extensively cross-subsidized its data network services from its transmission monopoly between 1989 and 1993, in the amount of 1.9 billion DM (approximately $1.3 billion).

FT offers these data network services through Transpac, a subsidiary that operates several types of data services, including the principal network based on the standard X.25 packet-switched protocol. FT and Transpac had a statutory monopoly in provision of public data network services in France until 1993, when competition in this area was first permitted. By the most current measures available, Transpac has a 94% share of French domestic data services, and a far more extensive network in France than any other competitor, including 597 node sites[12] and 105,000 customer connections.

DT has 833 data nodes and more than 86,500 access lines in its principal packet-switched data service network, Datex-P, which uses the standard X.25 data protocol. In 1994, DT had a share of more than 80% in packet-switched data network services in Germany. The next largest provider had less than 10% of the market, and the third largest provider was FT, through its 96.7% interest in its German-based subsidiary Info AG, which had a market share of less than 5%. All other providers of data network services in Germany depend on DT for access to DT's transmission infrastructure, and such access represents 50% to 90% of their costs of doing business.

Other means of delivering data through landline-based private networks, or through satellite-based telecommunications, are not fully adequate substitutes for FT's public data network in France or DT's public data network in Germany. FT and DT can be expected to continue to possess a dominant position in public data network services in their home countries, so long as they retain their legal or effective monopolies on transmission infrastructure.

4. Regulation and Opening of the French and German Markets

The transaction between FT, DT and Sprint takes place within a context of significant regulatory changes in Europe. Regulation of telecommunications in Europe is carried out through a combination of European Union ("EU") and national law. EU directives provide an overlay of requirements which all member states, including France and Germany, are obliged to transpose into national laws. Although EU authorities can intervene directly in some circumstances, such as enforcement of the competition provisions of the EU's governing treaties, for the most part telecommunications regulation is the responsibility of the authorities of the member states. In Germany, the Bundesministerium für Post und Telekommunikation (Federal Ministry of Posts and Telecommunication) ("BMPT") is the regulatory authority responsible for supervising the conduct of DT and granting licenses or otherwise determining conditions of entry for new providers of telecommunications services. BMPT also supervises the newly created federal agency in Germany that holds the government's ownership interest in DT. In France, the Direction Générale des Postes et Télécommunications (Directorate General of Posts and Telecommunications) ("DGPT") is the regulatory authority, responsible for supervising the conduct of FT and granting licenses or otherwise determining conditions of entry for new providers of telecommunications services. The French government's ownership interest in FT is held by a separate government ministry.

During the time that this transaction has been under investigation by the Department of Justice, regulatory developments in Europe have made it increasingly likely that the French and German telecommunications markets will be opened to competition within the next few years. The European Union, through its Commission and Council of Ministers, has set January 1, 1998 as the target date by which most member states, including France and Germany, are expected to fully "liberalize" the existing monopolies on public voice telecommunications services and transmission infrastructure, abolishing all exclusive rights or prohibitions on competition. Voice services liberalization had already been scheduled for 1998, but the Council of Ministers' resolution to fully liberalize the infrastructure at the same time was announced, much more recently, in June 1995. Carrying out the political agreement of the Council, the Commission of the European Union ("European Commission") adopted, on July 19, 1995, a draft directive that would mandate full liberalization of telecommunications infrastructure and voice services in most EU member states, including France and Germany, by 1998. Though the Council did not provide in its resolution for any partial liberalization of infrastructure at an earlier date, the European Commission's July 19 draft directive would also require EU member states to permit alternative infrastructure providers, such as electric, rail and water utilities, to begin using their networks in 1996 to carry all telecommunications services other than public switched voice. Although competitors would still need to make use of at least some of DT's and FT's infrastructure, owing to the much greater comprehensiveness of their networks, implementation of this directive would offer at least a partial infrastructure alternative to competitors and promote reductions in the prices for leased lines in France and Germany, which currently are several times higher than in the United States.

To achieve the 1998 target for liberalization, however, many other specific directives, laws and regulations must still be developed and adopted both by EU bodies and the governments of the member states. This process is only now beginning at the EU level and in France and Germany. The changes to be adopted included not only the formal lifting of the legal monopolies, but also

[11] To provide these services in France, operators must be individually licensed.

[12] The number of nodes in a data network provides a reliable measure of the penetration of data services. Nodes are the points of access for customers. Additional nodes bring the network physically closer to more users, which generally makes it less expensive for the users to access the services. Providers and users who face distance-sensitive tariffs (including the choice of making a local call or a more expensive long distance call to access the network) are likely to be competitively affected by the penetration of a data network.

the establishment of conditions for licensing of competitors and the development of interconnection rights and requirements for the public switched networks of FT and DT. The EU has anticipated the necessary steps that will need to be taken and has outlined the principal measures, but neither the EU nor the German and French governments have reached a final resolution of the crucial regulatory issues accompanying liberalization. Mere lifting of the legal prohibitions on competition would not alone bring about real competition, since actual competitors must also be licensed to operate.

The EU authorities have exercised a very significant role in bringing about telecommunications liberalization in Europe, but there are important limits on the scope of their authority. The decision whether to privatize the government-owned telecommunications carriers, and the pace at which this occurs, is wholly at the discretion of the member states. Moreover, the EU's powers to compel liberalization and protect competition relate to activities affecting commerce within or between the member states. The decision of whether and how to regulate the dealings of FT and DT with foreign telecommunications carriers outside the EU, including the terms on which operating agreements and leased lines are made available, has been left to the French and German authorities. It is not yet clear whether the EU's liberalization measures will confer any rights on providers from the United States and other countries outside the EU, or only on firms operating within the EU. The national governments at present are free to limit entry by such non-EU competitors, subject to the results of ongoing multilateral telecommunications trade negotiations.

C. The Competitive Effect of the Acquisition and Joint Venture

The Complaint alleges that the acquisition of 20% of Sprint by FT and DT, and the formation of the joint venture between Sprint, FT and DT may substantially lessen competition in the provision of international telecommunications services between the United States and France and Germany and in the provision of seamless international telecommunications services. Sprint's and Joint Venture Co.'s competitors in those markets must have access to the French and German public switched networks, infrastructure and public data networks to provide competitive services, and access to these services and facilities is controlled by FT and DT. After this transaction is consummated, FT and DT would benefit, through their ownership interests, in the competitive success of the services offered by Joint Venture Co. and Sprint.

FT and DT would therefore have increased incentives and the ability, using their monopolies and dominant positions in France and Germany respectively, to favor Sprint and Joint Venture Co. and to disfavor their United States competitors in international telecommunications services in various ways. This conduct would make competitors' offerings less attractive in quality and price than those of Sprint and Joint Venture Co., lessening the ability of Sprint and Joint Venture Co.'s rivals to compete effectively in these services. As a result of this anticompetitive conduct, the price of international telecommunications services to France and Germany available to United States consumers could be increased, and the quality lessened, relative to what United States consumers would pay and receive in the absence of this behavior.

First, FT's and DT's acquisition of a total of 20% of Sprint, and their formation of the joint venture with Sprint, will increase their incentives to use their market power over the public switched networks, transmission infrastructure and public data networks in France and Germany to discriminate in favor of Sprint and Joint Venture Co. vis-a-vis other United States international carriers, in the markets for international telecommunications services between the United States and France or Germany and for seamless international telecommunications services. Sprint could receive various forms of favorable treatment from FT and DT with respect to its international correspondent services between the United States and France and Germany. For example, FT or DT could favor Sprint or disfavor its competitors with respect to the prices, terms and conditions on which international services are provided, or the quality of the provision of those services, and could provide to Sprint advance information about planned changes to its network that is not made available to other providers. FT or DT could also alter protocols and network standards to exclude competitors' services. Such discrimination could place other United States international carriers at a competitive disadvantage to Sprint in international correspondent telecommunications services, enabling Sprint to charge more for its services or to provide a lower quality of service than it would otherwise be able to do without losing customers. It could also lessen the ability of the competitors of Sprint and Joint Venture Co. to develop and offer new seamless international telecommunications services to a compete effectively in these services. As a result of this anticompetitive conduct, the quality of seamless international telecommunications services available to United States consumers could be diminished, and the price increased, relative to what United States consumers would pay and receive in a competitive market.

Second, FT and DT will have an incentive to favor Joint Venture Co. and Sprint over their competitors, particularly new entrants and providers of new services, by denying operating agreements to the competitors, or by offering such agreements only on discriminatory terms. In order to have international traffic terminate in France or Germany through the correspondent system, an international carrier must enter into an operating agreements with FT or DT, and FT and DT can choose which carriers receive those agreements. The correspondent system is the only way to send public switched voice traffic, which represents the great majority of all telecommunications traffic, to France or Germany today, because of the FT and DT public switched voice monopolies. If new entrants and providers of new services are refused operating agreements with FT and DT and cannot otherwise have their traffic delivered to France and Germany and terms competitive with the carriers that have agreements, that could prevent or inhibit the development of competition in the markets for U.S.-France and U.S.-Germany international telecommunications services.

Third, FT and DT will have an increased incentive and ability to direct their switched telecommunications traffic from France and Germany disproportionately to Sprint rather than other U.S. international carriers, either directly as part of the correspondent system, or outside that system through the Joint Venture Co. backbone network. Because U.S. international telecommunications carriers typically send more traffic to France and Germany than they receive, they must make net settlement payments to FT and DT for delivery of their switched traffic.[13] Disproportionate return of

[13] The correspondent agreements governing switched services establish an "accounting rate" per minute of traffic, for each type of traffic sent over a particular international route. The carriers in each country pay half the accounting rate (the "settlement rate") to their foreign correspondence

Continued

incoming traffic from FT and DT to Sprint would increase the liability of Sprint's competitors to FT and DT for settlements paid on the net amounts of traffic sent and received between the U.S. and France or Germany, raising Sprint's competitors' costs of carrying such traffic. Because the settlement rates paid by FT and DT and the U.S. carriers to each other for delivering traffic are still well above the cost of delivery, notwithstanding decreases in recent years, this return traffic from France and Germany is of significant benefit to the carrier who receives it. The expectation of receiving a proportionate share of the return traffic has served to increase competition among the U.S. carriers for the traffic outbound from the U.S. This competition will be reduced to the extent that FT and DT are able to disproportionately return their traffic to Sprint. Moreover, to the extent that returning their traffic disproportionately to Sprint allows FT and DT to send traffic to the U.S. at a rate other than the settlement rate (which will still be the rate they receive from U.S. carriers for traffic sent to France or Germany) FT or DT will have an increased incentive to negotiate for higher settlement rates and resist efforts to lower accounting rates.

Fourth, DT and FT will have an increased incentive and ability to cross-subsidize Joint Venture Co. and Sprint by providing revenues from the monopoly services or by shifting costs of Joint Venture Co. and Sprint to the monopoly services. In both France and Germany, over three quarters of the revenues of FT and DT are derived from services and facilities that are legally protected against competition. These monopoly activities can be used to cross-subsidize competitive services. Such cross-subsidization would facilitate a strategy of placing competitors of Joint Venture Co. and Sprint in a "price squeeze" by keeping prices for the monopoly inputs they need well above true economic costs, while simultaneously undercutting them on price in the competitive markets through Joint Venture Co. and Sprint, whose costs will have been artificially reduced. The result could be a substantial lessening of competition in both international telecommunications services and seamless international telecommunications services in the U.S.

Fifth, FT's and DT's ownership interest in Sprint and Joint Venture Co. would increase FT's and DT's incentives to provide Sprint and Joint Venture Co. with confidential, competitively sensitive information that FT and DT obtain from other United States carriers and competitors through their correspondent relationships with FT and DT, or their arrangements to obtain interconnection with the French and German public switched networks or obtain transmission infrastructure from FT and DT. In order to use FT's and DT's correspondent switched and private line services and to negotiate terms of use, or to interconnect with FT and DT in France and Germany and obtain transmission infrastructure, United States international telecommunications providers must provide FT and DT various types of competitively sensitive information. This can include private line customer identities, service requirements, plans for the introduction of new services, changes in existing services, and future traffic projections. If FT or DT were to share this information with Sprint or Joint Venture Co., those firms could gain an anticompetitive advantage over their United States competitors. Disclosure of this competitively sensitive information to Sprint and Joint Venture Co. could substantially lessen competition in both international telecommunications services and in seamless international telecommunications services in the U.S. Allowing Sprint access to such competitively valuable information about its competitors would also increase the risk of price collusion.

(III)

Explanation of the Proposed Final Judgment

A. Prohibitions and Obligations

Under the provisions of the Antitrust Procedures and Penalties Act, the proposed Final Judgment may only be entered if the Court finds that it is in the public interest. The United States has tentatively concluded that the proposed Final Judgment is in the public interest.

1. Overview of the Proposed Final Judgment

Section 7 of the Clayton Act, 15 U.S.C. 18, prohibits an acquisition of stock or assets where "the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly." Thus, the United States has sought to address in the proposed Final Judgment the competitive effects on United States markets that would result from the consummation of the transaction between Sprint, FT and DT. The issue properly considered by the United States under Section 7 is how the creation of vertical relationships between United States providers of international telecommunications services and these foreign telecommunications monopolies could further lessen competition in markets within the scope of the United States antitrust laws.[14]

for each minute of traffic completed. Settlement payments for outgoing traffic are offset by the settlement payments for incoming traffic. When there is an imbalance in the amount of outgoing and incoming traffic between carriers, the carrier with the most outgoing traffic makes a net settlement payment to its correspondent. In 1993, according to FCC data, the net outpayment of all U.S. international carriers to FT for IMTS calls between the U.S. and France wes $28,913,657, and the net outpayment of all U.S. international carriers to DT for IMTS calls between the U.S. and Germany was $144,492,724. 1993 Internetionel Telecommunications Data, International Traffic Data for All U.S. Points, Teble A1.

Today, United States carriers accept the same proportion of the total switched traffic from each of their correspondents in a foreign country as the proportion of total switched traffic to the correspondent that each of the United States carriers send. Federal Communications Commission policy supports this proportionate allocation of switched traffic, although the FCC has not edopted regulations governing proportionate allocation.

[14] In addition to the vertical issues presented by the affiliation between FT, DT, the joint venture and Sprint, the United States also considered in its investigetion horizontel competitive issues involving Sprint and Infonet Services Corporation, which is one of Sprint's principal competitors in the provision of various types of domestic and internationel data telecommunications services in the United States. FT and DT, as of the time of entering into the Joint Venture Agreement and the Investment Agreement with Sprint, were the largest shareholders of Infonet Services Corporetion and were represented on Infonet's Board of Directors. The United States was concerned thet violetions would occur of both Section 7 of the Cleyton Act and Section 8 of the Clayton Act, which prohibits interlocking directorates, had FT and DT become the largest shareholders of both Sprint and Infonet, with representation on both compenies' boards of directors. This horizontal issue hes now been fully remedied, end so does not form e part of the terms of the proposed Final Judgment. On June 20, 1995, FT and DT entered into e separete egreement with Infonet, requiring FT end DT to sell a substantial part of their shareholdings back to Infonet by August 3, 1995, and to fully divest the remainder of their shareholdings back to Infonet 45 deys efter the earlier of (1) the date as of which FT or DT acquire any of the securities of Sprint, or (2) six months efter all governmental approvals necessary for the consummation of the investment in Sprint and the joint venture have been granted. Pursuant to the stipulation between Sprint and the United States entered on July 13, 1995, Sprint is prohibited from issuing any equity to be acquired by FT or DT, or acquiring an ownership interest in or contributing assets to the joint venture, until the initial divestiture of FT and DT shares in Infonet has been completed. The United States has been informed that as of the dete of the filing of this Competitive Impect Statement, all but one of the several other shareholders of Infonet have completed repurchase of the initial divestiture of the FT and DT shares, but because a part of the shares included in the initial divestiture has not yet been sold, the initial divestiture has not yet been completed. The sale of the remaining shares in the initial divestiture is now scheduled to occur by the end of August 1995. Additionally, the stipulation requires Sprint and Joint Venture Co. to be maintained as separate and independent businesses from Infonet, with no transfer of proprietary business or financial information, pending completion of the full divestiture. Sprint is precluded by the stipulation from permitting any

This narrow question differs significantly from the issues relating to this transaction that are still under consideration by other United States and European authorities. Both the Federal Communications Commission ("FCC") and the European Commission have separate pending investigations of this transaction, and the European Commission is also investigating the formation of the Atlas alliance between FT and DT. These authorities, based on their public statements, are expected to complete their investigations before the close of 1995. The FCC's review of this transaction, under the "public interest" mandate of the Communications Act of 1934, may involve broader issues of foreign market access and the appropriateness of permitting substantial investments in United States telecommunications carriers by foreign monopolists whose conduct already causes harm to United States consumers, subjects on which the FCC also has a general rulemaking procedure in progress.[15] The European Commission's jurisdictional responsibilities differ from those of United States antitrust and regulatory authorities, being focused on commerce among and within EU member states. The European Commission has already indicated that it has serious concerns about the loss of actual or potential competition between FT and DT in Europe resulting from the formation of the Altas alliance, an issue that is outside the scope of United States antitrust review and so is not addressed by the relief in the proposed Final Judgment.[16] Thus, the entry of this Final Judgment is not intended to affect the ability of the FCC or the European Commission to take additional measures they may find necessary to address the issues within their areas of responsibility.

The proposed Final Judgment in this case has many features and provisions in common with the consent decree previously entered by this Court on September 29, 1994 in *United States* v. *MCI Communications Corp.*, No. 94–1317 (TFH) (D.D.C.), and published in the **Federal Register** at 59 Fed. Reg. 33009 (June 27, 1994), following the United States' investigation of the strategic alliance between BT and MCI to form Concert. That transaction aimed to provide similar international telecommunications and enhanced telecommunications services, and also involved a 20% equity investment by a foreign telecommunications provider in a United States international carrier. There are, however, crucial differences between this transaction and the BT–MCI alliance. Although BT continued to have some market power in basic telecommunications services and facilities and control over local bottlenecks in the United Kingdom at the time it formed its alliance with MCI, all of its lines of business were already open to competition and BT actually faced facilities-based competition to some extent at all levels, from independent carriers and cable television companies. Moreover, since 1993 BT has ceased to be government-owned, so that it is independent from its government regulator in the United Kingdom. Here, in contrast, FT and DT retain legal monopolies over three-quarters of all telecommunications business in France and Germany, as measured by revenues, and have market power over additional types of services such as public data networks that have already become competitive in the United Kingdom. FT and DT do not have the same degree of independent regulatory oversight of their conduct by national authorities as BT, because of their continuing government ownership. Accordingly, in this transaction it was necessary to impose more stringent conditions governing the relationship between FT and DT on the one hand, and Sprint and the joint venture on the other, particularly in the period before France and Germany fully liberalize their telecommunications markets pursuant to EU requirements, in order adequately to protect competition.

The proposed Final Judgment reflects the differences between the French and German telecommunications markets and that in the United Kingdom by operating in two phases. The first phase, "Phase I," is that period of time after the entry of this Final Judgment and before all of the conditions that must be met to commence Phase II have been satisfied. Essentially, Phase I of the proposed Final Judgment will be in effect until all prohibitions on competition have been removed, and actual competitors have been licensed, in France and Germany. The shift from Phase I to Phase II is assessed separately for France and for Germany, so that the development of a competitive market in one country will be taken into account notwithstanding delays in the other.

Phase II begins for France, and for Germany, when the national government of that country has taken two key steps, as stated in Section V.Q. First, the government must have removed all of the legal prohibitions on (a) the construction, ownership or control of both domestic and international telecommunications facilities, and use of such facilities to provide any telecommunications or enhanced telecommunications services, and (b) the provision of public switched domestic and international voice services, by entities other than FT and DT and their affiliates. Second, the government must have issued one or more licenses or other necessary authorizations, to entities other than and unaffiliated with FT, DT, Sprint or Joint Venture Co., for all of the following: (a) The construction or ownership, control, of both (i) domestic telecommunications facilities to serve territory in which one-half or more of the national populations of France and Germany reside, and (ii) international telecommunications facilities capable of being used to provide a competitive facilities-based alternative, directly or indirectly, between France and Germany and the United States; and (b) the provision of public switched domestic long distance voice services, without any limitation on geographic scope or types of services offered, and international voice service between the United States and France and Germany. The phrase "competitive facilities-based alternative," as used herein, signifies that the licensed competitors must have authority to construct or own a sufficiently large amount of international capacity that other providers would have a realistic alternative to the use of the international facilities of FT or DT, and is not satisfied by authorization to construct or own an insubstantial number of international circuits. The requirement herein that all legal prohibitions on the provision of services and facilities have been removed refers only to prohibitions on entities' ability to provide service and to construct, own

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FT or DT directors to serve on its board if FT or DT directors of Infonet are still exercising voting rights, or if those directors remain on the Infonet board for more then 45 deys efter FT or DT heve acquired eny of Sprint's securities.

[15] See *Market Entry and Regulation of Foreign-affiliated Entities*, IB Docket No. 95–22, FCC 95–53, Notice of Proposed Rulemeking (releesed February 17, 1995), and the Reply Comments of the United States Department of Justice, filed in this FCC rulemaking proceeding on Mey 12, 1995.

[16] On May 23, 1995, the Europeen Commission sent a "warning letter" to FT and DT edvising them of the intent of Commission staff to teke e negetive position with regard to the Atles trensaction end to propose to the Commission thet the trensaction be prohibited. The Europeen Commission hes expressed particular concern ebout the dominant positions of FT and DT in their home markets end the loss of competition in data telecommunications services. FT end DT have been given until September 15, 1995 to present proposals to chenge their trensaction to meet the Europeen Commission's competition concerns. If no satisfactory ection is teken by thet time, the next step in the European Commission's investigation would be to issue a formal "statement of objections," the European equivelent of en antitrust compleint.3

and operate facilities. It is not intended to apply to the establishment of neutral conditions for the provision of service by the national governments of France or Germany, such as contributions to the funding of universal service or obligations to obtain a license.

The substantive restrictions and requirements contained in Section II of the proposed Final Judgment continue throughout the entire term of the decree, which is five years from the commencement of Phase II in both France and Germany. The Section II restrictions are for the most part similar to those in the MCI decree, including transparency and confidentiality requirements, though in some respects they are broader, in particular with respect to open licensing of other United States competitors. Other restrictions, those contained in Section III, terminate at the onset of Phase II, separately for France and for Germany unless specifically stated otherwise. The Section III restrictions lasting through Phase I include limits on the scope of activities of Sprint and Joint Venture Co., and behavioral prohibitions applicable to Sprint and Joint Venture Co. These provisions are intended to foster competition in international telecommunications services and seamless services, by ensuring that Sprint and Joint Venture Co. do not receive various types of advantages over competitors from their association with the FT and DT monopolies.

Generally speaking, during Phase II the proposed Final Judgment relies to a greater extent on enforcement by national regulatory authorities in Europe, the EU itself, and the FCC in the United States to protect competition, while during Phase I the proposed Final Judgment provides for additional types of injunctive relief to ensure that Sprint and Joint Venture Co. do not benefit from anticompetitive conduct by FT and DT. This distinction is reasonable in the circumstances of this transaction, because there is considerably greater potential for competitive abuses to occur in the period while competitors have no legal alternative to using FT's and DT's facilities and services, and before the EU and the French and German governments finish implementing their program of regulatory reform, which is necessary in order to ensure nondiscriminatory licensing and interconnection for competitors and provision of services by dominant carriers on an open and nondiscriminatory basis. Although the proposed Final Judgment does not specifically reference all of the directives and measures envisioned by the European authorities, an underlying assumption is that these authorities will carry out their publicly announced intention of having all the key regulatory measures needed for development of effective competition in place by the time full liberalization is to take effect in 1998.

The various requirements and restrictions of this proposed Final Judgment, in combination, will substantially diminish the risk of abuse of FT and DT's market power to discriminate or otherwise afford anticompetitive advantages to Sprint and Joint Venture Co.[17] They will do so by making discrimination, disproportionate return of traffic and cross-subsidization easier to detect and prevent, by precluding the misuse of confidential information obtained by FT and DT from Sprint's and Joint Venture Co.'s competitors, by precluding Sprint and Joint Venture Co. from benefiting by delays in licensing of competitors or refusal to license competitors by the French and German governments, by ensuring that Sprint and Joint Venture Co. are not the exclusive recipients of operating agreements from FT or DT for any services, and by ensuring that access to the public switched networks and public data networks in France and Germany is not impaired by adoption of proprietary or nonstandard protocols. The object of these substantive terms is to ensure that Sprint, as the result of its direct affiliation with FT and DT or its position as the exclusive distributor of Joint Venture Co. services in the United States, as well as Joint Venture Co. itself, are not given an advantage over their competitors in the United States to the detriment of competition or consumers.

Several key terms are employed throughout the substantive obligations and restrictions of Sections II and III of the Final Judgment, defining the scope of these provisions.

"Telecommunications service" (as defined in Section V.U) includes ordinary switched voice telephony and private circuits as well as conveyance (including transmission, switching and receiving) of data and video information, and signaling, translation and conversion in the network. These basic telecommunications services are the bulk of existing telecommunications, and are licensed and regulated to some degree in the United States and in France and Germany, although not in the same manner in each country. There are relatively few major providers of these services in the United States, and in France and Germany FT and DT remain the monopoly or the dominant providers of most of these services. In contrast, an "enhanced telecommunications service" (as defined in Section V.H), uses telecommunications services as a foundation to provide various advanced and intelligent applications of additional value to users. Enhanced telecommunications services are subject to little or no regulation in the United States, and face considerably less regulation than basic services in France and Germany, with few if any legal restrictions on entry.[18] The number of providers of enhanced telecommunications services is often greater than for basic telecommunications services, although all such providers must have access to basic telecommunications services, including network interconnection and transmission facilities, in order to do business.[19]

"FT or DT Products and Services" (as defined in Section V.L) are also referred to throughout the Final Judgment. This term encompasses any of an enumerated list of telecommunications and enhanced telecommunications services or facilities in France or Germany, or between the United States and France or the United States and Germany, that are provided by FT or DT. These services are correspondent services,[20] dedicated or switched transit services, leased lines, international half circuits between the United States and France and the United States and Germany,[21] and interconnection to the FT and DT public

[17] Joint Venture Co. is broadly defined in Sections V.A end V.O to ensure that the entire joint venture will be subject to the Final Judgment, regardless of the forms that it may take or restructuring thet may occur.

[18] The definitions of "telecommunications services" and "enhenced telecommunications services" in the Final Judgment are based on the distinction between basic services and enhanced services recognized by the FCC, as well as similer concepts in EU lew and in France and Germany, where "velue-added services" are referred to in a sense similar to enhanced services. The definitions do not duplicete those used by eny of the netional reguletory euthorities, which differ somewhet in terminology, but they incorporete es much es possible the underlying concepts, while ensuring consistent treatment within the context of this judgment for services offered in the United Stetes, France and Germany.

[19] If en ectivity is e "telecommunications service" as defined in the Finel Judgment, it remains so when it is offered or bundled with enhanced services or other equipment, fecilities, or services, or if it is called a "peckage of facilities" or something other than e telecommunications service.

[20] Correspondent services, under this proposed Finel Judgment, include not only the standard switched IDDD internetional voice call, but elso other services such es Virtuel Privete Networks offered on e correspondent basis.

[21] Leesed lines and internationel half-circuits may be excluded from the list by mutuel egreement of the United States and the defendants if they concur thet effective competition exists to such facilities provided by DT or FT.

switched telephone networks (including Integrated Services Digital Network interconnection). All of the services covered by this term are ones over which FT and DT continue to exercise market power in their home countries, and many of the services described as "FT or DT Products and Services" are those within the scope of FT's and DT's legal monopolies, but the list of FT or DT Products and Services is not limited to services or facilities that are reserved exclusively to FT or DT under the laws of France or Germany.

One significant category of services over which FT and DT continue to have market power in their home countries, public data networks, is not included in the list of FT or DT Products and Services. Because data networks operate in significantly different ways from the public voice networks, and face some actual competition in France and Germany, the competitive risks arising from this transaction due to FT's and DT's market power in data services differed from the competitive risks associated with FT's and DT's provision of correspondent services, transit services, leased lines or connection to the French and German public switched networks. Several specific provisions of the proposed Final Judgment do, however, place restrictions and obligations on the relationship of the joint venture and Sprint with FT's and DT's public data networks in their home countries, in order to limit risks of abuse of FT's and DT's market power in this area. Moreover, the most important components of the public data networks, the leased lines, are included in the definition of FT or DT Products and Services.

Although the proposed Final Judgment generally makes no distinction between FT, DT, and their Atlas alliance, but treats them all together so as to ensure that Atlas is not used as a vehicle to circumvent the decree, the definition of FT or DT Products and Services does not include enhanced correspondent services that Atlas provides on its own, rather than by reselling or acting as a sales agent for FT or DT, unless the enhanced correspondent services involve interconnection to the public data networks. This limited exception was intended to facilitate the development of enhanced services through Atlas, and not to permit FT or DT simply to transfer their existing correspondent activities into Atlas to escape the obligations of the proposed Final Judgment.

2. Restrictions in Effect for the Term of the Decree

Section II contains substantive restrictions and obligations which continue throughout the full duration of the decree. These include transparency requirements (Section II.A), confidentiality requirements (Section II.B.), and limitations on the ability of Sprint and Joint Venture Co. to offer international services involving France or Germany, or provide facilities to FT or DT for such services, if other United States international telecommunications providers are not permitted to provide the same services (Section II.C).

a. Transparency Requiremnts. Section II.A. forbids Sprint or Joint Venture Co. from offering, supplying, distributing, or otherwise providing any telecommunications or enhanced telecommunications service that makes use of telecommunications services provided by FT in France or between the United States and France, or DT in Germany or between the United States and Germany, unless Sprint or Joint Venture Co. disclose certain types of information. Because these transparency requirements may be affected by changes in regulation or other circumstances, Section II.A provides the United States with the ability to waive these requirements in whole or in part.

Pursuant to Section V.F., Sprint and Joint Venture Co. will provide the information to the Department of Justice, which may then disclose the information to any United States international telecommunications provider that holds or has applied for a license, from either the FCC, the French DGPT or the German BMPT, to provide international telecommunications services between the United States and either France or Germany, or who actually provides international telecommunications services between the United States and either France or Germany, for services where no license is required. This will enable the principal competitors of Sprint and Joint Venture Co. to monitor whether either of these companies is receiving more favorable treatment from either FT or DT than competitors receive, and would provide them with evidence that could be used to make a complaint to any governmental authorities in the United States or France or Germany. In particular, this information could be used by competitors to identify violations of the Phase I restrictions of the proposed Final Judgment to the Department of Justice while those provisions remain in effect, and the Department of Justice could also use the information to detect violations on its own initiative.

"United States international telecommunications provider," as defined in Section V.W., includes subsidiaries and affiliates of such providers, as well as entities with which a United States international telecommunications provider is affiliated, where a 10% or greater equity interest exists, so that international joint ventures and foreign strategic allies with equity investments in a U.S. provider, as in the BT-MCI Concert relationship, can qualify for access to the information.

Disclosure by the Department of Justice to any provider described above will be made only upon agreement by the provider, in the form prescribed in the Stipulation entered into by Sprint and Joint Venture Co. and the United States on July 13, 1995, not to use such non-public information for commercial purposes and not to disclose such non-public information to any other person, apart from governmental authorities in the United States, France or Germany. The term "governmental authorities" is used broadly and includes independent agencies. Entities receiving this information from the Department of Justice would be required to sign a confidentiality agreement with the Department, obligating them not to disclose non-public information to any persons other than governmental authorities. The stipulation between the defendants and the United States describes the form of a confidentiality agreement in more detail. This confidentiality provision was adopted to prevent wider dissemination of defendants' non-public business information than is necessary to detect and prevent anticompetitive conduct.

Seven categories of information must be disclosed pursuant to the transparency provisions in Section II.A. Three of the categories apply to Joint Venture Co., two apply to Sprint, and two apply to both companies.

Joint Venture Co. will make extensive use of interconnection with the public switched telephone networks of FT and DT in France and Germany to provide telecommunications and enhanced telecommunications services, as well as obtaining leased lines and international half-circuits from FT and DT for Joint Venture Co.'s backbone network. These relationships make it necessary to impose disclosure obligations on Joint Venture Co. in the following areas.

First, under Section II.A.1, Joint Venture Co. must disclose the prices, terms and conditions, including applicable discounts, on which FT or DT Projects and Services are provided in France or Germany to Joint Venture

Co. pursuant to interconnection agreements. Interconnection agreements are specific arrangement (see Section V.N) by which other service providers in France and in Germany receive rights to connect their systems to FT's or DT's public switched telephone networks and have FT and DT complete delivery of traffic, on terms that may differ from those available to retail customers. Section II.A.1 will compel Joint Venture Co. to disclose to competitors that actual prices FT and DT charges it for interconnection, as well as non-price terms. Such publication is not required under current French or German law, which permits FT and DT to enter into individual commercial negotiations with their competitors for interconnection and not disclose the terms to other providers, thereby increasing opportunities for discrimination.

Second, Section II.A.2 imposes similar disclosure obligations on Joint Venture Co. for the prices, terms and conditions, including any discounts, of any other FT or DT Products and Services it obtains in France from FT or in Germany from DT for use in providing telecommunications or enhanced telecommunications services between the United States and France or the United States and Germany. Among the most important FT or DT Products and Services covered by this provision are the leased lines and international half-circuits that would be used in Joint Venture Co.'s own backbone network for seamless services. Although some of these types of information are already disclosed by FT and DT in their retail tariffs pursuant to French and German regulation, Section II.A.2 ensures comprehensive transparency to prevent discrimination, including disclosure of any commercially negotiated off-tariff discounts or special service arrangements, and disclosure of arrangements for international facilities, which are subject to less regulatory oversight than are domestic services in France and Germany. This provision also applies to the terms on which FT and DT Products and Services are provided to customers in France and Germany in conjunction with Joint Venture Co. services when FT or DT is acting as the distributor for Joint Venture Co., thus facilitating detection of discrimination in bundling of services.

Third, Section II.A.4 requires Joint Venture Co. to provide additional information about the specific FT or DT Products and Services that it receives from FT in France and DT in Germany for use by Joint Venture Co. to supply telecommunications or enhanced telecommunications services between the United States and France or Germany, as well as the services FT provides directly to customers in France and the services DT provides directly to customers in Germany as the distributor for Joint Venture Co. Joint Venture Co. is required to disclose (i) the types of circuits, including their capacity, and other telecommunications services provided, (ii) information concerning the actual average times between order and delivery of circuits, and (iii) the number of outages and actual average times between fault report and restoration for various categories of circuits. These types of information are not otherwise disclosed under existing regulations in France or Germany, which only provide for disclosure of much more general and non-provider specific information concerning service quality. The mandated disclosures here are important to the detection of various types of discrimination involving provisioning and quality of services. Where Joint Venture Co. has to disclose particular telecommunications services provided, it is required to identify the services and provide reasonable detail about them (if not already published). However, if a product or service is sold as a unit, separate underlying facilities need only be disclosed to the extent necessary to identify the product or service and the means of interconnection. Joint Venture Co. is not required to identify individual customers or the locations of circuits and services dedicated to particular customers.

Sprint's relationship with FT and DT in the provision of international telecommunications services will be less complex than Joint Venture Co.'s, because of Sprint's agreements not to compete with Joint Venture Co. and not to compete with FT and DT in their home countries, France and Germany. Spring will continue to provide international correspondent switched services and private line services together with FT and DT. To ensure greater transparency in Sprint's dealings with FT and DT, Section II.A contains two sets of disclosure obligations specifically applicable to Sprint.

Section II.A.3 applies to any international switched telecommunications or enhanced telecommunications services provided by Sprint and FT or by Sprint and DT on a correspondent basis between the United States and France or between the United States and Germany. It requires Sprint to disclose both the accounting and settlement rates, and other terms and conditions, applicable to any of these services, including the methodology by which proportionate return of international traffic is calculated. When there is no specific agreement between Sprint and FT or between Sprint and DT setting forth this information, Sprint must state the rates, terms and conditions on which the service is actually provided. In addition, where different accounting rates exist for types of services that FT or DT combine for purposes of calculating the proportionate return due to United States international telecommunications providers, Sprint must disclose its own minutes of traffic in each separate accounting rate category so that the other United States providers can determine whether they are being sent the appropriate shares of traffic from FT or DT, unless they already receive the necessary data (such as total traffic volumes in each rate category). This latter obligation addresses a particular type of possible discrimination in international services, known as "grooming," by which a foreign carrier can favor particular United States correspondents with traffic of superior value while appearing to allocate minutes of traffic on a proportionate basis. Today some of the types of information covered by Section II.A.3, such as agreed-upon accounting rates, are supplied to the FCC and are published, but other types of information, including proportionate return data, are only provided at the discretion of FT and DT pursuant to voluntary arrangements with U.S. Carriers. Where information has already been made available to competitors, Section II.A.3 of the Final Judgment does not require Sprint to provide it to the Department of Justice. Section III.E, however, contains additional and more extensive obligations concerning disclosure of information on proportionate return traffic that are in effect during Phase I.

Section II.A.5 requires Sprint to provide information about the United States-France and the United States-Germany international circuits it provides jointly with either FT or DT. Sprint must disclose for international private circuits (i) the actual average times between order and delivery by FT or DT, and (ii) the actual average time intervals between fault report and restoration in specific areas of the international facility and the overseas network. This information is similar to types of information Joint Venture Co. provides under Section II.A.4 and serves similar purposes. Sprint is also required, for circuits used to provide international switched services on a correspondent basis between the United

States and France and between the United States and Germany, to identify (i) average numbers of circuit equivalents available to Sprint during the busy hour and (ii) the percentage of calls that failed to complete during the busy hour. None of the information disclosed under Section II.A.5 is made public today under existing regulation, and this information would have substantial value in facilitating detection of discrimination in the provision and quality of services.

Two types of information must be disclosed by both Joint Venture Co. and Sprint, as either company might be the beneficiary of discrimination in these areas. First, under Section II.A.6 Sprint and Joint Venture Co. are required to disclose information that either entity receives from FT or DT about any material change or decision relating to the design of, technical standards used in, or points of interconnection to the FT or DT public switched telephone networks that would materially affect the terms or conditions on which Sprint, Joint Venture Co. or any other person is able to have access to, or interconnect with these networks for telecommunications or enhanced telecommunications services within France or Germany or between the United States and France or the United States and Germany. Disclosure of information of this nature is important to ensure that Joint Venture Co. and Sprint, due to their affiliation with FT and DT, are not given commercial advantages over competitors through advance notice of network changes by FT and DT.

Second, under Section II.A.7, Sprint and Joint Venture Co. are required to disclose any discounts or more favorable terms offered by FT or DT to their customers, for FT or DT Products and Services, that are conditioned on Sprint or Joint Venture Co. being selected by the customers as the United States provider of a telecommunications or enhanced telecommunications service. This provision is closely related to section III.D.2, which prohibits during Phase I any such bundling or tying arrangements, but it continues for the duration of the decree to ensure that even after competition has been authorized, any such arrangements by FT and DT will have to be disclosed, permitting complaints to be made to regulatory authorities.

Under Section II.A, Sprint and Joint Venture Co. are required to disclose intellectual property or proprietary information only if it is one of the types of information expressly required to be disclosed by any of the transparency obligations, or if it is necessary for United States international telecommunications providers to interconnect with the public switched telephone networks of FT or DT, or is necessary for United States international telecommunications providers to use FT's or DT's international telecommunications or enhanced telecommunications correspondent services. Sprint and Joint Venture Co., as well as FT and DT indirectly, are thus protected against overly broad disclosure of such valuable commercial information.

b. Confidentiality Requirements. Section II.B of the proposed Final Judgment constrains the ability of Sprint and Joint Venture Co. to receive, or seek to receive, from FT or DT (including FT or DT-appointed directors on the board of Sprint), various types of confidential information that FT or DT obtain from Sprint and Joint Venture Co.'s United States competitors. Existing regulatory requirements do not adequately protect any of this information from disclosure.

Under Section II.B.1 Sprint and Joint Venture Co. cannot receive information from FT or DT that other United States international telecommunications providers identify as proprietary and maintain as confidential, but that has been obtained by FT or DT as the result of their provision of interconnection or other telecommunications services to U.S. providers in France or Germany. In order to obtain interconnection with FT or DT, other providers would have to provide FT and DT with detailed information about their planned services and interconnection needs. As interconnection needs change over time, FT and DT would receive more confidential information. FT and DT may also learn the identities and service needs of particular customers of their competitors who need to have private circuits interconnected with FT or DT. Of course, there is no alternative to interconnection with either FT or DT because of their monopolies in France and Germany, respectively, and even after these monopolies are lifted, competitors will still need to interconnect with FT and DT to some extent because of their dominant market positions and the ubiquity of their networks in France and Germany.

Section II.B.2 similarly forbids Sprint and Joint Venture Co. from receiving from FT or DT confidential, non-public information that FT or DT obtain from other United States international telecommunications providers through correspondent relationships. United States international telecommunications providers have no alternative at present to using FT or DT for the origination and termination of international correspondent traffic in France and Germany, and even after current monoploy restrictions are lifted, they are likely to remain at least partly dependent on FT and DT for delivery of much correspondent traffic. A limited exception is provided to allow Sprint to obtain certain types of aggregate information it may need to comply with its transparency obligations under Sections II.A.3(ii) and II.A.5, but in no circumstances may Sprint use this exception to receive individual information about other providers that is otherwise prohibited by this section.

Finally, Section II.B.3 addresses a specific competitive risk in the context of international correspondent relationships, by prohibiting Sprint or Joint Venture Co. from seeking or accepting from FT or DT any non-public information about the future prices or pricing plans of any competitor of Sprint in the provision of international telecommunications services between the United States and France or the United States and Germany. FT and DT and their United States correspondents, in the course of accounting rate negotiations, exchange considerable information including business plans and traffic projections. Section II.B.3 addresses the substantial risk of violation of Section 1 of the Sherman Act that would arise if FT or DT were to obtain non-public pricing information from Sprint's competitors once FT and DT become Sprint's largest owners, by precluding any sharing of price information through FT or DT. Risks of price collusion, tacit or explicit, are considerable in an industry with a small number of large providers offering similar types of services.

Finally, Section II.B.3 safeguards against the circumvention of the above prohibitions by prohibiting Sprint and Joint Venture Co. from employing personnel who either (i) are also employed by FT or DT and have access to the types of information that Sprint and Joint Venture Co. are not permitted to receive from FT or DT under Section II.B, or (ii) have been employed by FT or DT within the preceding six months if during that time, they received any of the types of information that Sprint and Joint Venture Co. are not permitted to receive under Section II.B.

c. Open Licensing. Continued government ownership of FT and DT creates risks that other United States international telecommunications providers may not receive licenses or other authorizations for the French and German governments that are needed to provide international telecommunications and enhanced telecommunications services, or may

have their applications substantially delayed. This is a particular concern in the emerging areas of seamless services, where a provider needs to able to offer a service on an end-to-end basis in both the United States and France or Germany. Conversely, Sprint and Joint Venture Co. may have more advantageous opportunities to obtain licenses in France and Germany due to their affiliation with FT or DT, or to provide seamless services using the licenses of their monopoly partners. Because the entire area of public voice services has not yet been opened to competition in France and Germany, and other new services may also be developed, it is not possible to identify each service for which this type of concern may arise. International voice resale services, however, clearly come within the area of potential concern. Competition in international telecommunications and enhanced telecommunications services between the United States and France and Germany, including seamless services, would be adversely affected if Sprint and Joint Venture Co. could obtain rights to provide any services that are not available to other U.S. firms. Exclusive licensing arrangements could also enable FT and DT to divert international traffic from their home countries to the United States disproportionately to Sprint through the Joint Venture Co's backbone network, or other facilities supplied by Sprint.

Accordingly, Section II.C precludes Sprint and Joint Venture Co. from offering, or providing facilities to FT or DT enabling them to offer, any particular international telecommunications or enhanced telecommunications service between the United States or France or Germany, unless one of the following three conditions, designed to ensure competitive entry, is met. First, the service may be offered if no license is required in France, or in Germany, to offer the service. Second, if a "class license," a form of general regulatory authorization that does not require individual application, is required, the service may be offered if such a class license is in effect in France and in Germany for other United States international telecommunications providers not affiliated with FT, DT, Sprint or Joint Venture Co. Third, if an individual license is required to offer a service in France or in Germany, established licensing procedures must be in effect as of the time of offering of the service by which other United States international telecommunications providers are also able to secure a license, and either (i) one or more United States international telecommunications providers other then, and unaffiliated with, FT, DT, Sprint or Joint Venture Co. must already have a license in France and in Germany, or (ii) if Sprint, Joint Venture Co., FT or DT is the first to seek a license, other United States international telecommunications providers are able to secure a license in France and in Germany within a reasonable time, in no event longer than it took Sprint, Joint Venture Co, FT or DT to obtain its license (unless the additional time required is due to delay caused by the applicant). These requirements are both service-specific and country-specific, so that Sprint and Joint Venture Co. would not be precluded from providing a service for which open licensing had been established merely because some other type of service remained closed, nor would they be precluded from providing a service involving one country that had open licensing merely because the other country had not satisfied any of the three conditions. Because government ownership of FT and DT is likely to continue even after the conditions for Phase II of the proposed Final Judgment have been satisfied, it is necessary to have this provision remain in effect for the entire duration of the decree.

Section II.C does not apply to existing correspondent services provided pursuant to bilateral agreements with FT or DT that have also been made available to other United States international telecommunications providers. It is not necessary for a U.S. carrier to have a license in France or Germany to offer voice services, or other types of telecommunications service, from the United States to France or Germany on a correspondent basis using FT or DT, although it is necessary to have an operating agreement with FT or DT to do so.

3. Restrictions Lasting Through Phase I

Section III contains the additional restrictions and obligations that are in effect through Phase I of the decree, prior to the removal of all prohibitions on facilities-based telecommunications competition in France and Germany and the licensing of competitors in those countries providing a substantial competitive alternative to FT and DT. These restrictions are necessary now to protect competition, due to the monopolies FT and DT continue to hold in their home countries combined with their government ownership, and the significant limitations on effective protection of competitors and consumers under the current French and German regulatory regimes. These restrictions in Section III are expected to become less necessary once competition has been introduced in France and Germany, which should occur concurrently with the regulatory reform program being undertaken by the EU authorities. At that point, competitors will be less vulnerable to abuses of market power by FT and DT because of the alternatives available for transmission infrastructure, and should be better protected by European regulatory requirements to the extent that they continue to depend on the services and facilities of FT and DT.

The Section III restrictions include: (i) Limitations on the ability of Sprint or Joint Venture Co. to acquire ownership interests in or control over certain types of facilities now owned or controlled by FT or DT (Section III. A-B); (ii) a prohibition on Sprint or Joint Venture Co. providing FT or DT Products and Services on an exclusive basis (III.C); (iii) a prohibition on Sprint or Joint Venture Co. obtaining FT or DT Products and Services on a discriminatory basis (III.D); (iv) prohibitions on Sprint's acceptance of correspondent telecommunications traffic on a disproportionate basis (III.E), or having any exclusive operating agreements with FT or DT (III.G); (v) prohibitions on cross-subsidization of Sprint or Joint Venture Co. by FT and DT (III.F), and (vi) requirements that Sprint and Joint Venture Co. not provide telecommunications or enhanced telecommunications services using FT or DT Products and Services or public data networks, if FT or DT have established proprietary or nonstandardized protocols or interfaces and have failed to continue to provide other competitors with access to those services and networks on a standardized basis (III.H-I).

a. Limitations on Facilities Ownership. Section III.A of the proposed Final Judgment prohibits Sprint and Joint Venture Co. from acquiring ownership interests in or control over (i) any facilities in France or Germany that are legally reserved to FT or DT (which would include, for example, the public switched networks and transmission infrastructure), or (ii) international half circuits terminating in France or Germany that are used for telecommunications services between the United States and France or Germany. If other providers unaffiliated with FT, DT, Sprint or Joint Venture Co. actually own and control such international half-circuits, Sprint and Joint Venture Co. can also acquire ownership and control of international

half-circuits, but only to the extent that and in no greater quantity than the aggregate amount of such half-circuits that other providers have. The limitation on ownership or control of international half-circuits can be lifted, if the United States and defendants agree that meaningful competition exists to the half-circuits provided by FT or DT. At present, although the international half-circuits terminating within France and Germany are strictly speaking not within the scope of the domestic monopolies, no providers other than FT and DT have been authorized to operate such facilities, and no meaningful competition to FT's and DT's international half-circuits exists. Precluding Sprint and the joint venture from acquiring ownership interests in, or any form of managerial or operational control over, these types of facilities will help to reinforce the effectiveness of the behavioral prohibitions and obligations and ensure that misconduct is more readily detected.

In addition, Section III.B of the proposed Final Judgment prohibits Sprint and Joint Venture Co. from acquiring ownership interests in or control over the Public Data Networks in France and Germany, which are now owned and controlled by FT and DT, respectively, either directly or through subsidiaries (the French public data network is operated by a company called Transpac, almost entirely owned by FT). While the Public Data Networks are not subject to any legal monopoly rights and face limited competition, the unmatched size and ubiquity of these networks in France and Germany give FT and DT effective market power in the provision of data telecommunications services in their home countries. Precluding Sprint or the joint venture from acquiring ownership interests in, or any operational or managerial control over, these Public Data Networks will help to ensure that the behavioral restrictions pertaining to those networks remain enforceable, and that Joint Venture Co. is not placed in a dominant position in providing data telecommunications services to and from France and Germany.

b. Non-Exclusive Distribution. Pursuant to Section III.C of the proposed Final Judgment, Sprint and Joint Venture Co. are prohibited from providing FT or DT Products and Services, except pursuant to a sales agency or resale agreement, and then only if the sales agency or resale agreements are non-exclusive. Non-exclusivity will be assessed not only on the facial terms of the agreement but also on the actual practice of FT and DT. Moreover, FT or DT Products and Services must continue to be available directly to other United States international telecommunications providers directly from FT and DT on a nondiscriminatory basis. The term "nondiscriminatory" in Section III.C will be construed in the same manner as the more specific nondiscrimination provisions of Section III.D. Section III.C ensures that Sprint and Joint Venture Co. cannot through their association with FT and DT obtain any exclusive rights or special advantages in marketing or providing any of the FT or DT Products and Services, which are needed by other United States international telecommunications providers to offer their own services, and over which FT and DT continue to have monopoly rights or market power.

c. Non-Discrimination Provisions. There are two antidiscrimination provisions of the proposed Final Judgment in Section III.D. The first, Section III.D.1, prohibits Sprint or Joint Venture Co. from purchasing, acquiring or accepting FT or DT Products and Services on terms which are more favorable to Sprint or Joint Venture Co. than are made available to other United States international telecommunications providers.[22] This section is designed to prevent FT or DT from using their monopolies and market power in France and Germany to favor Sprint and Joint Venture Co. in the provision of products and services that other providers must also have to compete effectively. In order to ensure clarity and specificity, and aid enforcement, Section III.D.1 specifies various types of conduct as to which discrimination is not permitted, including (i) prices of products and services, (ii) volume and other discounts, and material differences in non-price terms of service, (iii) material differences in the type and quality of service, including leased lines and international half-circuits, (iv) interconnection with the FT and DT public switched telephone networks and number availability, and (v) the terms of operating agreements for correspondent services and connection of international half-circuits. If defendants seek to rebut a claim of discrimination pursuant to this section by establishing the existence of a cost justification, they have the burden of proof, and must make available to the United States all of the information that was available to them, directly or indirectly from FT or DT.

Section III.D.2 prohibits Sprint and Joint Venture Co. from benefiting from any discount or more favorable term offered by FT or DT to any customer for FT or DT Products and Services, that is conditioned on Sprint or Joint Venture Co. being selected as the United States provider of a telecommunications or enhanced telecommunications service. This provision is designed to prevent Sprint and Joint Venture Co. from receiving benefits of discrimination indirectly, through special deals or arrangements that FT and DT offer to customers in order to induce them to obtain services from Sprint or Joint Venture Co., rather than through more favorable terms offered directly to Sprint or Joint Venture Co. addressed by III.D.1. Thus, this provision encompasses forms of discrimination in addition to those specified in III.D.1, including activities involving the sale marketing, and distribution of Sprint and Joint Venture Co. services by FT and DT. Any offering of such conditional deals by FT or DT would be considered a benefit to Sprint or Joint Venture Co.

Although FT and DT have some nondiscrimination obligations under French and German law and regulations, and the FCC has authority to preclude Sprint from accepting "special concessions" from foreign carriers, the provisions of the proposed Final Judgment are considerably more specific and comprehensive than any existing regulatory obligations applicable to Sprint, FT or DT, because Joint Venture Co. may not be subject to direct to complete oversight by any United States, French or Germany telecommunications regulator. Moreover, during the period while FT and DT continue both to be government-owned and to enjoy monopoly rights in France and Germany, and regulatory regimes in France and Germany are not fully developed, it is important for the protection of competition that additional safeguards be in place to that United States international telecommunications providers can have access to FT's and DT's facilities and services comparable to Sprint and Joint Venture Co.

d. Proportionate Return of Traffic. Section III.E prohibits Sprint from accepting correspondent voice telecommunications traffic from FT in France or DT in Germany, unless that traffic is transmitted to all licensed U.S. international telecommunications

[22] The proposed Final Judgment provides that for discrimination to exist, the United States international telecommunications providers who receive less favorable treatment must be "similarly situated" to Sprint and Joint Venture Co. For the purposes of this paragraph "similarly situated" means that the provider is generally comparable to Sprint and Joint Venture Co. with respect to the volume and type of service acquired from FT or DT, provided that volume and type are relevant distinctions in establishing service conditions.

carriers that have operating agreements with FT and DT in the same proportions as the correspondent voice telecommunications traffic from the United States to France or to Germany that FT and DT receive from such U.S. carriers. Nor may Sprint accept any correspondent telecommunications traffic from FT in France, or DT in Germany, in a manner inconsistent with the policies of the FCC concerning proportionate return. In addition, Sprint is also prohibited from accepting or benefiting from any change in the methodology by which FT or DT allocates proportionate return traffic among United States international telecommunications providers, if such a change would substantially favor Sprint in relation to all other United States international telecommunications providers either in the value or volume of traffic, or would be inconsistent with the policies of the FCC with respect to Sprint, FT and DT.

In order to ensure compliance with these provisions, section III.E.1 requires Sprint and Joint Venture Co. to disclose on a quarterly basis the volume of correspondent telecommunications traffic sent to and received from FT and DT, showing each type of traffic, how traffic has been pooled for purposes of calculating proportionate return, and what volume of traffic has been counted for the purposes of proportionate return and what has been excluded. These reporting requirements, which are substantially more detailed than the proportionate return reporting obligations in Section II.A.3, are in addition to the obligations of Section II.A.3 while Phase I of the decree remains in effect. Section III.E.2 provides that the United States, if it believes that Joint Venture Co. has accepted correspondent traffic in violation of Section III.E, shall notify Sprint and may also notify the FCC. Within 90 days of receipt of such notification, Sprint is required to respond in writing and take all necessary measures to ensure its compliance with the provisions of Section III.E.

At present, the FCC has a policy generally requiring proportionate allocation of incoming international traffic among U.S. international carriers, but this policy is not embodied in specific regulations, and the FCC does not supervise the methodology or details of proportionate return, or require the approval of proportionate return arrangements, which are negotiated among U.S. and foreign carriers. Nonetheless, the FCC has historically been the only regulatory agency that has addressed proportionate return at all, since foreign telecommunications regulators, including those in France and Germany, generally have dealt with a single international carrier in their home countries and have not imposed any form of proportionate allocation requirement on their national carriers. The provisions of Section III.E are intended to supplement for this particular transaction, not to supplant, the FCC's role in regulating proportionate return. Indeed, Section V.R provides that if the FCC adopts specific proportionate return policies for the relationship of Sprint, FT and DT that would conflict with the proportionate return commitment in this decree, Sprint's proportionate return obligation herein shall be modified to be consistent with the FCC policies.

e. Preclusion of Cross-Subsidization. Section III.F contains several provisions intended to ensure that FT and DT do not cross-subsidize Sprint or Joint Venture Co. during Phase I of this Final Judgment, while FT and DT continue to realize most of their revenues from their state-sanctioned monopolies. Existing regulatory safeguards against cross-subsidization in France and Germany are very limited and have not prevented instances of massive cross-subsidy, in particular the $1.3 billion transfer to DT's Datex-P public data network over several years that was uncovered by the German competition authorities in 1994. Once FT and DT face competition in the areas of their business now protected by monopoly rights, and the EU authorities have improved safeguards against cross-subsidy as part of their liberalization program, there is reason to believe that the risks of such conduct should diminish, but for now it is not possible to rely entirely on national regulatory authorities to prevent cross-subsidization of the joint venture or of Sprint by FT and DT.

The preclusion of cross-subsidization is here addressed by a combination of structural, behavioral and accounting requirements. Section III.F.1 requires that Joint Venture Co. be established and operated as a distinct entity separate from FT or DT until Phase II of the Final Agreement takes effect for both France and Germany. Under Section III.F.2, Joint Venture Co. and Sprint are required to obtain their own debt financing on their own credit, though Sprint, FT and DT may make capital contributions and commercially reasonable loans to Joint Venture Co., may pledge their business interests in Joint Venture Co. for non-recourse financings, and may guarantee the indebtedness of Joint Venture Co., provided that Sprint, FT and DT only make payments pursuant to such guarantee following a default by Joint Venture Co. Section III.F.3 requires that Sprint and Joint Venture Co. maintain accounting systems and records which are separate from those of FT and DT and which identify any payments or transfers to or from FT or DT relating to the purchase, acquisition or acceptance of any FT or DT Products and Services, as well as identifying those Joint Venture Co. services for which the FT or DT Products and Services are used. Section III.F.4 prohibits Sprint and Joint Venture Co. from allocating any part of their operating expenses, costs, depreciation, or other business expenses directly or indirectly to any parts of FT's or DT's business units responsible for FT or DT Products and Services. Finally, Section III.F.5 prohibits Joint Venture Co. and Sprint from receiving any material subsidy, including debt forgiveness, from FT or DT, and also prohibits any other investment or payment from FT or DT that is not recorded by Sprint or Joint Venture Co. as an investment in debt or equity. The net effect of these provisions is to allow FT and DT, as parent entities, to make their initial investments and capital contributions in Joint Venture Co., and to follow up those investments with legitimate loans in order to enable Joint Venture Co. to start up and conduct its business, but to prevent FT and DT otherwise from subsidizing Joint Venture Co. or Sprint, or from shifting costs from Joint Venture Co. or Sprint to FT's or DT's monopoly services.

f. Operating Agreements. FT and DT are not obligated by any French or German law or regulatory requirement to make operating agreements available to particular United States international telecommunications providers. Although four United States international carriers—AT&T, MCI, Sprint and IDB—now have operating agreements with both FT and DT for standard switched voice services and other types of traffic, the discretion that FT and DT enjoy to award or deny operating agreements to particular carriers could be used to favor Sprint with exclusive rights to provide new types of correspondent services. Moreover, denial of operating agreements can act as a barrier to new entry by smaller providers by limiting their ability to achieve cost economies and large volumes of traffic. For several years, IDB, the smallest of the U.S. facilities-based international carriers, was unable to obtain an operating agreement with DT, and only received its agreement in November 1994, during

the pendency of this antitrust investigation.

The potential competitive problems associated with denial of operating agreements are dealt with in two ways in the proposed Final Judgment. Section III.G.1 prohibits Sprint from offering, supplying, distributing or otherwise providing any correspondent telecommunications or enhanced telecommunications service between the United States and France or Germany, pursuant to any operating agreement with FT or DT, unless at least one other United States international telecommunications provider has also obtained an operating agreement with FT and DT to provide the same service between the United States and France and Germany. While Section III.G.1. does not mandate that all carriers seeking operating agreements have received them, Section III.G.2 ensures a competitive alternative for providers that have not yet been able to obtain operating agreements. Under this provision, where another United States international telecommunications provider has requested but not received an operating agreement to provide IDDD voice service or any other service that uses interconnection with the FT and DT public switched telephone networks, Sprint must offer to carry the international traffic for that provider on rates and terms that are competitive with other United States international telecommunications providers that are able to provide service pursuant to operating agreements. The rates charged by Sprint to carry traffic for these providers must reflect the estimated value of proportionate return traffic from France and Germany that is attributable to the traffic originated by providers that are using Sprint's international facilities to carry their traffic.

g. Access to FT and DT Products and Services. Section III.H. prohibits Sprint and Joint Venture Co. from providing telecommunications or enhanced telecommunications services involving use of FT or DT Products and Services, if FT or DT have established any proprietary or nonstandard protocols or interfaces used by Sprint or Joint Venture Co. for access to these products and services, and FT and DT no longer provide access to the products or services through non-proprietary or standardized interfaces or protocols on a basis consistent with previous operations. This provision ensures that Sprint and Joint Venture Co. will not be given effectively exclusive access to any FT or DT Products and Services, through the control that FT and DT can exercise over the protocols and interfaces used for access to their facilities and services. This provision will have a significant role in ensuring that competitors can obtain interconnection to the public switched networks in France and Germany. At the same time, it does not forbid FT and DT from developing any proprietary and nonstandardized protocols or interfaces for the seamless services to be offered by Joint Venture Co., so long as competitors are left with an alternative, nonproprietary means of obtaining access, and so strikes a balance between the goals of protecting competition and promoting the availability of new and innovative services for consumers.

h. Access to Public Data Networks. Section III.I is the counterpart to Section III.H. for the FT and DT public data networks, which are not within the definition of FT or DT Products and Services. This provision prohibits Sprint and Joint Venture Co. from providing any data telecommunications service or enhanced data telecommunications service making use of FT's and DT's public data networks in France and Germany, unless access to such networks is available to all other United States telecommunications providers on nondiscriminatory terms to complete data telecommunications between the United States and France or Germany, and within France and Germany, through standard protocols. The X.75 protocol for interconnection of data networks, specifically identified in this provision, is the standard one used in conjunction with data services operating on the X.25 protocol, which is the basis of both FT's and DT's public data networks. X.75 may not remain the only standard interconnection protocol, or may be changed, and so this provision permits use of any generally accepted standard network interconnection protocol that may modify or replace the X.75 standard. Section III.I is the principal safeguard in this proposed Final Judgment for competitive access to DT's and FT's public data networks in France and Germany.

4. Persons to Whom the Final Judgment is Applicable

Section IV of the proposed Final Judgment makes the judgment binding upon the defendants, who are Sprint and Joint Venture Co. as defined in Sections V.O. and V.T. It also makes the judgment binding on Sprint's and Joint Venture Co.'s affiliates, subsidiaries, successors and assigns, officers, agents, servants, employees and attorneys. However, the proposed Final Judgment will not continue to bind any Sprint business that is spun-off or otherwise divested and in which neither FT or DT has any ownership interest, thus facilitating Sprint's planned divestiture of its cellular radio proprieties. In addition, because affiliates and subsidiaries are broadly defined in Section V.A. to include any entity in which a person has equity ownership, Section V.A. also specifies that affiliates and subsidiaries of Sprint and Joint Venture Co. that are not controlled, as defined in Section V.C., by Sprint or by Joint Venture Co. do not have substantive compliance obligations under Sections II and III of the proposed Final Judgment.

5. Visitorial Provisions

Section VI of the Final Judgment allows the Department of Justice to monitor defendants' compliance by several means. Section VI.A obliges defendants to maintain records and documents sufficient to show their compliance with the Final Judgment's requirements. Sections VI.B and VI.C enable the United States to gain access to inspect and copy the records and documents of defendants, and also to have access to their personnel for interviews or to take sworn testimony. Section VI.B covers access to Sprint, as well as to Joint Venture Co.'s operations in the United States. To avoid difficulties that might arise in applying this visitorial procedure to discovery directed at foreign operations of Joint Venture Co., Section VI.C provides that Joint Venture Co. documents and personnel, wherever located (including abroad), would be produced by Joint Venture Co. in the United States, within sixty days of the request in the case of documents, and subject to the reasonable convenience of the persons involved in the case of requests for interviews or sworn testimony. Section VI.D permits the United States also to require any defendant to submit written reports relating to any matters contained in the Final Judgment. Finally, Section VI.E supplies confidentiality protections for information and documents furnished by defendants to the United States under the other provisions of Section VI. It permits the Department of Justice to share information and documents with the Federal Communications Commission (subject to confidentiality protections), and to share information with the French and German telecommunications regulators, DGPT and BMPT.

6. Modifications

Section VIII, the modifications provision, affords the means of expanding, altering or reducing the substantive terms of the Final Judgment.

and is essential to the protection of competition. Modifications that are not contested by any party to the Final Judgment are reviewed under a "public interest" test. See, *e.g., United States* v. *Western Electric Co.*, 993 F.2d 1572, 1576–77 (D.C. Cir. 1993). As it is not the intent of the parties to place Sprint at a competitive disadvantage in such a way as to harm competition, the Final Judgment recognizes in VIII.C that defendants are permitted to identify to the United States any changed circumstances that they believe cause any terms of the Final Judgment to operate in a way that is harmful to competition, but it is in the sole discretion of the United States whether to agree to any modification on this basis. The only grounds on which a modification can be obtained over the opposition of a party are those stated in VIII.A for contested modifications.

Where a proposed modification is contested by any party to the Final Judgment, the Court must determine both whether modification is required, and whether the particular modification proposed is appropriate. The United States is able to seek changes to the substantive terms and obligations of the Final Judgment from the Court, including additional requirements to prevent receipt of discriminatory treatment by defendants, in order to avoid substantial harm to competition or consumers in the United States. The defendants are able to seek modifications removing obligations of the Final Judgment in order to avoid substantial hardship to themselves. In either case, the party seeking modifications must make a clear showing that modification is required, based on a significant change in circumstances or a significant new event subsequent to the entry of the Final Judgment. As recognized in VIII.B, such a change in circumstances or an event subsequent to the entry of judgment need not have been unforeseen, nor need it have been referred to in the Final Judgment.

Section VIII.A would, for example, enable the United States to seek modification of the decree if, after the termination of Phase I, discrimination against other United States international telecommunications providers or other types of conduct occur that would have been prohibited under the Phase I restrictions, resulting in a substantial harm to competition. Such a harm to competition could occur if the entry of other licensed competitors in France or Germany has been significantly delayed after the granting of licenses, or has otherwise not proven sufficient to provide a competitive alternative, and the regulatory authorities in France or Germany have failed to take effective steps to prevent the misconduct. Before concluding that such discrimination or other conduct during Phase II required the United States to seek a modification of the Final Judgment to protect competition or consumers, the Department of Justice would ordinarily inquire at the outset whether injured competitors had availed themselves of existing regulatory remedies, if any, in France or Germany as well as the United States, and what relief had been provided or action taken, if any, by the telecommunications regulatory agencies.

If the Court concludes that any party has met its burden of showing that the Final Judgment should be modified over the opposition of another party, it would then be empowered to grant any particular modification that meets three criteria. The modification must be (i) in the public interest, (ii) suitably tailored to the changed circumstances or new event that gave rise to its adoption, and must not result in serious hardship to any defendant, and (iii) consistent with the purposes of the antitrust laws of the United States, and the telecommunications regulatory regimes of the United States, France and Germany. This standard protects against overbroad modifications. It also recognizes that mere inconvenience or some hardship to a defendant will not preclude a modification, by only "serious" hardship. The loss of opportunity to profit from anticompetitive conduct is not a "serious" hardship within the meaning of this standard. Any proposed modification, to be consistent with the antitrust laws, must not be of an anticompetitive character, and must protect competition or consumers in the United States. Modifications must also be consistent with the system of regulation of telecommunications in the United States, France and Germany. This does not mean that modifications must mirror the telecommunications regulations, but at the least, conflicting obligations should not be created.

Section VIII.B permits the United States, where any party has sought modifications of the Final Judgment, to invoke any of the visitorial provisions contained in Section VI of the Final Judgment in order to obtain from defendants any information or documents needed to evaluate the proposed modification prior to decision by the Court.

7. Term of Agreement

Section X.B of the proposed Final Judgment species that the substantive restrictions and obligations of the Final Judgment shall expire five years after the date that Phase II has taken effect with respect to both France and Germany. Only the substantive restrictions in Section III are removed at the conclusion of Phase I, but for these purposes the date on which Phase II has taken effect is assessed separately for France and for Germany, as one country might liberalize its telecommunications markets significantly sooner than the other. The duration of the proposed decree is reasonable because the international telecommunications markets, including the markets for international telecommunications services between the United States and France and Germany and the emerging markets for seamless international telecommunications services, may evolve rapidly during the next several years, in part due to the transactions under consideration in this case and the Final Judgment, as well as the regulatory changes taking place in the EU. In the BT–MCI transaction, this Court approved a duration for the consent decree of five years. The greater duration here is based on the important differences that now exist between the French and German telecommunications regimes and the more open environment in the United Kingdom. It is possible for this decree to have an indefinite duration, should France or Germany fail ever to meet the conditions set forth in Section V.Q for the shift to Phase II, but if liberalization is completed and competitors are licensed on the schedule now projected by the EU authorities, the total duration of the decree is most likely to be about eight years. The five-year duration of Phase II will give the United States ample time to evaluate whether competition is developing in France and Germany as anticipated, and to seek modifications of the decree if competition fails to develop and United States international telecommunications providers are subjected to anticompetitive conduct by FT or DT. Under these circumstances, the United States does not consider it necessary to impose a lengthier duration on the substantive provisions of the proposed Final Judgment.

B. Effects of the Proposed Final Judgment on Competition

The transaction contemplated between Sprint, FT and DT represents the second opportunity that the Department of Justice has had within the past three years to consider the major changes now taking place in international telecommunications, and the competitive significance for United

States consumers of the development of strategic alliances. Notwithstanding the many common features that the Sprint-FT–DT alliance and the MCI–BT alliance share, including the overall level of investment in the U.S. carrier, the non-compete agreements and the wide range of international services contemplated by the parties' joint venture, the important differences between the two transactions have meant that the Department has had to conduct a separate and thorough investigation of this new alliance, lasting for over a year from the initial announcement of the planned transaction. The differences between these transactions turn principally on the market positions of the foreign parents.

The Sprint-FT–DT joint venture may enable the parties to offer some international services of a type or on a scale that they would not otherwise provide. But the alliance as currently structured also poses substantial risks to competition in the United States, of an even greater magnitude than did the MCI–BT alliance. FT's and DT's monopolies over public voice services, the public switched network and transmission infrastructure in France and Germany, as well as their market power in public data network services, would when combined with Sprint's competitive long distance services and facilities in the U.S. and its strong position in data services give rise to increased incentives for FT's and DT's monopoly power to be used to favor Sprint and Joint Venture Co. and to disadvantage competitors in the United States. These factors made it necessary for the United States to obtain, by agreement with the parties, considerably more extensive relief than in the BT–MCI transaction, in order to be assured that the competitive problems here were adequately addressed.

In other circumstances involving vertical integration between large monopoly providers of local exchange telecommunications services and competitive long distance providers in the United States, the Department of Justice has obtained various forms of relief under the antitrust laws to protect competition. See, e.g., *United States* v. *American Telephone and Telegraph Co.*, 552 F. Supp. 131 (D.D.C. 1982), *aff'd mem. sub nom. Maryland* v. *United States*, 460 U.S. 1001 (1983); *United States* v. *GTE Corp.*, 603 F. Supp. 730 (D.D.C. 1984). In each of these cases, the United States has dealt with distinct factual situations and legal contexts. The relief proposed here, while not the same as in the other cases, serves a similar competitive purpose, taking into account the particular circumstances and risks associated with the transactions between Sprint, FT and DT. These include, as in the BT-MCI case, the unique practices and relationships between carriers in the provision of international telecommunications services, the continued existence of Sprint as a separate entity following these transactions, and the involvement of foreign telecommunications providers subject to distinct regulatory regimes overseas. In this case, an added complication was created by the government ownership of the foreign carriers at issue. While it was not appropriate in this transaction to accord deference to separate telecommunications regulation in France and Germany to the same extent as was done for the United Kingdom in the BT-MCI transaction, given the absence of privatization and the continued existence of de jure monopolies in France and Germany, the progress toward a more competitive telecommunications environment now being made in the EU and the plans for introduction of full competition in France and Germany by 1998 have been taken into account. These regulatory developments have fundamentally affected the two-stage structure of the proposed decree, and the feasibility of shifting to a more limited form of relief in Phase II.

The United States believes that the relief proposed here, including both the substantive restrictions and obligations and the ability of the Court to modify the Final Judgment to respond to additional competitive problems, will substantially benefit competition. The ability of Sprint and of Joint Venture Co. to realize anticompetitive advantages in the United States will be substantially constrained.

Entry of the proposed Final Judgment will allow the transactions between Sprint, FT and DT to proceed and any benefits to consumers to be realized, subject to further review by the Federal Communications Commission and the European Commission, and any additional modifications that may be made to satisfy their separate concerns. At the same time, entry of the proposed Final Judgment will provide extensive protections to competing United States international telecommunications providers during the period preceding full liberalization in France and Germany, as needed to protect competition. After liberalization, the Final Judgment will continue to provide United States competitors with increased means to detect discrimination, protection against the misuses of confidential business information, and safeguards against licensing advantages for Sprint and Joint Venture Co. for an additional five years, while competition develops in France and Germany. During the entire duration of the decree, the United States will have a mechanism to seek modification of the Final Judgment without having to initiate separate antitrust litigation, should competition and regulatory protections in the EU, France and Germany not develop as anticipated and substantial competitive harms arise. This opportunity to impose additional restrictions on defendants, or to extend the existing restrictions in Phase I for a longer time, in order to protect competition and consumers in the United States, responds to any risk that the other substantive provisions of the Final Judgment and separate regulatory requirements may prove insufficient to protect competition. Thus, the modification provision will serve as an additional important deterrent to anticompetitive behavior.

IV

Remedies Available to Potential Private Litigants

Section 4 of the Clayton Act, 15 U.S.C. 15, provides that any person who has been injured as a result of conduct prohibited by the antitrust laws may bring suit in federal court to recover three times the damages suffered, as well as costs and reasonable attorney's fees. Entry of the proposed Final Judgment will neither impair nor assist the bringing of such actions. Under the provisions of Section 5(a) of the Clayton Act, 15 U.S.C. 16(a), the proposed Final Judgment has no *prima facie* effect in any subsequent private lawsuits that may be brought against defendants in this matter.

In addition, persons affected by unreasonable discrimination on the part of Sprint, in violation of 47 U.S.C. 202, may complain to the Federal Communications Commission as provided by 47 U.S.C 208, for such relief as is available under the Communications Act and the Commission's regulations, or bring suit for damages pursuant to 47 U.S.C. 206. Persons affected by discrimination, refusal to interconnect or other conduct by FT or DT in violation of French or German law may complain to the French DGPT or the German BMPT for such relief as those bodies are authorized to provide, or to the competition authorities in Germany, France and the European Union. Entry of the proposed Final Judgment will not impair the bringing of such complaints

and actions, and indeed will likely facilitate the effective detection and prevention of anticompetitive conduct through existing regulatory mechanisms.

V

Procedures Available for Modification of the Proposed Final Judgment

As provided by the Antitrust Procedures and Penalties Act, any person believing that the proposed Final Judgment should be modified may submit written comments to Donald J. Russell, Chief, Telecommunications Task Force, U.S. Department of Justice, Antitrust Division, 555 Fourth Street, N.W., Room 8104, Washington, D.C. 20001, within the 60-day period provided by the Act. These comments and the Department's responses, will be filed with the Court and published in the **Federal Register**. All comments will be given due consideration by the Department of Justice, which remains free to withdraw its consent to the proposed Judgment at any time prior to entry. The proposed Final Judgment provides that the Court retains jurisdiction over this action, and the parties may apply to the Court for any order necessary or appropriate to carry out or construe the Final Judgment, to modify or terminate any of its provisions, to enforce compliance, and to punish any violations of its provisions. Modifications of the Final Judgment may be sought by the United States or by the defendants under the standards described therein.

VI

Alternatives to the Proposed Final Judgment

As an alternative to the proposed Final Judgment, the United States considered litigation to seek an injunction to prevent the proposed transaction between Sprint, FT or DT. The United States rejected that alternative based on a combination of the following considerations. First, the relief in the proposed Final Judgment, together with the planned liberalization of all telecommunications markets and developing regulatory safeguards in the EU, France and Germany, and existing U.S. telecommunications regulation applicable to Sprint, should provide a reasonable degree of protection against significant lessening of competition in the U.S. markets at issue. Second, litigation of this matter would have been highly complex and the result uncertain, in part because the United States would have borne the burden of proof in demonstrating the extent to which this transaction would have led to additional lessening of competition and also because foreign markets were involved. Therefore, avoiding litigation represents a substantial savings of public resources.

The United States also considered, in formulating the proposed Final Judgment, significantly limiting the level of equity investment that FT or DT would be permitted to make in Sprint prior to full liberalization of the telecommunications markets in France and Germany. Extensive changes to the equity investment contingent on full liberalization would, however, have created a substantial likelihood that the parties would have declined to consummate the transaction in any form, since full liberalization is still some three years away. To insist on such changes would have made it likely that the parties could not have entered into any settlement, leading to litigation. Had a restriction on the equity investment been the only way to prevent this transaction from giving rise to a further lessening of competition (beyond that already occurring in international markets due to the existence of DT's and FT's monopolies), this might nevertheless have been necessary. But, while the level of equity investment here does play a substantial role in creating additional incentives for FT and DT to favor Sprint, it was not clear that reducing the current investment in Sprint would have eliminated those incremental incentives, given the additional extensive investments that the parties also are planning to make in the joint venture. Ultimately, the United States concluded that the other provisions of the decree, particularly those in Section III, would provide a reasonable level of protection against increased harm to competition in United States markets arising from this specific transaction, so that it was not essential to insist on a change to the equity investment to accomplish the purposes of the antitrust laws.

The United States has also considered issues of international comity in shaping the proposed Final Judgment. International transactions, particularly where activities of foreign governments and their enterprises are in issue, give rise to special considerations not present in the domestic context. Consistently with its longstanding enforcement policy, see, e.g., U.S. Department of Justice and Federal Trade Commission, Antitrust Enforcement Guidelines for International Operations, at 20–28 (1995), the United States sought in the substantive restrictions and obligations of Sections II and III of the proposed Final Judgment to avoid situations that could give rise to international conflicts between sovereign governments and their agencies. The United States is not aware of any such conflict that would arise from the implementation of the substantive provisions of the proposed Final Judgment as currently drafted. FT and DT have not been made defendants in this case, so that the United States is not imposing direct obligations on any foreign government-owned entity. Moreover, the substantive obligations, to the extent that they may indirectly affect the conduct of FT and DT, apply to practices over which either foreign regulation is insubstantial or nonexistent, or, to the extent that regulation exists, it also condemns in a general sense the practices that the proposed Final Judgment seeks to prevent. The latter is particularly true with respect to the key prohibitions on discrimination and cross-subsidy. Here, the competitive concern is not that French or German regulation directs FT or DT to discriminate against competitors or to cross-subsidize their own competitive services—quite the contrary—but that regulation is at present insufficiently developed to safeguard competition adequately by itself, in the absence of alternative telecommunications infrastructure that can be used by all competitors in France and Germany.

VII

Standard of Review Under the Tunney Act for the Proposed Final Judgment

The APPA requires that proposed consent judgments in antitrust cases brought by the United States are subject to a sixty-day comment period, after which the court shall determine whether entry of the proposed final judgment "is in the public interest." In making that determination, the court *may* consider:

(1) the competitive impact of such judgment, including termination of alleged violations, provisions for enforcement and modification, duration or relief sought, anticipated effects of alternative remedies actually considered, and any other considerations bearing upon the adequacy of such judgment;

(2) the impact of entry of such judgment upon the public generally and individuals alleging specific injury from the violations set forth in the complaint including consideration of the public benefit, if any, to be derived from a determination of the issues at trial.

15 U.S.C. 16(e) (emphasis added). The courts have recognized that the term "public interest" "take[s] meaning from the purposes of the regulatory legislation." *NAACP* v. *Federal Power*

Comm'n, 425 U.S. 662, 669 (1976); *United States* v. *American Cyanamid Co.*, 719 F.2d 558, 565 (2d Cir. 1983), *cert. denied*, 465 U.S. 1101 (1984). Since the purpose of the antitrust laws is to "preserv[e] free and unfettered competition as the rule of trade," *Northern Pacific Railway Co.* v. *United States*, 356 U.S. 1, 4 (1958), the focus of the "public interest" inquiry under the Tunney Act is whether the proposed final judgment would serve the public interest in free and unfettered competition. *United States* v. *Waste Management, Inc.*, 1985–2 Trade Cas. ¶ 66,651, at 63,046 (D.D.C. 1985). In conducting this inquiry, "the Court is nowhere compelled to go to trial or to engage in extended proceedings which might have the effect of vitiating the benefits of prompt and less costly settlement through the consent decree process."[23] Rather,

> absent a showing of corrupt failure of the government to discharge its duty, the Court, in making the public interest finding, should * * * carefully consider the explanations of the government in the competitive impact statement and its responses to comments in order to determine whether those explanations are reasonable under the circumstances.

United States v. *Mid-America Dairymen, Inc.*, 1977–1 Trade Cas. ¶ 61,508, at 71,980 (W.D. Mo. 1977).

It is also unnecessary, and inappropriate, for the district court to "engage in an unrestricted evaluation of what relief would best serve the public." *United States* v. *Bechtel Corp.*, 648 F.2d 660, 666 (9th Cir.), *cert. denied*, 454 U.S. 1083 (1981), quoted with approval in *United States* v. *Microsoft Corp.*, 56 F.3d 1448, 1995–1 Trade Cas. ¶ 71,027, at ¶ 74,830 (D.C. Cir. 1995). In the recent *Microsoft* decision by the United States Court of Appeals for the District of Columbia Circuit, which reversed the district court's refusal to enter an antitrust consent decree proposed by the United States, the court of appeals held that the provision in Section 16(e)(1) of the Tunney Act allowing the district court to consider "any other considerations bearing upon the adequacy of such judgment," does not authorize extensive inquiry into the conduct of the case. 1995–1 Trade Cas. ¶ 71,027, at ¶ 74,830. The court of appeals concluded that "Congress did not mean for a district judge to construct his own hypothetical case and then evaluate the decree against that case." *Id.* To the contrary, "[t]he court's authority to review the decree depends entirely on the government's exercising its prosecutorial discretion by bringing a case in the first place," and so the district court "is only authorized to review the decree itself," not other matters that the government might have but did not pursue. *Id.*

The district court's legitimate functions in reviewing a proposed consent decree, according to the *Microsoft* decision, include consideration of both the decree's "clarity" in order to protect against ambiguity, and also its "compliance mechanisms" in order to avoid future "difficulties in implementation." *United States* v. *Microsoft Corp.*, 1995–1 Trade Cas. ¶ 71,027, at ¶¶ 74,832–33. The court may also appropriately consider claims of third parties "that they would be positively injured by the decree," when brought to the court's attention consistent with the requirements of the Tunney Act and accepted process in federal courts. *Id.* at ¶¶ 74,833–34. But

> [t]he balancing of competing social and political interests affected by a proposed antitrust consent decree must be left, in the first instance, to the discretion of the Attorney General. The court's role in protecting the public interest is one of insuring that the government has not breached its duty to the public in consenting to the decree. The court is required to determine not whether a particular decree is the one that will best serve society, but whether the settlement is "within the reaches of the public interest." More elaborate requirements might undermine the effectiveness of antitrust enforcement by consent decree.[24]

Although the court "is not obliged to accept [a proposed decree] that, on its face and even after government explanation, appears to make a mockery of judicial power * * * [s]hort of that eventuality, the Tunney Act cannot be interpreted as an authorization for a district judge to assume the role of Attorney General." *United States* v. *Microsoft Corp.*, 1995–1 Trade Cas. ¶ 71,027, at ¶ 74,833. In sum, a district judge "must be careful not to exceed his or her constitutional role." *Id.*

A proposed consent decree is an agreement between the parties which is reached after exhaustive negotiations and discussions. Parties do not hastily and thoughtlessly stipulate to a decree because, in doing so, they

> waive their right to litigate the issues involved in the case and thus save themselves the time, expense, and inevitable risk of litigation. Naturally, the agreement reached normally embodies a compromise; in exchange for the saving of cost and the elimination of risk, the parties each give up something they might have won had they proceeded with the litigation.

United States v. *Armour & Co.*, 402 U.S. 673, 681 (1971).

The proposed consent decree, therefore, should not be reviewed under a standard of whether it is certain to eliminate every anticompetitive effect of a merger or whether it mandates certainty of free competition in the future. The court may reject the agreement of the parties as to how the public interest is best served only if it has "exceptional confidence that adverse antitrust consequences will result * * *." *United States* v. *Western Electric Co.*, 993 F.2d 1572, 1577 (D.C. Cir.), *cert. denied*, 114 S. Ct. 487 (1993), quoted with approval in *United States* v. *Microsoft Corp.*, 1995–1 Trade Cas. ¶ 71,027, at ¶ 74,831.

Court approval of a final judgment requires a standard more flexible and less strict than the standard required for a finding of liability. "[A] proposed decree must be approved even if it falls short of the remedy the court would impose on its own, as long as it falls within the range of acceptability or is 'within the reaches of public interest.'"[25] Under the public interest standard, the court's role is limited to determining whether the proposed decree is within the "zone of settlements" consistent with the public interest, not whether the settlement diverges from the court's view of what would best serve the public interest. *United States* v. *Western Electric Co.*, 993 F.2d at 1576 (quoting *United States* v. *Western Electric Co.*, 900 F.2d 283, 307 (D.C. Cir. 1990)); *United States* v. *Microsoft Corp.*, 1995–1 Trade Cas. ¶ 71,027, at ¶ 74,831. Indeed, a district court should give a request for entry of a proposed decree even more deference

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[23] 119 Cong. Rec. 24598 (1973). See *United States* v. *Gillette Co.*, 406 F. Supp. 713, 715 (D. Mess. 1975). A "public interest" determination can be made properly on the basis of the Competitive Impect Statement and Response to Comments filed pursuent to the APPA. Although the APPA euthorizes the use of additional procedures, 15 U.S.C. § 16(f), those procedures are discretionary. A court need not invoke any of them unless it believes that the comments have reised significant issues and that further proceedings would aid the court in resolving those issues. See H.R. Rep. 93–1463, 93rd Cong. 2d Sess. 8–9 (1974), reprinted in 1974 U.S.C.C.A.N. 6535, 6538–39.

[24] *United States* v. *Bechtel*, 648 F.2d et 666 (quoting *United States* v. *Gillette Co.*, 406 F. Supp. et 716). See *United States* v. *Microsoft Corp.*, 1995–1 Trede Cas. ¶ 71,027, at ¶ 74,832; *United States* v. *BNS, Inc.*, 858 F.2d 456, 463 (9th Cir. 1988); *United States* v. *National Broadcasting Co.*, 449 F. Supp. 1127, 1143 (C.D. Cal.; 1978); see also *United States* v. *American Cyanamid Co.*, 719 F.2d et 565.

[25] *United States* v. *American Tel. and Tel. Co.*, 552 F. Supp. 131, 151 (D.D.C. 1982), *aff'd sub nom. Maryland* v. *United States*, 460 U.S. 1001 (1983) (quoting *United States* v. *Gillette Co.*, 406 F. Supp. et 716); *United States* v. *Alcan Aluminum, Ltd.*, 605 F. Supp. 619, 622 (W.D. Ky 1985). See also, *United States* v. *Microsoft Corp.*, 1995–1 Trade Cas. ¶ 71,027, at ¶ 74,831, citing *United States* v. *Western Electric Co.*, 900 F.2d 283, 309 (D.C. Cir. 1990) (citing and quoting *Bechtel*. 648 F.2d at 666, in turn quoting *Gillette*, 406 F. Supp. at 716).

than a request by a party to an existing decree for approval of a modification, for in dealing with an initial settlement the court is unlikely to have substantial familiarity with the market involved. *United States* v. *Microsoft Corp.*, 1995–1 Trade Cas. ¶ 71,027, at ¶¶ 74,831–32.

VIII

Determinative Materials and Documents

No documents were determinative in the formulation of the proposed Final Judgment. Consequently, the United States has not attached any such documents to the proposed Final Judgment.

Dated: August 14, 1995.

Anne K. Bingaman,

Assistant Attorney General.

Constance K. Robinson,

Director, Office of Operations, Antitrust Division, U.S. Department of Justice.

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BILLING CODE 4410–01–M

Office of Justice Programs

[OJP (NIJ) No.1057C]

RIN 1121–ZA19

National Institute of Justice; Clarification to the National Institute of Justice Solicitation "NIJ Requests Proposals for Research in Action Partnerships"

AGENCY: U.S. Department of Justice, Office of Justice Programs, National Institute of Justice.

ACTION: Clarification of eligibility of applicants for the National Institute of Justice Solicitation "NIJ Requests Proposals for Research in Action Partnerships".

ADDRESSES: National Institute of Justice, 633 Indiana Avenue NW., Washington, DC 20531.

DATES: The deadline for receipt of proposals is close of business on September 8, 1995.

FOR FURTHER INFORMATION CONTACT: The National Criminal Justice Reference Service (NCJRS) at 1–800–851–3420 to obtain a copy of "NIJ Requests Proposals for Research in Action Partnerships" (refer to document no. SL000128).

SUPPLEMENTARY INFORMATION: The following supplementary information is provided:

Authority

This action is authorized under the Omnibus Crime Control and Safe Streets Act of 1968, Sections 201–03, as amended, 42 U.S.C. 3721–23 (1988).

Background

This notice is to clarify eligibility for the National Institute of Justice solicitation, NIJ Requests Proposals for Research in Action Partnerships (July 1995). The solicitation is open to national professional and membership organizations representing various professional groups within criminal justice or elected officials at the State or local level. National membership organizations focused on crime prevention and crime control activities are eligible to apply under this competitive solicitation, independent of whether their members are full time employees of law enforcement and criminal justice organizations. Through this solicitation the National Institute of Justice is seeking to encourage the development of partnerships, with two goals in mind—to encourage the understanding and use of research results, and to encourage the use of new communications technologies. Interested persons should call the National Criminal Justice Reference Service (NCJRS) at 1–800–851–3420 to obtain a copy of "NIJ Requests Proposals for Research in Action Partnerships" (refer to document no. SL000128). The solicitation is available electronically via the NCJRS Bulletin Board, which can be accessed via Internet. Telnet to ncjrsbbs.aspensys.com, or gopher to ncjrs.aspensys.com 71. Those without Internet access can dial the NCJRS Bulletin Board via modem: dial 301–738–8895. Set modem at 9600 baud, 8–N–1.

Jeremy Travis,

Director, National Institute of Justice.

[FR Doc. 95–21048 Filed 8–23–95; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

Employment and Training Administration

Determinations Regarding Eligibility to Apply for Worker Adjustment Assistance and NAFTA Transitional Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, as amended, the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers (TA–W) issued during the period of August, 1995.

In order for an affirmative determination to be made and a certification of eligibility to apply for worker adjustment assistance to be issued, each of the group eligibility requirements of section 222 of the Act must be met.

(1) That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated,

(2) That sales or production, or both, of the firm or subdivision have decreased absolutely, and

(3) That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Negative Determinations for Worker Adjustment Assistance

In each of the following cases the investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

None

In the following cases, the investigation revealed that the criteria for eligibility have not been met for the reasons specified.

TA–W–31,126; Sikorsky Aircraft Corp., Stratford, CT

U.S. imports of military helicopters declined absolutely in the period April 1994 through March 1995 as compared to the year earlier.

TA–W–31,135; Greif Brothers Corp., Amherst, NY

TA–W–31,340; Kaiser Porcelain (US), Inc., Niagara Falls, NY

The workers' firm does not produce an article as required for certification under section 222 of the Trade Act of 1974.

TA–W–31,248; Crown Pacific Ltd, Redmond, OR

The investigation revealed that criterion (1) has not been met. A significant number or proportion of the workers did not become totally or partially separated as required for certification.

TA–W–31,209; M&V Acquisition Corp., Buffalo, NY

U.S. imports of articles of jewelry decreased in 1994 compared with 1993 and also declined in April through March 1994–1995 compared with the same period one year earlier.

Affirmative Determinations for Worker Adjustment Assistance

TA–W–31,236; Ford Electronics & Refrigeration Corp., North Penn Electronics Facility, Lansdale, PA

A certification was issued covering all workers separated on or after June 29, 1994.

TA–W–31,142; Downhole Pressure Service, Inc., Casper, WY

A certification was issued covering all workers separated on or after June 7, 1994.

TA–W–31,241 & A; Tamara Imports, New York, NY and Majesty, Dallas, TX

A certification was issued covering all workers separated on or after June 30, 1994.

TA–W–31,267; Woolrich, Inc., Alliance, NE

A certification was issued covering all workers separated on or after July 12, 1994.

TA–W–31,151; Caffall Brothers Forest Products, Inc., Oregon City, OR

A certification was issued covering all workers separated on or after February 3, 1994.

TA–W–31,121; Standard Pennant Co., Inc., Big Run, PA

A certification was issued covering all workers separated on or after June 2, 1994.

TA–W–31,344; Clint Hurt & Associates, Inc., Charleston, WV

A certification was issued covering all workers separated on or after August 3, 1994.

TA–W–31,289; Graham Energy Services (Braeloch Holdings), Covington, LA

A certification was issued covering all workers separated on or after June 17, 1995.

TA–W–31,256; EIS Brake Parts Div., Berlin, CT

A certification was issued covering all workers separated on or after June 27, 1994.

TA–W–31,191; Ottenheimer & Co., Hillsville, VA

A certification was issued covering all workers separated on or after June 9, 1994.

TA–W–31, 224; R. Manufacturing, Lilly, PA

A certification was issued covering all workers separated on or after June 23, 1994.

TA–W–31, 162; Bergstein Oilfield Services, Inc., (Now Known as S&E Oilfield Service, Inc), Andrews, TX

A certification was issued covering all workers separated on or after May 10, 1994.

TA–W–31, 119; Wirekraft Industries, Inc., Burcliff Industries Div., Cardington, OH

A certification was issued covering all workers separated on or after May 26, 1994.

TA–W–31, 294; Newline Manufacturing (formerly Lynhurst Coat), South Hackensack, NJ

A certification was issued covering all workers separated on or after March 19, 1995.

TA–W–31, 251; Babcock Ultrapower Jonesboro, Jonesboro, ME Including Contract Employees of Maine Power Systems

TA–W–31, 251A; Babcock Ultrapower West Enfield, West Enfield, ME

A certification was issued covering all workers separated on or after July 14, 1994.

TA–W–31, 182 & TA–W–31, 183; Willwear Hosiery, Shogren Industries, Marion, NC and Chattanooga, TN

A certification was issued covering all workers separated on or after May 23, 1994.

TA–W–31, 184 & TA–W–31, 185; Shogren Industries, Concord, NC and Upper Brookville, NY

A certification was issued covering all workers separated on or after May 23, 1994.

TA–W–31, 268; Maxus Energy Corp., Dallas, TX

TA–W–31, 269; Maxus Energy Corp., Kearny, NJ

TA–W–31, 270; Maxus Exploration Co., Amarillo, TX, Including:

TA–W–31, 271, TA–W–31, 272, TA–W–31, 273, TA–W–274; Canadian, TX, Dumas, TX, Jeanerette, LA and Pampa, TX

A certification was issued covering all workers separated on or after June 30, 1994.

TA–W–31, 275, TA–W–31, 276, TA–W–31, 277, TA–W–31, 278; Maxus Exploration Co., Perryton, TX, Leedey, OK, Spearman, TX Stinnett, TX

A certification was issued covering all workers separated on or after June 30, 1994.

TA–W–31, 279; Maxus Aviation Co., Dallas, TX

TA–W–31, 280; Riverside Farms, Hamilton, TX

TA–W–31, 281; Riverside Lodge, Hamilton, TX

TA–W–31, 282; Sunray Gas Plant, Dumas, TX

A certification was issued covering all workers separated on or after June 30, 1994.

Also, pursuant to Title V of the North American Free Trade Agreement Implementation Act (Pub. L. 103–182) concerning transitional adjustment assistance hereinafter called (NAFTA–TAA) and in accordance with section 250(a) Subchapter D, Chapter 2, Title II, of the Trade Act as amended, the Department of Labor presents summaries of determinations regarding eligibility to apply for NAFTA–TAA issued during the month of August, 1995.

In order for an affirmative determination to be made and a certification of eligibility to apply for NAFTA–TAA the following group eligibility requirements of section 250 of the Trade Act must be met:

(1) That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, (including workers in any agricultural firm or appropriate subdivision thereof) have become totally or partially separated from employment and either—

(2) That sales or production, or both, of such firm or subdivision have decreased absolutely,

(3) That imports from Mexico or Canada of articles like or directly competitive with articles produced by such firm or subdivision have increased, and that the increases in imports contributed importantly to such workers' separations or threat of separation and to the decline in sales or production of such firm or subdivision; or

(4) That there has been a shift in production by such workers' firm or subdivision to Mexico or Canada of articles like or directly competitive with articles which are produced by the firm or subdivision.

Negative Determinations NAFTA–TAA

NAFTA–TAA–00509; Varco Logging, Superior, MT

NAFTA–TAA–00527; Suak River Cutting, Arlington, WA

The investigation revealed that criteria (3) and (4) were not met. There was no shift in production of raw timber (logs) from the workers' firm to Canada or Mexico during the relevant period.

NAFTA–TAA–00503; Tampella Power Corp., Williamsport, PA

The investigation revealed that criteria (3) and (4) were not met. There was no shift in production of boiler-pressure part components from the workers' firm to Canada or Mexico during the relevant period.

NAFTA–TAA–00514; KGS Systems, Inc., Harlingen, TX

The investigation revealed that the workers of the subject firm do not produce an article within the meaning of Section 250(a) of the Trade Act, as amended.

Affirmative Determinations NAFTA–TAA

NAFTA–TAA–00525; Key Plastics, Inc., Mt. Olivet & Cherry Street Plants, Felton, PA

A certification was issued covering all workers separated on or after July 5, 1994.

NAFTA–TAA–00506; R Manufacturing, Lilly, PA

A certification was issued covering all workers separated on or after June 23, 1994.

NAFTA–TAA–00511; National Oilwell, McAlester, OK

A certification was issued covering all workers separated on or after June 19, 1994.

NAFTA–TAA–00510; U.S. Industries/ Keystone Lighting, Hayden Lake, ID

A certification was issued covering all workers separated on or after June 29, 1994.

NAFTA–TAA–00508; Kentucky West Virginia Gas Co., Prestonsburg, KY

A certification was issued covering all workers separated on or after May 30, 1994.

NAFTA–TAA–00507; Blue Eagle Exploration, Inc., Salisbury, NC

A certification was issued covering all workers separated on or after June 21, 1994.

NAFTA–TAA–00527; Sauk River Cutting, Arlington, WA

NAFTA–TAA–00512; Cantwell Trucking, Inc., Long Hauling Div., Klamath Falls, OR

NAFTA–TAA–00509; Varco Logging, Superior, MT

An affirmative finding regarding qualification as a secondary firm was issued pursuant to the statement of Administrative Action accompanying the NAFTA Implementation Act.

NAFTA–TAA–00534; MCE Technical Services (Employees Contracted to Washington Public Power Supply System), Richland, WA

A certification was issued covering all workers separated on or after July 19, 1994.

I hereby certify that the aforementioned determinations were issued during the month of August, 1995. Copies of these determinations are available for inspection in room C–4318, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210 during normal business hours or will be mailed to persons who write to the above address.

Dated: August 16, 1995.

Russell Kile,

Acting Program Manager, Office of Trade Adjustment Assistance.

[FR Doc. 95–21043 Filed 8–23–95; 8:45 am]

BILLING CODE 4510–30–M

[TA–W–29, 744]

Xerox Corporation, Webster, New York; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 USC 2273) the Department of Labor issued a Notice of Certification Regarding Eligibility to Apply for Worker Adjustment Assistance on September 21, 1994, applicable to all workers of Xerox Corporation engaged in employment related to the production of copiers and printers in Webster, New York. The notice was published in the **Federal Register** on October 21, 1994 (59 FR 53211).

The Department amended the certification on July 28, 1995, to provide coverage to former Xerox workers that were transferred to EDS as the result of the sale of the subject facility. The notice was published in the **Federal Register** on August 9, 1995 (60 FR 40615).

The Department has been notified by the Company that Xerox Corporation was not sold to EDS. Some work functions previously performed by Xerox workers at the Webster facility were contracted to EDS. Some of the EDS employees are former Xerox employees.

The intent of the Department's certification is to include all workers of Xerox Corporation, and the EDS employees contracted to Xerox, who were adversely affected by increased imports.

The amended notice applicable to TA–W–29,744 is hereby issued as follows:

"All workers of Xerox Corporation, and employees of EDS contracted to Xerox Corporation, Webster, New York engaged in employment related to the production of copiers and printers who became totally or partially separated from employment on or after March 29, 1993 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974."

Signed at Washington, D.C. this 15th day of August 1995.

Arlene O'Connor,

Acting Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 95–21041 Filed 8–23–95; 8:45 am]

BILLING CODE 4510–30–M

Job Training Partnership Act: Native American Employment and Training Council Notice of Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), as amended, and section 401(h)(1) of the Job Training Partnership Act (JTPA), as amended (29 U.S.C. 1671(h)(1)), notice is hereby given of a meeting of the Native American Employment and Training Council.

Time and Date: The meeting will begin at 9:00 a.m. on September 21, 1995, and continue until close of business that day, and will reconvene at 9:00 a.m. on September 22, 1995, and adjourn at close of business that day. Time will be reserved for participation and presentations by members of the public from 3:30 to 5:00 p.m. on September 21, 1995.

Place: U.S. Department of Labor, Rooms S–4215 A, B and C, 200 Constitution Avenue NW., Washington, DC 20210.

Status: The meeting will be open to the public. Persons with disabilities, who need special accommodations, should contact the undersigned no less than 10 days before the meeting.

Matters To Be Considered: The agenda will focus on the following topics: Legislative Update, Partnership Plan, Evaluation, Automated Reporting System Update, Electronic Communication, Technical Assistance and Training, and Grant Closeouts.

Contact Person For More Information: Thomas Dowd, Chief, Division of Indian and Native American Programs, Employment and Training Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–4641, Washington, DC 20210. Telephone: 202–219–8502 (this is not a toll-free number).

Signed at Washington, DC, this 18th day of August 1995.

Timothy M. Barnicle,

Assistant Secretary of Labor.

[FR Doc. 95–21042 Filed 8–23–95; 8:45 am]

BILLING CODE 4510–30–M

NATIONAL SCIENCE FOUNDATION

Permit Applications Received Under the Antarctic Conservation Act of 1978 (Pub. L. 95–541)

AGENCY: National Science Foundation.

ACTION: Notice of Permit Applications Received Under the Antarctic Conservation Act of 1978, Pub. L. 95–541.

SUMMARY: The National Science Foundation (NSF) is required to publish notice of permit applications received to conduct activities regulated under the Antarctic Conservation Act of 1978. NSF has published regulations under the Antarctic Conservation Act at title 45 part 670 of the Code of Federal Regulations. This is the required notice of permit applications received.

DATES: Interested parties are invited to submit written data, comments, or views with respect to these permit applications by September 16, 1995. Permit applications may be inspected by interested parties at the Permit Office, address below.

ADDRESSES: Comments should be addressed to Permit Office, Room 755, Office of Polar Programs, National Science Foundation, 4201 Wilson Boulevard, Arlington, Virginia 22230.

FOR FURTHER INFORMATION CONTACT: Nadene G. Kennedy at the above address or (703) 306–1031.

SUPPLEMENTAL INFORMATION: The National Science Foundation, as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95–541), has developed regulations that implement the "Agreed Measures for the Conservation of Antarctic Fauna and Flora" for all United States citizens. The Agreed Measures, developed by the Antarctic Treaty Consultative Parties, recommended establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas a requiring special protection. The regulations establish such a permit system to designate Specially Protected Areas and Sites of Special Scientific Interest.

The applications received are as follows:

[Permit Application No. 96–001]

1. *Applicant:* Carol M. Vleck and Theresa Bucher, Department of Zoology and Genetics, Iowa State University, Ames, Iowa 50011

Activity for Which Permit Is Requested

The applicants propose to handle approximately 550 birds (500 adults, 50 chicks) each season during a two-year study on the reproductive endocrinology of free-living Adelie Penguins near Palmer Station, Antarctica. Over the course of several different experiments, birds will be banded and blood samples taken from up to 450 to determine levels of reproductive hormones at all stages of the reproductive cycle. In addition blood samples will also be used to determine levels of stress hormone from birds in a colony with frequent human visitation and compared with those at a control site. Observations of birds will be conducted to assess reproductive state and success rates. If penguins have eggs or chicks in the nest at the time of handling, the eggs and chicks will be protected from predation and/or cooling while the parents are being held.

Location

Vicinity of Palmer Station, Anners Island, Antarctica Peninsula.

Dates

October 1, 1995–March 31, 1996.

[Permit Application No. 96–002]

2. *Applicant:* Diana W. Freckman, Natural Resource Ecology Laboratory, Colorado State University, Fort Collins, Colorado 80523

Activity for Which Permit Is Requested

Import into the U.S. and Enter Site of Special Scientific Interest.

The applicant proposes to enter five (5) Sites of Special Scientific Interest to collect soil samples to examine the dispersal and survival of nematodes in the soils, as well as examining how functional communities develop, and how these communities may be affected by disturbance. Site access will be by helicopter to the landing pad designated for each site and the duration of the visit to the site will be limited to several hours with a group of no more than 4–5 people. Soil sampling protocols have been selected to minimize site disturbance. Manner of taking: Soil and/or rock samples will be placed in sterile plastic bags and returned to McMurdo where the nematodes will be immediately extracted. Remaining soil samples will be shipped to the U.S. for further biological and chemical analyses, and will be handled according to USDA guidelines.

Location

Cape Royds, Ross Island (SSSI #1); Cape Crozier, Ross Island (SSSI #4); Caughley Beach, Cape Bird, Ross Island (SSSI #10); Canada Glacier, Lake Fryxell, Taylor Valley, Victoria Land (SSSI #12); and, Linnaeus Terrace, Asgaard Range, Victoria Land (SSSI #19).

Dates

October 26, 1995–January 31, 1996.

[Permit Application No. 96–003]

3. *Applicant:* Wayne Z. Trivelpiece, Department of Biology, Montana State University, Bozeman, Montana 59717

Activity for Which Permit Is Requested

Taking; Import into the U.S.; and, Enter Site of Special Scientific Interest.

Approximately 1,000 Adelie and Gentoo chicks will be banded, as well as 300 adults of Adelie, Gentoo and Chinstrap penguins, as needed to fulfill research goals in the continuing study of the behavioral ecology and population biology of these species and the interactions among these species and their principal avian predators: Skuas, gulls, sheathbills, and giant fulmars. Up to 50 adults of each penguin species will be fitted with radio transmitters and time-depth recorders to continue studying penguin foraging habits. The study also involves stomach pumping of 40 adult penguins per species. In addition the principal avian predators of the penguins, mentioned above, will also be studied, requiring up to 200 adults and chicks of each species to be banded, if possible. One (1) milliliter sample of blood will be collected from each of a maximum of 20 breeding adults of each penguin species for DNA analysis as part of a collaborative genetic study. All captured birds will be released unharmed. Carcasses and skeletons of penguins and other birds salvaged at the study site will be imported into the U.S. for educational and scientific study.

Location

SSSI #8—Western Shore of Admiralty Bay, King George Island, South Shetland Islands, Antarctica.

Dates

October 1, 1995–April 1, 1996.

[Permit Application No. 96–004]

4. *Applicant:* Donald B. Siniff, 100 Ecology Building, University of Minnesota, 1987 Upper Buford Circle, St. Paul, Minnesota 55108

Activity for Which Permit Is Requested

Take. Import into the U.S. Enter Site of Special Scientific Interest.

The applicant proposes the enter the White Island Site of Special Scientific Interest (SSSI #18) to tag up to 15 adult Weddell seals, and tag and draw blood samples from approximately 5 Weddell pups, as part of a continuing population biology study conducted by the Smithsonian Institution. The White Island seal population has been a focus of interest dating to the early 1960's.

This group of seals represents an isolated population that is very small and the evidence suggests it has very limited exchange of individuals with the McMurdo Sound population. Thus, the genetics of this population is of interest because it will increase understanding of such concepts as inbreeding depression and genetic drift.

Location

SSSI #18—North-west White Island, McMurdo Sound, Antarctica.

Dates

October 1, 1995–September 30, 1996.

[Permit Application No. 96–005]

5. *Applicant:* Donald B. Siniff, 100 Ecology Building, University of Minnesota, 1987 Upper Buford Circle, St. Paul, Minnesota 55108

Activity for Which Permit Is Requested

Taking. Import into the U.S.

The applicant plans to tag and release approximately 350 Weddell adult seals and approximately 550 Weddell pups as part of a continuing investigation of the McMurdo Sound Weddell seal population, which was begun in the early 1960's and has continued to the present. In addition, blood samples will be taken from up to 180 individuals, with up to 100 samples being imported to the U.S. for further analyses on the genetic characteristics of the Antarctic seal populations. Objectives of this research are (1) to continue the long-term tagging studies by tagging all pups born into the McMurdo Sound population and to replace tags on previously tag individuals so they will not be lost from the tagged population, and (2) to update estimates of population parameters annually and to continue the analyses and test of hypotheses associated with this data base. Mark-recapture surveys, necessary to obtain all the estimates required for current capture-recapture models, will also be conducted.

Location

McMurdo Sound vicinity, Antarctica.

Dates

October 1, 1995–September 30, 1996.

[Permit Application No. 96–006]

6. *Applicant:* Colin M. Harris, International Centre for Antarctic, Information and Research, PO Box 14–199, Christchurch, New Zealand

Activity for Which Permit Is Requested

Enter Specially Protected Areas and Sites of Special Scientific Interest.

The applicant proposes to enter Cape Hallett (SPA #7), Cape Royds (SSSI #1), Arrival Heights (SSSI #2), Barwick Valley (SSSI #3), Cape Crozier (SSSI #4), Northwest White Island (SSSI #18), and Linneaus Terrace (SSSI #19) in a continuation of a joint U.S./N.Z. project to review management plans for protected areas in the Ross Sea region. Thus far, thirteen (13) of the fifteen (15) sites have been visited. This season the applicant proposes to visit Cape Hallett, one of the two remaining sites, to describe and map geographical features, including important natural and historical features, evidence of human modifications, structures, markers, impacts, landing and access points and paths; document natural or human features of special significance; describe scientific work being conducted in the area, its effects and influences; assess whether the area is continuing to serve the purpose for which it was designated, including re-assessment of boundaries and management objectives; and, use a Global Positioning Satellite (GPS) to map boundaries and define designated photo points covering the most important features of the site as practical. In addition, the applicant proposes to return to several previously visited sites to gather and assist with management problems identified in previous visit reports. Access to Cape Hallett vicinity may be provided by Twin Otter, while direct site access will be on foot. Access to other site locations will be provided by helicopter or vehicle, as appropriate. Access will comply with existing management plan provisions for each site.

Location

Cape Hallett (SPA #7), Cape Royds (SSSI #17), Arrival Heights (SSSI #2), Barwick Valley (SSSI #3), Cape Crozier (SSSI #4), Northwest White Island (SSSI #18), and Linneaus Terrace (SSSI #19).

Dates

November 1, 1995–February 1, 1996.

[Permit Application No. 96–007]

7. *Applicant:* Arthur L. DeVries, Department of Molecular and Integrated Physiology, 524 Burrill Hall, University of Illinois, 407 South Goodwin Avenue, Urbana, Illinois 61801

Activity for Which Permit Is Requested

Introduction of Non-indigenous Species into Antarctica.

Fifteen specimens of adult male and female wetas, *Hemideina maori* (flightless insects), will be transported from New Zealand to the Crary Science and Engineering Center at McMurdo Station, Antarctica. The wetas are a freeze tolerant insect which will be used in experiments to determine if small amounts of fish antifreeze glycopeptides (AFGP's) can enhance freezing tolerance. The wetas are the only freeze-tolerant insects large enough (2 to 3 inches) for implanting a cannula for removal of hemolymph and injection of AFGP's, which makes the proposed experiments feasible. The insects will be maintained in a temperature controlled walk-in freezer. Upon completion of experiments, the wetas or their remains will be returned to New Zealand or preserved in formalin.

Location

McMurdo Station, Antarctica.

Dates

October 1, 1995–February 27, 1996.

[Permit Application No. 96–008]

8. *Applicant:* Arthur L. DeVries, Department of Molecular and Integrative Physiology, 524 Burrill Hall, University of Illinois, 407 South Goodwin Avenue, Urbana, Illinois 61801

Activity for Which Permit Is Requested

Introduction of Non-indigenous Species into Antarctica.

Fifteen (15) specimens of New Zealand black cod, *Notothenia angustata*, will be cold acclimated in a closed seawater system in the aquarium at McMurdo Station. The cold acclimated specimens will be used in experiments to determine the role of the antifreeze glycopeptides in freezing avoidance, and for isolating DNA. The DNA will be screened for the presence of an "unexpressed" antifreeze glycopeptide gene. Upon completion of experiments, the black code will be sacrificed and preserved in formalin.

Location

McMurdo Station, Ross Island, Antarctica.

Dates

October 1, 1995–February 27, 1996.

[Permit Application No. 96–009]

9. *Applicant:* Brenda Hall and George Denton, Institute for Quaternary Studies, 320 Boardman Hall, University of Maine, Orono, Maine 04469–5711

Activity of Which Permit Is Requested

Enter Site of Special Scientific Interest.

The applicants are carrying out a large mapping project to determine the former extent of a grounded ice sheet in the Ross Sea during the last glaciation. Much of the work has been concentrated on the Dry Valley regions where lobes of the grounded Ross Sea Ice Sheet flowed inland into the mouths of the valleys. Barwick Valley (SSSI #3) was last mapped in the 1960's. According to that work, inland ice advanced down Barwick Valley simultaneously with ice

advance into Lower Victoria Valley. The Lower Victoria Valley deposits indicate the presence of a lake, not an ice tongue. Based on descriptions of Barwick Valley deposits from previous mapping and observations during last season's reconnaissance, the applicants believe a lake may have also extended into this area. The applicants have identified several deltas around Lake Vashka in the Barwick Valley that are at the same elevation as deltas in the Lower Victoria Valley which indicate the possible presence of a large lake that would have filled all of Victoria Valley and extended into the Barwick.

Work in the Barwick Valley will primarily involve mapping by taking detailed elevation measurements of Lake Vashka deltas, however, small (10 cm x 10 cm) fossil algae samples will be collected for AMS radiocarbon dating. Determining the age and precise elevation of deltas will provide information on the timing of lake-level high-stand in the Victoria Valley System. Comparisons between the valleys will yield important information about lake-level variations during the glacial period and valuable paleoclimate data. Access to Barwick Valley will be by foot from the Victoria Valley.

Location

Barwick Valley, Victoria Land (SSSI #3).

Dates

October 10, 1995–February 15, 1996.

[Permit Application No. 96–019]

10. *Applicant:* Ronald G. Koger, Project Director, Antarctic Support Associates, 61 Inverness Drive East, Suite 300, Englewood, Colorado 80112

Activity for Which Permit Is Requested

Enter Specially Protected Area. The applicant proposes to enter the Litchfield Island Specially Protected Area (SPA #17) to conduct an annual inspection and resupply of the survival cache located on the island for boating safety, and assess the condition of notification signs located at three primary landing sites which indicate Litchfield Island is a Specially Protected Area.

Location

SPA #17—Litchfield Island, Arthur Harbor, Palmer Archipelago.

Dates

May 1, 1995–April 30, 2000.

[Permit Application No. 96–011]

11. *Applicant:* Donal T. Manahan, Department of Biological Sciences, University of Southern California, Los Angeles, California 90089–0371

Activity for Which Permit Is Requested

Export from the United States and Introduce Non-indigenous Species into Antarctica.

The applicant proposes to culture species of unicellular algae for use in investigations of molecular evolution and UV-photobiology of antarctic algae and as food for antarctic larval forms (sea urchins) used in studying the physiology and biochemistry of larval development of antarctic invertebrates. The applicant will culture the imported unicellular algae in aseptic conditions. For this purpose, it is requested to export from the U.S. approximately 10 ml of algae culture per species originally isolated in Antarctica. These cultures will be used for investigations of the effects of UV on the biology of algae (DNA damage, etc.) The algae species now in culture in the U.S., that were originally isolated in Antarctica, and to be exported from the U.S. are: *Acrochaetium sp., Acrosiphonia sp., Bangia sp., Chaeoceros flexuosum, Desmarestia antarctica, Halochorococcum sp., Halococcus sp., Nitzchia curta, Phaeocystis sp., Phyllophora antarctica, Porosira glacialis, Porphyra cf. plocamienstris, Rhodochorton purpureum, Thallassiosira antarctica, Urospora sp.*

In addition, the applicant proposes to introduce algal species that are not of Antarctic origin for use as food for antarctic larval forms (sea urchins) that will be reared at McMurdo Station during the period of the course study. The non-indigenous algal species to be introduced into Antarctica are: *Dunaliella teriolecta, Isochrysis galbana, Skeletonema costatum, Thalassiosira pseudonana, Rhodomonas sp.*

After use, all algae and seawater containing algae will be autoclaved to kill the algal cells.

Location

McMurdo Station, Antarctica.

Dates

October 1, 1995–February 20, 1998.

[Permit Application No. 96–012]

12. *Applicant:* Ronald G. Koger, Project Director, Antarctic Support Associates, 61 Inverness Drive East, Suite 300, Englewood, Colorado 80112

Activity for Which Permit Is Requested

Taking. The applicant proposes to continue operations at Cape Hallett in an effort to clean up remnants of past operations. The location of the proposed work lies within a penguin rookery with a population of approximately 80,000 Adelie penguins (*Pygoscelis adeliae*). The proposed work for 1995–96 involves a reconnaissance flight to assess site conditions and removing drums containing old fuel, oil, solvents, and anti-freeze from the area using a U.S. Coast Guard icebreaker. An assessment will also be conducted to evaluate plans to dismantle and remove a large fuel tank and building from the area. The effort would be conducted in following years. The proposed work is justified by the fact the cleanup operations are an effort to eliminate a potentially hazardous situation which poses a threat to the health and well being of the penguin population should the present containers leak due to corrosion or some other accidental event.

All proposed work has the potential of disturbing the local penguin population. However, every effort will be taken to schedule activities at times when the penguins are least susceptible to these disturbances, for example, during times when the birds are not mating, breeding, or nesting.

Location

Seabee Hook, Cape Hallett, Victoria Land, Antarctica.

Dates

October 1, 1995–March 1, 2000.

[Permit Application No. 96–014]

13. *Applicant:* James A. Raymond, Department of Biological Sciences, University of Nevada, Las Vegas, Nevada 89154–4004

Activity for Which Permit Is Requested

Enter Site of Special Scientific Interest. The applicant proposes to collect marine uni-algal samples (single species samples) from a variety of locations, including sea water accessible through ice cracks within the White Island Site of Special Scientific Interest (SSSI #18). The samples will be used to determine the distribution of antifreeze-like proteins in Antarctic marine algae. Access to White Island SSSI is desirable due to the dense algal bloom in late November–early December. Sampling at this location could possibly provide new species of algae on which protein assays can be conducted.

Location

SSSI #18—Northwest White Island, McMurdo Sound.

Dates

November 11, 1995–December 20, 1995.

[Permit Application No. 96–015]

14. *Applicant: Gerald L. Kooyman, Center for Marine Biotechnology and Biomedicine, Scripps Institution of Oceanography,*

University of California, San Diego, La Jolla, California 92093–0204

Activity for Which Permit is Requested

Taking; Import into the U.S.; Enter Specially Protected Area; and Enter Site of Special Scientific Interest.

Ground counts will be made at two major Emperor colonies (Cape Washington and Coulman Island) and at a third smaller and most southern Emporer colony (Cape Crozier) bordering the Ross Sea. This is a continuation of the longest series of censuses of Emperor penguins in Antarctica. The Coulman Island census is especially important because the colony declined nearly 50 percent in 1993 and 1994 from that in 1992. Cape Crozier remains small, less than 600 chicks, and its existence still seems tenuous after its decline to 15 chicks in the 1970's.

The applicant also proposes to capture up to 40 adult Emperor penguins, near the McMurdo ice edge or at Cape Washington, which will be maintained in an enclosure on the sea ice for up to 2 months while behavioral and physiological experiments are conducted. The birds will be allowed to dive at will through an ice hole. The birds will be weighed daily, and will be hand-fed a fish supplement, in addition to their foraging, to ensure weight is maintained or increased while captive. This experiment is designed to explore and comprehend the physiological responses that support the great diving capacities of these birds. A total of 50 Emperor chicks will be captured and released at Cape Washington over the course of the season. Blood and muscle samples will be obtained from 30 chicks. In early January, 4 Emperor fledglings will be captured and released after the attachment of a satellite transmitter. Furthermore, 15 chicks that have failed to fledge at Cape Washington will be collected and moved to an enclosure in the vicinity of McMurdo Station where they will be hand-fed and the development of their diving abilities studied. After one month, they will be released at the ice edge. If possible the applicant proposes to collect 10 frozen eggs and salvage 2 adult Emperor carcasses for importation into the U.S. The eggs will remain frozen at Scripps until destructive analysis is completed. The two carcasses will also be held at Scripps until a full necropsy can be performed, after which the remains will be destroyed.

Location

Beaufort Island (SPA #5), Cape Crozier (SSSI #4), Coulman Island, and Cape Washington, McMurdo Sound vicinity.

Dates

October 1, 1995–March 31, 1996.

[Permit Application No. 96–016]

15. *Applicant: Warwick F. Vincent, Department of Biology, Université Laval, Sainte Foy, Quebec, Canada*

Activity for Which Permit Is Requested

Enter Site of Special Scientific Interest.

The applicant proposes to enter the Canada Glacier Site of Special Scientific Interest (SSSI #12) for the purpose of conducting a site visit to inspect the current state of the environment within the SSSI. The applicant is currently involved in editing the Environmental Code of Conduct and Environmental Management Workshop report for the Dry Valleys and intends to apply the environmental perturbation matrix developed to this site and others.

Location

Canada Glacier, Fryxell Stream, Lake Fryxell, Taylor Valley, Victoria Land (SSSI #12).

Dates

December 1, 1995–December 20, 1995.

[Permit Application No. 96–018]

16. *Applicant: Ronald G. Koger, Project Director, Antarctic Support Associates, 61 Inverness Drive, East, Suite 300, Englewood, Colorado 80112*

Activity for Which Permit Is Requested

Taking.

The applicant proposes to remove antarctic animals from McMurdo Station runways, roads, and ice pier as is necessary for operational safety and well being of the animals and U.S. Antarctic Program participants. The affected animals include Adelie penguins (*Pygoscelis adeliae*), Emperor penguins (*Aptenodytes forsteri*), Weddell seals (*Leptonychotes weddelli*), Crabeater seals (*London carcinophagus*), and Skuas (*catharacta loonbergi* and *catharacta maccormicki*). The movements of airplanes, ships and support vehicles into and out of McMurdo Station are essential to USAP for transportation of personnel, equipment, supplies, and waste materials. Periodically, native seal, penguin and skua species enter aircraft runways, roads, and the ice pier. Such invasions pose operational safety concerns, as well as potential harm to the animals. Removal activities will be conducted in a nonlethal and humane manner in order to cause as little disturbance as possible. Herding and reporting procedures have been developed and training for individuals with responsibility for removal of animals will be conducted by science laboratory personnel.

Location

McMurdo Station vicinity and its associated airfields (Williams Field, Pegasus, Ice Runway), roads and ice pier.

Dates

October 1, 1995–March 1, 2000.

[Permit Application No. 96–019]

17. *Applicant:* John Splettstoesser; 235 Camden Street, #32, Box 132, Rockland, Maine 04841

Activity for Which Permit Is Requested

Taking, and Import into the U.S.

The applicant proposes to salvage up to ten (10) Emperor penguin chick carcasses and up to four (4) abandoned Emperor penguin eggs in frozen condition for mounting and display in two separate museum educational exhibits. The applicant will serve as a naturalist lecturer onboard a cruise ship this coming season. As a result of prior experience in visiting Emperor penguin rookeries in the eastern Weddell Sea during the last two summers, large numbers of chicks were observed to have died from unknown causes (starvation, weather extremes, diseases, etc.). Two museums (1) Maritime Museum, Port Stanley, the Falkland Islands, and (2) Natural History Museum, College of the Atlantic, Bar Harbor, Maine, have expressed interest in obtaining specimens (5 chick corpses and 2 eggs, each) for educational exhibits. The applicant will be returning to the eastern Weddell Sea area this season. Collection of specimens will be done by qualified naturalist staff onboard the cruise ship (icebreaker) and preserved for transport under frozen conditions to their destinations. The specimens destined for the Maritime Museum will be delivered directly to Port Stanley from Antarctica and will not enter the U.S. Remaining samples will be delivered to the museum in Maine.

Location

Atka Bay, Riiser-Larsen Iceshelf and other Emperor colonies in the eastern Weddell Sea vicinity.

Dates

November 1, 1995–March 31, 1996.

[Permit Application No. 96–020]

18. *Applicant:* Bruce D. Marsh, Department of Earth and Planetary Sciences, 323 Olin Hall, Johns Hopkins University, Baltimore, Maryland 21218

Activity for Which Permit Is Requested

Enter Site of Special Scientific Interest.

The applicant proposes to enter the Barwick Valley Site of Special Scientific Interest (SSSI #3) to conduct geologic mapping and sample collecting. The nature and style of the Ferrar dolerites (specific rock formation) will be traced on topographic maps and samples of rock will be collected to characterize each formation at a number of locations. Rock samples will be shipped to the U.S. for cutting and crushing for analysis.

Location

SSSI #3—Barwick Valley, Victoria Land, Antarctica.

Dates

January 1, 1996–January 24, 1996.

Nadene G. Kennedy,

Permit Office, Office of Polar Programs.

[FR Doc. 95–20939 Filed 8–23–95; 8:45 am]

BILLING CODE 7555–01–M

Advisory Committee for Computer and Information Science and Engineering; Notice of Subcommittee Meetings

In accordance with the Federal Advisory Committee Act, Pub. L. 92–463, as amended, the National Science Foundation announces that the Advisory Committee for Computer and Information Science and Engineering (#1115) will hold three subcommittee meetings during September. All meetings are open to the public and will be held at NSF located at 4201 Wilson Blvd., Arlington, Va. Names, dates, room numbers are as follows:

Name	Dates	Times	Location
1. Subcommittee on Research in Computing Systems	9/11	8:30–4:00	Room 375.
	9/12	8:30–4:00	
	9/13	9:00–10:30	
AGENDA: Review Current and Planned Activities in Computing Systems.			
2. Subcommittee on Research in Human-Centered Systems	9/20	8:30–5:00	1295.
	9/21	8:30–3:00	
AGENDA: Review Current and Planned Activities in Human-Centered Systems.			
3. Subcommittee on Research in Networking, Communications and Convergence of Computing & Communications.	9/28	8:30–5:00	1295.
	9/29	8:30–5:00	

Agenda:

Review Current and Planned Activities in Networking, Communications and Convergence of Computing & Communications.

Purpose of Meetings

To help shape the Directorate's plans and priorities for research and to assess the extent to which current and planned programs provide the necessary base for future research directions.

Contact Person

Odessa Dyson, Administrative Officer, Office of the Assistant Director, Directorate for Computer and Information Science and Engineering, 4201 Wilson Blvd., Arlington, VA. 22230. Phone: (703) 306–1900.

Minutes

May be obtained from the contact person at the above address.

Dated: August 21, 1995.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 95–21049 Filed 8–23–95; 8:45 am]

BILLING CODE 7555–01–M

Special Emphasis Panel in Design, Manufacture, and Industrial Innovation; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting:

Name: Special Emphasis Panel in Design, Manufacture, and Industrial Innovation—#1194.

Date and Time: September 18, 19, & 20, 1995, 8 a.m.–5 p.m., each day.

Place: Room 565, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230.

Type of Meeting: Closed.

Contact Person: Charles Hauer, Program Director, SBIR Office, (703) 306–1390.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to the NSF for financial support.

Agenda: To review and evaluate Phase I Small Business proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c) (4) and (6) of the Government in the Sunshine Act.

Dated: August 21, 1995.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 95–21050 Filed 8–23–95; 8:45 am]

BILLING CODE 7555–01–M

Special Emphasis Panel in Design, Manufacture, and Industrial Innovation; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting:

Name: Special Emphasis Panel in Design, Manufacture, and Industrial Innovation—#1194.

Date and Time: September 15, 1995.

Place: Room 375, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230.

Type of Meeting: Closed.

Contact Person: Tony Centodocati, Program Director, SBIR Office, (703) 306–1390 or John Van Rosendale, CISE, (703) 306–1962, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to the NSF for financial support.

Agenda: To review and evaluate Phase I Small Business proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c) (4) and (6) of the Government in the Sunshine Act.

Dated: August 21, 1995.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 95–21051 Filed 8–23–95; 8:45 am]

BILLING CODE 7555–01–M

Special Emphasis Panel in Design, Manufacture, and Industrial Innovation; Notice of Meetings

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces that the Special Emphasis Panel in Design, Manufacture, and Industrial Innovation (1194) will be holding panel meetings for the purpose of reviewing proposals submitted to the Small Business Innovation Research Program in the areas of Civil and Mechanical Systems, Photonics, and Astronomy. In order to review the large volume of proposals, panel meetings will be held on September 12, 13, and 14 in rooms 330, 365, 580, and 1005. All meetings will be closed to the public and will be held at the National Science Foundation, 4201 Wilson Blvd., Arlington, VA, from 8 to 5 each day.

Contact Person: Charles Hauer, Darryl Gorman, and Pat Johnson SBIR Office, (703) 306–1390, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c)(4) and (6) of the Government in Sunshine Act.

Dated: August 21, 1995.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 95–21052 Filed 8–23–95; 8:45 am]

BILLING CODE 7555–01–M

Special Emphasis Panel in Design, Manufacture, and Industrial Innovation; Notice of Meetings

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces that the Special Emphasis Panel in Design, Manufacture, and Industrial Innovation (1194) will be holding panel meetings for the purpose of reviewing proposals submitted to the Small Business Innovation Research Program in the areas of Computer and Information Science and Engineering and SSM. In order to review the large volume of proposals, panel meetings will be held on September 15, 1995 in rooms 365, 380, 390, 530 and 580. All meetings will be closed to the public and will be held at the National Science Foundation, 4201 Wilson Blvd., Arlington, VA from 8:00 to 5:00 each day.

Contact Person: Anthony Centodocati and Ritchie Coryell, SBIR Office, (703) 306–1390, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c) (4) and (6) of the Government in the Sunshine Act.

Dated: August 21, 1995.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 95–21053 Filed 8–23–95; 8:45 am]

BILLING CODE 7555–01–M

Special Emphasis Panel in Design, Manufacture, and Industrial Innovation; Notice of Meetings—1194

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces that the Special Emphasis Panel in Design, Manufacture, and Industrial Innovation (1194) will be holding panel meetings for the purpose of reviewing proposals submitted to the Small Business Innovation Research Program in the area of Superconductivity and Advanced Scientific Computing. In order to review the large volume of proposals, panel meetings will be held on September 11, 1995, in rooms 310, 320, and 340. All meetings will be closed to the public and will be held at the National Science Foundation, 4201 Wilson Blvd., Arlington, VA, from 8 to 5 each day.

Contact Person: Anthony Centodocati and Darryl Gorman, SBIR Office, (703) 306–1390, Dr. John Van Rosendale, Program Director, CISE, (703) 306–1962, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c) (4) and (6) of the Government in the Sunshine Act.

Dated: August 21, 1995.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 95–21054 Filed 8–23–95; 8:45 am]

BILLING CODE 7555–01–M

Earth Sciences Proposal Review Panel; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting.

Name: Earth Sciences Proposal Review Panel (1569).

Dates: September 13, 14, & 15, 1995.

Time: 8 a.m. to 6 p.m. each day.

Place: Room 375, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230.

Type of Meeting: Closed.

Contact Person: Dr. Alan M. Gaines, Section Head, Division of Earth Sciences, Room 785, National Science Foundation, Arlington, VA, (703) 306–1553.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: To review and evaluate earth sciences proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: August 21, 1995.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 95–21055 Filed 8–23–95; 8:45 am]

BILLING CODE 7555–01–M

Special Emphasis Panel in Engineering Education and Centers; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting.

Name and Committee Code: Special Emphasis Panel in Engineering Education and Centers (173).

Date and Time: September 11–14, 1995; 8 a.m. to 5 p.m.

Place: National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230, Room 530.

Type of Meeting: Closed.

Contact Person: Lynn Preston, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230. Telephone: (703) 306–1381.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: To review and evaluate Engineering Research Centers proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: August 21, 1995.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 95–21056 Filed 8–23–95; 8:45 am]

BILLING CODE 7555–01–M

Special Emphasis Panel in Materials Research; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting.

Name: Special Emphasis Panel in Materials Research.

Date and Time: September 11–13, 1995; 8 a.m. to 5 p.m.

Place: Florida State University, Tallahassee, FL.

Type of Meeting: Closed.

Contact Person: Dr. Adriaan M. de Graaf, Executive Officer, Division of Materials Research, Room 1065, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230. Telephone: (703) 306–1812; Fax (703) 306–0515.

Purpose of Meeting: To provide advice and recommendations concerning the continued support for the National High Magnetic Field Laboratory (NHMFL) being established by Florida State University, the University of Florida, and Los Alamas National Laboratory.

Agenda: To review and evaluate the progress report and proposal for continued funding from the NHMFL.

Reason for Closing: The progress report being reviewed includes information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposal. These matters are exempt under 5 U.S.C. 552b(c)(4) and (6) of the Government in the Sunshine Act.

Dated: August 21, 1995.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 95–21057 Filed 8–23–95; 8:45 am]

BILLING CODE 7555–01–M

Special Emphasis Panel in Polar Programs; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting.

Name and Committee Code: Special Emphasis Panel in the Polar Programs.

Date and Time: September 12–13, 1995; 8:30 a.m.–5 p.m.

Place: National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230, Room 365.

Type of Meeting: Closed.

Contact Person: Dr. Polly A. Penhale, Program Manager, OPP, Room 755 Telephone: (703) 306–1033.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: To review and evaluate Polar Biology and Medicine proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c) (4) and (6) of the Government in the Sunshine Act.

Dated: August 21, 1995.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 95–21058 Filed 8–23–95; 8:45 am]

BILLING CODE 7555–01–M

Special Emphasis Panel in Undergraduate Education; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting:

Name: Special Emphasis Panel in Undergraduate Education.

Date and Time: September 11, 1995, 7:30 p.m. to 9 p.m.; September 12, 1995, 8:30 a.m. to 5 p.m.; September 13, 1995, 8:30 a.m. to 5 p.m.; September 14, 1995, 8:30 a.m. to 5 p.m.

Place: National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230.

Type of Meeting: Closed.

Contact Person: Dr. Terry Woodin, Program Director, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230. Telephone: (703) 306–1665.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: To review and evaluate unsolicited proposals submitted to the NSF Collaboratives for Excellence in Teacher Preparation (CETP) Program for a Reverse Site Visit Panel Meeting.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552 b. (c) (4) and (6) of the Government in the Sunshine Act.

Dated: August 21, 1995.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 95–21059 Filed 8–23–95; 8:45 am]

BILLING CODE 7555–01–M

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–369 and 50–370]

Duke Power Company, et al., McGuire Nuclear Station, Unit Nos. 1 and 2; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of amendments to Facility Operating License Nos. NPF–9 and NPF–17, issued to Duke Power Company (the licensee), for operation of the McGuire Nuclear Station, Units 1 and 2, located in Mecklenburg County, North Carolina.

Environmental Assessment

Identification of the Proposed Action

The proposed action would change the Technical Specifications (TS) to (a) allow the maximum enrichment for fuel stored in the fuel pools to increase from a nominal value of 4.0 to 5.0 weight percent Uranium-235, (b) establish new loading patterns for new and irradiated fuel in the spent fuel pool to accommodate this increase, (c) add a TS to establish a limit for boron concentration for all modes of operation, (d) add BASES to correspond to the TS that were added, (e) add TS to reflect limits for fuel storage criticality analysis, and (f) reformat the TS to bring them more in line with the standard format in the NRC report NUREG–1431, "Standard Technical Specifications Westinghouse Plants."

The proposed action is in accordance with the licensee's application for amendment dated June 13, 1994, as supplemented by letters dated August 15, 1994, March 23 and April 18, 1995.

The Need for the Proposed Action

The proposed action is needed so that the licensee can use higher fuel enrichment to provide additional flexibility in the licensee's reload design efforts and to increase the efficiency of fuel storage cell use in the spent fuel pools.

Environmental Impacts of the Proposed Action

The Commission has completed its evaluation of the proposed revisions to the TS. The proposed revisions would permit storage of fuel enriched to a nominal 5.0 weight percent Uranium-235. The safety considerations associated with storing new and spent fuel of a higher enrichment have been evaluated by the NRC staff. The staff has concluded that such changes would not adversely affect plant safety. The

proposed changes have no adverse effect on the probability of any accident. No changes are being made in the types or amounts of any radiological effluents that may be released offsite. There is no significant increase in the allowable individual or cumulative occupational radiation exposure.

The environmental impacts of transportation resulting from the use of higher enrichment fuel and extended irradiation were published and discussed in the staff assessment entitled, "NRC Assessment of the Environmental Effects of Transportation Resulting from Extended Fuel Enrichment and Irradiation," dated July 7, 1988, and published in the **Federal Register** (53 FR 30355) on August 11, 1988, as corrected on August 24, 1988 (53 FR 32322), in connection with Shearon Harris Nuclear Power Plant, Unit 1: Environmental Assessment and Finding of No Significant Impact. As indicated therein, the environmental cost contribution of the proposed increase in the fuel enrichment and irradiation limits are either unchanged or may, in fact, be reduced from those summarized in Table S–4 as set forth in 10 CFR 51.52(c). The results of the Shearon Harris assessment are applicable to McGuire, Units 1 and 2. Accordingly, the Commission concludes that there are no significant radiological environmental impacts associated with the proposed amendment.

With regard to potential nonradiological impacts, the proposed action involves features located entirely within the restricted area as defined in 10 CFR Part 20. It does not affect nonradiological plant effluents and has no other environmental impact. Accordingly, the Commission concludes that there are no significant nonradiological environmental impacts associated with the proposed action.

Alternatives to the Proposed Action

Since the Commission has concluded there is no measurable environmental impact associated with the proposed exemption, any alternatives with equal or greater environmental impact need not be evaluated. The principal alternative to this action would be to deny the request for exemption. Such action would not reduce the environmental impacts of plant operations.

Alternative Use of Resources

This action does not involve the use of resources not previously considered in the "Final Environmental Statement Related to the Operation of McGuire Nuclear Station Units 1 and 2," dated April 1976 and its addendum dated January 1981.

Agencies and Persons Consulted

In accordance with its stated policy, on August 17, 1995, the NRC staff consulted with the North Carolina State official, Mr. Dayne H. Brown, Director, Department of Environmental Health and Natural Resources, Division of Radiation Protection, regarding the environmental impact of the proposed action. The State official had no comments.

Finding of No Significant Impact

Based upon the environmental assessment, the Commission concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the Commission has determined not to prepare an environmental impact statement for the proposed exemption.

For further details with respect to this action, see the licensee's letter dated June 13, 1994, as supplemented by letters dated August 15, 1994, March 23 and April 18, 1995, which are available for public inspection at the Commission's Public Document Room, The Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room located at the Atkins Library, University of North Carolina, Charlotte (UNCC), North Carolina.

Dated at Rockville, Maryland, this 17th day of August 1995.

For the Nuclear Regulatory Commission.

Louis L. Wheeler,

Acting Director, Project Directorate II–2, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 95–21029 Filed 8–23–95; 8:45 am]

BILLING CODE 7590–01–P

[Docket No. 50–271]

Vermont Yankee Nuclear Power Corporation; Vermont Yankee Nuclear Power Station; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an exemption and revocation of an exemption from Facility Operating License No. DPR–28, issued to Vermont Yankee Nuclear Power Corporation (the licensee), for operation of the Vermont Yankee Nuclear Power Station (the facility) located in Windham County, Vermont.

Environmental Assessment

Identification of Proposed Actions

The proposed exemption would grant relief in certain outdoor areas of the protected area of the facility to allow use of security lighting for outdoor access and egress and the performance of one specified task for compliance with Section III.J of Appendix R to 10 CFR Part 50. The exemption would include outdoor portions of the protected area for access and egress and for hookup of a portable fuel oil transfer pump.

The proposed exemption is in accordance with the licensee's application for exemption dated June 29, 1995.

The exemption proposed for revocation related to emergency lighting requirements in the Reactor Building. The exemption was issued June 26, 1989, and is no longer needed by the licensee because conforming emergency lighting has been installed in the affected area.

The Need for the Proposed Actions

The proposed exemption is needed because the features described in the licensee's request regarding existing security lighting at the facility are the most practical method for satisfying the underlying purpose of Appendix R and literal compliance with the regulation would not further enhance the fire protection capability significantly.

Revocation of the 1989 exemption is needed to accurately reflect actual plant conditions, given conforming lighting has been installed in the affected areas.

Environmental Impacts of the Proposed Actions

The Commission has completed its evaluation of the proposed exemption and revocation of exemption and concludes that the proposed exemption and revocation will provide a degree of fire protection such that there is no increase in the risk of fires at the facility. Consequently, the probability of fires has not been increased and the post-fire radiological releases will not be greater than previously determined, nor do the proposed exemption and revocation otherwise affect radiological plant effluents.

The change will not increase the probability or consequences of accidents, no changes are being made in the types of any effluents that may be released offsite, and there is no significant increase in the allowable individual or cumulative occupational radiation exposure. Accordingly, the Commission concludes that there are no significant radiological environmental

impacts associated with the proposed actions.

With regard to potential nonradiological impacts, the proposed actions involve features located entirely within the restricted area as defined in 10 CFR Part 20. They do not affect nonradiological plant effluents and have no other environmental impact. Accordingly, the Commission concludes that there are no significant nonradiological environmental impacts associated with the proposed actions.

Alternatives to the Proposed Actions

Since the Commission has concluded there is no measurable environmental impact associated with the proposed actions, any alternatives with equal or greater environmental impact need not be evaluated. As an alternative to the proposed actions, the staff considered denial of the proposed actions. Denial of the application would result in no change in current environmental impacts. The environmental impacts of the proposed actions and the alternative action are similar.

Alternative Use of Resources

These actions do not involve use of resources not previously considered in the Final Environmental Statement for the Vermont Yankee Nuclear Power Station.

Agencies and Persons Consulted

In accordance with its stated policy, on July 21, 1995, the staff consulted with the Vermont State official, Mr. William K. Sherman of the Vermont Department of Public Service, regarding the environmental impact of the proposed actions. The State official had no comments.

Finding of No Significant Impact

Based upon the environmental assessment, the Commission concludes that the proposed actions will not have a significant effect on the quality of the human environment. Accordingly, the Commission has determined not to prepare an environmental impact statement for the proposed exemption and revocation of exemption.

For further details with respect to the proposed actions, see the application dated June 29, 1995, which is available for public inspection at the Commission's Public Document Room, The Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room located at the Brooks Memorial Library, 224 Main Street, Brattleboro, VT 05301.

Dated at Rockville, Maryland this 17th day of August 1995.

For the Nuclear Regulatory Commission.

Ronald W. Hernan,

Acting Director, Project Directorate I–3, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 95–21030 Filed 8–23–95; 8:45 am]

BILLING CODE 7590–01–P

[Docket No. 50–414]

Duke Power Company, et al. (Catawba Nuclear Station, Unit No. 2); Exemption

I

The Duke Power Company, et al. (DPC or the licensee) is the holder of Facility Operating License No. NPF–52, which authorizes operation of the Catawba Nuclear Station, Unit No. 2 (the facility), at a steady-state reactor power level not in excess of 3411 megawatts thermal. The facility is a pressurized water reactor located at the licensee's site in York County, South Carolina. The license provides, among other things, that the Catawba Nuclear Station is subject to all rules, regulations, and Orders of the U.S. Nuclear Regulatory Commission (the Commission or NRC) now or hereafter in effect.

II

Section III.D.1.(a) of Appendix J to 10 CFR Part 50 requires the performance of three Type A containment integrated leakage rate tests (ILRTs) at approximately equal intervals during each 10-year service period of the primary containment. The third test of each set shall be conducted when the plant is shut down for the 10-year inservice inspection of the primary containment.

III

By letters dated May 18, 1995, and May 31, 1995, the licensee requested temporary relief from the requirement to perform a set of three Type A tests at approximately equal intervals during each 10-year service period of the primary containment. The requested exemption would permit a one-time interval extension of the third Type A test by approximately 30 months (from the 1995 refueling outage, which begins in October 1995, to the end-of-cycle 8 (EOC–8) refueling outage, currently scheduled for March 1997) and would permit the third Type A test of the second 10-year inservice inspection period to not correspond with the end of the current inservice inspection interval.

The licensee's request concluded that the proposed change, a one-time extension of the interval between the second and third ILRTs at Catawba Unit 2, is justified for the following reasons.

The previous testing history at Catawba Unit 2 provides substantial justification for the proposed test interval extension. In each of the two previous periodic ILRTs at Catawba Unit 2, the as-found leakage was less than or equal to 48.7% of the allowable leakage, thereby demonstrating that Catawba Unit 2 is a low-leakage containment. There are no mechanisms which would adversely affect the structural integrity of the containment, or that would be a factor in extending the test interval by 30 months. However, as a preventative maintenance measure, a containment civil inspection, currently required by Appendix J prior to a Type A test, will be performed during EOC–7 in October 1995 to verify that no structural degradation exists. Any additional risk created by the longer interval between ILRTs is considered to be negligible, primarily because Type B and C testing will continue unchanged.

Additionally, the licensee stated that its exemption request meets the requirements of 10 CFR 50.12, paragraphs (a)(1) and (a)(2)(ii), for the following reasons:

In order to justify the granting of an exemption to the requirements of 10 CFR Part 50, paragraph 50.12(a)(1) requires that the licensee show that the proposed exemption will not pose an undue risk to the public. That this proposed change will not pose an undue risk is demonstrated by the analysis presented in draft NUREG–1493, which concludes that an increase in the test interval to once every 20 years would "lead to an imperceptible increase in risk." The analyses in draft NUREG–1493 are considered to be specifically applicable to Catawba because: (1) The requested exemption would result in a one-time increase in the test interval to about 5 years, not 20; (2) the population density around Catawba is less than that used in the study (329 people per square mile, vs. 340 used in the study); (3) no ILRT at Catawba has failed; 4) the core inventory used in the study was represented by a 3412 Mwt PWR [pressurized water reactor]. Catawba is a 3411 Mwt PWR. Other factors which lead to the conclusion that the proposed change will not pose an undue risk include the fact that local leak rate testing, which identifies 97% of leakage in excess of prescribed limits, will remain in place at its current test frequency; the detailed, proceduralized containment civil inspection which is normally performed in conjunction with an ILRT will be performed in place of the scheduled ILRT, to identify potential structural deteriorations; and the historical leak-tightness of the containment structure, as evidenced by two successive ILRTs in which the as-found leakage did not exceed 48.7% of the allowable leakage rate. A table which shows the leak test history of Catawba Unit 2 follows this Attachment.

A comparison was made between the risk analysis presented in draft NUREG–1493 and a probabilistic risk assessment performed for Catawba Nuclear Station. While the quantitative results of the NUREG are not directly applicable to plants not used in the study, conclusions similar to those presented in the NUREG can be made concerning Catawba. NUREG–1493 indicates that reactor accident risks are dominated by accident sequences that result in failure or bypass of the containment. This conclusion is also valid for Catawba. Considering only the Catawba accident sequences that do not result in containment failure, containment leakage contributes approximately 0.08 to 0.09 percent to off-site risk (whole-body person-rem, thyroid nodules, and latent fatalities). NUREG–1493 indicated that containment leakage contributed from 0.02 to 0.10 percent to latent cancer risk. The comparison between the analysis of NUREG–1493 and the Catawba PRA concludes that increases in containment leakage at Catawba are expected to produce increases in accident risk similar to the results in NUREG–1493.

Special circumstances, as defined in 10 CFR 50.12(a)(2)(ii), are considered to exist if "application of the regulation * * * is not necessary to achieve the underlying purpose of the rule." The purposes of the rule, as stated in Section I of Appendix J, are to ensure that: a) leakage through the primary reactor containment and systems and components penetrating containment shall not exceed allowable values, and b) periodic surveillance of reactor containment penetrations and isolation valves is performed so that proper maintenance and repairs are made. One of the significant factors in assuring that the proposed exemption will not pose an undue risk to the public, as noted above, is the local leak rate testing (LLRT) which is performed. That the LLRT program at Catawba provides an effective mechanism for maintaining containment integrity is perhaps best demonstrated by the fact that the most recent ILRT at Catawba Unit 2 was performed at the front end of the refueling outage; before any repairs or adjustments were made to valves or penetrations. Nevertheless, the as-found leakage did not exceed 48.7% of the allowable leakage rate. The fact that no leakage paths were identified by an ILRT, and that the ILRT met the acceptance criteria with significant margin confirms the results of the Type B and C testing.

The frequency and scope of the Type B and C LLRT program are not being changed by this exemption request. The LLRT program will continue to effectively detect containment leakage resulting from the degradation of active containment isolation components, as well as containment penetrations. Administrative limits have been established for each Type B or C component at a fraction of the allowable leak rate, such that any leakage detected in excess of the administrative limit will indicate a potential valve or penetration degradation. In instances in which a component's leakage exceeds its administrative limit, proceduralized controls in the test program require that a work order be written to repair the component.

IV

Section III.D.1.(a) of Appendix J to 10 CFR Part 50 states that a set of three Type A leakage rate tests shall be performed at approximately equal intervals during each 10-year service period.

The licensee proposes an exemption to this section which would provide a one-time interval extension for the Type A test by approximately 30 months. The Commission has determined that, pursuant to 10 CFR 50.12(a)(1), this exemption is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security. The Commission further determined, for the reasons discussed below, that special circumstances, as provided in 10 CFR 50.12(a)(2)(ii), are present justifying the exemption; namely, that application of the regulation in the particular circumstances is not necessary to achieve the underlying purpose of the rule. The underlying purpose of the requirement to perform Type A containment leak rate tests at approximately equal intervals during the 10-year service period, is to ensure that any potential leakage pathways through the containment boundary are identified within a time span that prevents significant degradation from continuing or becoming unknown. The NRC staff has reviewed the basis and supporting information provided by the licensee in the exemption request. The NRC staff has noted that the licensee has a good record of ensuring a leak-tight containment. All Type A tests have passed with significant margin and the licensee has noted that the results of the Type A testing have been confirmatory of the Type B and C tests which will continue to be performed. The licensee has stated that it will continue to perform the general containment civil inspection although it is only required by Appendix J (Section V.A.) to be performed in conjunction with Type A tests. The NRC staff considers that these inspections, though limited in scope, provide an important added level of confidence in the continued integrity of the containment boundary.

The NRC staff has also made use of a draft staff report, NUREG–1493, which provides the technical justification for the present Appendix J rulemaking effort which also includes a 10-year test interval for Type A tests. The integrated leakage rate test, or Type A test, measures overall containment leakage. However, operating experience with all types of containments used in this country demonstrates that essentially all containment leakage can be detected by local leakage rate tests (Type B and C). According to results given in NUREG–1493, out of 180 ILRT reports covering 110 individual reactors and approximately 770 years of operating history, only 5 ILRT failures were found that local leakage rate testing could not detect. This is 3% of all failures. This study agrees with previous NRC staff studies which show that Type B and C testing can detect a very large percentage of containment leaks. The Catawba Unit 2 experience has also been consistent with this.

The Nuclear Management and Resources Council (NUMARC), now the Nuclear Energy Institute (NEI), collected and provided the NRC staff with summaries of data to assist in the Appendix J rulemaking effort. NUMARC collected results of 144 ILRTs from 33 units; 23 ILRTs exceeded $1.0L_a$. Of these, only nine were not due to Type B or C leakage penalties. The NEI data also added another perspective. The NEI data show that in about one-third of the cases exceeding allowable leakage, the as-found leakage was less than $2L_a$; in one case the leakage was found to be approximately $2L_a$; in one case the as-found leakage was less than $3L_a$; one case approached $10L_a$; and in one case the leakage was found to be approximately $21L_a$. For about half of the failed ILRTs, the as-found leakage was not quantified. These data show that, for those ILRTs for which the leakage was quantified, the leakage values are small in comparison to the leakage value at which the risk to the public starts to increase over the value of risk corresponding to L_a (approximately $200L_a$, as discussed in NUREG–1493).

Based on generic and plant-specific data, the NRC staff finds the licensee's proposed one-time exemption to permit a schedular extension of one cycle for the performance of the Appendix Type A test to be acceptable.

Pursuant to 10 CFR 51.32, the Commission has determined that granting this exemption will not have a significant impact on the human environment (60 FR 32567).

This exemption is effective upon issuance and shall expire at the completion of the 1997 refueling outage.

Dated at Rockville, Maryland, this 17th day of August 1995

For the Nuclear Regulatory Commission.

Steven A. Varga,

Director, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 95–21032 Filed 8–23–95; 8:45 am]

BILLING CODE 7590–01–P

[Docket No. 50–346]

Toledo Edison Company; Centerior Service Company; The Cleveland Electric Illuminating Company; Notice of Consideration of Issuance of Amendment to Facility Operating License, Proposed no Significant Hazards Consideration Determination, and Opportunity for a Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. NPF–3 issued to the Toledo Edison Company, Centerior Service Company, and The Cleveland Electric Illuminating Company (the licensees) for operation of the Davis-Besse Nuclear Power Station, Unit No. 1, located in Ottawa County, Ohio.

The proposed amendment would modify Technical Specification (TS) 3/4.7.5.1, Ultimate Heat Sink, which presently requires that the ultimate heat sink (UHS) average water temperature be less than or equal to 85 °F during plant operating Modes 1 through 4. The proposed amendment would require an UHS average water temperature of less than or equal to 90 °F during plant operating Modes 1 through 4.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

The Commission has made a proposed determination that the amendment request involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

Toledo Edison has reviewed the proposed changes and determined that a significant hazards consideration does not exist because operation of the Davis-Besse Nuclear Power Station, Unit No. 1, in accordance with these changes would:

1a. Not involve a significant increase in the probability of an accident previously evaluated because no accident initiators, conditions, or assumptions are significantly affected by the proposed change. The proposed change does not result in the operation of equipment important to safety outside their acceptable operating range.

1b. Not involve a significant increase in the consequences of an accident previously evaluated because the proposed change does not change the source term, containment isolation, or allowable releases.

2. Not create the possibility of a new or different kind of accident from any accident previously evaluated because no new accident initiators or assumptions are introduced by the proposed change. The proposed change does not result in installed equipment being operated in a manner outside its design operating range. No new or different equipment failure modes or mechanisms are introduced by the proposed change.

3. Not involve a significant reduction in a margin of safety because the proposed change is not a significant change to the initial conditions contributing to accident severity or consequences, consequently there are no significant reductions in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should circumstances change during the notice period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received. Should the Commission take this action, it will publish in the **Federal Register** a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to Room 6D22, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received may be examined at the NRC Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC.

The filing of requests for hearing and petitions for leave to intervene is discussed below.

By September 25, 1995, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR Part 2. Interested persons should consult a current copy of 10 CFR 2.714 which is available at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room located at the University of Toledo Library, Documents Department, 2801 Bancroft Avenue, Toledo, Ohio. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for

leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to 15 days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than 15 days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Services Branch, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, by the above date. Where petitions are filed during the last 10 days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at 1-(800) 248–5100 (in Missouri 1-(800) 342–6700). The Western Union operator should be given Datagram Identification Number N1023 and the following message addressed to Gail H. Marcus: petitioner's name and telephone number, date petition was mailed, plant name, and publication date and page number of this **Federal Register** notice. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to Jay E. Silberg, Esquire, Shaw, Pittman, Potts and Trowbridge, 2300 N Street, NW., Washington, DC 20037, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of the factors specified in 10 CFR 2.714(a)(1)(i)-(v) and 2.714(d).

For further details with respect to this action, see the application for amendment dated August 18, 1995, which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room located at the University of Toledo Library, Documents Department, 2801 Bancroft Avenue, Toledo, Ohio.

Dated at Rockville, Maryland, this 21st day of August 1995.

For the Nuclear Regulatory Commission.

Linda L. Gundrum,

Project Manager, Project Directorate III–3, Division of Reactor Projects III/IV, Office of Nuclear Reactor Regulation.

[FR Doc. 95–21033 Filed 8–23–95; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–36107; File No. SR–MBSCC–95–05]

Self-Regulatory Organizations; MBS Clearing Corporation; Notice of Filing of a Proposed Rule Change Seeking Authority to Release Clearing Data Relating to Participants

August 16, 1995.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] notice is hereby given that on June 28, 1995, the MBS Clearing Corporation ("MBSCC") filed with the Securities and Exchange Commission ("Commission") the proposed rule change (File No. SR–MBSCC–95–05) as described in Items I, II, and III below, which items have been prepared primarily by MBSCC. On July 24, 1995, MBSCC filed an amendment to the proposed rule change to clarify the parties to whom MBSCC will release clearing data.[2] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The purpose of the proposed rule change is to modify Article V of MBSCC's Rules by adding a new Rule 14 concerning the release of participants' clearance and settlement data.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, MBSCC included statements concerning the purpose of and basis for the proposed rule change and discussed any comments that it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. MBSCC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.[3]

[1] 15 U.S.C. 78s(b)(1) (1988).

[2] Letter from Anthony H. Davidson, MBSCC, to Peter R. Geraghty, Division of Market Regulation, Commission (July 21, 1995).

[3] The Commission has modified the text of the summaries submitted by MBSCC.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of the proposed rule change is to modify Article V of MBSCC's Rules by adding a new Rule 14 concerning the release of data relating to participants' clearance and settlement activity. MBSCC receives transaction data and other data relating to its participants in the normal course of its business. The rule change sets forth MBSCC's obligation to preserve its participants' rights with respect to such data and the conditions under which MBSCC will disclose such data.

The proposed rule will permit MBSCC to disclose such data to regulatory organizations, self-regulatory organizations, clearing organizations affiliated with or designated by contract markets trading specific futures products under the oversight of the Commodity Futures Trading Commission, and others under certain conditions. The proposed rule change provides that generally, the release of a participant's clearing data shall be conditioned upon that participant's submission of a written request.[4] The proposed rule also defines "clearing data" to mean transactions and other data which is received by MBSCC in the clearance and/or settlement process or such reports or summaries which may be produced as a result of processing such data.

The proposed rule change also will facilitate MBSCC's participation in the National Securities Clearing Corporation's ("NSCC") Collateral Management Service ("CMS").[5] The proposed rule change will enable MBSCC to provide information regarding MBSCC's Participants Fund, including excess or deficit amounts, and comprehensive data on underlying collateral to NSCC for inclusion in the CMS. Participants of MBSCC that desire access to the CMS data will be required to submit a CMS participation application to NSCC. The execution of a CMS application will constitute the written request required under the proposed rule change to authorize MBSCC to release a participant's clearing data to the participant.[6]

MBSCC believes the proposed rule change is consistent with Section 17A of the Act and the rules and regulations thereunder because the rule proposal should help to safeguard securities and funds in its custody or control or for which it is responsible.

(B) Self-Regulatory Organization's Statement on Burden on Competition

MBSCC does not believe that the proposed rule change will impact or impose a burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

No written comments relating to the proposed rule change have been solicited or received. MBSCC will notify the Commission on any written comments received by MBSCC.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within thirty-five days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to ninety days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which MBSCC consents, the Commission will:

(a) By order approve such proposed rule change or

(b) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street NW., Washington, DC 20549. Copies of such filing will also be available for inspection and copying at the principal office of MBSCC. All submissions should refer to the file number SR–MBSCC–95–05 and should be submitted by September 14; 1995.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[7]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 95–20950 Filed 8–23–95; 8:45 am]

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[4] As a self-regulatory organization, MBSCC currently is permitted without obtaining a participant's written authorization to cooperate and share data with other regulatory or self-regulatory organizations for regulatory purposes.

[5] Generally, the CMS will provide participating participants and clearing agencies with access to information regarding clearing fund, margin, and other similar requirements and deposits. For a complete description of the CMS, refer to Securities Exchange Act Release No. 35809 (June 5, 1995), 60 FR 30912 [File No. SR–NSCC–95–06] (notice of filing of proposed rule change).

[6] The CMS agreement sets forth MBSCC's and NSCC's authorizations to collect and provide information relating to the participants' clearing fund and margin requirements and the participants' clearing fund and margin deposits.

[7] 17 CFR 200.30–3(a)(12) (1994).

[Release No. 34–36112; File No. SR–NSCC–95–11]

Self-Regulatory Organizations; National Securities Clearing Corporation; Notice of Filing of a Proposed Rule Change Concerning Book-Entry Money Settlements With Members

August 17, 1995.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] notice is hereby given that on August 8, 1995, the National Securities Clearing Corporation ("NSCC") filed with the Securities and Exchange Commission ("Commission") the proposed rule change (File No. SR–NSCC–95–11) as described in Items I, II, and III below, which items have been prepared primarily by NSCC. The Commission is publishing this notice to solicit comments from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Change

NSCC is asking for renewal of its temporary authority to allow intrabank funds transfers between NSCC and its members in satisfaction of settlement obligations.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, NSCC included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. NSCC has prepared

[1] 15 U.S.C. 78s(b)(1) (1988).

summaries, set forth in sections A, B, and C below of such statements.[2]

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

On October 5, 1990, NSCC filed a proposed rule change with the Commission that was noticed in the **Federal Register**[3] and was subsequently amended three times.[4] On September 4, 1992, the proposal as amended was approved on a temporary basis through August 31, 1993.[5] The temporary approval subsequently was extended through August 31, 1995.[6] The current filing requests an extension of the temporary approval order until such time as NSCC implements its same-day funds settlement system.

As discussed in detail in the approval order of September 4, 1992, the rule change permits NSCC members to satisfy their settlement obligations to NSCC and permits NSCC to satisfy its settlement obligations to its members by means of electronic intrabank funds transfers between members' accounts and NSCC's accounts at various settlement banks. Under the proposal, two types of intrabank funds transfers are available: (1) Electronic transfers whereby on settlement day NSCC pays members by check for next-day value and members pay NSCC by NSCC directing the settlement banks to make irrevocable transfers from the members' accounts to NSCC's accounts for next-day availability or whereby members pay NSCC by check and NSCC effects payments by electronic transfers ("one-way electronic transfers") and (2) electronic transfers whereby on settlement day both NSCC and members pay by NSCC directing the settlement banks to make irrevocable transfers for next-day value without any netting ("two-way electronic transfers").

As a prerequisite to either NSCC or any of its members making a settlement payment by an electronic funds transfer, the proposed rule change imposes three requirements. First, any such payment must be effected on a next-day funds availability basis.[7] Second, any such payment must be in conformity with an agreement, which must be executed by NSCC and any bank that acts as a payment intermediary, which stipulates that any such funds transfer must be effected on an irrevocable and final basis.[8] Third, any bank that acts as an intermediary for such funds transfers must meet NSCC's standards for letter of credit issuers.[9]

NSCC believes that a renewal of the approval of the rule change would be consistent with the Act and particularly with Section 17A thereof.[10] Section 17A(a)(1) of the Act encourages the use of efficient, effective, and safe procedures for securities clearance and settlement. Moreover, section 17A(b)(3)(F) of the Act requires that the rules of clearing agencies be designed to assure the safeguarding of funds in the custody or control of clearing agencies or for which they are responsible.

NSCC believes that substantial marketplace efficiencies can be achieved by authorizing NSCC to effect electronic intrabank funds transfers to satisfy settlement obligations between itself and its members. NSCC also believes that the exchange of checks is labor intensive and that physical movement of checks can involve loss or delay. NSCC therefore believes that intrabank funds transfers should enhance the safeguarding of funds and that earlier finality of settlement provides certainty to the marketplace and serves to increase investor confidence in the markets.

The Commission temporarily approved the proposed rule change to permit NSCC and other interested parties to assess prior to permanent Commission approval the effects intrabank funds transfers have on money settlement payments at NSCC. Because the assessment process is not complete, the facts and circumstances justifying temporary approval of the rule change have not changed significantly from the date of original temporary approval. NSCC also expects to implement a same-day funds settlement system and to file a proposed rule change with the Commission in connection therewith. Therefore, NSCC is requesting that temporary approval be extended until such time as NSCC implements its same-day funds settlement system.

B. Self-Regulatory Organization's Statement on Burden on Competition

NSCC does not believe that the proposed rule change will have an impact on or impose a burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments have been solicited or received. NSCC will notify the Commission of any written comments received by NSCC.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within thirty-five days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to ninety days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which self-regulatory organizations consent, the Commission will:

(A) By order approve such proposed rule change or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street NW., Washington, DC 20549. Copies of the submissions, all subsequent

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[2] The Commission has altered some of these statements.

[3] Securities Exchange Act Release No. 28715 (December 12, 1990), 55 FR 715 [File No. SR–NSCC–90–21].

[4] Letters from: (1) Jeffrey F. Ingber, Associate General Counsel, NSCC, to Jonathan Kallman, Assistant Director, Division of Market Regulation ("Division"), Commission (August 14, 1991); (2) Peter J. Axilrod, Associate General Council NSCC, to Jerry Carpenter, Branch Chief, Division, Commission (March 23, 1992); and (3) Peter J. Axilrod, Associate General Counsel, NSCC, to Thomas C. Etter, Jr., Attorney, Division, Commission (July 22, 1992).

[5] Securities Exchange Act Release No. 31157 (September 4, 1992), 57 FR 42602 [File No. SR–NSCC–90–21].

[6] Securities Exchange Act Release No. 32836 (September 2, 1993), 58 FR 47483 [File No. SR–NSCC–93–08]; Securities Exchange Act Release No. 34573 (August 22, 1994), 49 FR 44443 [File No. SR–NSCC–94–17].

[7] The term "next-day funds" refers to funds paid today that will be available tomorrow. By contrast, "same-day funds" refers to funds that are immediately available.

[8] The September 4, 1992, order noted that on March 24, 1992, NSCC filed with the Commission a letter representing that NSCC will: (1) Submit for Division approval the current form of any agreement pursuant to which intrabank funds transfers are to be made and (2) notify the Division of the identity of each bank that enters into any such contract. Letter from Peter J. Axilrod, Associate General Counsel, NSCC, to Jerry Carpenter, Branch Chief; Division, Commission (March 23, 1992).

[9] For a bank or trust company to be approved by NSCC to issue letters of credit on behalf of members for purposes of clearing fund requirements, the bank or trust company must meet specific standards in terms of: (1) Minimum levels of stockholders' equity and (2) certain credit ratings for its short term obligations as determined by Standard and Poor's Corporation or Moody's Investor Service, Inc. NSCC Rule 4, Section 1; Securities Exchange Act Release No. 29444 (July 16, 1991), 56 FR 34081 [File No. SR–NSCC–91–03] (order approving NSCC's revised standards for approved issuers of letters of credit for clearing fund purposes).

[10] 15 U.S.C. 78q–1 (1988).

amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 5th Street NW., Washington, DC 20549. Copies of such filing also will be available for inspection and copying at the principal office of NSCC. All submissions should refer to File No. SR–NSCC–95–11 and should be submitted by September 14, 1995.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[11]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 95–20953 Filed 8–23–95; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–36115; File No. SR–NASD–95–33]

Self-Regulatory Organizations; Notice of Filing and Order Granting Partial Accelerated Approval of Proposed Rule Change by National Association of Securities Dealers, Inc., Relating to Actions Taken During Extraordinary Market Conditions

August 17, 1995.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 21, 1995, the National Association of Securities Dealers, Inc. ("NASD" or "Association") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III below; Items I and II have been prepared by the NASD. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons. As discussed below, the Commission has also granted accelerated approval to a portion of the proposal.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The NASD seeks the authority to modify temporarily the operation of its SelectNet service and its Small Order Execution System ("SOES") during periods of unusually high Nasdaq broadcast volume. Specifically, the NASD proposes that, during periods with a high number of quotation updates, SelectNet broadcast orders and/or trade reports, it be permitted to take the following action without having to file a proposed rule change with the Commission:

(a) Suspend the entry of SelectNet broadcast orders from 9:30 to 10:30 a.m.;

(b) Execute immediately matched or crossed customer limit orders in the SOES limit order file (*i.e.*, rather than delay execution for five minutes); and

(c) Increase from five minutes to ten minutes the standard grace period in which market makers must refresh their SOES minimum exposure limit.

The NASD requests the Commission to find good cause, pursuant to Section 19(b)(2) of the Act, for approving the proposed rule change prior to the thirtieth day after publication in the **Federal Register.**

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the NASD included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The NASD has prepared summaries, set forth in Sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Pursuant to article VII, section 3 of the NASD By-Laws, a special committee of the NASD Board of Governors was convened on July 20, 1995 to authorize action regarding the operation of certain Nasdaq automated systems. Article VII, section 3 permits a committee consisting of the Chairman, an Executive Committee member and the President of the NASD, in lieu of full Board consideration, to take immediate action when extraordinary market conditions exist.[3] Extraordinary market conditions are such conditions where the market is experiencing highly volatile trading conditions that require prompt intervention to permit continued efficient operation of the market. Until the new network[4] is completely implemented later this year, and as long as Nasdaq continues to experience trading activity exceeding the existing network's stated capacity of 450 million shares per day, the NASD believes Nasdaq must be considered to be experiencing extraordinary market conditions that must be immediately addressed by appropriate steps that will permit the continued efficient operation of the market.[5]

Therefore, until the new network is fully implemented, the special committee of the NASD Board authorized the following actions to be taken to permit its network to operate efficiently during such periods as the Nasdaq market is experiencing, or reasonably anticipates, heavy trading activity in excess of 450 million shares per day:

1. Between the hours of 9:30 to 10:30 a.m., SelectNet orders must be directed to specific market makers;

2. The standard grace period for a market maker in a National Market security to restore its minimum exposure limit in SOES will be expanded from five minutes to ten minutes; and

3. Priced orders entered into the SOES limit order file on the opposite side of the market from each other that match or cross in price will be executed against each other immediately rather than after five minutes.[6]

The NASD seeks to be able to implement these changes under the described conditions without having to submit a proposed rule change with the Commission each time it implements one of these changes. Under the NASD's emergency authority, the NASD is required, among other things, to file a proposed rule change under section 19(b)(3)(A) promptly after exercising this authority.[7] Under section

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[11] 17 CFR 200.30–3(a)(12) (1994).

[1] 15 U.S.C. 78s(b)(1)(1988).

[2] 17 CFR 240.19b–4 (1994).

[3] In the event of an emergency or extraordinary market conditions, Article VII, Section 3 permits the NASD to take any action regarding the trading in or operation of the over-the-counter securities market, the operation of any automated system owned or operated by the NASD, and the participation in any such system of any or all persons or the trading therein of any or all securities. See NASD Securities Dealers Manual ¶1182A.

[4] That is, the migration from Nasdaq Workstation I to Nasdaq Workstation II.

[5] For example, on Wednesday, July 19, 1995, the NASD experienced its highest trading volume ever, 597.5 million shares. In addition, quotation updates were up to four times higher than the previous peak update traffic.

[6] The NASD notes that the Committee also authorized and approved the actions and regulatory changes described above for the extraordinary market conditions experienced on July 19–21, 1995.

[7] Securities Exchange Act Release No. 26072 (Sept. 12, 1988), 53 FR 36143 (Sept. 16, 1988) (order

Continued

19(b)(3)(A), an NASD proposal becomes effective upon filing with the Commission, but is subject to abrogation by the Commission within 60 days.[8]

The NASD believes these modifications to the operation of its systems and rules associated with its systems are necessary and appropriate for the protection of investors and to maintain the orderly operation of the Nasdaq Stock Market as long as it continues to experience the extremely high levels of trading activity (which includes quotation updates, trade executions through automated execution systems operated by Nasdaq, cancellations of orders, and trade reporting) associated with 450 million share days, and the new network is not yet fully implemented. As a prophylactic measure until the new network is in place, therefore, the NASD will operate its market with these changes (or a subset thereof, at the NASD's discretion) in effect unless market conditions subside to an average daily trading volume of less than 450 million and the associated network traffic drops to acceptable levels.[9]

The NASD states that during periods when these procedures have been implemented, the Nasdaq operations have continued to experience accurate and timely quotations. The primary concern of the NASD during these extraordinary market conditions has been to maintain the accuracy and timeliness of its pricing mechanism. All executions of customer orders, whether such orders are delivered to member firms by means of the telephone, SOES, SelectNet, or member firm internal execution systems, are ultimately driven by the Nasdaq quotation. Therefore, the NASD believes it is essential to price discovery and market integrity that Nasdaq maintain the validity of the quotations it displays.

The NASD believes the modification to SelectNet is the most prudent possible change to Nasdaq services that provides the greatest benefit to system capacity while having the smallest effect on investors. SelectNet messages generally consume greater amounts of network capacity than other messages sent through the network. By eliminating the broadcast feature of SelectNet,[10] the network obtains approximately 20 percent more capacity than when broadcast messages were permitted. Compared to any other option, the elimination of the broadcast of a SelectNet message provides the most significant capacity benefits to the network.

The NASD believes the immediate execution of matched or crossed limit orders in SOES provides two benefits. First, it permits customers that place priced orders in the file an increased opportunity for rapid execution of their orders, a measure that should be beneficial in heavy trading days. Second, the step provides some minor benefit to the network capacity constraints in that it eliminates a small number of last sale reports that would have occurred had the orders been executed separately.[11]

The NASD also notes that the change to the standard grace period is also important to the overall well-being of the market during these conditions. Because of the extraordinary levels of market activity that are occurring, member firm trading desks are extremely busy handling the multiple points of order flow; Because of the extent of such activity at the trading desks, the NASD fears that the standard grace period of five minutes to update the market maker's minimum exposure limit in SOES is not sufficient to provide market makers a reasonable opportunity to update their exposure limit. If the market maker fails to update the exposure limit in a security within five minutes under current SOES rules, the market maker may be deemed to have withdrawn as a market maker in that security.[12] In extraordinary market conditions, the NASD believes that it would be unwise to lose the liquidity provided by a market maker because such market maker was unable to direct attention to its exposure limit within five minutes. Accordingly, the NASD has determined to expand the standard grace period to ten minutes.[13]

2. Statutory Basis

The NASD believes that the proposed rule change is consistent with the provisions of section 15A(b)(6) of the Act[14] in that the proposed changes are designed to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing, information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a fair and open market. The actions taken by the NASD and proposed herein facilitate the continued operation of the systems during those periods of extraordinary market conditions until the expanded network is ready to be fully implemented.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The NASD does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

A. By order approve such proposed rule change, or

B. Institute proceedings to determine whether the proposed rule change should be disapproved.

The NASD has requested, however, that the Commission find good cause pursuant to section 19(b)(2) for approving the proposed rule change prior to the 30th day after publication in the **Federal Register**.

As discussed below, the Commission finds that the portion of the proposed rule change that modifies the operation of SOES to execute immediately matched or crossed customer limit

approving proposed rule change to provide the NASD Board of Governors and a proposed committee the authority to take action during extraordinary market conditions). The NASD is also required to use best efforts to consult with the Commission in advance of exercising its emergency authority, provide the Commission with a written report describing the action taken and the reasons therefore, and prepare and maintain with its corporate records a record of any actions taken under the proposed rule change.

[8] 15 U.S.C. 78s(b)(3)(C).

[9] The NASD will provide its Board and the SEC with regular updates on the status of these actions and the need for continuation of these special measures.

[10] By "broadcast," it is meant that a single order is broadcast over the network to all available market makers. The broadcasting of a message of such length to multiple sources consumes significantly more capacity than a message directed to a single point. Thus, limiting SelectNet to directed orders minimizes network traffic while continuing to allow a firm to communicate an order directly to an individual market maker.

[11] Letter to Mark Barracca, Branch Chief, SEC, for Richard G. Ketchum, Chief Operating Officer and Executive Vice President (July 31, 1995).

[12] See SOES Rules of Procedure, (c) 2.(G). NASD Securities Dealers Manual ¶ 2460.

[13] The NASD has taken similar action in other extraordinary market conditions. See *e.g.*, Securities Exchange Act Release No. 27369 (Oct. 19, 1989), 54 FR 45832 (Oct. 31, 1989) and Securities Exchange Act Release No. 29664 (Sept. 10, 1991), October 1989 Market Break and the political upheaval in the former Soviet Union in August 1991.

[14] 15 U.S.C. 78*o*–3.

orders in the SOES limit order file is consistent with the requirements of the Act. Further, the Commission finds good cause for approving, prior to the 30th day after the date of publication of notice of filing in the **Federal Register**, the proposal to execute immediately matched or crossed limit orders in SOES. The Commission believes that accelerated approval of this portion of the proposal will benefit investors by creating a greater assurance that the Nasdaq market will continue to operate efficiently during periods of market stress and high volume.

IV. Commission's Findings and Order Granting Partial Accelerated Approval of Proposed Rule Change

The Commission finds that the proposal to permit the NASD to modify the operation of SOES to allow matched or crossed customer limit orders in the SOES limit order file to execute immediately against each other (*i.e.*, rather than be delayed for five minutes) is consistent with the Act and the rules and regulations promulgated thereunder. Specifically, the Commission finds that the proposed rule change is consistent with the requirements of Section 15A(b)(6) which requires that the NASD rules be designed, among other things, to facilitate securities transactions and protect investors and the public interest. Removing the five-minute delay in the execution of matched or crossed limit orders in the SOES limit order file will facilitate the NASD's load shedding efforts by increasing the speed of execution and removing orders from the Nasdaq system more quickly. Moreover, the greater likelihood that an investor will receive an execution of a limit order placed in SOES may encourage greater use of the SOES limit order file. This will further decrease the burden on market makers and increase the message handling capabilities of Nasdaq during high volume periods. Finally, the Commission notes that the proposal will further the Congressional objective to increase the opportunity for investors' orders to be executed without the participation of a dealer.[15]

Nonetheless, the Commission is concerned about the effects of service changes on the Nasdaq market. Accordingly, the Commission directs the NASD to notify, prior to implementing this change to SOES or as soon as practicable thereafter, its members via the Nasdaq Workstation and the staff of the Division of Market Regulation by telephone. In addition, on a weekly basis, the NASD should submit a written report to the Division of Market Regulation providing information on any service changes since the last report.[16] The information provided should include: (a) a brief description of the change; (b) the event(s) triggering the change; and (c) the NASD's assessment of the effect of the change on the Nasdaq system.

As a more general matter, the Commission is concerned about capacity limitations in the Nasdaq system. Since 1989, the Commission has urged self-regulatory organizations, among other things, to develop current and future capacity estimates, conduct capacity stress tests, and contract with independent reviewers to assess annually whether their systems can perform adequately under varying degrees of market activity.[17] While the Commission recognizes that the NASD expects that its planned system changes will address these issues, we are concerned about the ongoing stress in the Nasdaq system, as well as the inability to resolve that stress without service reductions. Accordingly, the Commission has requested the NASD to obtain an independent review of its current capacity.

V. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. The Commission specifically requests that commenters address the appropriateness of the NASD's approaches to address system capacity during periods of market stress. The Commission shares the NASD's concerns about timely and accurate quotes and trade reports in high volume market conditions. While the Commission understands that suspending SelectNet's broadcast feature during high volume markets will free up broadcast capacity, the Commission requests that the NASD elaborate on the effects of this modification on quotes and trade reports. In this regard, it would be helpful if the NASD and market participants described their experience over the past month with the timeliness and accuracy of quotes and trade reports during SelectNet broadcast suspensions.

In addition, the NASD has stated that suppression of the SelectNet broadcast feature offers the greatest benefits in terms of system capacity with the least effect on investors. The Commission invites comment on the implications of this modification for investors and firms in terms of market access, execution quality, transparency, and price discovery. The Commission also invites comment on whether there may be alternatives available for improving system capacity that would have a smaller impact on market participants.

The Commission also seeks comments on the NASD's proposal to double the length of the standard grace period in which market makers must refresh their SOES minimum exposure limit. SOES—with mandatory market maker participation and an automatic twenty-day suspension for failure to refresh exposure limits within the grace period—was enhanced in 1988 to provide small investors with access to market during periods of extraordinary activity. In the pending proposal, the NASD wishes to reduce the availability of SOES under precisely those conditions. The Commission invites comment on whether this proposal undermines the purpose of SOES and any relevant experience from either of the last two times that the NASD extended the grace period.

The Commission also notes that the practical effect of the NASD's proposal is to limit the availability of automatic execution in order to protect the liquidity of the overall market. That is, market makers will be permitted to remain active in a security despite more lengthy periods of inactivity on SOES. The Commission solicits comments on whether there are alternatives available that would continue the availability of automatic executions for small orders that would not have a negative impact on the liquidity of the overall Nasdaq market. For example, given the availability of auto-refresh in the Nasdaq market, comments are invited on whether such a system is adequate to address this concern, and whether private systems exist that can notify market makers when they have been executed against the SOES and are about to be taken off the screen because of the expiration of the grace period.

Finally, given that the NASD will implement these changes based on its continuing assessment of market conditions and the need to implement any one or any combination of the changes, comment is invited on the potential for confusion, both to investors and to other market participants as to which changes are in place on any given day and the implications of these changes for trading in the over-the-counter market.

[15] *Id.* section 78k–1(a)(1)(C)(v).

[16] The NASD's notification via the telephone and its written report to the Commission should be directed to the Branch Chief, Office of Automation & International Markets, Division of Market Regulation or his designee.

[17] Securities Exchange Act Release No. 29185 (May 19, 1991), 56 FR 22490 (May 15, 1991) and Securities Exchange Act Release No. 27445 (Nov. 16, 1989), 54 FR 48703 (Nov. 24, 1989).

Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to the file No. SR–NASD–95–33 and should be submitted by September 8, 1995.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that the portion of the proposed rule change (SR–NASD–95–33) providing the NASD the authority to modify the operation of SOES by allowing matched or crossed limit orders to execute automatically is approved until January 5, 1996 or the completion of the roll-out of Workstation II, whichever occurs first.

By the Commission.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 95–21044 Filed 8–23–95; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–36114; File No. SR–PHLX–95–50]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the Philadelphia Stock Exchange, Inc., Relating to PHLX Rule 722, "Margins"

August 17, 1995.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on July 3, 1995, the Philadelphia Stock Exchange, Inc. ("PHLX" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Currently, PHLX Rule 722(c)(6), "Time Within Which Margin or 'Mark-to-Market' Must Be Obtained," provides that margin for a short foreign currency option ("FCO") position in a customer account or full cash payment for a long FCO position in a customer account must be obtained within seven business days following the date on which the customer enters into the FCO position. Recently, the Board of Governors of the Federal Reserve System ("Board") amended Regulation T under the Act to reduce from seven business days after the trade date to five business days after the trade date the amount of time in which a customer must meet initial margin calls or make full cash payment for securities.[1] To be consistent with Regulation T, as amended, the PHLX proposes to amend Exchange Rule 722(c)(6) to reduce from seven business days to five business days the time in which a customer must either pay for a long FCO position or post initial margin for a short FCO position.

The text of the proposed rule change is available at the Office of the Secretary, PHLX, and at the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

[1] Regulation T, as amended, provides that a margin call must be satisfied within one payment period after the margin deficiency was created or increased. Under Regulation T, a "payment period" is the number of business days in the standard securities settlement cycle in the United States, as defined in SEC Rule 15c6–1 under the Act, plus two business days. As of June 7, 1995, SEC Rule 15c6–1 establishes a standard three business day settlement cycle for most securities transactions in the United States. Accordingly, after June 7, 1995, the payment period for satisfying a margin call under Regulation T is five business days.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

Commission Rule 15c6–1, which became effective on June 7, 1995,[2] reduced the standard time for securities settlement from five business days ("T+5") to three business days ("T+3"). At the same time, the Board amended Regulation T under the Act to define the payment period in which a margin call must be satisfied or a cash payment received as two business days after the standard securities settlement cycle. According to the PHLX, T+3 has impacted securities trading in many ways, primarily in the systems and procedures utilized by broker-dealers, exchanges, and clearing agencies.

In addition, the Exchange states that PHLX Rule 722 has been impacted by T+3. Specifically, PHLX Rule 722(c)(6) currently provides that FCO margin and cash payment must be obtained as promptly as possible but before the expiration of seven full business days following the trade date. This time period was originally established by allowing two days after the regular T+5 settlement time for securities. With T+5 reduced to T+3, the Exchange proposes to reduce the time period by which margin or cash payment must be obtained to five business days.

The purpose of the proposed rule change is to reduce the payment period to correspond to the recent amendments to Regulation T. However, the Exchange notes that this time period is a maximum, as PHLX Rule 722(c)(6) requires the payment of margin "as promptly as possible." According to the PHLX, most Exchange member firms clearing FCO trades require payment to be paid or margin collected by the date following the trade.

The Exchange believes that the proposal is consistent with Section 6 of the Act, in general, and, in particular, with section 6(b)(5), in that it is designed to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, by reducing the time frame for margin or cash payment to reflect the reduced securities settlement time period.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The PHLX does not believe that the proposed rule change will impose any inappropriate burden on competition.

[2] 17 CFR 240.15c6–1.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were either received or requested.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reason for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(a) By order approve such proposed rule change, or

(b) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Section, 450 Fifth Street NW., Washington, DC. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted by September 14, 1995.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[3]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 95–20954 Filed 8–23–95; 8:45 am]

BILLING CODE 8010–01–M

[3] 17 CFR 200.30–3(a)(12) (1994).

[File No. 500–1]

Enviro-Green Tech, Inc.; Order of Suspension of Trading

August 18, 1995.

It appears to the Securities and Exchange Commission that there is a lack of adequate and accurate information concerning the securities of Enviro-Green Tech, Inc. ("Enviro-Green"), of Fort Lauderdale, Florida, and that questions have been raised about the accuracy and adequacy of Enviro-green's financial statements and other disclosures. The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above-listed company.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the securities of the above-listed company, over-the-counter or otherwise, is suspended for the period from 9:30 a.m. (EDT), August 18, 1995 through 11:59 p.m. (EDT), on September 1, 1995.

By the Commission.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 95–21045 Filed 8–23–95; 8:45 am]

BILLING CODE 8010–01–M

[Rel. No. IC–21312; No. 812–8924]

Merrill Lynch Life Insurance Company, et al.

August 17, 1995.

AGENCY: Securities and Exchange Commission ("Commission").

ACTION: Notice of application for an exemption pursuant to the Investment Company Act of 1940 (the "1940 Act").

APPLICANTS: Merrill Lynch Life Insurance Company; ML Life Insurance Company of New York; Merrill Lynch Variable Life Separate Account; Merrill Lynch Variable Life Separate Account II; ML of New York Variable Life Separate Account; ML of New York Variable Life Separate Account II; Merrill Lynch Variable Series Funds, Inc. (the "Fund"); and Merrill Lynch Asset Management, L.P.

RELEVANT 1940 ACT SECTIONS: Order requested pursuant to Section 6(c) granting exemptions from the provisions of Sections 9(a), 13(a), 15(a), and 15(b) of the 1940 Act and Rules 6e–2(b)(15) and 6e–3(T)(b)(15) thereunder.

SUMMARY OF APPLICATION: Applicants seek an order permitting shares of the Fund to be sold to and held by variable annuity and variable life insurance separate accounts of both affiliated and unaffiliated life insurance companies.

FILING DATE: The application was filed on April 11, 1994, and amended and restated on April 12, 1995. Applicants have undertaken to amend the application during the notice period to make the representations contained herein.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Secretary of the Commission and serving Applicants with a copy of the request, personally or by mail. Hearing requests must be received by the Commission by 5:30 p.m. on September 11, 1995, and must be accompanied by proof of service on Applicants in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons may request notification of a hearing by writing to the Secretary of the Commission.

ADDRESSES: Secretary, Securities and Exchange Commission, 450 5th Street NW., Washington, DC 20549. Applicants, c/o Barry G. Skolnick, Esq., Merrill Lynch Life Insurance Company, and Philip L. Kirstein, Esq., Merrill Lynch Asset Management, L.P., both at 800 Scudders Mill Road, Plainsboro, New Jersey 08536.

FOR FURTHER INFORMATION CONTACT: Kevin M. Kirchoff, Senior Counsel, or Wendy Friedlander, Deputy Chief, Office of Insurance Products (Division of Investment Management), at (202) 942–0670.

SUPPLEMENTARY INFORMATION: The following is a summary of the application; the complete application is available for a fee from the Public Reference Branch of the Commission.

Applicants' Representatives

1. Merrill Lynch Life Insurance Company ("Merrill Lynch") is a stock life insurance company organized under the laws of the State of Arkansas. Merrill Lynch Variable Life Separate Account and Merrill Lynch Variable Life Separate Account II are separate investment accounts established by Merrill Lynch and registered with the Commission pursuant to the 1940 Act as unit investment trusts.

2. ML Life Insurance Company of New York ("ML Life") is a stock life insurance company organized under the laws of the State of New York. ML of New York Variable Life Separate Account and ML of New York Variable Life Separate Account II are separate

investment accounts established by ML Life and registered with the Commission pursuant to the 1940 Act as unit investment trusts.

3. The Fund was incorporated on October 16, 1981, as a Maryland corporation and is registered with the Commission pursuant to the 1940 Act as an open-end, management investment company. The Fund currently consists of seventeen separate portfolios (the "Portfolios"), each of which has its own investment objective, or objectives, and policies.

4. Merrill Lynch Asset Management, L.P. ("MLAM"), a limited partnership, is the investment adviser for the Fund. MLAM is registered with the Commission as an investment adviser pursuant to the Investment Advisers Act of 1940. Princeton Services, Inc., the general partner of MLAM, is a wholly-owned subsidiary of Merrill Lynch & Co., Inc.

5. Shares of the Portfolios currently are sold to Merrill Lynch, ML Life (collectively, the "Merrill Insurance Companies") and Family Life Insurance Company ("Family Life," together with the Merrill Insurance Companies, the "Current Participating Insurance Companies"). The Merrill Insurance Companies are affiliated because they are both wholly-owned subsidiaries of Merrill Lynch & Co., Inc. Family Life is not affiliated with the Merrill Insurance Companies.

6. Currently, shares of certain Portfolios are sold either to: (a) the Merrill Insurance Companies for their separate accounts to fund variable annuity contracts; (b) the Merrill Insurance Companies to fund variable life insurance contracts; or (c) to Family Life to fund benefits under variable annuity contracts.

7. Applicants state that, upon the granting of the exemptive relief requested by the Application, the Fund intends to offer shares of its existing Portfolios, and any future portfolios, to separate accounts of insurance companies, including both the Current Participating Insurance Companies and other insurance companies not affiliated with them ("Other Insurance Companies") to serve as the investment vehicle for various types of insurance products, which may include variable annuity contracts, single premium variable life insurance contracts, scheduled premium variable life insurance contracts, and flexible premium variable life insurance contracts (collectively, "variable contracts"). The Current Participating Insurance Companies and Other Insurance Companies which elect to purchase shares of one or more Portfolios are collectively referred to herein as "Participating Insurance Companies." The Participating Insurance Companies will establish their own separate accounts ("Participating Separate Accounts") and design their own variable annuity or variable life insurance contracts.

Applicants' Legal Analysis

1. The use of a common management investment company as the underlying investment medium for both variable annuity and variable life insurance separate accounts of the same life insurance company or of any affiliated life insurance company is referred to as "mixed funding." The use of a common management investment company as the underlying investment medium for variable life insurance separate accounts of one insurance company and separate accounts funding variable contracts of one or more unaffiliated life insurance companies is referred to as "shared funding." Applicants request an order exempting the Participating Insurance Companies and Participating Separate Accounts (and, to the extent necessary, any principal underwriter and depositor of Participating Separate Accounts) from Sections 9(a), 13(a), 15(a), and 15(b) of the 1940 Act, and Rules 6e–2(b)(15) and 6e–3(T)(b)(15) thereunder, to the extent necessary to permit mixed and shared funding.[1]

2. Rule 6e–2(b)(15) provides the exemptions from Sections 9(a), 13(a), 15(a), and 15(b) of the 1940 Act that are discussed below only if the separate account is organized as a unit investment trust, all the assets of which consist of the shares of one or more registered management investment companies which offer their shares exclusively to variable life insurance separate accounts of the life insurer or of any affiliated life insurer. Thus, those exemptions provided by Rule 6e–2 are not available if a separate account invests in a fund engaged in mixed and/or shared funding.

3. Rule 6e–3(T)(b)(15) provides similar exemptions, but only if the separate account is organized as a unit investment trust, all the assets of which consist of the shares of one or more registered management investment companies which offer their shares exclusively to: (a) Separate accounts or variable annuity separate accounts of the life insurance company, or of any affiliated life insurance company; or (b) the life insurance company or affiliated life insurance company in consideration solely for advances made by the life insurance company in connection with the operation of the separate account. Thus, the exemptions provided by Rule 6e–3(T)(b)(15) are available if the underlying fund is engaged in mixed funding, but are not available if the fund is engaged in shared funding.

4. Section 9(a) of the 1940 Act provides, among other things, that it is unlawful for any company to serve as investment adviser or principal underwriter of any registered open-end investment company if an affiliated person of that company is subject to a disqualification enumerated in Sections 9(a)(1) or (2) of the 1940 Act. Rules 6e–2(b)(15)(i) and (ii) and Rules 6e–3(T)(b)(15)(i) and (ii) under the 1940 Act provide exemptions from Section 9(a) under certain circumstances, subject to the limitations on mixed and shared funding imposed by the 1940 Act and the rules thereunder. These exemptions limit the application of the eligibility restrictions to affiliated individuals or companies that directly participate in the management of the underlying management company. Rules 6e–2(b)(15)(iii) and 6e–3(T)(b)(15)(iii) each provide a partial exemption from Sections 13(a), 15(a), and 15(b) of the 1940 Act to the extent those sections have been deemed by the Commission to require "pass-through" voting with respect to an underlying fund's shares.

5. Applicants state that the partial relief granted in Rules 6e–2(b)(15) and 6e–3(T)(b)(15) from the requirements of Section 9 of the 1940 Act, in effect, limits the amount of monitoring necessary to ensure compliance with Section 9 to that which is appropriate in light of the policy and purposes of Section 9. Applicants state that those 1940 Act rules recognize that it is not necessary for the protection of investors or the purposes fairly intended by the policy and provisions of the 1940 Act to apply the provisions of Section 9(a) to the many individuals in a large insurance company complex, most of whom will have no involvement in matters pertaining to investment companies in that organization. Applicants state that it is unnecessary to

[1] Since shares of those Portfolios that currently are sold to Family Life are sold to the Merrill Insurance Companies only for their separate accounts to fund benefits under variable annuity contracts, there is no mixed funding presently occurring with respect to those Portfolios. Similarly, since shares of those Portfolios that currently are sold to the Merrill Insurance Companies for certain of their separate accounts to fund flexible premium variable life insurance contracts are not sold to Family Life, the mixed funding that occurs with respect to those Portfolios occurs only with respect to insurance companies that are affiliates of each other. Accordingly, Applicants do not believe they require relief, nor are they by the Application requesting relief, with respect to the manner in which shares of the various Portfolios of the Fund are currently sold.

apply Section 9(a) to individuals in various unaffiliated Participating Insurance Companies (or affiliated companies of Participating Insurance Companies) that may utilize the Fund as the funding medium for variable contracts. According to Applicants, there is no regulatory purpose in extending the Section 9(a) monitoring requirements because of mixed or shared funding. The Participating Insurance Companies are not expected to play any role in the management or administration of the Fund. Moreover, those individuals who participate in the management or administration of the Fund will remain the same regardless of which separate accounts or insurance companies use the Fund. Applicants argue that applying the monitoring requirements of Section 9(a) because of investment by other insurers' separate accounts would be unjustified and would not serve any regulatory purpose. Further, the increased monitoring costs would reduce the net rates of return realized by contract owners.

6. Rules 6e–(2)(b)(15)(iii) and 6e–3(T)(b)(15)(iii) under the 1940 Act assume the existence of a pass-through voting requirement with respect to management investment company shares held by a separate account. Applicants state that pass-through voting privileges will be provided with respect to all variable contract owners with respect to Separate Accounts registered under the 1940 Act ("registered Separate Accounts") so long as the Commission interprets the 1940 Act to require such pass-through voting privileges. Rules 6e–2(b)(15)(iii) and 6e–3(T)(b)(15)(iii) under the 1940 Act provide exemptions from the pass-through voting requirement with respect to several significant matters, assuming that the limitations on mixed and shared funding imposed by the 1940 Act and the rules promulgated thereunder are observed.

7. Rules 6e–2(b)(15) and 6e–3(T)(b)(15) under the 1940 Act give the Participating Insurance Companies the right to disregard voting instructions of contract holders. Rules 6e–2(b)(15)(iii)(A) and 6e–3(T)(b)(15)(iii)(A)(*1*) each provide that the insurance company may disregard the voting instructions of its contract owners with respect to the investments of an underlying fund, or any contract between a fund and its investment adviser, when required to do so by an insurance regulatory authority (subject to the provisions of paragraphs (b)(5)(i) and (b)(7)(ii)(A) of Rules 6e–2 and 6e–3(T) under the 1940 Act). Rules 6e–2(b)(15)(iii)(B) and 6e–3(T)(b)(15)(iii)(A)(*2*) each provide that the insurance company may disregard voting instructions of contract owners if the contract owners initiate any change in the underlying investment company's investment policies, principal underwriter, or any investment adviser (subject to the provisions of paragraphs (b)(5)(ii), (b)(7)(ii)(B), and (b)(7)(ii)(C) of Rules 6e–2 and 6e–3(T) under the 1940 Act). Applicants represent that these rights do not raise any issues different from those raised by the authority of state insurance administrators over separate accounts. Under Rules 6e–2(b)(15) and 6e–3(T)(b)(15), an insurer can disregard voting instructions of contract owners only with respect to certain specified items. Applicants also note that the potential for disagreement among Participating Separate Accounts is limited by the requirements in Rules 6e–2 and 6e–3(T) that a Participating Insurance Company's disregard of voting instructions be reasonable and based on specific good faith determinations.

8. Applicants state that making the Fund available for mixed and shared funding will encourage more insurance companies to offer variable contracts, and that this should result in increased competition with respect to both variable contract design and pricing, which can be expected to result in more product variation and lower charges. Applicants believe that mixed and shared funding should provide several benefits to variable contract owners. Mixed and shared funding would eliminate a significant portion of the costs of establishing and administering separate funds. Mixed and shared funding also would provide the Fund with a larger pool of funds, thereby promoting economies of scale and permitting increased safety through greater diversification.

9. Applicants see no significant legal impediment to permitting mixed and shared funding. Separate accounts organized as unit investment trusts historically have been employed to accumulate shares of mutual funds which have not been affiliated with the depositor or sponsor of the separate account. Applicants do not believe that mixed and shared funding will have any adverse Federal income tax consequences.

Applicants' Conditions

Applicants have consented to the following conditions if the exemptive relief requested by the Application is granted:

1. A majority of the Board of Directors of the Fund (the "Board") shall consist of persons who are not "interested persons" of the Fund, as defined by Section 2(a)(19) of the 1940 Act, and the rules promulgated thereunder, and as modified by any applicable orders of the Commission, except that if this condition is not met by reason of the death, disqualification, or bona-fide resignation of any director or directors, then the operation of this condition shall be suspended: (a) For a period of 45 days if the vacancy or vacancies may be filled by the Board; (b) for a period of 60 days if a vote of shareholders is required to fill the vacancy or vacancies; or (c) for such longer period as the Commission may prescribe by order upon application.

2. The Board will monitor the Fund for the existence of any material irreconcilable conflict between the interests of the contract owners of all separate accounts investing in the Fund. A material irreconcilable conflict may arise for a variety of reasons including, without limitation: (a) an action by any state insurance regulatory authority; (b) a change in applicable Federal or state insurance, tax, or securities laws or regulations; (c) a public ruling, private letter ruling, no-action or interpretative letter, or any similar action by federal or state insurance, tax, or securities regulatory authorities; (d) an administrative or judicial decision in any relevant proceeding; (e) the manner in which the investments of any series are being managed; (f) a difference in voting instructions given by variable annuity contract owners and variable life insurance contract owners; or (g) a decision by a Participating Insurance Company to disregard the voting instructions of contract owners.

3. Participating Insurance Companies and MLAM will report any potential or existing conflicts to the Board. Participating Insurance Companies and MLAM will be responsible for assisting the Board in carrying out the Board's responsibilities under these conditions by providing the Board with all information reasonably necessary for the Board to consider any issues raised. This includes, but is not limited to, an obligation by each Participating Insurance Company to inform the Board whenever contract owner voting instructions are disregarded. The responsibility to report such information and conflicts to the Board and to assist the Board will be a contractual obligation of all insurers investing in the Fund under their agreements governing participation in the Fund and these responsibilities will be carried out with a view only to the interests of the contract owners.

4. If it is determined by a majority of the Board, or a majority of the disinterested directors of the Board, that

a material irreconcilable conflict exists, then the relevant insurance companies, at their expense and to the extent reasonably practicable (as determined by a majority of the disinterested directors), shall take whatever steps are necessary to remedy or eliminate the material irreconcilable conflict, up to and including: (a) withdrawing the assets allocable to some or all of the separate accounts from the Fund or any Portfolio and reinvesting such assets in a different investment medium, including another Portfolio of the Fund, or submitting the question as to whether such segregation should be implemented to a vote of all affected contract owners and, as appropriate, segregating the assets of any appropriate group (i.e., annuity contract owners or life insurance contract owners of one or more Participating Insurance Companies) that votes in favor of such segregation, or offering to the affected contract owners the option of making such a change; and (b) establishing a new registered management investment company or managed separate account. If a material irreconcilable conflict arises because of a decision by a Participating Insurance Company to disregard the voting instructions of contract owners, and that decision represents a minority position or would preclude a majority vote, then the insurance company may be required, at the Fund's election, to withdraw the insurance company's Separate Account's investment in the Fund and no charge or penalty will be imposed as a result of such withdrawal. The responsibility to take remedial action in the event of a Board determination of a material irreconcilable conflict and to bear the cost of such remedial action shall be a contractual obligation of all Participating Insurance Companies under their agreements governing participation in the Fund and these responsibilities will be carried out with a view only to the interests of contract owners.

For purposes of this Condition 4, a majority of the disinterested members of the Board shall determine whether or not any proposed action adequately remedies any material irreconcilable conflict, but in no event will the Fund or MLAM be required to establish a new funding medium for any variable contract. No Participating Insurance Company shall be required by this Condition 4 to establish a new funding medium for any variable contract if any offer to do so has been declined by vote of a majority of the contract owners materially adversely affected by the material irreconcilable conflict.

5. The Board's determination of the existence of a material irreconcilable conflict and its implications shall be made known in writing promptly to all Participating Insurance Companies.

6. Participating Insurance Companies will provide pass-through voting privileges to all variable contract owners with respect to registered Separate Accounts so long as the Commission continues to interpret the 1940 Act as requiring pass-through voting privileges for variable contract owners. Accordingly, Participating Insurance Companies will vote shares of the Fund held in their registered Separate Accounts in a manner consistent with voting instructions timely-received from contract owners. Each Participating Insurance Company will vote shares of the Fund held in the Participating Insurance Company's registered Separate Accounts for which no voting instructions from contract owners are timely-received, as well as shares of the Fund which the Participating Insurance Company itself owns, in the same proportion as those shares of the Fund for which voting instructions from contract owners are timely-received. Participating Insurance Companies shall be responsible for assuring that each of their registered Separate Accounts participating in the Fund calculates voting privileges in a manner consistent with other Participating Insurance Companies. The obligation to calculate voting privileges in a manner consistent with all other registered Separate Accounts investing in the Fund shall be a contractual obligation of all Participating Insurance Companies under their agreements governing participation in the Fund.

7. The Fund will comply with all provisions of the 1940 Act requiring voting by shareholders, and, in particular, the Fund will either provide for annual meetings (except to the extent that the Commission may interpret Section 16 of the 1940 not to require such meetings) or comply with Section 16(c) of the 1940 Act (although the Fund is not one of the trusts described in Section 16(c) of the 1940 Act), as well as with Section 16(a) of the 1940 Act and, if and when applicable, Section 16(b) of the 1940 Act. Further, the Fund will act in accordance with the Commission's interpretation of the requirements of Section 16(a) with respect to periodic elections of directors and with whatever rules the Commission may promulgate with respect thereto.

8. The Fund shall disclose in its prospectus that: (a) The Fund is intended to be a funding vehicle for all types of variable annuity and variable life insurance contracts offered by various insurance companies; (b) material irreconcilable conflicts possibly may arise; and (c) the Board will monitor events in order to identify the existence of any material irreconcilable conflicts and to determine what action, if any, should be taken in response to any such conflict. The Fund will notify all Participating Insurance Companies that separate account prospectus disclosure regarding the potential risks of mixed and shared funding may be appropriate.

9. If and to the extent that Rule 6e–2 and Rule 6e–3(T) under the 1940 Act are amended, or Rule 6e–3 under the 1940 Act is adopted, to provide exemptive relief from any provision of the 1940 Act, or the rules promulgated thereunder, with respect to mixed or shared funding, on terms and conditions materially different from any exemptions granted in the order requested by Applicants, then the Fund and/or Participating Insurance Companies, as appropriate, shall take such steps as may be necessary to comply with Rules 6e–2 and 6e–3(T), or Rule 6e–3, as such rules are applicable.

10. The Participating Insurance Companies and/or MLAM, at least annually, shall submit to the Board such reports, materials, or data as the Board reasonably may request so that the Board can fully carry out the obligations imposed upon it by the conditions provided for by the order granting the exemptive relief requested by the Application. Such reports, materials, and data shall be submitted more frequently if deemed appropriate by the Board. The obligations of the Participating Insurance Companies to provide these reports, materials, and data to the Board, when the Board so reasonably requests, shall be a contractual obligation of all Participating Insurance Companies under their agreements governing participation in the Fund.

11. All reports of potential or existing conflicts received by the Board, and all Board action with regard to determining the existence of a conflict, notifying Participating Insurance Companies of a conflict, and determing whether any proposed action adequately remedies a conflict, will be properly recorded in the minutes of the Board or other appropriate records, and such minutes or other records shall be made available to the Commission upon request.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 95–20955 Filed 8–23–95; 8:45 am]

BILLING CODE 8010–01–M

[Rel. No. IC–21314; 812–9520]

Merrill, Lynch, Pierce, Fenner & Smith Incorporated, et al.

August 18, 1995.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of application for exemption under the Investment Company Act of 1940 (the "Act").

APPLICANTS: Merrill Lynch, Pierce, Fenner & Smith Incorporated ("Merrill Lynch"), Smith Barney Inc., Prudential Securities Incorporated, Dean Witter Reynolds Inc., and PaineWebber Incorporated (the "Sponsors"); and Defined Asset Funds—Municipal Investment Trust Fund, Liberty Street Trust Municipal Monthly Payment Series, Defined Asset Funds—Municipal Income Fund ("DAF–MIF"), and Municipal Investment Trust Fund (the "Trusts").

RELEVANT ACT SECTIONS: Order requested under sections 6(c) and 17(b) of the Act that would exempt applicants from section 17(a) of the Act.

SUMMARY OF APPLICATION: Applicants request an order to permit the trustees of certain unit investment trusts to place orders to sell municipal bond portfolio securities of the trusts with the trust sponsors, who then will serve as introducing dealers. As introducing dealers, the sponsors will retain a clearing broker to sell the securities for the trusts through a wire service.

FILING DATE: The application was filed on March 13, 1995 and amended on July 20, 1995 and August 17, 1995.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on September 12, 1995 and should be accompanied by proof of service on the applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons may request notification of a hearing by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 5th Street, NW., Washington, DC 20549. Applicants, c/o Merrill Lynch, Pierce, Fenner & Smith Incorporated, Unit Investment Trusts, P.O. Box 9051, Princeton, New Jersey 08543–9051.

FOR FURTHER INFORMATION CONTACT: Sarah A. Buescher, Staff Attorney, at (202) 942–0573, or Robert A. Robertson, Branch Chief, at (202) 942–0564 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee from the SEC's Public Reference Branch.

Applicants' Representations

1. Each series of the Trusts is a separate unit investment trust created under New York law by a trust indenture and agreement ("Trust Agreement") among one or more of the Sponsors, a trustee ("Trustee"), and an evaluator. The investment objective of each series is receipt of interest income exempt from federal income taxation through investment in a fixed portfolio of interest-bearing municipal bonds ("Bonds"). Applicants request that the order extend to future unit investment trusts sponsored by one or more of the sponsors.

2. The Sponsors intend to maintain a market for units of each Trust and continuously offer to purchase those units at the redemption price. If the Sponsors no longer maintain a secondary market, certificate holders may redeem their units. If cash held by a Trust is insufficient to pay any redemption, the Trustee is authorized to sell Bonds held by the Trust. The Trustee also may sell Bonds to meet expenses. In addition, the Sponsors may direct the Trustee to sell Bonds in specific circumstances, such as a default by an issuer or the Bonds becoming subject to federal income taxation.

3. Trustees have two principal methods for selling Bonds: (1) The Trustee can approach several non-Sponsor dealers and sell to the non-Sponsor dealer making the highest bid; or (2) the Trustee can place an order to sell Bonds with one non-Sponsor dealer ("Introducing Dealer"), who in turn retains a broker ("Clearing Broker") to communicate the availability of the Bonds by posting the offer on a wire system with contact to 300 to 400 dealers. The Clearing Broker receives the bids and selects the highest bidder. Applicants represent that the latter method has obtained more favorable prices for the Trusts because of the broader exposure to the bond offering by potential purchasers. The Clearing Broker and the Introducing Dealer retain a concession. Merrill Lynch has negotiated a fixed fee of $2 per bond with independent Introducing Dealers. Pursuant to an SEC order (Investment Company Act Release No. 14958) (Feb. 25, 1986)) ("1986 Exemption"), sales of Bonds from the Trusts may be made to any of the Sponsors if, among other conditions, the Sponsor is the highest bidder. DAF–MIF was not a party to this order.

4. Clearing Brokers only will accept transactions from Introducing Dealers who are registered as broker-dealers under the Securities Exchange Act of 1934 ("Exchange Act"). Since the Trustee is not a registered broker-dealer, it must retain an Introducing Dealer who receives a concession for writing an order and approaching a Clearing Broker. Each of the Sponsors is a municipal securities dealer who acts as Introducing Dealer in connection with non-Trust Bond sales.

5. Applicants represent that if the requested exemptive relief is granted, not only would the Trusts continue to be permitted to effect principal transactions with the Sponsors in selling Bonds from their portfolios, but the conditions to the 1986 Exemption would be modified to permit the Trusts to use Sponsors as Introducing Dealers in those and other sale transactions. Merrill Lynch's Defined Asset Funds Division will select a Sponsor to act as Introducing Dealer for a wire service transaction for the Trusts only if it believes in good faith that those Trusts are reasonably likely to receive a better execution thereby.

6. Applicants represent that permitting the proposed transaction will benefit the Trusts and the certificateholders. The Sponsors have resources to bear the financial responsibility if a trade is not completed properly and experience with wire service executions of municipal securities transactions. Merrill Lynch believes that these firms can be of substantial value in obtaining more timely and cost-effective executions of wire service transactions for the Trusts. In addition, with the continuing consolidation of major broker-dealers, if the Sponsors continue to be excluded from acting as Introducing Dealers, the Trusts are likely to be permitted only to use smaller, less capitalized firms, which applicants believe may result in less favorable prices and execution for the Trusts.

7. Merrill Lynch submits that the fee of $2 per Bond that it has negotiated with independent Introducing Dealers is reasonable compensation for performing these services. Because Bonds can only be sold under limited circumstances specified in the Trust Agreement, a Sponsor could not cause a Trust to sell Bonds merely to generate commissions. Applicants represent that the Trustee and Merrill Lynch will monitor currently prevailing rates of Introducing Dealers to assure that the Trusts are charged no more than the current rates.

8. The requested relief would amend the 1986 Exemption in several respects. First, applicants request that the relief granted in the 1986 Exemption, amended as requested herein, be extended to DAF–MIF. Second, applicants request that the first condition of the 1986 Exemption be deleted. This condition reads as follows:

> Merrill Lynch will not advise the [Merrill Lynch, White Weld Capital Markets] Group or the municipal securities dealer department of any other Sponsor when giving instructions to sell a Municipal Bond.

Since a municipal dealer's trading department (which may make bids to purchase the Bonds) is generally not separate from the personnel who act as Introducing Dealers on wire services transactions, applicants wish to delete this condition. Applicants also request to amend other conditions so as to permit any Sponsor to act as an Introducing Dealer. Applicants represent that the transactions would remain anonymous even if a Sponsor is both the Introducing Dealer and a purchasing dealer since the transaction would be effected through the Clearing Broker, an independent party.

Applicant's Legal Analysis

1. Applicants request an order under sections 6(c) and 17(b) of the Act from section 17(a) to permit a Sponsor to purchase Bonds from the Trustee as an Introducing Dealer. Section 17(a) of the Act generally makes it unlawful for an affiliated person of a registered investment company, acting as principal, knowingly to purchase securities from the company.

2. Section 17(b) permits the SEC to exempt a proposed transaction from section 17(a) if evidence establishes that: (a) The terms of the proposed transaction are reasonable and fair and do not involve overreaching; (b) the proposed transaction is consistent with the policy of each registered investment company concerned; and (c) the proposed transaction is consistent with the general purposes of the Act. Under section 6(c), the SEC may exempt classes of transactions if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants believe that the proposed transactions satisfy the requirements of sections 6(c) and 17(b).

3. Applicants state that the regulations to which the Sponsors and the Trusts are subject, the provisions of the Trust Agreement, and the conditions stated below will prevent any overreaching. Because the price received by the Trust upon the sale of a security depends on bids made by purchasing dealers through the wire service, the Sponsor cannot influence the price received by the Trust. The Sponsors are registered as municipal securities dealers, and acknowledge that they are subject to the rules of the Municipal Securities Rulemaking Board ("MSRB"), which require members to deal fairly with all persons and to use reasonable efforts to obtain a fair and reasonable price. Merrill Lynch has agreed, and each Sponsor before acting as Introducing Dealer for any Trust will agree, to make available for ready inspection by the SEC all records required to be kept by applicants relating to the proposed transactions pursuant to the Exchange Act and MSRB rules.

4. Applicants represent that the sales will be consistent with the policy of the selling series, as recited in its registration statement and Trust Agreement.

Applicants' Conditions

Applicants agree that the order granting the requested relief shall be subject to the following conditions:

1. The Clearing Broker will in all cases be not affiliated with any Sponsor.

2. Offers will be made through a major wire service in municipal bonds and will be kept open for three hours after initial appearance on the wire, to be reduced to not less than two hours in the discretion of the Clearing Broker in a declining market.

3. A Sponsor's bid will be accepted only if a minimum of three bids are received from persons other than a Sponsor or its affiliates.

4. The Trustee will be instructed not to inquire as to the identity of a bidding dealer, and if it receives such information, will not transmit it to any Sponsor or its agents.

5. Clearing Brokers effecting the sales will be instructed to obtain the best available price and execution and will instruct the wire services not to report any bid from a Sponsor unless it is higher than the best price available from non-affiliated broker-dealers.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 95–21046 Filed 8–23–95; 8:45 am]

BILLING CODE 8010–01–M

[Rel. No. IC–21313; No. 812–9518]

Minnesota Mutual Life Insurance Company, et al.

August 17, 1995.

AGENCY: Securities and Exchange Commission ("Commission" or "SEC").

ACTION: Notice of application for order under the Investment Company Act of 1940 ("1940 Act").

APPLICANTS: The Minnesota Mutual Life Insurance Company ("Minnesota Mutual"), Minnesota Mutual Variable Life Account ("Separate Account"), and MIMLIC Sales Corporation ("MIMLIC").

RELEVANT 1940 ACT SECTIONS: Order requested pursuant to Section 6(c) of the 1940 Act for exemptions from Sections 27(a)(1) and 27(a)(3) of the 1940 Act and paragraphs (b)(13)(i) and (b)(13)(ii) of Rule 6e–2 thereunder.

SUMMARY OF APPLICATION: Exemptions requested to the extent necessary to permit the issuance and sale of a Policy Enhancement Agreement ("PE Rider") as a new rider to Minnesota Mutual's Variable Adjustable Life Insurance Contracts ("VAL Contracts"). The PE Rider will provide VAL Contract owners the option of scheduling automatic face amount increases each Contract year in an amount selected by VAL Contract owners at the time of initial purchase of the VAL Contracts.

FILING DATE: The application was filed on March 9, 1995.

HEARING OR NOTIFICATION OF HEARING: If no hearing is ordered, the application will be granted. Any interested person may request a hearing on this application, or ask to be notified if a hearing is ordered. Any request must be received by the SEC by 5:30 p.m. on September 11, 1995. Request a hearing in writing, giving the nature of your interest, the reason for the request, and the issues you contest. Serve the Applicants with the request either personally or by mail, and also send it to the Secretary of the SEC, with proof of service by affidavit, or, for lawyers, by certificate. Request notification of the date of a hearing by writing to the Secretary of the SEC.

ADDRESSES: Secretary, SEC, 450 5th Street, N.W., Washington, D.C. 20549.

Applicants, 400 North Robert Street, St. Paul, Minnesota 55101–2098.

FOR FURTHER INFORMATION CONTACT: Yvonne M. Hunold, Special Counsel, or Wendy Friedlander, Deputy Chief, at (202) 942–0670, Office of Insurance Products (Division of Investment Management).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application is available for a fee from the SEC's Public Reference Branch.

Applicants' Representations

1. Minnesota Mutual is a mutual life insurance company that is authorized to conduct a life insurance business in the District of Columbia, Canada, Puerto Rico and all states of the United States except New York, where it is an authorized reinsurer.

2. The Separate Account was established by Minnesota Mutual to fund the VAL Contracts. The Separate Account is registered under the 1940 Act as a unit investment trust.

3. MIMLIC, the principal underwriter for the Separate Account, is an indirect wholly-owned subsidiary of Minnesota Mutual. MIMLIC is registered as a broker-dealer under the Securities Exchange Act of 1934 and is a member of the National Association of Securities Dealers, Inc.

4. The VAL Contracts are scheduled premium variable life insurance contracts that permit Contract owners to make non-scheduled premium payments. Applicants represent that VAL Contracts are offered in reliance upon exemptive relief previously granted by the Commission.[1]

5. Most VAL Contracts are issued with a Cost of Living Agreement Rider ("COL Rider"). The COL Rider permits a VAL Contract owner to increase the face amount of the Contract every three Contract years until age 56, without evidence of insurability.[2] The COL Rider increase, which allows for life insurance coverage that can keep pace with inflation, with be in an amount equal to the percentage increase in the consumer price index during those three years, provided that the VAL Contract owner has not made a face amount adjustment during that time. Absent Minnesota Mutual's consent, the amount of a such an increase is limited to the lesser of $100,000 or 20% of the face amount prior to the increase. A face amount increase effected under the COL Rider increases the scheduled premium by the same percentage. Increases in face amount pursuant to the COL Rider result in a: (a) New first-year sales load deduction of 23% of the incremental scheduled premiums paid in the year following the increase; (b) 7% sales load applicable to all scheduled premiums payments, including the base and incremental premiums in the first year after the increase; and (c) cost-based policy adjustment charge of $25.

6. Minnesota Mutual now proposes to offer the PE Rider as an alternative to the COL Rider. The PE Rider would be offered at the time of initial purchase of the VAL Contract to prospective VAL Contract owners who are age 52 or less. Contract owners electing the PE Rider could commit in advance to annual face amount increases of 3% to 10% with no new evidence of insurability and with the right to cancel that commitment at any time. The maximum automatic increase would be limited to the lesser of $35,000 or 10% of the face amount immediately prior to the increase. Once a VAL Contract's face amount reaches $350,000, the annual increase would be limited to $35,000. The base premium would increase at the same percentage as the increase in face amount. Increases under the PE Rider continue until: (1) Cancelled at any time, in writing, by the Contract owner; (2) cancelled by a Contract owner exercising the free look rights in connection with the incremental coverage; (3) the Contract is surrendered, terminated or continued in force as extended term insurance; or (4) the insured reaches age 59 or dies.

7. The PE Rider would result in the payment of a premium, currently expected to be $25 per year, and a new first-year sales load on incremental scheduled premium payments for the first year after an increase. An increase pursuant to the PE Rider would occur only if: (1) There had been no adjustment (increase or decrease) to the face amount of the VAL Contract during the six-month period preceding the Contract anniversary; (2) an annual base premium of at least $300 had been paid during the immediately preceding Contract year; and (3) the resulting plan of insurance would provide a level face amount of insurance for the minimum time period specified in the VAL Contract.

8. Applicants assert that the ability to increase insurance coverage automatically each year (rather than every three years) in an amount expected to exceed inflation rates without new evidence of insurability could be an important feature to prospective VAL Contract purchasers whose earnings are expected to increase over time. Applicants submit that prospective purchasers currently must either commit to more insurance than they initially can afford or must risk that the insured will continue to remain insurable in the future.

9. Applicants note that, unlike the COL Rider face amount increases, no positive action would be required to effect an increase under the PE Rider. Applicants submit that, when an increase results from taking no action (a "negative option"), more increases can be expected than if positive action is required. Applicants assert that in either situation an insured who is in bad health would be among those increasing the Contract's face amount. Thus, Applicants submit, the broader base of additional increases from negative options should be expected to come from other, healthier insureds and should reduce somewhat the related mortality risks that ultimately might have to be reflected in increased cost of insurance charges under the VAL Contracts. Accordingly, Applicants assert that the adverse-selection risks to Minnesota Mutual of PE Rider increases would be reduced somewhat by the negative option aspect of their implementation.

10. Applicants note further that PE Rider increases can be expected to involve larger absolute and percentage amounts than COL Rider increases. COL Rider increases can occur only every three years and, thus, there is less compounding of the percentage limits and inflation rates are unlikely to be so high that they will approach the 10% per year increase permitted under the PE Rider. Because larger increases would be possible under the PE Rider than under the COL Rider, Applicants assert that it is important that adverse-selection mortality risks be reduced in the PE Rider by use of a negative option. Absent the negative option, Applicants submit that it is likely that the PE Rider either could not be offered, could only be offered if cost of insurance charges were increased on the incremental coverage added by PE Rider increases, or could only be offered in significantly reduced amounts.

11. Applicants note that PE Rider increases would involve additional sales efforts in connection with the initial sale of the VAL Contract. COL Rider

[1] *Minnesota Mutual Life Insurance Company*, Investment Co. Act Rel. Nos. 15523 (Jan 7, 1987) ("1987 Order") and 15468 (Dec. 8, 1986) (Notice); 16942 (Apr. 28, 1989) (Order), and 16902 (Apr. 4, 1989) (Notice); 17253 (Dec. 5, 1989) (Order) and 17203 (Nov. 6, 1989) (Notice).

[2] A VAL Contract owner must specifically accept the increase of the amount of additional coverage offered under the COL Rider by responding in writing to the notification of offer. If the insured is over age 21 and the Contract owner fails to accept an increase, no further COL Rider will be offered. Thereafter, the VAL Contract owner could increase the face amount only with new evidence of insurability.

increases, in comparison, involve no additional sales effort at the initial sale but would require such effort to convince VAL Contract owners to exercise their increase rights under the COL Rider. In either situation, Applicants state that sales representatives would deserve additional commissions at the time the additional premiums began to be paid to Minnesota Mutual, when the increase occurs.

Applicants' Legal Analysis

1. Applicants request exemptive relief under Section 6(c) of the 1940 Act from Sections 27(a)(1) and 27(a)(3) of the 1940 Act and from subparagraphs (b)(13)(i) and (b)(13)(ii) of Rule 6e–2 to the extent necessary to permit the deduction of first-year sales loads under the VAL Contract in connection with the PE Rider face amount increases.

2. Section 6(c) of the 1940 Act, in relevant part, authorizes the Commission, by order and upon application, to conditionally or unconditionally exempt any person, security or transaction or class of such, from any provision of the 1940 Act or rule thereunder, if and to the extent that the exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the 1940 Act.

3. Variable life insurance contracts, including the VAL Contract, are regulated under the 1940 Act as periodic payment plan certificates. The Separate Account is regulated under the 1940 Act as if it were an issuer of periodic payment plan certificates. Accordingly, the Separate Account, Minnesota Mutual as the Separate Account's depositor, and MIMLIC Sales as principal underwriter of the VAL Contracts, are deemed to be subject to the provisions of section 27 of the 1940 Act.

Section 27(a)(1) and Rule 6e–2(b)(13)(i)

4. Section 27(a)(1) of the 1940 Act prohibits a registered investment company issuing periodic payment plan certificates, or its depositor or underwriter, from selling such certificates if the sales load exceeds 9% of the total payments to be made on the certificates. Rule 6e–2(b)(13)(i) provides exemptive relief from Section 27(a)(1) of the 1940 Act by requiring compliance with the 9% limit of Section 27(a)(1) over a period of the lesser of twenty years or the anticipated life expectancy of the insured. Therefore, Section 27(a)(1) of the 1940 Act and Rule 6e–2(b)(13)(i) together limit the sales loads to be assessed under the VAL Contracts to 9% of the premiums to be paid over the lesser of 20 years or the anticipated life expectancy of the insured.

5. Applicants assert that the sales load requirements of Section 27(a)(1) are satisfied at the time of issuance of the VAL Contracts. Applicants note, however, that a new first year sales load is assessed upon any Contract adjustment involving an increase in the base premium, which sales load may be in addition to a first year sales load being taken at the time the adjustment is made. Applicants submit that, in that event, it is possible that the 9% sales load limitation could be viewed as being exceeded if the relevant time period for measurement were from the time the VAL Contract was initially issued rather than from the time of the relevant adjustment. Accordingly, Applicants request exemptive relief from Section 27(a)(1) and Rule 6e–2(b)(13)(i) to deduct first-year loads in connection with PE Rider face amount increases.

Section 27(a)(3) and Rule 6e–2(b)(13)(ii)

6. Section 27(a)(3) of the 1940 Act makes it unlawful for any registered investment company issuing periodic payment plan certificates, or for its depositor or underwriter, to sell such certificates if the amount of sales load deducted from any of the first twelve monthly payments exceeds proportionately that amount deducted from any other such payment. Sale of such certificates similarly is prohibited if the amount of sales load deducted from any subsequent payment exceeds proportionately that amount deducted from any other subsequent payment. Rule 6e–2(b)(13)(ii) provides relief from the "stair-step" provisions of Section 27(a)(3) in connection with offerings of scheduled premium variable life insurance contracts, provided that the sales load deducted from any payment is not proportionately greater than that deducted from any prior payment under the contract.

7. Applicants state that the relief from Section 27(a)(3) provided by Rule 6e–2(b)(13)(ii) is not available to the VAL Contracts because the new 23% first-year sales load imposed upon a contract adjustment that involves an increase in base premium normally would be higher than that deducted from earlier payments. Accordingly, Applicants submit that an exemptive order therefore would be required. Accordingly, Applicants request exemptive relief from Section 27(a)(3) and Rule 6e–2(b)(13)(ii) to deduct first year sales loads in connection with the PE Rider face amount increases.

8. Applicants represent that sales efforts are exerted in connection with the proposed PE Rider at the time the VAL Contract is issued and the PE Rider is selected, although no additional sales effort would be required for PE Rider increases at the time of the increase. Applicants note that the PE Rider is an optional feature that is sold by separate rider for an additional premium charge, and that the PE Rider must specifically be selected or rejected by an eligible VAL Contract owner. Thus, sale of the VAL Contract would not necessarily involve sale of the PE Rider.[3] Further, the sales representative would have to exert special effort to make sure that the VAL Contract owner understands the benefits offered by the PE Rider. Moreover, the PE Rider would likely result in sales of more insurance than the COL Rider. Applicants, therefore, assert that these sales efforts would not be minimal but would involve transactions, when made, that increase base premiums.

9. Applicants submit that collection of a new first year sales load upon an automatic adjustment involving an increase in base premium is appropriate and justified in view of the fact that such an adjustment is not expected to occur in typical cases without substantial sales effort for which first-year sales compensation will be required. Moreover, Applicants believe that it would be anomalous for sales representatives to earn less for special efforts required at the time of initial sale of the VAL Contract in connection with the PE Rider than for comparable sales efforts made in connection with effecting a smaller COL Rider increase. Both COL Rider and PE Rider increases can be rejected; once rejected, neither will be re-offered (except that eligibility for COL Rider increases will continue for insureds under age 21 at the time of rejecting an increase). Absent the ability to earn a subsequent first-year commission, Applicants believe that a sales representative would be unlikely to exert any effort to sell the PE Rider.

10. Applicants assert that potential VAL Contract owners will be protected from unwanted increases in insurance through use of the automatic PE Rider increases because the Contract owner must expressly elect the PE Rider at the time of initial purchase of the VAL Contract. Applicants submit that this protection from unwanted sales of insurance is in addition to the VAL Contract owner's ability to cancel the PE

[3] In contrast, sale of the VAL Contract would necessarily involve sale of the COL Rider, whose increases involve a positive option that requires additional sales efforts at the time of exercise.

Rider at any time or to exercise the free look right to reject a PE Rider increase and all subsequent increases.

Conclusion

For the reasons discussed above, Applicants submit that the requested exemptions from Sections 27(a)(1) and 27(a)(3) of the 1940 Act and paragraphs (b)(13)(i) and (b)(13)(ii) of Rule 6e–2 thereunder, are necessary and appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the 1940 Act.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 95–20956 Filed 8–23–95; 8:45 am]

BILLING CODE 8010–01–M

[Rel. No. IC–21311; File No. 812–9460]

New England Variable Life Insurance Company, et al.

August 16, 1995.

AGENCY: Securities and Exchange Commission (the "SEC" or the "Commission").

ACTION: Notice of application for exemption under the Investment Company Act of 1940 (the "1940 Act" or "Act").

APPLICANTS: New England Variable Life Insurance Company ("NEVLICO"), New England Variable Life Separate Account ("Variable Account") and New England Securities Corporation ("New England Securities").

RELEVANT 1940 ACT SECTIONS: Exemption requested under Section 6(c) of the Act from Sections 27(a)(3) and 27(e) of the Act and Rules 6e–3(T)(b)(13)(ii), 6e–3(T)(b)(13)(vii), and 27e–1 thereunder.

SUMMARY OF APPLICATION: Applicants seek an order to permit the offer and sale of certain flexible premium variable life insurance policies ("Policies") that permit Applicants to (i) waive or reimpose the front-end sales charge imposed on premiums paid after the twentieth Policy year, and (ii) waive notice of refund and withdrawal rights.

FILING DATE: The application was filed on January 27, 1995.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving Applicants with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on September 11, 1995, and should be accompanied by proof of service on Applicants in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street, N.W., Washington, D.C. 20549. Applicants, 501 Boylston Street, Boston, Massachusetts 02117.

FOR FURTHER INFORMATION CONTACT: Joyce Merrick Pickholz, Senior Counsel, or Wendy Finck Friedlander, Deputy Chief, at (202) 942–0670, Office of Insurance Products, Division of Investment Management.

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application is available for a fee from the Public Reference Branch of the SEC.

Applicants' Representations

1. NEVLICO, a stock life insurance company organized in 1980 under Delaware law, is a wholly-owned subsidiary of the New England Mutual Life Insurance Company ("The New England"), a mutual life insurance company organized in Massachusetts in 1835. The Variable Account was established as a separate investment account on January 31, 1983, and is registered under the 1940 Act as a unit investment trust. The Variable Account is a separate account within the meaning of Section 2(a)(37) of the 1940 Act.

2. The Variable Account currently consists of twelve investment sub-accounts each of which invests in a different portfolio of the New England Zenith Fund, the Variable Insurance Products Fund or the Variable Insurance Products Fund II (collectively, "Eligible Funds"). Sub-accounts may be added to or deleted from the Variable Account from time to time.

3. Policies issued through the Variable Account, including the Policies, will be sold through agents who are licensed by state authorities to sell NEVLICO's variable insurance policies and who are also registered representatives of New England Securities, the principle underwriter of the Variable Account. New England Securities is a wholly-owned subsidiary of The New England.

4. The Policy will be issued in reliance on Rule 6e–3(T) under the 1940 Act. The Policy provides for premium flexibility and a death benefit and a surrender value that may increase or decrease daily depending in part on the investment performance of the Eligible Funds. Net premiums under the Policy may be allocated to the sub-accounts of the Variable Account or to a "Fixed Account".

5. NEVLICO determines a three-year minimum premium amount based on the Policy's face amount, the insured's age, sex (unless unisex rates apply) and underwriting class, the current level of Policy charges, and any rider benefit selected. Generally, during this three-year period, as long as the minimum premium amount, which is set forth in the Policy, has been timely paid, the Policy is guaranteed not to lapse even if the Policy's net cash value is insufficient to pay the Monthly Deduction (defined in paragraph 20 below) of certain charges under the Policy in any month.

6. NEVLICO also determines a guaranteed minimum death benefit premium (to maturity) ("Death Benefit A Premium"), which, if paid as set forth in the Policy, guarantees that the Policy will mature for the net cash value (equal to the Policy's cash value, less any Policy loan balance, and less any surrender charge that would apply on surrender) at age 100 of the insured. The Death Benefit A Premium, which is set forth in the Policy, is based on the Policy's face amount, the insured's age, sex (unless unisex rates apply) and underwriting class, the death benefit option chosen, the guaranteed level of cost of insurance charges, the current level of other Policy charges, and any rider benefits selected. NEVLICO also determines a guaranteed minimum death benefit premium ("Death Benefit B Premium"), which, if paid as set forth in the Policy, guarantees that the Policy will stay in force until the later of age 80 of the insured, or 20 years after the Policy was issued, but no later than the maturity date of the Policy. The Death Benefit B Premium, which is set forth in the Policy, is based on factors similar to the Death Benefit A Premium, but is based on the guaranteed level of both cost of insurance and other Policy charges, and is actuarially determined to provide guaranteed coverage to the earlier age. This premium will always be less than or equal to the Death Benefit A Premium.

7. The Policy provides for two alternate death benefit options. The Option 1 (Face Amount) death benefit provides a death benefit equal to the face amount of the Policy, subject to increases required by the Internal Revenue Code of 1986, as amended (the "Code"). The Option 2 (Face Amount Plus Cash Value) death benefit provides

a death benefit equal to the face amount of the Policy plus the amount, if any, of the Policy's cash value, subject to increases required by the Code. The Policy's death benefit is always at least equal to the amount required to satisfy tax law requirements to qualify as life insurance.

8. The Policy provides two minimum guaranteed death benefits. If either minimum guaranteed death benefit is in effect, as determined on the first day of each Policy month, the Policy will not lapse even if the Policy's net cash value is insufficient to cover the Monthly Deduction due for that month. If the death of the insured occurs while either minimum guaranteed death benefit is in effect, then the death benefit under the Policy will be based on the death benefit option in effect on the date of death. The death benefit will be adjusted before death benefit proceeds are paid. If premiums are paid in certain amounts (Death Benefit A Premiums or Death Benefit B Premiums, described above), then a minimum guaranteed death benefit may be in effect unless certain Policy transactions are made. No minimum guaranteed death benefit applies while a Policy loan is outstanding, regardless of premium payments. A minimum guaranteed death benefit may apply to the Policy once the loan is repaid.

9. A Policy owner may surrender the Policy for its net cash value at any time while the insured is living. The net cash value equals the cash value reduced by any Policy loan and accrued interest and by any applicable Surrender Charge. The net cash value is increased by the portion of any cost of insurance charge deducted that applies to the period beyond the date of surrender. The net cash value is paid on the Policy's maturity date if the insured is living and the Policy is in force. After the Policy's "free look" period, a Policy owner may also make a partial surrender of the Policy to receive a portion of its net cash value, subject to certain limits. A Policy owner may borrow all or part of a Policy's loan value at any time after the end of the "free look" period.

10. After the first Policy year, the Policy owner may request an increase in the face amount of the Policy. A new Surrender Charge period will apply to each portion of the Policy resulting from a face amount increase starting with the effective date of the increase. A separate premium will apply to the face amount increase, (based on the insured's age and underwriting class at the time of the increase), and a Sales Charge will be deducted from the portion of each premium that is attributable to the face amount increase for at least 20 years from the date of the increase. The Monthly Deduction will also be adjusted beginning with the effective date of the increase to reflect the new face amount and amount at risk under the Policy. NEVLICO also permits face amount reductions under the Policy, but not below NEVLICO's minimum face amount requirements for issue (unless NEVLICO consents).

11. NEVLICO deducts 4% from each premium as a Sales Charge. NEVLICO currently intends to waive this charge on premiums paid after the twentieth Policy year, and on the portion of premiums attributable to a face amount increase after twenty years from the date of the increase. NEVLICO retains the right not to waive the charge or to reimpose it prospectively on a nondiscriminatory basis. In addition, NEVLICO deducts 1% from each premium to recover a portion of its federal income tax liability that is determined solely by the amount of life insurance premiums it receives.[1] NEVLICO also deducts 2.5% from each premium to cover state premium tax and administrative costs.

12. During the first eleven Policy years, if a Policy is totally surrendered or lapses, the face amount is reduced, or a partial surrender reduces the face amount, a Surrender Charge will be deducted from the cash value. The Surrender Charge includes a Deferred Sales Charge and a Deferred Administrative Charge. A new Surrender Charge period and a separate premium will apply to each portion of the Policy resulting from a face amount increase, starting with the date of the increase.

13. The Deferred Sales Charge is based on a percentage of the Policy's Target Premium. A Policy's Target Premium is less than or equal to 75% of the annual premium necessary to maintain a fixed benefit whole life insurance policy for the same face amount on the life of the insured, using an assumed interest rate of 4%, guaranteed cost of insurance charges, and the current level of other Policy charges. Applicants represent that the Target Premium will never equal or exceed the "guideline annual premium" as defined in Rule 6e–3(T)(c)(8). A separate Target Premium amount applies to any face amount increase, based on the insured's age and underwriting class at the time of the increase.

[1] NEVLICO includes this 1% charge in the calculation of sales load for purposes of the definition in Rule 6e–3(T)(c)(4). However, NEVLICO does not intend to waive the 1% charge after the twentieth Policy year.

14. For Policies that cover insureds whose issue age is 55 or less at issue, the highest Deferred Sales Charge is paid if the Policy owner lapses or surrenders the Policy, or reduces its face amount, in Policy years three through five. The Deferred Sales Charge in these years equals 45% of premiums paid up to one Target Premium, plus 13.5% of additional premiums paid in excess of one Target Premium to a second Target Premium, plus 13.5% of additional premiums paid in excess of two Target Premiums up to a third Target Premium. The Deferred Sales Charge during the first policy is equal to 25% of premiums paid up to one Target Premium. The Deferred Sales Charge during the second Policy year is equal to 25% of premiums paid up to one Target Premium plus 5% of additional premiums paid up to a second Target Premium. In no event will the Deferred Sales Charge exceed the limits set forth in subparagraphs (i) and (v) of Rule 6e-3(T)(b)(13).

15. The table below shows the maximum Deferred Sales Charge that may apply to Policies covering insureds whose issue age is 55 or less at issue, expressed as a percentage of each Target Premium paid prior to surrender, lapse, or face amount reduction, assuming that one Target Premium per year has been paid under the Policy prior to such date. The table shows the applicable charge if the lapse, surrender or face amount reduction occurs at the end of each of the Policy years shown. During Policy years six through eleven, the Deferred Sales Charge declines on a monthly basis.

For policies, which are surrendered, lapsed or reduced during	The maximum deferred sales charge is the following percentage of each target premium paid per year to date of surrender, lapse, or reduction
Entire Policy Year:	
3	24.00
4	18.00
5	14.40
Last Month of Policy Years:	
6	10.00
7	6.86
8	4.50
9	2.67
10	1.20
11	0.00

16. For insureds whose issue age is above 55 at issue, the Deferred Sales Charge percentages are less than or equal to those described above, with the maximum charge occurring in Policy years 3 through 5 for insureds with an

issue age up through 65, in Policy years 2 through 4 for insureds with an issue age from 66 through 75, and in Policy year 2 for insureds with an issue age above 75.

17. In the case of a partial surrender or reduction in face amount, any Deferred Sales Charge that applies is deducted from the Policy's cash value in an amount proportional to the amount of the Policy's face amount surrendered.

18. The table below shows the Deferred Administrative Charge that will be deducted from the Policy's available cash value in the event of a total or partial surrender, lapse or face amount reduction. After the end of the first Policy year the charge declines monthly.

For policies which are deferred, surrendered, lapsed or reduced during	Administrative charge per $1,000 of face amount
Entire Policy Year:	
1	$2.50
Last Month of Policy Years:	
2	2.25
3	2.00
4	1.75
5	1.50
6	1.25
7	1.00
8	0.75
9	0.50
10	0.25
11	0.00

19. For an insured whose issue age is above 65, the Deferred Administrative Charge is less than or equal to that in the table above. The Deferred Administrative Charge partially covers the administrative costs of processing surrenders, lapses, and reductions in face amount, as well as legal, actuarial, systems, mailing and other overhead costs connected with NEVLICO's variable life insurance operations. Applicants represent that this charge has been designed to cover actual costs and is not intended to produce a profit.

20. On the first day of each Policy Month, starting with the Policy Date, NEVLICO will make a deduction from a Policy's cash value (the "Monthly Deduction"). If either minimum guaranteed death benefit is in effect, or if the Policy is protected against lapse by payment of the minimum premium during the first three Policy years, the Monthly Deduction will be made, whether or not premiums are paid, until the cash value equals zero. Otherwise, the Monthly Deduction will be made, whether or not premiums are paid, as long as the net cash value is sufficient to cover the entire Monthly Deduction. The Monthly Deduction will reduce the cash value in each sub-account of the Variable Account and in the Fixed Account in proportion to the cash value in each. The Monthly Deduction includes the following charges:

(i) *Policy Fee.* The Policy Fee is currently equal to $4.50 per month (guaranteed not to exceed $7.00 per month).

(ii) *Administrative Charge.* The Administrative Charge is currently equal to $0.06 per $1,000 of Policy face amount in the first Policy year, and $0.02 per $1,000 of Policy face amount thereafter (guaranteed not to exceed $0.08 per $1,000 of face amount in the first Policy year and $0.04 per $1,000 of Policy face amount thereafter).

The Policy Fee and the Administrative Charge together partially cover the cost of administering the Policies (such as the cost of processing Policy transactions, issuing Policy Owner statements and reports, and record keeping), as well as legal, actuarial, systems, mailing and other overhead costs connected with NEVLICO's variable life insurance operations. These charges have been designed to cover actual costs and are not intended to produce a profit.

(iii) *Minimum Death Benefit Guarantee Charge.* The Minimum Death Benefit Guarantee Charge is $0.01 per $1,000 of Policy face amount.

(iv) *Monthly Charges for the Cost of Insurance.* This charge covers the cost of providing insurance protection under a Policy.

(v) *Charges for Additional Benefits.* Charges will be imposed for the cost of any additional rider benefits as described in the rider form.

21. At the time of a face amount increase, a Face Amount Increase Administrative Charge of $2.50 per $1,000 of face amount increase will be deducted from the Policy's cash value in the sub-accounts and the Fixed Account in proportion to the amount of the Policy's cash value in each. The Face Amount Increase Administrative Charge covers the cost of processing the face amount increase and, like the Deferred Administrative Charge, Policy Fee and Administrative Charge, has been designed to cover actual costs and is not intended to produce a profit. NEVLICO currently limits this charge to a maximum of $200.00.

22. NEVLICO charges the subaccounts of the Variable Account for the mortality and expense risks that NEVLICO assumes. Currently, the charge is made daily at an annual rate of 0.75% of the sub-accounts' assets. This charge is guaranteed not to exceed an annual rate of 0.90% of the value of each sub-account's assets attributable to the Policies. The mortality risk NEVLICO assumes is that insureds may live for shorter periods of time than NEVLICO estimated. The expense risk NEVLICO assumes is that NEVLICO's costs of issuing and administering Policies may be more than NEVLICO estimated. Charges for investment advisory fees and other expenses incurred by the Eligible Funds are deducted from the assets of the relevant fund and are indirectly borne by owners of Policies.

Applicants' Legal Analysis

1. Section 6(c) of the Act provides that the Commission, by order upon application, may conditionally or unconditionally exempt any person, security or transaction, or any class or classes of persons, securities or transactions, from any provision of the Act, if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

2. Section 27(a)(3) of the Act generally provides that the amount of sales load deducted from any one of the first twelve monthly payments under a periodic payment plan certificate, or their equivalent, cannot exceed proportionately the amount deducted from any other such payment, and that the amount deducted from any subsequent payment cannot exceed proportionately the amount deducted from any other subsequent payment.

3. Rule 6e–3(T)(b)(13)(ii) grants an exemption from Section 27(a)(3), provided that the proportionate amount of sales load deducted from any payment during the contract period does not exceed the proportionate amount deducted from any prior payment, unless the increase is caused by the grading of cash values into reserves or reductions in the annual cost of insurance.

4. The amount of the Sales Charge deducted from premium payments under the Policy is 4%. NEVLICO intends to waive this charge on premiums paid after the twentieth Policy year and on the portion of premiums attributable to a face amount increase after twenty years from the date of the increase. The continuation of this waiver, however, is not contractually guaranteed, and NEVLICO may withdraw or modify the waiver at any time. Thus, it is possible that the waiver could apply at some times with respect to a given Policy and not at a subsequent time with respect to the same Policy. Arguably Section 27(a)(3) and Rule 6e–3(T)(b)(13)(ii) could prohibit this sales load structure. Applicants request an exemption from

those provisions to the extent necessary to permit the waiver, modification and reinstatement of the sales load as described in this paragraph.

5. Applicants assert that the purpose of the proposed waiver of Sales Charge after the twentieth Policy year is to more closely reflect NEVLICO's expenses in connection with Policy sales. To the extent that NEVLICO determines that the full 4% Sales Charge on premiums made after the twentieth Policy year could generate more revenue than NEVLICO believes necessary, it may waive the charge. Applicants submit that it would not be in the interest of owners to require the imposition of a Sales Charge on premiums paid after the twentieth Policy year that is higher than Applicants deem necessary. Applicants assert that the policies and purposes of Section 27(a)(3) and Rule 6e–3(T)(b)(13)(ii) do not require such a result.

6. Section 27(e) of the Act and Rules 27e–1 and 6e–3(T)(b)(13)(vii), in effect, require a notice of right of withdrawal and refund, on Form N–27l–1, to be provided to Policy owners entitled to a refund of sales load in excess of the limits permitted by Rule 6e–3(T)(b)(13)(v).

7. Applicants request exemptions from Section 27(e) of the Act and Rules 27e–1 and 6e–3(T)(b)(13)(vii) thereunder to the extent necessary to waive the requirements to provide notice to policy owners entitled to a refund of sales load in excess of the limits permitted by Rule 6e–3(T)(b)(13)(v).

8. The Policy limits the amount of the Deferred Sales Charge that may be deducted upon surrender, face amount reduction or lapse, by the excess sales load limits set forth in Rule 6e–3(T)(b)(13)(v). Thus, no excess sales load is ever paid by a Policy owner surrendering, effecting a face amount reduction, or lapsing in the first two Policy years.

9. Rule 27e–1 specifies in paragraph (e) that no notice need be mailed when there is otherwise no entitlement to receive any refund of sales load. Moreover, Rule 27e–1 and Rule 6e–2 were adopted in the context of front-end loaded products only and in the broader context of the companion requirements in Section 27 for the depositor or underwriter to maintain segregated funds as security to assure the refund of any excess sales load. In the context of the Policy's Deferred Sales Charge structure, where no excess sales load is ever paid or refunded, Form N–27l–1 could at best confuse Policy owners, and could at worst encourage a Policy owner to surrender the Policy during the first two Policy years when it may not be in the owner's best interest to do so. An owner of a Policy with a declining contingent deferred sales charge, unlike a front-end loaded policy, does not foreclose his or her opportunity, at the end of the first two Policy years, to receive a refund of monies spent. Not only has such an owner not paid any excess load, but also, because the deferred charge declines over the life of the Policy, he or she may never have to pay it. Encouraging a surrender during the first two Policy years could cost such an owner more in total sales load (relative to total premium) than he or she would otherwise pay if the Policy, which is designed as a long-term investment vehicle, were held for the period originally intended.

Applicants' Conclusion

For the reasons stated above, Applicants submit that the requested exemptions, in accordance with the standards of Section 6(c) of the Act, are consistent with the protection of investors and the purposes intended by the policy and provisions of the Act.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 95–20957 Filed 8–23–95; 8:45 am]

BILLING CODE 8010–01–M

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster Loan Area #2802]

Florida; Declaration of Disaster Loan Area

Pasco County and the contiguous Counties of Hernando, Hillsborough, Pinellas, Polk, and Sumter in the State of Florida constitute a disaster area as a result of damages caused by Hurricane Erin which occurred on August 2, 1995. Applications for loans for physical damages as a result of this disaster may be filed until the close of business on October 10, 1995, and for economic injury until the close of business on May 10 1996, at the address listed below:

U.S. Small Business Administration, Disaster Area 2 Office, One Baltimore Place, Suite 300, Atlanta, GA 30308

or other locally announced locations.

The interest rates are:

For Physical Damage:

Homeowners with credit available elsewhere—8.000%

Homeowners without credit available elsewhere—4.000%

Businesses with credit available elsewhere—8.000%

Businesses and non-profit organizations without credit available elsewhere—4.000%

Others (including non-profit organizations) with credit available elsewhere—7.125%

For Economic Injury:

Businesses and small agricultural cooperatives without credit available elsewhere—4.000%

The number assigned to this disaster for physical damage is 280208 and for economic injury the number is 860400.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008).

Dated: August 10, 1995.

Philip Lader,

Administrator.

[FR Doc. 95–20988 Filed 8–23–95; 8:45 am]

BILLING CODE 8025–01–P

[Declaration of Disaster Loan Area #2803]

Florida; Declaration of Disaster Loan Area

As a result of the President's major disaster declaration on August 10, 1995, and an amendment thereto on August 11, I find that Bay, Brevard, Escambia, Okaloosa, Santa Rosa, and Walton Counties in the State of Florida constitute a disaster area due to damages caused by Hurricane Erin which occurred on August 2–3, 1995. Applications for loans for physical damages may be filed until the close of business on October 8,1995, and for loans for economic injury until the close of business on May 10,1996 at the address listed below:

U.S. Small Business Administration, Disaster Area 2 Office, One Baltimore Place, Suite 300, Atlanta, GA 30308

or other locally announced locations. In addition, applications for economic injury loans from small businesses located in the following contiguous counties may be filed until the specified date at the above location: Calhoun, Gulf, Holmes, Indian River, Jackson, Orange, Osceola, Volusia, and Washington Counties in Florida, and Baldwin, Covington, Escambia, and Geneva Counties in Alabama.

Interest rates are:

For Physical Damage:

Homeowners with credit available elsewhere—8.000%

Homeowners without credit available elsewhere—4.000%

Businesses with credit available elsewhere—8.000%

Businesses and non-profit organizations without credit available elsewhere—4.000%

Others (including non-profit organizations) with credit available elsewhere—7.125%

For Economic Injury:

Businesses and small agricultural cooperatives without credit available elsewhere—4.000%

The number assigned to this disaster for physical damage is 280308. For economic injury the numbers are 860700 for Florida and 860800 for Alabama.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008).

Dated: August 17, 1995.

Bernard Kulik,

Associate Administrator, for Disaster Assistance.

[FR Doc. 95–20989 Filed 8–23–95; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice 2242]

Fine Arts Committee; Notice of Meeting

The Fine Arts Committee of the Department of State will meet on Friday, October 6, 1995 at 2:30 p.m. in the John Quincy Adams State Drawing Room. The meeting will last until approximately 4:00 p.m. and is open to the public.

The agenda for the committee meeting will include a summary of the work of the Fine Arts Office since its last meeting in April 1995 and the announcement of gifts and loans of furnishings as well as financial contributions from January 1, 1995 to September 1, 1995. The Committee will elect a new chairman at this meeting.

Public access to the Department of State is strictly controlled. Members of the public wishing to take part in the meeting should telephone the Fine Arts Office by Friday, September 29, 1995, telephone (202) 647–1990 to make arrangements to enter the building. The public may take part in the discussion as long as time permits and at the discretion of the chairman.

Dated: August 11, 1995.

Gail F. Serfaty,

Vice Chairman, Fine Arts Committee.

[FR Doc. 95–21083 Filed 8–23–95; 8:45 am]

BILLING CODE 4710–38–M

DEPARTMENT OF TRANSPORTATION

Coast Guard

[CGD 95–068]

Differential Global Positioning System; Youngstown, New York: Environmental Assessment and Finding of No Significant Impact

AGENCY: Coast Guard, DOT.

ACTION: Notice of availability.

SUMMARY: The Coast Guard has prepared a Programmatic Environmental Assessment (EA) and Finding of No Significant Impact (FONSI) for its activating of a broadcast site of the Differential Global Positioning System (DGPS) service at Youngstown, New York. The EA concludes that there will be no significant impact on the environment and that preparation of an Environmental Impact Statement will not be necessary. This Notice announces the availability of the EA and FONSI and solicits comments on them.

DATES: Comments must be received on or before September 25, 1995.

ADDRESSES: Comments may be mailed to the Executive Secretary, Marine Safety Council, U.S. Coast Guard Headquarters, 2100 Second Street SW., Washington, DC 20593–0001, or may be delivered to room 3406 at the same address between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is (202) 267–1477.

FOR FURTHER INFORMATION CONTACT: CWO Roger Hughes, United States Coast Guard Navigation Center, at (703) 313–5889. Copies of the EA and FONSI may be obtained by calling Mr. Hughes, or by faxing him at (703) 313–5920. Copies of the EA—without enclosures—are also available on the Electronic Bulletin Board System (BBS) at the Navigation Information Service (NIS) in Alexandria, Virginia, at (703) 313–5910. For information on the BBS, call the watchstander of NIS at (703) 313–5900.

SUPPLEMENTARY INFORMATION

Request for Comments

Copies of the EA and FONSI are available from the address given in **ADDRESSES** and from the numbers given in **FOR FURTHER INFORMATION CONTACT.** The Coast Guard encourages interested persons to submit comments on these documents. It may revise these documents in view of the comments. If it does, it will announce their availability in revised form by a later notice in the **Federal Register.**

Background

As required by Congress, the Coast Guard is preparing to install the equipment necessary to implement DGPS service in the northeastern United States. DGPS uses a new radionavigation technique that improves upon the 100-meter accuracy of the existing Global Positioning System to provide an accuracy of 8 to 20 meters. For vessels, this degree of accuracy is critical for precise electronic navigation in harbors and their approaches: It will reduce the number of groundings, collisions, personal injuries, fatalities, and spills of hazardous cargo resulting from such incidents.

After extensive study, the Coast Guard has chosen a site at Youngstown, New York. Significant concerns had been raised about siting DGPS equipment at U.S. Coast Guard Group Buffalo; the fear was that birds from the wetland at Times Beach, nearby, might strike the tower and guy wires. DGPS will broadcast signals in the marine radiobeacon frequency band (283.5 to 325 KHz) using less than 35 watts' effective radiated power. Signals broadcast at these low frequencies and powers have not been found harmful to the surrounding environment.

Proposed Installation at Youngstown, New York

(a) Site—The site at Youngstown occupies about 5.7 acres at the Youngstown Army National Guard Training Facility in the town of Porter, New York.

(b) Radiobeacon Antenna—The Coast Guard will install a 90-foot guyed antenna with an accompanying ground plane. A ground plane for this antenna consists of approximately 120 copper radials, each of 6-gauge copper wire and each installed 6 inches (or less) beneath the soil and projecting from the antenna base. The optimal length for a radial is 300 feet, but this length may be shortened to fit within property boundaries. Wherever possible, a cable plow-method will be used in the radial installation to minimize soil disturbance.

(c) DGPS Antennas—Two 30-foot masts to support six small receiving antennas, each 4 inches by 18 inches in diameter, will be necessary. The masts will stand on concrete foundations. The antennas support the primary and backup reference receivers and the integrity monitors.

(d) Equipment shelter—Transmitting equipment will be housed in a shelter 10 feet by 16 feet. This will be built on a concrete pad, which itself will be built in a site now in its natural state.

(e) Utilities—The Coast Guard proposes to use available commercial power as the primary source for the electronic equipment. A telephone line

will be necessary at each site for remote monitoring and operation.

Finding

Implementation of DGPS service at Youngstown, New York, will neither have a significant effect on the quality of the human environment nor require preparation of an Environmental Impact Statement.

Dated: August 17, 1995.

Rudy K. Peschel,

Rear Admiral, U.S. Coast Guard Chief, Office of Navigation Safety and Waterway Service.

[FR Doc. 95–20944 Filed 8–23–95; 8:45 am]

BILLING CODE 4910–14–M

[CGD 95–070]

Civil GPS Service Interface Committee, Announcement of Meeting

AGENCY: Coast Guard, DOT.

ACTION: Notice of meeting.

SUMMARY: The Civil GPS Service Interface Committee (CGSIC) will meet September 11 and 12, 1995 at the Spa Hotel in Palm Springs, California. The CGSIC was formed to exchange GPS information and to identify GPS issues that affect nonmilitary users. The CGSIC is open to representatives of relevant private, government, and industry users groups, both U.S. and international. The meeting is chaired by the Chief of the Department of Transportation's Radionavigation Policy and Planning Staff.

DATES: The full committee will meet on September 11, 1995. The subcommittees will meet on September 12, 1995.

FOR FURTHER INFORMATION CONTACT: Rebecca Casswell, United States Coast Guard Navigation Center, at (703) 313–5930 or [FAX] (703) 313–5805. The meeting agenda is available on the Electronic Bulletin Board System (BBS) at the Navigation Information Service (NIS) in Alexandria, Virginia, at (703) 313–5910. For information on the BBS, call the watchstander of NIS at (703) 313–5900.

SUPPLEMENTARY INFORMATION

Background

The CGSIC was established to identify needs of civil GPS users (navigation, timing, and positioning) in support of the DOT's Civil GPS Service program and to promote the Assistant Secretary for Transportation Policy's program of outreach to civil users of GPS Service. Pursuant to this responsibility, the CGSIC will work with the Office of the Assistant Secretary for Transportation Policy, the Joint Working Group of the Department of Defense and the Department of Transportation on Radionavigation, and the U.S. Coast Guard's Office of Navigation Safety and Waterway Services.

Dated: August 17, 1995.

Rudy K. Peschel,

Rear Admiral, U.S. Coast Guard, Chief, Office of Navigation Safety and Waterway Services.

[FR Doc. 95–20945 Filed 8–23–95; 8:45 am]

BILLING CODE 4910–14–M

Federal Aviation Administration

RTCA, Inc., Special Committee 184; Minimum Performance and Installation Standards for Runway Guard Lights

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (P.L. 92–463, 5 U.S.C., Appendix 2), notice is hereby given for a Special Committee 184 meeting to be held September 7–8, 1995, starting at 9:30 a.m. The meeting will be held at RTCA, 1140 Connecticut Avenue, NW., Suite 1020, Washington, DC 20036.

The agenda will be as follows: (1) Administrative Announcements; (2) Chairman's Introductory Remarks; (3) Review and Approval of Meeting Agenda; (4) Review and Approval of Minutes of July 27–28 Meeting; (5) Review Status of Action Items; (6) Review Draft Document Inputs; (7) Work Group Drafting Session; (8) Other Business; (9) Date and Place of Next Meeting.

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the RTCA Secretariat, 1140 Connecticut Avenue, NW., Suite 1020, Washington, DC 20036; (202) 833–9339 (phone) or (202) 833–9434 (fax). Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on August 18, 1995.

Janice L. Peters,

Designated Official.

[FR Doc. 95–21016 Filed 8–23–95; 8:45 am]

BILLING CODE 4810–13–M

Notice of Intent To Rule on Application To Impose and Use the Revenue from a Passenger Facility Charge (PFC) at Mason City Municipal Airport, Mason City, IA

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of intent to rule on application.

SUMMARY: The Federal Aviation Administration (FAA) proposes to rule and invites public comment on the application to impose and use the revenue from a PFC at Mason City Municipal Airport under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (Title IX of the Omnibus Budget Reconciliation Act of 1990) (Public Law 101–508) and part 158 of the Federal Aviation Regulations (14 CFR part 158).

DATES: Comments must be received on or before September 25, 1995.

ADDRESSES: Comments on this application may be mailed or delivered in triplicate to the FAA at the following address: Federal Aviation Administration, Central Region, Airports Division, 601 E. 12th Street, Kansas City, MO 64106.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Mr. Jerome Thiele, Director of Aviation, Mason City Airport Commission, at the following address: Mason City Airport Commission, P.O. Box 1484, Mason City, Iowa 50402–1484.

Air carriers and foreign air carriers may submit copies of written comments previously provided to the Mason City Airport Commission under section 158.23 of part 158.

FOR FURTHER INFORMATION CONTACT: Ellie Anderson, PFC Coordinator, FAA, Central Region, Airports Division, 601 E. 12th Street, Kansas City, MO 64106, (816) 426–4728. The application may be reviewed in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA proposes to rule and invites public comment on the application to impose and use the revenue from a PFC at Mason City Municipal Airport under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (Title IX of the Omnibus Budget Reconciliation Act of 1990) (Pub. L. 101–508) and part 158 of the Federal Aviation Regulations (14 CFR part 158).

On August 15, 1995, the FAA determined that the application to impose and use the revenue from a PFC submitted by the Mason City Airport Commission was substantially complete within the requirements of section 158.25 of part 158. The FAA will approve or disapprove the application, in whole or in part, no later than November 29, 1995.

The following is a brief overview of the application.

Level of the proposed PFC: $3.00.

Proposed charge effective date: February 1, 1996.

Proposed charge expiration date: August 1, 2000.

Total estimated PFC revenue: $302,790.00.

Brief description of proposed project(s): Land acquisition and fencing, airfield crack repair and slurry seal, reconstruct airfield storm water intakes; install airfield directional signage, slurry seal Runways 12/30 & 17/35; Americans with Disabilities Act terminal improvements, taxiway slurry seal, storm drainage; purchase snowblower, aircraft rescue and firefighting radio communication system; purchase snowbroom and endloader; purchase high speed snow plow; reconstruct airfield electrical system; utility improvements and acquisition of sander truck and motor grader; overlay entrance/service roads and parking lot; replace security fence and gates; and expand snow removal equipment building.

Class or classes of air carriers which the public agency has requested not be required to collect PFCs: none.

Any person may inspect the application in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT.**

In addition, any person may, upon request, inspect the application, notice and other documents germane to the application in person at the Mason City Municipal Airport, Mason City, Iowa.

Issued in Kansas City, Missouri on August 15, 1995.

James W. Brunskill,

Acting Manager, Airports Division, Central Region.

[FR Doc. 95–21017 Filed 8–23–95; 8:45 am]

BILLING CODE 4910–13–M

Research and Special Programs Administration Revision of the Emergency Response Guidebook, Notice of Public Meetings; Request for Comments

AGENCY: Research and Special Programs Administration (RSPA), DOT.

ACTION: Notice of public meetings; request for comments.

SUMMARY: This notice advises interested persons that RSPA will conduct public meetings to discuss the development and publication of the 1996 North American Emergency Response Guidebook (NAERG). At the first meeting, the concept of the NAERG will be introduced; a draft document will be presented at the second meeting. The NAERG will supersede the 1993 Emergency Response Guidebook (ERG) and will encompass information from both the U.S. Department of Transportation's 1993 ERG and Transport Canada's Initial Emergency Response Guide 1992. The development of the NAERG is a joint effort involving the transportation agencies of the United States, Canada and Mexico. This notice solicits comments on the development of the NAERG, particularly from those who have used the ERG during hazardous materials incidents.

DATES: *Public Meetings.* The first public meeting will be held on September 21, 1995, in Room 332, Federal Trade Commission, 6th & Pennsylvania Avenue, N.W., Washington, DC 20580. The second meeting will be November 8, 1995, in Room 8236 of the Nassif Building, 400 Seventh Street S.W., Washington, DC 20590–0001. Meeting times are from 9:30 a.m. to 5 p.m. The public is invited to attend without advance notification.

Comments. Written comments should be submitted on or before October 19, 1995, to the Office of Hazardous Materials Initiatives and Training (DHM–50), Research and Special Programs Administration, U.S. Department of Transportation, 400 Seventh Street S.W., Washington, DC 20590–0001; comments may be faxed to (202) 366–7342; or E-mailed via the Internet to WELISTEN@rspa.dot.gov

FOR FURTHER INFORMATION CONTACT: David Henry or Gigi Corbin, Research and Special Programs Administration (DHM–50), 400 Seventh Street S.W., Washington, DC 20590–0001; (202) 366–4900; Internet E-mail to henryd@rspa.dot.gov or corbing@rspa.dot.gov

SUPPLEMENTARY INFORMATION:

Background

The Federal hazardous materials transportation law, 49 U.S.C. 5101 *et seq,* empowers the Secretary of Transportation to issue and enforce regulations deemed necessary to ensure the safe transport of hazardous materials. In addition, the law directs the Secretary of Transportation to provide law enforcement and fire fighting personnel with technical information and advice for meeting emergencies connected with the transportation of hazardous materials.

The Emergency Response Guidebook was developed by RSPA for use by emergency services personnel to provide guidance for initial response to hazardous materials incidents. Since 1980, it has been the goal of RSPA for all emergency response vehicles, including fire fighting, police and rescue squad vehicles, to carry a copy of the ERG. To accomplish this, RSPA has published five editions of the ERG and has distributed over 4.9 million copies to emergency services agencies, without charge.

The NAERG is being jointly developed by RSPA, Transport Canada and the Secretary of Communication and Transport of Mexico. The NAERG will supersede the 1993 ERG and will be published in English, French and Spanish for use by emergency response personnel in each of the three North American Free Trade Agreement countries. Publication of the 1996 NAERG will facilitate transport of hazardous materials through North America and increase public safety by providing consistent emergency response procedures to hazardous materials accidents and incidents in North America. In order to continually improve the ERG, RSPA actively solicits comments from interested parties, especially those who have used the ERG during hazardous materials incidents. RSPA will continue to use a network of state agencies to distribute the NAERG to state and local emergency responders.

Request for Comments

Comments are solicited on ERG user concerns and on the following questions:

1. Has the National Response Center (NRC) provided accurate and timely assistance to emergency responders during hazardous materials incidents?
2. Have emergency responders experienced a problem of inconsistent guidance between the 1993 ERG and other sources of technical information? If so, in what way could the NAERG be revised to reduce this inconsistency?
3. Have emergency responders experienced confusion or difficulty in understanding the scope or purpose of the 1993 ERG? If so, in what way could the NAERG be revised to reduce this difficulty?
4. Have emergency responders experienced confusion or difficulty in understanding the application of the 1993 ERG? If so, in what way could the NAERG be revised to reduce this difficulty?
5. How could the "Table of Initial Isolation and Protective Action Distances" or its introduction be made easier to comprehend and use?
6. In the "Table" does the distinction between day and night protective action distances add useful information for the first responder? How could the distinction be improved?
7. Should the guidebook in any way describe materials which emit poisonous vapors when spilled in water? If so, what format would be best?

(i.e. separate guide, distinct list, special footnote attached to these material names, etc.)

8. Have emergency responders experienced difficulty understanding the capabilities of chemical protective clothing, and the limitations of structural fire fighter's protective clothing in hazardous materials incidents? If so, in what way can the NAERG be revised to improve understanding?

9. Aside from Gasoline, has any identification number (ID No.) been incorrectly assigned to a material (Name of Material)?

10. Has any identification number/material been assigned to the "wrong" guide?

11. Are the responses on each guide appropriate for the material assigned to the guide?

12. Have emergency responders experienced difficulty with legibility of the 1993 ERG's print style, its format or its durability?

13. Have emergency response agencies experienced difficulty in obtaining copies of 1993 ERG for their vehicles?

Supporting data and analyses will enhance the value of comments submitted.

Alan I. Roberts,

Associate Administrator for Hazardous Materials Safety.

[FR Doc. 95–21023 Filed 8–23–95; 8:45 am]

BILLING CODE 4910–60–P

National Highway Traffic Safety Administration

Research and Development Programs Meeting

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Notice.

SUMMARY: This notice announces a public meeting at which NHTSA will describe and discuss specific research and development projects. Further, the notice requests suggestions for topics to be presented by the agency.

DATES AND TIMES: The National Highway Traffic Safety Administration will hold a public meeting devoted primarily to presentations of specific research and development projects on September 21, 1995, beginning at 1:30 p.m. and ending at approximately 5 p.m. The deadline for interested parties to suggest agenda topics is 4:15 p.m. on September 5, 1995. Questions may be submitted in advance regarding the agency's research and development projects. They must be submitted in writing by September 12, 1995, to the address given below. If sufficient time is available, questions received after the September 12 date will be answered at the meeting in the discussion period. The individual, group, or company asking a question does not have to be present for the question to be answered. A consolidated list of the questions submitted by September 12 will be available at the meeting and will be mailed to requesters after the meeting.

ADDRESSES: The meeting will be held at the Holiday Inn Capitol, 550 C Street SW., Washington, DC 20024. Suggestions for specific R&D topics as described below and questions for the September 21, 1995, meeting relating to the agency's research and development programs should be submitted to the Office of the Associate Administrator for Research and Development, NRD–01, National Highway Traffic Safety Administration, Room 6206, 400 Seventh St. SW., Washington, DC 20590. The fax number is 202–366–5930.

SUPPLEMENTARY INFORMATION: NHTSA intends to provide detailed presentations about its research and development programs in a series of quarterly public meetings. The series started in April 1993. The purpose is to make available more complete and timely information regarding the agency's research and development programs. This eleventh meeting in the series will be held on September 21, 1995.

NHTSA requests suggestions from interested parties on the specific agenda topics to be presented. NHTSA will base its decisions about the agenda, in part, on the suggestions it receives by close of business at 4:15 p.m. on September 5, 1995. Before the meeting, it will publish a notice with an agenda listing the research and development topics to be discussed. The agenda can also be obtained by calling or faxing the information numbers listed elsewhere in this notice. NHTSA asks that the suggestions be limited to six, in priority order, so that the presentations at the September 21 R&D meeting can be most useful to the audience. Specific R&D topics are listed below. Many of these topics have been discussed at previous meetings. Suggestions for agenda topics are not restricted to this listing, and interested parties are invited to suggest other R&D topics of specific interest to their organizations.

Specific R&D topic is:

On-line tracking system for NHTSA's research projects.

Specific Crashworthiness R&D topics are:

Improved frontal crash protection problem analysis and program status,
Advanced glazing research,
Highway traffic injury studies,
Head and neck injury research,
Lower extremity injury research,
Thorax injury research,
Human injury simulation and analysis,
Crash test dummy component development,
Vehicle aggressivity and fleet compatibility,
Upgrade side crash protection,
Upgrade seat and occupant restraint systems,
Child safety research (specifically ISOFIX),
Electric and alternate fuel vehicle safety, and,
Truck crashworthiness/occupant protection.

Specific Crash Avoidance R&D topics are:

Truck tire traction,
Portable data acquisition system for crash avoidance research,
Systems to enhance EMS response (automatic collision notification),
Vehicle motion environment data collection system,
Crash causal analysis,
Human factors guidelines for crash avoidance warning devices,
Longer combination vehicle safety,
Drowsy driver monitoring,
Driver workload assessment,
Performance guidelines for ITS systems (approach),
Variable dynamics test vehicle,
Engineering description of precrash events,
Preliminary rearend collision avoidance system guidelines,
Preliminary road departure collision avoidance system guidelines, and
Preliminary intersection collision avoidance system guidelines.

Separately, questions regarding research projects that have been submitted in writing not later than close of business on September 12, 1995, will be answered. A transcript of the meeting, copies of materials handed out at the meeting, and copies of the suggestions offered by commenters will be available for public inspection in the NHTSA's Technical Reference Section, Room 5108, 400 Seventh St. SW., Washington, DC 20590. Copies of the transcript will then be available at 10 cents a page, upon request to NHTSA's Technical Reference Section. The Technical Reference Section is open to the public from 9:30 a.m. to 4 p.m.

NHTSA will provide technical aids to participants as necessary, during the Research and Development Programs Meeting. Thus, any person desiring the

assistance of "auxiliary aids" (e.g., sign-language interpreter, telecommunication devices for deaf persons (TTDs), readers, taped texts, braille materials, or large print materials and/or a magnifying device), please contact Rita Gibbons on 202–366–4862 by close of business September 15, 1995.

FOR FURTHER INFORMATION CONTACT: Rita Gibbons, Staff Assistant, Office of Research and Development, 400 Seventh Street, SW., Washington, DC 20590. Telephone: 202–366–4862. Fax number: 202–366–5930.

Issued: August 18, 1995.

William A. Boehly,

Associate Administrator for Research and Development.

[FR Doc. 95–21002 Filed 8–23–95; 8:45 am]

BILLING CODE 4910–59–M

DEPARTMENT OF THE TREASURY

[Treasury Order Number 100–13]

Delegation of Authority Related to the Community Adjustment and Investment Program in Support of NAFTA, and Designation of Representative on the Community Adjustment and Investment Program Finance Committee

Dated: August 17, 1995.

By virtue of the authority vested in the Secretary of the Treasury, including the authority in 31 U.S.C. 321(b), it is hereby ordered as follows:

1. *Delegation of Authority.*

a. I delegate to the Under Secretary (Domestic Finance) all duties, powers, rights and obligations delegated to the Secretary of the Treasury by sections 4 and 5 of Executive Order No. 12916, dated May 13, 1994, ("the Executive Order") relating to implementing the Community Adjustment and Investment Program ("the Program") authorized by the North American Free Trade Agreement Implementation Act (Pub. L. 103–182, 107 Stat. 2057).

b. This authority may be redelegated in writing to an appropriate subordinate official.

2. *Designation of Treasury Representative.*

a. I designate the Under Secretary (Domestic Finance) as the Department of the Treasury representative on the Community Adjustment and Investment Program Finance Committee established by section 7 of the Executive Order to administer the Program.

b. This designation may be delegated in writing to an appropriate subordinate official.

Robert E. Rubin,

Secretary of the Treasury.

[FR Doc. 95–21026 Filed 8–23–95; 8:45 am]

BILLING CODE 4810–25–P

Fiscal Service

[Dept. Circular 570; 1995 Revision]

Companies Holding Certificates of Authority as Acceptable Sureties on Federal Bonds and as Acceptable Reinsuring Companies Effective July 1, 1995; Correction

In notice document 95–16154 beginning on page 34436 in the issue of Friday, June 30, 1995, many typographical errors appeared. It has resulted in the following corrections:

Page	Error	As published on 6/30/95	Correction
34436	Name	Aetna Casualty Surety Company of America	Aetna Casualty & Surety Company of America.
34437	Name	AMERICAN BANKERS INSURANCE OF FLORIDA	AMERICAN BANKERS INSURANCE COMPANY OF FLORIDA.
34439	Phone	Continental Reinsurance Corporation, (21) 440–7800	(212) 440–7800.
34443	Phone	Integrand Assurance Company, (809) 781–0708x–269	(809) 781–0707x–269.
34443	Name	International Business & Mercantile Reassurance Company	International Business & Mercantile Reassurance Company.
34448	Busi. address	TRANSATLANTIC REINSURANCE COMPANY, 80 Pine Street, New York, NY 1005.	80 Pine Street, New York, NY 10005.
34449	Busi. address	Universal Surety Company, P.O. Box 80468, Lincoln, NE 00936.	P.O. Box 80468, Lincoln, NE 68501.
34440	State license	CUMIS INSURANCE SOCIETY, INC	Add: AR
34440	State license	EXPLORER INSURANCE COMPANY (THE)	Remove MN and add NM.
34442	State license	Highlands Insurance Company	Remove FA and add GA.
34443	State license	Insurance Company of the State of Pennsylvania	Remove SC and add SD.
34444	State license	Nationwide Mutual Insurance Company	Add VI.
34445	State license	North American Speciality Insurance Company	Add IN.
34445	State license	Old Republic Insurance Company	Add IN and VI.
34445	State license	Old Republic Surety Company	Add NM.
34445	State license	Pacific Employers Insurance Company	Add AR.
34446	State license	Reinsurance Corporation of New York (The)	Add AS.
34446	State license	Reliance Insurance Company	Add AS.
34446	State license	Reliance National Indemnity Company	Add AS.
34447	State license	Seaboard Surety Company	Add KY.
34447	State license	Sentry Insurance A Mutual Company	Remove NH.
34447	State license	St. Paul Fire and Marine Insurance Company	Add GU.
34448	State license	Travelers Indemnity Company of Illinois (The)	Remove PI and add RI.
34448	State license	Ulico Casualty Company	Add AR.
34449	State license	United Pacific Insurance Company	Remove GV and add GU & NY.
34449	State license	United States Fire Insurance Company	Remove GV and add GU.
34450	State license	Winterthur Reinsurance Corporation of America	Add NM.

The following companies' names should have appeared in all upper case letters as reflected in their Articles of Incorporation:

ACCREDITED SURETY AND CASUALTY COMPANY, INC.

ACSTAR INSURANCE COMPANY
AMERICAN CONTRACTORS INDEMNITY COMPANY
AMERICAN RELIABLE INSURANCE COMPANY
AMERICAN ROAD INSURANCE COMPANY (THE)
FEDERATED MUTUAL INSURANCE COMPANY
FIDELITY AND GUARANTY INSURANCE COMPANY
FIRST FINANCIAL INSURANCE COMPANY
FRONTIER INSURANCE COMPANY
GENERAL ACCIDENT INSURANCE COMPANY (PUERTO RICO) LIMITED
GENERAL ACCIDENT INSURANCE COMPANY OF AMERICA
GRAMERCY INSURANCE COMPANY
HARCO NATIONAL INSURANCE COMPANY
ILLINOIS NATIONAL INSURANCE CO.
INTEGRAND ASSURANCE COMPANY
ISLAND INSURANCE COMPANY, LIMITED
KEMPER REINSURANCE COMPANY
MARKEL INSURANCE COMPANY
MID-CONTINENT CASUALTY COMPANY
MOTORS INSURANCE CORPORATION
MUTUAL SERVICE CASUALTY INSURANCE COMPANY
NATIONAL REINSURANCE CORPORATION
NAVIGATORS INSURANCE COMPANY
NORTH AMERICAN SPECIALTY INSURANCE COMPANY
NORTHBROOK PROPERTY AND CASUALTY INSURANCE COMPANY
NORTHWESTERN PACIFIC INDEMNITY COMPANY
PLANET INDEMNITY COMPANY
PREFERRED NATIONAL INSURANCE COMPANY
PROTECTION MUTUAL INSURANCE COMPANY
SCOR REINSURANCE COMPANY
SECURITY INSURANCE COMPANY OF HARTFORD
SENTINEL INSURANCE COMPANY, LTD.
SOREMA NORTH AMERICA REINSURANCE COMPANY
ST. PAUL GUARDIAN INSURANCE COMPANY
ULICO CASUALTY COMPANY
UNDERWRITERS REINSURANCE COMPANY
UNITED NATIONAL INSURANCE COMPANY
UNITED STATES FIRE INSURANCE COMPANY
UNITED SURETY AND INDEMNITY COMPANY
UNIVERSAL BONDING INSURANCE COMPANY
UNIVERSAL INSURANCE COMPANY
VAN TOL SURETY COMPANY, INCORPORATED
VESTA FIRE INSURANCE CORPORATION
WINTERTHUR REINSURANCE CORPORATION OF AMERICA
ZENITH INSURANCE COMPANY

Copies of the Treasury Department Circular 570, which are error free, may be obtained by calling the U.S. Department of Treasury, Financial Management Service, computerized public bulletin board system (FMS Inside Line) at (202) 874–6817/7034/6953/6872 or by purchasing a hard copy from the Government Printing Office (GPO), Washington, DC, telephone (202) 512–1800. When ordering the Circular from GPO, use the following stock number: 048–000–00489–0. For further assistance, contact the Surety Bond Branch, Funds Management Division, Financial Management Service, U.S. Department of the Treasury, 3700 East-West Highway, Room 6F04, Hyattsville, MD 20782, telephone (202) 874–6850 (voice) or (202) 874–9978 (fax).

Dated: August 11, 1995.

Charles F. Schwan III,

Director, Funds Management Division, Financial Management Service.

[FR Doc. 95–21047 Filed 8–23–95; 8:45 am]

BILLING CODE 1505–01–M

Office of Thrift Supervision

[No. 95–157]

Proposed Reduction of Data Collected on the Thrift Financial Report

AGENCY: Office of Thrift Supervision, Treasury.

ACTION: Notice; request for comment.

SUMMARY: The Office of Thrift Supervision (OTS) requests comment on a proposal to fully consolidate and substantially reduce the amount of data submitted on the quarterly Thrift Financial Report (TFR). A streamlined, consolidated TFR has been developed in an effort to reduce the thrift industry's regulatory reporting burden while ensuring that the OTS will still collect information necessary to monitor safety and soundness. The effective date for the streamlined TFR would be June 1996.

DATES: Comments must be received on or before October 23, 1995.

ADDRESSES: Send comments to Chief, Dissemination Branch, Thrift Supervision, 1700 G Street, NW., Washington DC 20552, Attention Docket No. 95–157. These submissions may be hand delivered to 1700 G Street NW. from 9:00 a.m. to 5:00 p.m. on business days; they may be sent by facsimile transmission to FAX Number (202) 906–7755. Comments will be available for inspection at 1700 G Street NW., from 1:00 p.m. until 4:00 p.m. on business days.

FOR FURTHER INFORMATION CONTACT: Patrick G. Berbakos, Assistant Director, Financial Reporting Division, (202) 906–6720, or Catherine Shepard, Senior Attorney, Regulations and Legislation Division, Office of Chief Counsel (202) 906–7275; Office of Thrift Supervision, 1700 G Street NW., Washington, D.C. 20552.

SUPPLEMENTARY INFORMATION: As part of its continuing effort to reduce the regulatory burden for the thrift industry, the OTS proposes to significantly streamline the TFR beginning in June 1996. The agency, after consulting with its Washington and Regional examination, supervisory, and legal staff, has identified several TFR schedules and over 300 lines of data that can be eliminated. More than half of these items are being deleted as a result of converting the TFR into a fully consolidated format. Today OTS is seeking public comment on whether these proposed eliminations will reduce long-term regulatory costs and burdens for the industry and be consistent with safety and soundness and other public policy objectives.

I. Background

The OTS has implemented a number of program changes during the past three years in an effort to enhance the efficiency of the financial reporting process, reduce the industry's reporting burden, increase customer service, and reduce the costs for both the industry and the OTS. The program changes included the elimination of the monthly data collection for the TFR, amending the reporting schedule to provide additional time for report preparation, and providing the industry with electronic filing software that facilitates the electronic preparation and filing of all regulatory reports.

II. Description of Proposed Changes to 1996 TFR

After reviewing its current supervisory and examination needs, the OTS is proposing to eliminate 324 lines of data currently collected on the TFR. This decrease represents 40 percent of the TFR, exclusive of Schedule CMR, which is unaffected by this proposal. Lines of data and schedules that are no longer necessary because of changes in the industry's portfolio or OTS's supervisory priorities will no longer be collected. Only data that remain critical to meet supervisory needs, statutory

mandates, or other important policy objectives will be collected.

OTS is providing copies of this notice and a line-by-line description of the proposed TFR changes to all OTS-regulated savings associations. All other interested parties may obtain a line-by-line description of the proposal by calling (202) 906–6078. The following gives a schedule-by-schedule overview of the types of changes the OTS is proposing:

Schedule SC—Statement of Condition

1. Delete the detail regarding real estate held for investment; retain a subtotal for real estate held for investment.
2. Delete the breakdown of equity investment in and loans to service corporations and subsidiaries; retain a subtotal for investments and loans to service corporations and subsidiaries.
3. Delete the detail of office premises and equipment; retain a subtotal for office premises and equipment.
4. Delete SC–680 (Property Leased to Others).

Schedule SO—Statement of Operations

1. Delete the item for penalties on early withdrawal of deposits.
2. Delete four items under noninterest income, which will be included in other noninterest income.
3. Combine net income from REO operations with gains and losses from the sale of REO and other repossessed assets.
4. Combine gains and losses on the sale of assets.

Schedule CA—Capital Accounts

Delete the entire schedule as it will be replaced by the expanded reconciliation of equity in Schedule CSI.

Schedule VA—Valuation Allowances

Delete the detail of charge-offs and recoveries for Cash, Deposits, and Investment Securities and Real Estate Held for Investment; retain a subtotal for these assets.

Schedule PD—Past Due

Delete the miscellaneous data on Schedule PD.

Schedule TA—Troubled Assets

Retain troubled debt restructured and classification of assets data and delete all other data in this schedule. Add a new item summarizing mortgage loans foreclosed during the quarter.

Schedule CC—Commitments and Contingencies

Delete information on futures, options, new commitments, and other miscellaneous data on commitments.

Schedule CF—Selected Cash Flow Information

Retain activity data on mortgage pool securities, mortgage loans, nonmortgage loans, and deposits and delete other miscellaneous data.

Schedule SI—Supplemental Information Deposit Data

1. Delete reference to deposits of $80,000, retaining only the $100,000 cut-off.
2. Delete data that can be obtained from Schedule CMR.

Other Data

Delete all data items in this section with the exception of SI–350 (Approximate Value of Trust Assets Administered) and SI–370 (Number of Full-time Equivalent Employees).

Equity Investments

Delete this section in its entirety.

Regulatory Liquidity

Retain the liquidity ratio and delete the amount of assets eligible for regulatory liquidity.

FSLIC Guarantees and Assistance

Delete these sections in their entirety.

Schedule SQ—Supplemental Questions

Retain questions concerning the structure of assets and liabilities and accounting considerations and delete all other questions.

Schedule TR—Assets in Trading Accounts

Delete this entire schedule and move data items regarding total assets held in trading accounts and securities available for sale and assets held for sale to Schedule SI.

Schedule YD—Yields on Deposits

Delete items referencing $80,000—$100,000 certificate amounts.

Schedule AS—Annual Supplement

Delete the entire schedule.

Schedule SB—Small Business Loans

This schedule remains unchanged in accordance with Section 122 of the FDIC Improvement Act.

Schedules CSC and CSO—Consolidated Statements of Condition and Operations

Delete these two schedules in their entirety because Schedules SC and SO will be redefined to contain consolidated data.

Schedule CSI—Consolidated Supplemental Information

Delete all line items in this schedule except loan servicing, reconciliation of equity capital, asset repricing/maturing data and mutual fund and annuity sales, all of which will be moved to Schedule SI.

Schedule CSS—Consolidated Subsidiary Listing

Collect this schedule annually at December 31.

Schedule CCR—Consolidated Capital Requirement

Retain this schedule as is with the addition of one line to capture the assets of subsidiary depository institutions because these assets will not be consolidated in Schedule SC.

Schedule CMR—Consolidated Maturity/Rate

No changes to this schedule.

III. Alternatives Considered

The OTS considered several alternatives to make the TFR reporting process less burdensome. The OTS considered reducing the frequency of the reporting cycle from a quarterly report to a semiannual report, pursuant to the President's Memorandum of April 21, 1995 on "Regulatory Reform—Waiver of Penalties and Reduction of Reports," 60 FR 20621 (April 26, 1995). However, the reporting cycle has already been reduced from monthly to quarterly, and the OTS believes that for reasons of safety and soundness it cannot further reduce the reporting cycle. In light of the rapidity with which an institution's balance sheet can change, OTS is concerned that reducing the reporting cycle to semiannually may prevent the early identification of a deteriorating situation.

Section 307(b) of the Riegle Community Development and Regulatory Improvement Act of 1994 requires the Federal banking agencies to work jointly in adopting a single form for the filing of core financial information and to streamline the schedules supplementing the core information by eliminating data requirements that are not warranted for reasons of safety and soundness or other public interest purposes. The Federal banking agencies under the auspices of the Federal Financial Institutions Examination Council (FFIEC) have begun work on the development of a core report which may take several years to complete. Since the Commercial Bank Call Report (Call Report) is already prepared on a consolidated basis, the current OTS proposal to consolidate and condense the TFR is a critical first step in reaching a uniform core report. OTS believes that at this time, this alternative

provides greater benefit for both the thrift industry and OTS and avoids the extensive systems modifications and retraining of personnel required by converting to the Call Report immediately.

Finally, OTS considered whether the reporting burden for small savings associations could be appreciably reduced by developing a separate TFR for those institutions. OTS believes that such a separate schedule would not be consistent with supervisory needs. If an association is engaged in an activity, OTS's supervisory interest is the same regardless of the institution's size. Under the current TFR structure, savings associations need not complete line items on schedules for activities in which they are not engaged.

IV. Request for Comment

The OTS invites comment on all aspects of the proposal and, in particular, whether the proposal will in fact reduce the TFR reporting burden. Consideration should be given to the amount of data collected, the ease of obtaining the data, and the extent to which cost savings would be realized over time as well as the estimated amount of implementation costs. The current average burden associated with the collection of the 1995 TFR is estimated to be 39.1 hours per response, including the completion of Schedule CMR. The projected average burden for the proposed TFR, including Schedule CMR, is 29.1 hours. Comment is also desired on whether an implementation date of June 1996 (rather than March) would impose a hardship on reporting savings associations or on other users of the financial data.

The OTS is also interested in receiving comments on whether the filing deadline for Schedule CMR should be changed from the current 45 days after the close of the quarter to 40 days, or 30 days to coincide with the TFR filing deadline. This change in the CMR reporting deadline would facilitate an earlier transmittal of the OTS Interest Rate Risk Exposure Report to reporting savings associations. Currently, a number of savings associations of all sizes and with a variety of portfolios file Schedule CMR within 30 days of the end of the quarter.

V. Paperwork Reduction Act

The reporting requirements contained in this notice have been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3504(h)). Comments on the collections of information should be sent to the Office of Management and Budget, Paperwork Reduction Project (1550), Washington, DC 20503, with copies to the Office of Thrift Supervision, 1700 G Street, N.W., Washington DC 20552.

The reporting requirements in this notice are found in 12 CFR 562.1(b)(2). The information is needed by the OTS to supervise savings associations and develop regulatory policy. The likely record keepers are OTS regulated savings associations.

Estimated number of record keepers: 1,514.

Estimated average annual burden per record keeper: 116.4 hours.

Estimated annual frequency of record keeping: 4 (Quarterly).

Estimated total annual record keeping burden: 176,230 hours.

Dated: August 18, 1995.

By the Office of Thrift Supervision.

Jonathan L. Fiechter,

Acting Director.

[FR Doc. 95–20948 Filed 8–22–95; 8:45 am]

BILLING CODE 6720–01 P

Sunshine Act Meetings

Federal Register
Vol. 60, No. 164
Thursday, August 24, 1995

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Agency Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 10:00 a.m. on Monday, August 21, 1995, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider (1) reports of the Office of Inspector General, and (2) matters relating to the Corporation's supervisory activities.

In calling the meeting, the Board determined, on motion of Vice Chairman Andrew C. Hove, Jr., seconded by Stephen R. Steinbrink, acting in the place and stead of Director Eugene A. Ludwig (Comptroller of the Currency), concurred in by John F. Downey, acting in the place and stead of Director Jonathan L. Fiechter (Acting Director, Office of Thrift Supervision), and Chairman Ricki Helfer, that Corporation business required its consideration of the matters on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B)).

The meeting was held in the Board Room of the FDIC Building located at 550 17th Street, N.W., Washington, D.C.

Dated: August 21, 1995.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Deputy Executive Secretary.

[FR Doc. 95–21166 Filed 8–23–95; 8:45 am]
BILLING CODE 6714–01–M

Corrections

Federal Register
Vol. 60, No. 164
Thursday, August 24, 1995

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Parts 1, 2, and 7

[Docket No. 950501124-5185-02]

RIN 0651-AA74

Revision of Patent and Trademark Fees

Correction

In rule document 95–19763 beginning on page 41018 in the issue of Friday, August 11, 1995, make the following correction:

On page 41021, in the third column, in the third full paragraph, in the sixth line from the bottom, "35 U.S.C. 42(f)." should read "35 U.S.C. 41(f)."

BILLING CODE 1505–01–D

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 131

[WW-FRL-5196-1]

Water Quality Standards: Establishment of Numeric Criteria for Priority Toxic Pollutants; States' Compliance--Revision of Metals Criteria

Correction

In rule document 95–10148 beginning on page 22229 in the issue of Thursday, May 4, 1995, make the following correction:

On page 22236, in the table under the heading "11 Silver" "^{m}1.9" which appears under column "B Freshwater" should appear in the column headed "C Saltwater".

BILLING CODE 1505–01–D

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA-940-5700-00; CACA 35718]

Notice of Proposed Withdrawal and Opportunity for Public Meeting; California

Correction

In notice document 95-15296 beginning on page 32559 in the issue of Thursday, June 22, 1995, make the following correction:

In the same page, in the third column, in the land description, T. 2 S., R. 17 E., in Sec. 13, the first line should read "SW¼SW¼, S½SE¼SW¼, E½SE¼,".

BILLING CODE 1506–01–D

federal register

Thursday
August 24, 1995

Part II

Department of Agriculture

Office of the Secretary

7 CFR Parts 3015 and 3019
Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Nonprofit Organizations; Interim Rule

DEPARTMENT OF AGRICULTURE

Office of the Secretary

7 CFR Parts 3015 and 3019

Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Nonprofit Organizations

AGENCY: Office of the Secretary, USDA.

ACTION: Interim final rule.

SUMMARY: This interim final rule is the U.S. Department of Agriculture's (USDA) implementation of Office of Management and Budget (OMB) Circular A–110, "Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations." In OMB's final revision to Circular A–110, which was published in the **Federal Register** (58 FR 62992) on November 29, 1993, Federal agencies were directed to publish these standards that are imposed on grantees, as codified regulations.

Through this action USDA is creating a new Part, 7 CFR 3019, which will contain the Department's codification of OMB's revised Circular A–110, "Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations." The new Part will apply only to institutions of higher education and other nonprofit organizations that are recipients of Federal assistance.

The Department's regulations covering the administration of grants and agreements to these entities was previously found at 7 CFR 3015. This notice will also amend 7 CFR 3015 to reflect the change in the scope of that Part as a result of the creation of 7 CFR 3019.

EFFECTIVE DATE: August 24, 1995.

FOR FURTHER INFORMATION CONTACT: Mr. Gerald Miske, Supervisory Program Analyst, U.S. Department of Agriculture, Office of Finance and Management, Rm. 3031—South Building, 14th St. & Independence Avenue SW., Washington, DC 20250, (202) 720–1553.

SUPPLEMENTARY INFORMATION:

Background

OMB originally published Circular A–110 in 1976. The Circular remained virtually unchanged until a minor revision was published in February 1987. In November 1988, OMB proposed that Circular A–110 be merged with OMB's new Common Rule (formerly Circular A–102), "Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments." This proposal was later dropped due to substantial opposition from both Federal agencies and the university community.

In November 1990 representatives from a number of Federal agencies met with OMB and agreed that the original Circular A–110 should be revised. An interagency task force was established to develop, to the maximum extent possible, a set of common principles for the administration of grants and agreements with institutions of higher education, hospitals and other non-profit organizations. The task force developed such a proposal and submitted it to OMB. On August 27, 1992, after several modifications, OMB published that document as a notice in the **Federal Register**, requesting comments on the proposed revisions to the Circular. OMB received and considered over 200 comments in developing the final publication of the Circular.

On November 29, 1993, OMB published that revision to Circular A–110, "Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit organizations," in the **Federal Register** at 58 FR 62992. The revised Circular has, in a number of ways, significantly reduced the administrative burdens placed on recipients by the Federal agencies. The most notable attempt to relieve the burden on recipients was achieved by an agreement with Federal agencies to publish regulations that, to the maximum extent possible, contained the text of the Circular as published by OMB. Additionally, the format of the Circular was changed to make the document more "user friendly," and to enable Federal agencies to more easily adopt the text of the circular in regulatory format.

In support of OMB's desired uniformity in the publication of this regulation, USDA has elected to provide the following clarifications to several issues that were raised during the Department's internal clearance process in lieu of making changes to the language in the rule.

Section .11(b), Public Notice and Priority Setting, states that Federal awarding agencies "* * * shall notify the public of its intended funding priorities for discretionary grant programs * * *" USDA agencies are fulfilling this requirement in various ways. Some agencies publish a prioritized list of programs on an annual basis. Other agencies publish a list of programs that concentrate on a number of special initiatives or special emphasis areas that they intend to fund over the course of the fiscal year. Because applications are accepted and considered for all of these special programs on an equal basis, according to merit, it is difficult to list any particular priority beforehand. Occasionally, the lists of special emphasis programs or priorities that are listed are changed for various reasons, often on very short notice. In these cases USDA will accept that the agency has met its responsibility under this section by listing "* * * its intended funding priorities * * *," or by listing those priorities that it was aware of at the time of publication.

With regard to Section .23, Cost Sharing and Matching, USDA has historically held that recipients may "contribute," or use as part of their cost sharing or matching proposal, the value of services and/or property owned by the recipient, that have not already been used to satisfy any other Federal cost sharing or matching requirement. It is the position of the Department that Section .23 of this regulation clearly permits such recipient contributions.

Applicability to Commercial Organizations

The definition of the term "recipient" in 7 CFR 3015, included for-profit organizations (commercial organizations) thereby making those entities subject to that regulation in the absence of any other specific guidance provided by the agency. To affirm this coverage, agencies generally incorporated reference to the rule in the terms and conditions of the award clearly indicating that the recipient should follow that regulation.

The new regulation, 7 CFR 3019, provides that the term, recipient, "* * * may include commercial organizations * * * at the discretion of the Federal awarding agency." USDA has defined the term " Federal awarding agency" to mean the U.S. Department of Agriculture or any subagency of the U.S. Department of Agriculture.

Awards of Federal financial assistance to commercial organizations are atypical of the majority of awards made by USDA. Most of the awards that are made to commercial organizations are made to small businesses or "emerging technology" firms that do not have the experience, or in some cases the capacity, to meet these requirements without a great deal of help from the agency. Therefore, the Department wishes to provide USDA agencies with

the maximum amount of flexibility by allowing them to continue to apply either the provisions of 7 CFR 3015 or the provisions of this new 7 CFR 3019 to those awards. Agencies will continue to specify, in the terms of the award document, which regulation shall apply.

Justification for Waiver of Proposed Rulemaking

Section 5 U.S.C. 553 of the Administrative Procedures Act (APA) requires Federal agencies to publish in the **Federal Register**, Notices of Proposed Rulemaking (NPRM) except in those instances when the subject matter concerns, among other things, grants, loans, benefits or contracts. In spite of this exception USDA, as a matter of policy, normally publishes all NPRM's in the **Federal Register** regardless of the subject matter. In this case USDA has, for a number of reasons, decided to publish this regulation as an interim final rule.

The primary reason for publishing this document as an interim final rule is that OMB already published it for comment in the **Federal Register** on August 27, 1992. Following that publication OMB received over 200 comments from universities, non-profit organizations, Federal agencies, professional organizations and others. These comments were considered, and addressed in the final rule that was published on November 29, 1993. Secondly, we believe that publishing this rule for comment at this time would be contrary to the public good because USDA would be unable to make any changes to the rule based on those comments. In an effort to publish uniform administrative procedures throughout government, OMB has directed Federal agencies responsible for awarding and administering grants and other agreements covered by the Circular to publish and adopt the specific language contained in the Circular" * * * unless different provisions are required by statute * * *." In an effort to bring about that uniformity, USDA has published the text of the Circular verbatim. The only change that was made to the text of the rule was redefining the generic term "Federal awarding agency" to "USDA" throughout the document.

Additionally, USDA believes that it is important to expedite the final publication and implementation of this deadline in order to assist the recipients of Federal awards and USDA subagencies that have been waiting for the rule to be published.

Effect on Other Issuances

USDA's original regulation which established Departmentwide policies and standards for the administration of all grants and cooperative agreements with all recipient types including institutions of higher education, hospitals and other nonprofit organizations was codified at 7 CFR Part 3015, "Uniform Federal Assistance Regulations." The rule implemented all of the OMB Circulars related to grants administration including OMB Circular A–110, "Grants and Agreements with Institutions of Higher Education, Hospitals and Other Nonprofit Organizations." Part 3015 also set forth the requirements for Executive Order 12372, "Intergovernmental Review of Federal Programs," the Department's policy on competition in awarding discretionary grants and cooperative agreements, and makes applicable the cost principles specified in Circular A–21 for universities, A–87 for State and local governments, A–122 for nonprofit organizations, and 48 CFR Subpart 31.2 for commercial organizations. In addition, Part 3015 had previously included the administrative requirements for grants and cooperative agreements to State and local governments that were prescribed by OMB Circular A–102. These requirements were moved to 7 CFR Part 3016 on March 11, 1988, upon publication of the grants management common rule entitled, "Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments."

Through this action, USDA is creating a new Part, 7 CFR 3019, which will contain the Department's codification of OMB's revised Circular A–110, "Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations." The new Part will apply to nongovernmental recipients of Federal assistance, specifically institutions of higher education, hospitals and non-profit organizations. Additionally, USDA agencies may, at their discretion, use this rule to administer grants and agreements with commercial organizations.

Part 3019 will not apply to transactions entered into under sections 1472(b) and 1473A of the National Agricultural Research, Extension, and Teaching Policy Act of 1977, as amended (7 U.S.C. 3318 and 3319a).

Amendments to 7 CFR Part 3015

Through USDA's codification of this Circular, Part 3015 will no longer prescribe the general administrative regulations for Federal assistance relationships with institutions of higher education, hospitals and other non-profit organizations. The administrative regulations for the Department's entitlement programs will remain in 7 CFR Part 3015, pending issuance of a future guidance or regulations in this area.

Pending issuance of those regulations, the open-ended entitlement programs of USDA's Food and Consumer Services listed below will remain subject to the requirements of 7 CFR Part 3015.

(a) State Administrative Matching Grants for Food Stamp Program.
(b) National School Lunch Program.
(c) School Breakfast Program.
(d) Summer Food Service Program.
(e) Child and Adult Care Food Program.
(f) Special Milk Program for Children.
(g) State Administrative Expenses Under the Child Nutrition Act (sect. 7 of the Child Nutrition Act.)

In addition, the following sections of 7 CFR 3015 will be revised for the following reasons:

Section 3015.1, Purpose and scope of this Part, is being revised to reflect the current purpose and scope of the Part after withdrawal of the administrative regulations for grants and cooperative agreements with institutions of higher education, hospitals and other non-profit organizations.

Section 3015.2, Applicability, is being revised to update the list of recipients to which Part 3015 does and does not apply.

Section 3015.194, For-profit organizations, is being revised to update the reference to the cost principles that are applicable to for-profit organizations from 41 CFR 1–15.2, Federal Procurement Regulations, to 48 CFR Subpart 31.2, Federal Acquisition Regulation.

Amendments to §§ 3015.1, 3015.2 and, 3015.194 will redefine the purpose, scope and applicability of the part (as indicated above) and the recipients to which this rule now applies.

Regulatory Impact Analyses

Executive Order 12866

In accordance with the provisions of Executive Order 12866, this rule was not reviewed by the Office of Management and Budget.

Paperwork Reduction Act

The information collection requirements for this rule have been submitted to OMB for approval under previously approved #0505–0008. The information collection requirements are not effective until approved by OMB.

Regulatory Flexibility Act

In accordance with the requirements of the Regulatory Flexibility Act (5 U.S.C. 605(b)), USDA has reviewed this rule and certifies that it does not have a significant economic impact on a substantial number of small entities.

List of Subjects

7 CFR Part 3015

Grant programs (Agriculture), Intergovernmental relations.

7 CFR Part 3019

Grant programs (Agriculture).

For the reasons set forth in the preamble, USDA amends 7 CFR Chapter XXX as set forth below.

Dated: July 20, 1995.

Anthony A. Williams,

Chief Financial Officer.

Dated: August 3, 1995.

Dan Glickman,

Secretary.

PART 3015—UNIFORM FEDERAL ASSISTANCE REGULATIONS [AMENDED]

1. The authority citation for Part 3015 continues to read as follows:

Authority: 5 U.S.C. 301, Subpart I, 31 U.S.C. 7505, unless otherwise noted.

2. USDA is amending Subpart A of 7 CFR Part 3015 as follows:

a. Section 3015.1 is amended by revising paragraph (a)(1) and adding a new paragraph (a)(4) as follows:

Subpart A—General

§ 3015.1 Purpose and scope of this part.

(a) (1) This Part establishes USDA-wide uniform requirements for the administration of open-ended entitlement grants and specifies the set of principles for determining allowable costs under USDA grants and cooperative agreements to State and local governments, universities, non-profit and for-profit organizations as set forth in OMB Circulars A–87, A–21, A–122, and 48 CFR 31.2, respectively. This Part also contains the general provisions that apply to all grants and cooperative agreements made by USDA.

* * * * *

(4) Rules for nonentitlement grants and cooperative agreements to institutions of higher education, hospitals, and other non-profit organizations are found in part 3019.

* * * * *

b. Section 3015.2 is amended by adding paragraph (d)(6) as follows:

§ 3015.2 Applicability.

* * * * *

(d) * * *

(6) Institutions of higher education, hospitals and other non-profit organizations except open-ended entitlements to those entities.

* * * * *

3. USDA is amending Subpart T of 7 CFR 3015 as follows:

Subpart T—Cost Principles

a. Section 3015.194 is revised to read as follows:

§ 3015.194 For-profit organizations.

The principles to be used when determining the allowable costs of activities conducted by for-profit organizations are contained in the Federal Acquisition Regulation at 48 CFR Subpart 31.2. Exception: Independent research and development costs including any indirect costs allocable to them are unallowable. Independent research and development are defined in the Federal Acquisition Regulation at 48 CFR 31.205–18.

4. Title 7 of the Code of Federal Regulations is being amended by adding Part 3019 as follows:

PART 3019—UNIFORM ADMINISTRATIVE REQUIREMENTS FOR GRANTS AND AGREEMENTS WITH INSTITUTIONS OF HIGHER EDUCATION, HOSPITALS, AND OTHER NON-PROFIT ORGANIZATIONS

Subpart A—General

Authority: 5 U.S.C. 301.

Subpart A—General

§ 3019.1 Purpose.

This part establishes uniform administrative requirements for Federal grants and agreements awarded to institutions of higher education, hospitals, and other non-profit organizations. Federal awarding agencies shall not impose additional or inconsistent requirements, except as provided in §§ 3019.4, and 3019.14 or unless specifically required by Federal statute or executive order. Non-profit organizations that implement Federal programs for the States are also subject to State requirements.

§ 3019.2 Definitions.

(a) *Accrued expenditures* means the charges incurred by the recipient during a given period requiring the provision of funds for:

(1) Goods and other tangible property received;

(2) Services performed by employees, contractors, subrecipients, and other payees; and

(3) Other amounts becoming owed under programs for which no current services or performance is required.

(b) *Accrued income* means the sum of:

(1) Earnings during a given period from:

(i) services performed by the recipient, and

(ii) Goods and other tangible property delivered to purchasers, and

(2) Amounts becoming owed to the recipient for which no current services or performance is required by the recipient.

(c) *Acquisition cost of equipment* means the net invoice price of the equipment, including the cost of modifications, attachments, accessories, or auxiliary apparatus necessary to make the property usable for the purpose for which it was acquired. Other charges, such as the cost of installation, transportation, taxes, duty or protective in-transit insurance, shall be included or excluded from the unit acquisition cost in accordance with the recipient's regular accounting practices.

(d) *Advance* means a payment made by Treasury check or other appropriate payment mechanism to a recipient upon its request either before outlays are made by the recipient or through the use of predetermined payment schedules.

(e) *Award* means financial assistance that provides support or stimulation to accomplish a public purpose. Awards include grants and other agreements in the form of money or property in lieu of money, by the Federal Government to an eligible recipient. The term does not include: technical assistance, which provides services instead of money; other assistance in the form of loans, loan guarantees, interest subsidies, or insurance; direct payments of any kind to individuals; contracts which are required to be entered into and administered under procurement laws and regulations; and those agreements that are entered into under the authorities provided by sections 1472(b), 1473A, and 1473C of the National Research Extension, and Teaching Policy Act of 1977 (as amended by the Food Security Act (7 U.S.C. 3318, 3319a and 3319c.) and subsequent authorizations. The term also does not include entitlement grants and subgrants under the National School Lunch Act:

(1) School Lunch (section 4 of the Act),

(2) Commodity Assistance (section 6 of the Act),

(3) Special Meal Assistance (section 11 of the Act),

(4) Summer Food Service for Children (section 13 of the Act), and,

(5) Child and Adult Care Food Program (section 17 of the Act), and entitlements grants and subgrants under the following programs of the Child Nutrition Act of 1966:

(i) Special Milk (section 3 of the Act), and,

(ii) School Breakfast (section 4 of the Act).

(f) *Cash contributions* means the recipient's cash outlay, including the outlay of money contributed to the recipient by third parties.

(g) *Closeout* means the process by which a Federal awarding agency determines that all applicable administrative actions and all required work of the award have been completed by the recipient and Federal awarding agency.

(h) *Contract* means a procurement contract under an award or subaward, and a procurement subcontract under a recipient's or subrecipient's contract.

(i) *Cost sharing or matching* means that portion of project or program costs not borne by the Federal Government.

(j) *Date of completion* means the date on which all work under an award is completed or the date on the award document, or any supplement or amendment thereto, on which Federal sponsorship ends.

(k) *Disallowed costs* means those charges to an award that the Federal awarding agency determines to be unallowable, in accordance with the applicable Federal cost principles or other terms and conditions contained in the award.

(l) *Equipment* means tangible nonexpendable personal property including exempt property charged directly to the award having a useful life of more than one year and an acquisition cost of $5000 or more per unit. However, consistent with recipient policy, lower limits may be established.

(m) *Excess property* means property under the control of any Federal awarding agency that, as determined by the head thereof, is no longer required for its needs or the discharge of its responsibilities.

(n) *Exempt property* means tangible personal property acquired in whole or in part with Federal funds, where the Federal awarding agency has statutory authority to vest title in the recipient without further obligation to the Federal Government. An example of exempt property authority is contained in the Federal Grant and Cooperative Agreement Act (31 U.S.C. 6306), for property acquired under an award to conduct basic or applied research by a non-profit institution of higher education or non-profit organization whose principal purpose is conducting scientific research.

(o) *Federal awarding agency* means the U.S. Department of Agriculture (USDA) or any subagency of the U.S. Department of Agriculture that provides an award to the recipient.

(p) *Federal funds authorized* means the total amount of Federal funds obligated by the Federal Government for use by the recipient. This amount may include any authorized carryover of unobligated funds from prior funding periods when permitted by agency regulations or agency implementing instructions.

(q) *Federal share* of real property, equipment, or supplies means that percentage of the property's acquisition costs and any improvement expenditures paid with Federal funds.

(r) *Funding period* means the period of time when Federal funding is available for obligation by the recipient.

(s) *Intangible property and debt instruments* means, but is not limited to, trademarks, copyrights, patents and patent applications and such property as loans, notes and other debt instruments, lease agreements, stock and other instruments of property ownership, whether considered tangible or intangible.

(t) *Obligations* means the amounts of orders placed, contracts and grants awarded, services received and similar transactions during a given period that require payment by the recipient during the same or a future period.

(u) *Outlays or expenditures* means charges made to the project or program. They may be reported on a cash or accrual basis. For reports prepared on a cash basis, outlays are the sum of cash disbursements for direct charges for goods and services, the amount of indirect expense charged, the value of third party in-kind contributions applied and the amount of cash advances and payments made to subrecipients. For reports prepared on an accrual basis, outlays are the sum of cash disbursements for direct charges for goods and services, the amount of indirect expense incurred, the value of in-kind contributions applied, and the net increase (or decrease) in the amounts owed by the recipient for goods and other property received, for services performed by employees, contractors, subrecipients and other payees and other amounts becoming owed under programs for which no current services or performance are required.

(v) *Personal property* means property of any kind except real property. It may be tangible, having physical existence,

or intangible, having no physical existence, such as copyrights, patents, or securities.

(w) *Prior approval* means written approval by an authorized official evidencing prior consent.

(x) *Program income* means gross income earned by the recipient that is directly generated by a supported activity or earned as a result of the award (see exclusions in §§ 3019.24 (e) and (h)). Program income includes, but is not limited to, income from fees for services performed, the use or rental of real or personal property acquired under federally-funded projects, the sale of commodities or items fabricated under an award, license fees and royalties on patents and copyrights, and interest on loans made with award funds. Interest earned on advances of Federal funds is not program income. Except as otherwise provided in Federal awarding agency regulations or the terms and conditions of the award, program income does not include the receipt of principal on loans, rebates, credits, discounts, etc., or interest earned on any of them.

(y) *Project costs* means all allowable costs, as set forth in the applicable Federal cost principles, incurred by a recipient and the value of the contributions made by third parties in accomplishing the objectives of the award during the project period.

(z) *Project period* means the period established in the award document during which Federal sponsorship begins and ends.

(aa) *Property* means, unless otherwise stated, real property, equipment, intangible property and debt instruments.

(bb) *Real property* means land, including land improvements, structures and appurtenances thereto, but excludes movable machinery and equipment.

(cc) *Recipient* means an organization receiving financial assistance directly from Federal awarding agencies to carry out a project or program. The term includes public and private institutions of higher education, public and private hospitals, and other quasi-public and private non-profit organizations such as, but not limited to, community action agencies, research institutes, educational associations, and health centers. The term may include commercial organizations, foreign or international organizations (such as agencies of the United Nations) which are recipients, subrecipients, or contractors or subcontractors of recipients or subrecipients at the discretion of the Federal awarding agency. The term does not include government-owned contractor-operated facilities or research centers providing continued support for mission-oriented, large-scale programs that are government-owned or controlled, or are designated as federally-funded research and development centers.

(dd) *Research and development* means all research activities, both basic and applied, and all development activities that are supported at universities, colleges, and other non-profit institutions. "Research" is defined as a systematic study directed toward fuller scientific knowledge or understanding of the subject studied. "Development" is the systematic use of knowledge and understanding gained from research directed toward the production of useful materials, devices, systems, or methods, including design and development of prototypes and processes. The term research also includes activities involving the training of individuals in research techniques where such activities utilize the same facilities as other research and development activities and where such activities are not included in the instruction function.

(ee) *Small awards* means a grant or cooperative agreement not exceeding the small purchase threshold fixed at 41 U.S.C. 403(11) (currently $25,000).

(ff) *Subaward* means an award of financial assistance in the form of money, or property in lieu of money, made under an award by a recipient to an eligible subrecipient or by a subrecipient to a lower tier subrecipient. The term includes financial assistance when provided by any legal agreement, even if the agreement is called a contract, but does not include procurement of goods and services nor does it include any form of assistance which is excluded from the definition of "award" in paragraph (e) of this section.

(gg) *Subrecipient* means the legal entity to which a subaward is made and which is accountable to the recipient for the use of the funds provided. The term may include foreign or international organizations (such as agencies of the United Nations) at the discretion of the Federal awarding agency.

(hh) *Supplies* means all personal property excluding equipment, intangible property, and debt instruments as defined in this section, and inventions of a contractor conceived or first actually reduced to practice in the performance of work under a funding agreement ("subject inventions"), as defined in 37 CFR part 401, "Rights to Inventions Made by Nonprofit Organizations and Small Business Firms Under Government Grants, Contracts, and Cooperative Agreements."

(ii) *Suspension* means an action by a Federal awarding agency that temporarily withdraws Federal sponsorship under an award, pending corrective action by the recipient or pending a decision to terminate the award by the Federal awarding agency. Suspension of an award is a separate action from suspension under Federal agency regulations implementing E.O.s 12549 and 12689, "Debarment and Suspension."

(jj) *Termination* means the cancellation of Federal sponsorship, in whole or in part, under an agreement at any time prior to the date of completion.

(kk) *Third party in-kind contributions* means the value of non-cash contributions provided by non-Federal third parties. Third party in-kind contributions may be in the form of real property, equipment, supplies and other expendable property, and the value of goods and services directly benefiting and specifically identifiable to the project or program.

(ll) *Unliquidated obligations*, for financial reports prepared on a cash basis, means the amount of obligations incurred by the recipient that have not been paid. For reports prepared on an accrued expenditure basis, they represent the amount of obligations incurred by the recipient for which an outlay has not been recorded.

(mm) *Unobligated balance* means the portion of the funds authorized by the Federal awarding agency that has not been obligated by the recipient and is determined by deducting the cumulative obligations from the cumulative funds authorized.

(nn) *Unrecovered indirect cost* means the difference between the amount awarded and the amount which could have been awarded under the recipient's approved negotiated indirect cost rate.

(oo) *Working capital advance* means a procedure where by funds are advanced to the recipient to cover its estimated disbursement needs for a given initial period.

§ 3019.3 Effect on other issuances.

For awards subject to this part, all administrative requirements of codified program regulations, program manuals, handbooks and other nonregulatory materials which are inconsistent with the requirements of this part shall be superseded, except to the extent they are required by statute, or authorized in accordance with the deviations provision in § 3019.4.

§ 3019.4 Deviations.

The Office of Management and Budget (OMB) may grant exceptions for classes of grants or recipients subject to the requirements of this part when exceptions are not prohibited by statute. However, in the interest of maximum uniformity, exceptions from the requirements of this part shall be permitted only in unusual circumstances. Federal awarding agencies may apply more restrictive requirements to a class of recipients when approved by OMB. Federal awarding agencies may apply less restrictive requirements when awarding small awards, except for those requirements which are statutory. Exceptions on a case-by-case basis may also be made by Federal awarding agencies.

§ 3019.5 Subawards.

Unless sections of this part specifically exclude subrecipients from coverage, the provisions of this part shall be applied to subrecipients performing work under awards if such subrecipients are institutions of higher education, hospitals or other non-profit organizations. State and local government subrecipients are subject to the provisions of regulations implementing the grants management common rule, "Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Government," codified at 7 CFR part 3016.

Subpart B—Pre-Award Requirements

§ 3019.10 Purpose.

Sections 3019.11 through 3019.17 prescribe forms and instructions and other pre-award matters to be used in applying for Federal awards.

§ 3019.11 Pre-award policies.

(a) *Use of grants and cooperative agreements, and contracts.* In each instance, the Federal awarding agency shall decide on the appropriate award instrument (i.e., grant, cooperative agreement, or contract). The Federal Grant and Cooperative Agreement Act (31 U.S.C. 6301–08) governs the use of grants, cooperative agreements and contracts. A grant or cooperative agreement shall be used only when the principal purpose of a transaction is to accomplish a public purpose of support or stimulation authorized by Federal statute. The statutory criterion for choosing between grants and cooperative agreements is that for the latter, "substantial involvement is expected between the executive agency and the State, local government, or other recipient when carrying out the activity contemplated in the agreement." Contracts shall be used when the principal purpose is acquisition of property or services for the direct benefit or use of the Federal Government.

(b) *Public notice and priority setting.* Federal awarding agencies shall notify the public of its intended funding priorities for discretionary grant programs, unless funding priorities are established by Federal statute.

§ 3019.12 Forms for applying for Federal assistance.

(a) Federal awarding agencies shall comply with the applicable report clearance requirements of 5 CFR part 1320, "Controlling Paperwork Burdens on the Public," with regard to all forms used by the Federal awarding agency in place of or as a supplement to the Standard Form 424 (SF–424) series.

(b) Applicants shall use the SF–424 series or those forms and instructions prescribed by the Federal awarding agency.

(c) For Federal programs covered by E.O. 12372, "Intergovernmental Review of Federal Programs," the applicant shall complete the appropriate sections of the SF–424 (Application for Federal Assistance) indicating whether the application was subject to review by the State Single Point of Contact (SPOC). The name and address of the SPOC for a particular State can be obtained from the Federal awarding agency or the Catalog of Federal Domestic Assistance. The SPOC shall advise the applicant whether the program for which application is made has been selected by that State for review. The U.S. Department of Agriculture procedures implementing E.O. 12372 are found at CFR part 3015.

(d) Federal awarding agencies that do not use the SF–424 form should indicate whether the application is subject to review by the State under E.O. 12372.

§ 3019.13 Debarment and suspension.

Federal awarding agencies and recipients shall comply with the nonprocurement debarment and suspension common rule implementing E.O.s 12549 and 12689, "Debarment and Suspension," codified at 7 CFR 3017. This common rule restricts subawards and contracts with certain parties that are debarred, suspended or otherwise excluded from or ineligible for participation in Federal assistance programs or activities.

§ 3019.14 Special award conditions.

If an applicant or recipient:

(a) Has a history of poor performance,

(b) Is not financially stable,

(c) Has a management system that does not meet the standards prescribed in this part,

(d) Has not conformed to the terms and conditions of a previous award, or

(e) Is not otherwise responsible,

Federal awarding agencies may impose additional requirements as needed, provided that such applicant or recipient is notified in writing as to: the nature of the additional requirements, the reason why the additional requirements are being imposed, the nature of the corrective action needed, the time allowed for completing the corrective actions, and the method for requesting reconsideration of the additional requirements imposed. Any special conditions shall be promptly removed once the conditions that prompted them have been corrected.

§ 3019.15 Metric system for measurement.

The Metric Conversion Act, as amended by the Omnibus Trade and Competitiveness Act (15 U.S.C. 205) declares that the metric system is the preferred measurement system for U.S. trade and commerce. The Act requires each Federal agency to establish a date or dates in consultation with the Secretary of Commerce, when the metric system of measurement will be used in the agency's procurements, grants, and other business-related activities. Metric implementation may take longer where the use of the system is initially impractical or likely to cause significant inefficiencies in the accomplishment of federally-funded activities. Federal awarding agencies shall follow the provisions of E.O. 12770, "Metric Usage in Federal Government Programs."

§ 3019.16 Resource Conservation and Recovery Act.

Under the Resource Conservation and Recovery Act (RCRA) (Pub. L. 94–580 codified at 42 U.S.C. 6962), any State agency or agency of a political subdivision of a State which is using appropriated Federal funds must comply with section 6002. Section 6002 requires that preference be given in procurement programs to the purchase of specific products containing recycled materials identified in guidelines developed by the Environmental Protection Agency (EPA) (40 CFR parts 247–254). Accordingly, State and local institutions of higher education, hospitals, and non-profit organizations that receive direct Federal awards or other Federal funds shall give preference in their procurement programs funded with Federal funds to the purchase of recycled products pursuant to the EPA guidelines.

§ 3019.17 Certifications and representations.

Unless prohibited by statute or codified regulation, each Federal awarding agency is authorized and encouraged to allow recipients to submit certifications and representations required by statute, executive order, or regulation on an annual basis, if the recipients have ongoing and continuing relationships with the agency. Annual certifications and representations shall be signed by responsible officials with the authority to ensure recipients' compliance with the pertinent requirements.

Subpart C—Post-Award Requirements

Financial and Program Management

§ 3019.20 Purpose of financial and program management.

Sections 3019.21 through 3019.28 prescribe standards for financial management systems, methods for making payments and rules for: satisfying cost sharing and matching requirements, accounting for program income, budget revision approvals, making audits, determining allowability of cost, and establishing fund availability.

§ 3019.21 Standards for financial management systems.

(a) Federal awarding agencies shall require recipients to relate financial data to performance data and develop unit cost information whenever practical.

(b) Recipients' financial management systems shall provide for the following.

(1) Accurate, current and complete disclosure of the financial results of each federally-sponsored project or program in accordance with the reporting requirements set forth in § 3019.52. If a Federal awarding agency requires reporting on an accrual basis from a recipient that maintains its records on other than an accrual basis, the recipient shall not be required to establish an accrual accounting system. These recipients may develop such accrual data for its reports on the basis of an analysis of the documentation on hand.

(2) Records that identify adequately the source and application of funds for federally-sponsored activities. These records shall contain information pertaining to Federal awards, authorizations, obligations, unobligated balances, assets, outlays, income and interest.

(3) Effective control over and accountability for all funds, property and other assets. Recipients shall adequately safeguard all such assets and assure they are used solely for authorized purposes.

(4) Comparison of outlays with budget amounts for each award. Whenever appropriate, financial information should be related to performance and unit cost data.

(5) Written procedures to minimize the time elapsing between the transfer of funds to the recipient from the U.S. Treasury and the issuance or redemption of checks, warrants or payments by other means for program purposes by the recipient. To the extent that the provisions of the Cash Management Improvement Act (CMIA) (Pub. L. 101–453) govern, payment methods of State agencies, instrumentalities, and fiscal agents shall be consistent with CMIA Treasury-State Agreements or the CMIA default procedures codified at 31 CFR part 205, "Withdrawal of Cash From the Treasury for Advances Under Federal Grant and Other Programs."

(6) Written procedures for determining the reasonableness, allocability and allowability of costs in accordance with the provisions of the applicable Federal cost principles and the terms and conditions of the award.

(7) Accounting records including cost accounting records that are supported by source documentation.

(c) Where the Federal Government guarantees or insures the repayment of money borrowed by the recipient, the Federal USDA awarding agency, at its discretion, may require adequate bonding and insurance if the bonding and insurance requirements of the recipient are not deemed adequate to protect the interest of the Federal Government.

(d) The Federal awarding agency may require adequate fidelity bond coverage where the recipient lacks sufficient coverage to protect the Federal Government's interest.

(e) Where bonds are required in the situations described in paragraphs (c) and (d) of this section, the bonds shall be obtained from companies holding certificates of authority as acceptable sureties, as prescribed in 31 CFR part 223, "Surety Companies Doing Business With the United States."

§ 3019.22 Payment.

(a) Payment methods shall minimize the time elapsing between the transfer of funds from the United States Treasury and the issuance or redemption of checks, warrants, or payment by other means by the recipients. Payment methods of State agencies or instrumentalities shall be consistent with Treasury-State CMIA agreements or default procedures codified at 31 CFR part 205.

(b) Recipients are to be paid in advance, provided they maintain or demonstrate the willingness to maintain: written procedures that minimize the time elapsing between the transfer of funds and disbursement by the recipient, and financial management systems that meet the standards for fund control and accountability as established in § 3019.21. Cash advances to a recipient organization shall be limited to the minimum amounts needed and be timed to be in accordance with the actual, immediate cash requirements of the recipient organization in carrying out the purpose of the approved program or project. The timing and amount of cash advances shall be as close as is administratively feasible to the actual disbursements by the recipient organization for direct program or project costs and the proportionate share of any allowable indirect costs.

(c) Whenever possible, advances shall be consolidated to cover anticipated cash needs for all awards made by the Federal awarding agency to the recipient.

(1) Advance payment mechanisms include, but are not limited to, Treasury check and electronic funds transfer.

(2) Advance payment mechanisms are subject to 31 CFR part 205.

(3) Recipients shall be authorized to submit requests for advances and reimbursements at least monthly when electronic fund transfers are not used.

(d) Requests for Treasury check advance payment shall be submitted on SF–270, "Request for Advance or Reimbursement," or other forms as may be authorized by OMB. This form is not to be used when Treasury check advance payments are made to the recipient automatically through the use of a predetermined payment schedule or if precluded by special Federal awarding agency instructions for electronic funds transfer.

(e) Reimbursement is the preferred method when the requirements in paragraph (b) of this section cannot be met. Federal awarding agencies may also use this method on any construction agreement, or if the major portion of the construction project is accomplished through private market financing or Federal loans, and the Federal assistance constitutes a minor portion of the project.

(1) When the reimbursement method is used, the Federal awarding agency shall make payment within 30 days after receipt of the billing, unless the billing is improper.

(2) Recipients shall be authorized to submit request for reimbursement at least monthly when electronic funds transfers are not used.

(f) If a recipient cannot meet the criteria for advance payments and the Federal awarding agency has determined that reimbursement is not feasible because the recipient lacks sufficient working capital, the Federal awarding agency may provide cash on a working capital advance basis. Under this procedure, the Federal awarding agency shall advance cash to the recipient to cover its estimated disbursement needs for an initial period generally geared to the awardee's disbursing cycle. Thereafter, the Federal awarding agency shall reimburse the recipient for its actual cash disbursements. The working capital advance method of payment shall not be used for recipients unwilling or unable to provide timely advances to their subrecipient to meet the subrecipient's actual cash disbursements.

(g) To the extent available, recipients shall disburse funds from repayments to and interest earned on a revolving fund, program income, rebates, refunds, contract settlements, audit recoveries and interest earned on such funds before requesting additional cash payments.

(h) Unless otherwise required by statute, Federal awarding agencies shall not withhold payments for proper charges made by recipients at any time during the project period unless paragraphs (h)(1) and (h)(2) of this section apply.

(1) A recipient has failed to comply with the project objectives, the terms and conditions of the award, or Federal reporting requirements.

(2) The recipient or subrecipient is delinquent in a debt to the Untied States as defined in OMB Circular A–129, "Managing Federal Credit Programs."

(3) Under such conditions, the Federal awarding agency may, upon reasonable notice, inform the recipient that payments shall not be made for obligations incurred after a specified date until the conditions are corrected or the indebtedness to the Federal Government is liquidated.

(i) Standards governing the use of banks and other institutions as depositories of funds advanced under awards are as follows.

(1) Except for situations described in paragraph (i)(2) of this section, Federal awarding agencies shall not require separate depository accounts for funds provided to a recipient or establish any eligibility requirements for depositories for funds provided to a recipient. However, recipients must be able to account for the receipt, obligation and expenditure of funds.

(2) Advances of Federal funds shall be deposited and maintained in insured accounts whenever possible.

(j) Consistent with the national goal of expanding the opportunities for women-owned and minority-owned business enterprises, recipients shall be encouraged to use women-owned and minority-owned banks (a bank which is owned at least 50 percent by women or minority group members).

(k) Recipients shall maintain advances of Federal funds in interest bearing accounts, unless paragraphs (k)(1), (k)(2) or (k)(3) of this section apply.

(1) The recipient receives less than $120,000 in Federal awards per year.

(2) The best reasonably available interest bearing account would not be expected to earn interest in excess of $250 per year on Federal cash balances.

(3) The depository would require an average or minimum balance so high that it would not be feasible within the expected Federal and non-Federal cash resources.

(l) For those entities where CMIA and its implementing regulations do not apply, interest earned on Federal advances deposited in interest bearing accounts shall be remitted annually to Department of Health and Human Services, Payment Management System, P.O. Box 6021, Rockville, MD 20852. Interest amounts up to $250 per year may be retained by the recipient for administrative expense. In keeping with the Electronic Funds Transfer rules, (31 CFR Part 206), interest should be remitted to the HHS Payment Management System through an electronic medium such as the FEDWIRE Deposit system. Recipients which do not have this capability should use a check. State universities and hospitals shall comply with CMIA, as it pertains to interest. If an entity subject to CMIA uses its own funds to pay pre-award costs for discretionary awards without prior written approval from the Federal awarding agency, it waives its right to recover the interest under CMIA.

(m) Except as noted elsewhere in this part, only the following forms shall be authorized for the recipients in requesting advances and reimbursements. Federal agencies shall not require more than an original and two copies of these forms.

(1) SF–270, Request for Advance or Reimbursement. Each Federal awarding agency shall adopt the SF–270 as a standard form for all nonconstruction programs when electronic funds transfer or predetermined advance methods are not used. Federal awarding agencies, however, have the option of using this form for construction programs in lieu of the SF–271, "Outlay Report and Request for Reimbursement for Construction Programs."

(2) SF–271, Outlay Report and Request for Reimbursement for Construction Programs. Each Federal awarding agency shall adopt the SF–271 as the standard form to be used for requesting reimbursement for construction programs. However, a Federal awarding agency may substitute the SF–270 when the Federal awarding agency determines that it provides adequate information to meet Federal needs.

§ 3019.23 Cost sharing or matching.

(a) All contributions, including cash and third party in-kind, shall be accepted as part of the recipient's cost sharing or matching when such contributions meet all of the following criteria.

(1) Are verifiable from the recipient's records.

(2) Are not included as contributions for any other federally-assisted project or program.

(3) Are necessary and reasonable for proper and efficient accomplishment of project or program objectives.

(4) Are allowable under the applicable costs principles.

(5) Are not paid by the Federal Government under another award, except where authorized by Federal statute to be used for cost sharing or matching.

(6) Are provided for in the approved budget when required by the Federal awarding agency.

(7) Conform to other provisions of this part, as applicable.

(b) Unrecovered indirect costs may be included as part of cost sharing or matching only with the prior approval of the Federal awarding agency.

(c) Values for recipient contributions of services and property shall be established in accordance with the applicable cost principles. If a Federal awarding agency authorizes recipients to donate buildings or land for construction/facilities acquisition projects or long-term use, the value of the donated property for cost sharing or matching shall be the lesser of paragraphs (c)(1) or (c)(2) of this section.

(1) The certified value of the remaining life of the property recorded in the recipient's accounting records at the time of donation.

(2) The current fair market value. However, when there is sufficient justification, the Federal awarding agency may approve the use of the

current fair market value of the donated property, even if it exceeds the certified value at the time of donation to the project.

(d) Volunteer services furnished by professional and technical personnel, consultants, and other skilled and unskilled labor may be counted as cost sharing or matching if the service is an integral and necessary part of an approved project or program. Rates for volunteer services shall be consistent with those paid for similar work in the recipient's organization. In those instances in which the required skills are not found in the recipient organization, rates shall be consistent with those paid for similar work in the labor market in which the recipient competes for the kind of services involved. In either case, paid fringe benefits that are reasonable, allowable, and allocable may be included in the valuation.

(e) When an employer other than the recipient furnishes the services of an employee, these services shall be valued at the employee's regular rate of pay (plus an amount of fringe benefits that are reasonable, allowable, and allocable, but exclusive of overhead costs), provided these services are in the same skill for which the employee is normally paid.

(f) Donated supplies may include such items as expendable equipment, office supplies, laboratory supplies or workshop and classroom supplies. Value assessed to donated supplies included in the cost sharing or matching share shall be reasonable and shall not exceed the fair market value of the property at the time of the donation.

(g) The method used for determining cost sharing or matching for donated equipment, buildings and land for which title passes to the recipient may differ according to the purpose of the award, if paragraphs (g)(1) or (g)(2) of this section apply.

(1) If the purpose of the award is to assist the recipient in the acquisition of equipment, buildings or land, the total value of the donated property may be claimed as cost sharing or matching.

(2) If the purpose of the award is to support activities that require the use of equipment, buildings or land, normally only depreciation or use charges for equipment and buildings may be made. However, the full value of equipment or other capital assets and fair rental charges for land may be allowed, provided that the Federal awarding agency has approved the charges.

(h) The value of donated property shall be determined in accordance with the usual accounting policies of the recipient, with the following qualifications.

(1) The value of donated land and buildings shall not exceed its fair market value at the time of donation to the recipient as established by an independent appraiser (e.g., certified real property appraiser or General Services Administration representative) and certified by a responsible official of the recipient.

(2) The value of donated equipment shall not exceed the fair market value of equipment of the same age and condition at the time of donation.

(3) The value of donated space shall not exceed the fair rental value of comparable space as established by an independent appraisal of comparable space and facilities in a privately-owned building in the same locality.

(4) The value of loaned equipment shall not exceed its fair rental value.

(5) The following requirements pertain to the recipient's supporting records for in-kind contributions from third parties.

(i) Volunteer services shall be documented and, to the extent feasible, supported by the same methods used by the recipient for its own employees.

(ii) The basis for determining the valuation of personal service, material, equipment, buildings and land shall be documented.

§ 3019.24 Program income.

(a) Federal awarding agencies shall apply the standards set forth in this section in requiring recipient organizations to account for program income related to projects financed in whole or in part with Federal funds.

(b) Except as provided in paragraph (h) of this section, program income earned during the project period shall be retained by the recipient and, in accordance with Federal awarding agency regulations or the terms and conditions of the award, shall be used in one or more of the ways listed in the following.

(1) Added to funds committed to the project by the Federal awarding agency and recipient and used to further eligible project or program objectives.

(2) Used to finance the non-Federal share of the project or program.

(3) Deducted from the total project or program allowable cost in determining the net allowable costs on which the Federal share of costs is based.

(c) When an agency authorizes the disposition of program income as described in paragraphs (b)(1) or (b)(2) of this section, program income in excess of any limits stipulated shall be used in accordance with paragraph (b)(3) of this section.

(d) In the event that the Federal awarding agency does not specify in its regulations or the terms and conditions of the award how program income is to be used, paragraph (b)(3) of this section shall apply automatically to all projects or programs except research. For awards that support research, paragraph (b)(1) of this section shall apply automatically unless the awarding agency indicates in the terms and conditions another alternative on the award or the recipient is subject to special award conditions, as indicated in § 3019.14.

(e) Unless Federal awarding agency regulations or the terms and conditions of the award provide otherwise, recipients shall have no obligation to the Federal Government regarding program income earned after the end of the project period.

(f) If authorized by Federal awarding agency regulations or the terms and conditions of the award, costs incident to the generation of program income may be deducted from gross income to determine program income, provided these costs have not been charged to the award.

(g) Proceeds from the sale of property shall be handled in accordance with the requirements of the Property Standards (See §§ 3019.30 through 3019.37).

(h) Unless Federal awarding agency regulations or the terms and condition of the award provide otherwise, recipients shall have no obligation to the Federal Government with respect to program income earned from license fees and royalties for copyrighted material, patents, patent applications, trademarks, and inventions produced under an award. However, Patent and Trademark Amendments (35 U.S.C. 18) apply to inventions made under an experimental, developmental, or research award.

§ 3019.25 Revision of budget and program plans.

(a) The budget plan is the financial expression of the project or program as approved during the award process. It may include either the Federal and non-Federal share, or only the Federal share, depending upon Federal awarding agency requirements. It shall be related to performance for program evaluation purposes whenever appropriate.

(b) Recipients are required to report deviations from budget and program plans, and request prior approvals for budget and program plan revisions, in accordance with this section.

(c) For nonconstruction awards, recipients shall request prior approvals from Federal awarding agencies for one or more of the following program or budget related reasons.

(1) Change in the scope or the objective of the project or program (even if there is no associated budget revision requiring prior written approval).

(2) Change in a key person specified in the application or award document.

(3) The absence for more than three months, or a 25 percent reduction in time devoted to the project, by the approved project director or principal investigator.

(4) The need for additional Federal funding.

(5) The transfer of amounts budgeted for indirect costs to absorb increases in direct costs, or vice versa, if approval is required by the Federal awarding agency.

(6) The inclusion, unless waived by the Federal awarding agency, of costs that require prior approval in accordance with OMB Circular A–21, "Cost Principles for Institutions of Higher Education," OMB Circular A–122, "Cost Principles for Non-Profit Organizations," or 45 CFR part 74 Appendix E, "Principles for Determining Costs Applicable to Research and Development under Grants and Contracts with Hospitals," or 48 CFR part 31, "Contract Cost Principles and Procedures," as applicable.

(7) The transfer of funds allotted for training allowances (direct payment to trainees) to other categories of expense.

(8) Unless described in the application and funded in the approved awards, the subaward, transfer or contracting out of any work under an award. This provision does not apply to the purchase of supplies, material, equipment or general support services.

(d) No other prior approval requirements for specific items may be imposed unless a deviation has been approved by OMB.

(e) Except for requirements listed in paragraphs (c)(1) and (c)(4) of this section, Federal awarding agencies are authorized, at their option, to waive cost-related and administrative prior written approvals required by this part and OMB Circulars A–21 and A–122. Such waivers may include authorizing recipients to do any one or more of the following.

(1) Incur pre-award costs 90 calendar days prior to award or more than 90 calendar days with the prior approval of the Federal awarding agency. All pre-award costs are incurred at the recipient's risk (i.e., the Federal awarding agency is under no obligation to reimburse such costs if for any reason the recipient does not receive an award or if the award is less than anticipated and inadequate to cover such costs).

(2) Initiate a one-time extension of the expiration date of the award of up to 12 months unless one or more of the following conditions apply. For one-time extensions, the recipient must notify the Federal awarding agency in writing with the supporting reasons and revised expiration date at least 10 days before the expiration date specified in the award. This one-time extension may not be exercised merely for the purpose of using unobligated balances.

(i) The terms and conditions of award prohibit the extension.

(ii) The extension requires additional Federal funds.

(iii) The extension involves any change in the approved objectives or scope of the project.

(3) Carry forward unobligated balances to subsequent funding periods.

(4) For awards that support research, unless the Federal awarding agency provides otherwise in the award or in the agency's regulations, the prior approval requirements described in this paragraph (e) are automatically waived (i.e., recipients need not obtain such prior approvals) unless one of the conditions included in paragraph (e)(2) of this section applies.

(f) The Federal awarding agency may, at its option, restrict the transfer of funds among direct cost categories or programs, functions and activities for awards in which the Federal share of the project exceeds $100,000 and the cumulative amount of such transfers exceeds or is expected to exceed 10 percent of the total budget as last approved by the Federal awarding agency. No Federal awarding agency shall permit a transfer that would cause any Federal appropriation or part thereof to be used for purposes other than those consistent with the original intent of the appropriation.

(g) All other changes to nonconstruction budgets, except for the changes described in paragraph (j) of this section, do not require prior approval.

(h) For construction awards, recipients shall request prior written approval promptly from Federal awarding agencies for budget revisions whenever paragraphs (h)(1), (h)(2) or (h)(3) of this section apply.

(1) The revision results from changes in the scope or the objective of the project or program.

(2) The need arises for additional Federal funds to complete the project.

(3) A revision is desired which involves specific costs for which prior written approval requirements may be imposed consistent with applicable OMB cost principles listed in § 3019.27.

(i) No other prior approval requirements for specific items may be imposed unless a deviation has been approved by OMB.

(j) When a Federal awarding agency makes an award that provides support for both construction and nonconstruction work, the Federal awarding agency may require the recipient to request prior approval from the Federal awarding agency before making any fund or budget transfers between the two types of work supported.

(k) For both construction and nonconstruction awards, Federal awarding agencies shall require recipients to notify the Federal awarding agency in writing promptly whenever the amount of Federal authorized funds is expected to exceed the needs of the recipient for the project period by more than $5000 or five percent of the Federal award, whichever is greater. This notification shall not be required if an application for additional funding is submitted for a continuation award.

(l) When requesting approval for budget revisions, recipients shall use the budget forms that were used in the application unless the Federal awarding agency indicates a letter of request suffices.

(m) Within 30 calendar days from the date of receipt of the request for budget revisions, Federal awarding agencies shall review the request and notify the recipient whether the budget revisions have been approved. If the revision is still under consideration at the end of 30 calendar days, the Federal awarding agency shall inform the recipient in writing of the date when the recipient may expect the decision.

§ 3019.26 Non-Federal audits.

(a) Recipients and subrecipients that are institutions of higher education or other non-profit organizations shall be subject to the audit requirements contained in OMB Circular A–133, "Audits of Institutions of Higher Education and Other Non-Profit Institutions," codified at 7 CFR 3051.

(b) State and local governments shall be subject to the audit requirements contained in the Single Audit Act (31 U.S.C. 7501–7) and Federal awarding agency regulations implementing OMB Circular A–128, "Audits of State and Local Governments."

(c) Hospitals not covered by the audit provisions of OMB Circular A–133 shall be subject to the audit requirements of the Federal awarding agencies.

(d) Commercial organizations shall be subject to the audit requirements of the Federal awarding agency or the prime

recipient as incorporated into the award document.

§ 3019.27 Allowable costs.

For each kind of recipient, there is a set of Federal principles for determining allowable costs. Allowability of costs shall be determined in accordance with the cost principles applicable to the entity incurring the costs. Thus, allowability of costs incurred by State, local or federally-recognized Indian tribal governments is determined in accordance with the provisions of OMB Circular A–87, "Cost Principles for State and Local Governments." The allowability of costs incurred by non-profit organizations is determined in accordance with the provisions of OMB Circular A–122, "Cost Principles for Non-Profit Organizations." The allowability of costs incurred by institutions of higher education is determined in accordance with the provisions of OMB Circular A–21, "Cost Principles for Educational Institutions." The allowability of costs incurred by hospitals is determined in accordance with the provisions of Appendix E of 45 CFR part 74, "Principles for Determining Costs Applicable to Research and Development Under Grants and Contracts with Hospitals." The allowability of costs incurred by commercial organizations and those non-profit organizations listed in Attachment C to Circular A–122 is determined in accordance with the provisions of the Federal Acquisition Regulation (FAR) at 48 CFR part 31.

§ 3019.28 Period of availability of funds.

Where a funding period is specified, a recipient may charge to the grant only allowable costs resulting from obligations incurred during the funding period and any pre-award costs authorized by the Federal awarding agency.

Property Standards

§ 3019.30 Purpose of property standards.

Sections 3019.31 through 3019.37 set forth uniform standards governing management and disposition of property furnished by the Federal Government whose cost was charged to a project supported by a Federal award. Federal awarding agencies shall require recipients to observe these standards under awards and shall not impose additional requirements, unless specifically required by Federal statute. The recipient may use its own property management standards and procedures provided it observes the provisions of §§ 3019.31 through 3019.37.

§ 3019.31 Insurance coverage.

Recipients shall, at a minimum, provide the equivalent insurance coverage for real property and equipment acquired with Federal funds as provided to property owned by the recipient. Federally-owned property need not be insured unless required by the terms and conditions of the award.

§ 3019.32 Real property.

Each Federal awarding agency shall prescribe requirements for recipients concerning the use and disposition of real property acquired in whole or in part under awards. Unless otherwise provided by statute, such requirements, at a minimum, shall contain the following.

(a) Title to real property shall vest in the recipient subject to the condition that the recipient shall use the real property for the authorized purpose of the project as long as it is needed and shall not encumber the property without approval of the Federal awarding agency.

(b) The recipient shall obtain written approval by the Federal awarding agency for the use of real property in other federally-sponsored projects when the recipient determines that the property is no longer needed for the purpose of the original project. Use in other projects shall be limited to those under federally-sponsored projects (i.e., awards) or programs that have purposes consistent with those authorized for support by the Federal awarding agency.

(c) When the real property is no longer needed as provided in paragraphs (a) and (b), the recipient shall request disposition instructions from the Federal awarding agency or its successor Federal awarding agency. The Federal awarding agency shall observe one or more of the following disposition instructions.

(1) The recipient may be permitted to retain title without further obligation to the Federal Government after it compensates the Federal Government for that percentage of the current fair market value of the property attributable to the Federal participation in the project.

(2) The recipient may be directed to sell the property under guidelines provided by the Federal awarding agency and pay the Federal Government for that percentage of the current fair market value of the property attributable to the Federal participation in the project (after deducting actual and reasonable selling and fix-up expenses, if any, from the sales proceeds). When the recipient is authorized or required to sell the property, proper sales procedures shall be established that provide for competition to the extent practicable and result in the highest possible return.

(3) The recipient may be directed to transfer title to the property to the Federal Government or to an eligible third party provided that, in such cases, the recipient shall be entitled to compensation for its attributable percentage of the current fair market value of the property.

§ 3019.33 Federally-owned and exempt property.

(a) Federally-owned property.

(1) Title to federally-owned property remains vested in the Federal Government. Recipients shall submit annually an inventory listing of federally-owned property in their custody to the Federal awarding agency. Upon completion of the award or when the property is no longer needed, the recipient shall report the property to the Federal awarding agency for further Federal agency utilization.

(2) If the Federal awarding agency has no further need for the property, it shall be declared excess and reported to the General Services Administration, unless the Federal awarding agency has statutory authority to dispose of the property by alternative methods (e.g., the authority provided by the Federal Technology Transfer Act (15 U.S.C. 3710(I)) to donate research equipment to educational and non-profit organizations in accordance with E.O. 12821, "Improving Mathematics and Science Education in Support of the National Education Goals"). Appropriate instructions shall be issued to the recipient by the Federal awarding agency.

(b) Exempt property. When statutory authority exists, the Federal awarding agency has the option to vest title to property acquired with Federal funds in the recipient without further obligation to the Federal Government and under conditions the Federal awarding agency considers appropriate. Such property is "exempt property." Should a Federal awarding agency not establish conditions, title to exempt property upon acquisition shall vest in the recipient without further obligation to the Federal Government.

§ 3019.34 Equipment.

(a) Title to equipment acquired by a recipient with Federal funds shall vest in the recipient, subject to conditions of this section.

(b) The recipient shall not use equipment acquired with Federal funds to provide services to non-Federal outside organizations for a fee that is less than private companies charge for

equivalent services, unless specifically authorized by Federal statute, for as long as the Federal Government retains an interest in the equipment.

(c) The recipient shall use the equipment in the project or program for which it was acquired as long as needed, whether or not the project or program continues to be supported by Federal funds and shall not encumber the property without approval of the Federal awarding agency. When no longer needed for the original project or program, the recipient shall use the equipment in connection with its other federally-sponsored activities, in the following order of priority:

(1) Activities sponsored by the Federal awarding agency which funded the original project, then

(2) Activities sponsored by other Federal awarding agencies.

(d) During the time that equipment is used on the project or program for which it was acquired, the recipient shall make it available for use on other projects or programs if such other use will not interfere with the work on the project or program for which the equipment was originally acquired. First preference for such other use shall be given to other projects or programs sponsored by the Federal awarding agency that financed the equipment; second preference shall be given to projects or programs sponsored by other Federal awarding agencies. If the equipment is owned by the Federal Government, use on other activities not sponsored by the Federal Government shall be permissible if authorized by the Federal awarding agency. User charges shall be treated as program income.

(e) When acquiring replacement equipment, the recipient may use the equipment to be replaced as trade-in or sell the equipment and use the proceeds to offset the costs of the replacement equipment subject to the approval of the Federal awarding agency.

(f) The recipient's property management standards for equipment acquired with Federal funds and federally-owned equipment shall include all of the following.

(1) Equipment records shall be maintained accurately and shall include the following information.

(i) A description of the equipment.

(ii) Manufacturer's serial number, model number, Federal stock number, national stock number, or other identification number.

(iii) Source of the equipment, including the award number.

(iv) Whether title vests in the recipient or the Federal Government.

(v) Acquisition date (or date received, if the equipment was furnished by the Federal Government) and cost.

(vi) Information from which one can calculate the percentage of Federal participation in the cost of the equipment (not applicable to equipment furnished by the Federal Government).

(vii) Location and condition of the equipment and the date the information was reported.

(viii) Unit acquisition cost.

(ix) Ultimate disposition data, including date of disposal and sales price or the method used to determine current fair market value where a recipient compensates the Federal awarding agency for its share.

(2) Equipment owned by the Federal Government shall be identified to indicate Federal ownership.

(3) A physical inventory of equipment shall be taken and the results reconciled with the equipment records at least once every two years. Any differences between quantities determined by the physical inspection and those shown in the accounting records shall be investigated to determine the causes of the difference. The recipient shall, in connection with the inventory, verify the existence, current utilization, and continued need for the equipment.

(4) A control system shall be in effect to ensure adequate safeguards to prevent loss, damage, or theft of the equipment. Any loss, damage, or theft of equipment shall be investigated and fully documented; if the equipment was owned by the Federal Government, the recipient shall promptly notify the Federal awarding agency.

(5) Adequate maintenance procedures shall be implemented to keep the equipment in good condition.

(6) Where the recipient is authorized or required to sell the equipment, proper sales procedures shall be established which provide for competition to the extent practicable and result in the highest possible return.

(g) When the recipient no longer needs the equipment, the equipment may be used for other activities in accordance with the following standards. For equipment with a current per unit fair market value of $5000 or more, the recipient may retain the equipment for other uses provided that compensation is made to the original Federal awarding agency or its successor. The amount of compensation shall be computed by applying the percentage of Federal participation in the cost of the original project or program to the current fair market value of the equipment. If the recipient has no need for the equipment, the recipient shall request disposition instructions from the Federal awarding agency. The Federal awarding agency shall determine whether the equipment can be used to meet the agency's requirements. If no requirement exists within that agency, the availability of the equipment shall be reported to the General Services Administration by the Federal awarding agency to determine whether a requirement for the equipment exists in other Federal agencies. The Federal awarding agency shall issue instructions to the recipient no later than 120 calendar days after the recipient's request and the following procedures shall govern.

(1) If so instructed or if disposition instructions are not issued within 120 calendar days after the recipient's request, the recipient shall sell the equipment and reimburse the Federal awarding agency an amount computed by applying to the sales proceeds the percentage of Federal participation in the cost of the original project or program. However, the recipient shall be permitted to deduct and retain from the Federal share $500 or ten percent of the proceeds, whichever is less, for the recipient's selling and handling expenses.

(2) If the recipient is instructed to ship the equipment elsewhere, the recipient shall be reimbursed by the Federal Government by an amount which is computed by applying the percentage of the recipient's participation in the cost of the original project or program to the current fair market value of the equipment, plus any reasonable shipping or interim storage costs incurred.

(3) If the recipient is instructed to otherwise dispose of the equipment, the recipient shall be reimbursed by the Federal awarding agency for such costs incurred in its disposition.

(4) The Federal awarding agency may reserve the right to transfer the title to the Federal Government or to a third party named by the Federal Government when such third party is otherwise eligible under existing statutes. Such transfer shall be subject to the following standards.

(i) The equipment shall be appropriately identified in the award or otherwise made known to the recipient in writing.

(ii) The Federal awarding agency shall issue disposition instructions within 120 calendar days after receipt of a final inventory. The final inventory shall list all equipment acquired with grant funds and federally-owned equipment. If the Federal awarding agency fails to issue disposition instructions within the 120 calendar day period, the recipient shall

apply the standards of this section, as appropriate.

(iii) When the Federal awarding agency exercises its right to take title, the equipment shall be subject to the provisions for federally-owned equipment.

§ 3019.35 Supplies and other expendable property.

(a) Title to supplies and other expendable property shall vest in the recipient upon acquisition. If there is a residual inventory of unused supplies exceeding $5000 in total aggregate value upon termination or completion of the project or program and the supplies are not needed for any other federally-sponsored project or program, the recipient shall retain the supplies for use on non-Federal sponsored activities or sell them, but shall, in either case, compensate the Federal Government for its share. The amount of compensation shall be computed in the same manner as for equipment.

(b) The recipient shall not use supplies acquired with Federal funds to provide services to non-Federal outside organizations for a fee that is less than private companies charge for equivalent services, unless specifically authorized by Federal statute as long as the Federal Government retains an interest in the supplies.

§ 3019.36 Intangible property.

(a) The recipient may copyright any work that is subject to copyright and was developed, or for which ownership was purchased, under an award. The Federal awarding agency(ies) reserve a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use the work for Federal purposes, and to authorize others to do so.

(b) Recipients are subject to applicable regulations governing patents and inventions, including government-wide regulations issued by the Department of Commerce at 37 CFR part 401, "Rights to Inventions Made by Nonprofit Organizations and Small Business Firms Under Government Grants, Contracts and Cooperative Agreements."

(c) Unless waived by the Federal awarding agency, the Federal Government has the right to:

(1) Obtain, reproduce, publish or otherwise use the date first produced under an award, and

(2) Authorize others to receive, reproduce, publish, or otherwise use such data for Federal purposes.

(d) Title to intangible property and debt instruments acquired under an award or subaward vests upon acquisition in the recipient. The recipient shall use that property for the originally-authorized purpose, and the recipient shall not encumber the property without approval of the Federal awarding agency. When no longer needed for the originally authorized purpose, disposition of the intangible property shall occur in accordance with the provisions of § 3019.34(g).

§ 3019.37 Property trust relationship.

Real property, equipment, intangible property and debt instruments that are acquired or improved with Federal funds shall be held in trust by the recipient as trustee for the beneficiaries of the project or program under which the property was acquired or improved. Agencies may require recipients to record liens or other appropriate notices of record to indicate that personal or real property has been acquired or improved with Federal funds and that use and disposition conditions apply to the property.

Procurement Standards

§ 3019.40 Purpose of procurement standards.

Sections 3019.41 through 3019.48 set forth standards for use by recipients in establishing procedures for the procurement of supplies and other expendable property, equipment, real property and other services with Federal funds. These standards are furnished to ensure that such materials and services are obtained in an effective manner and in compliance with the provisions of applicable Federal statutes and executive orders. No additional procurement standards or requirements shall be imposed by the Federal awarding agencies upon recipients, unless specifically required by Federal statute or executive order or approved by OMB.

§ 3019.41 Recipient responsibilities.

The standards contained in this section do not relieve the recipient of the contractual responsibilities arising under its contract(s). The recipient is the responsible authority, without recourse to the Federal awarding agency, regarding the settlement and satisfaction of all contractual and administrative issues arising out of procurements entered into in support of an award or other agreement. This includes disputes, claims, protests of award, source evaluation or other matters of a contractual nature. Matters concerning violation of statute are to be referred to such Federal, State or local authority as may have proper jurisdiction.

§ 3019.42 Codes of conduct.

The recipient shall maintain written standards of conduct governing the performance of its employees engaged in the award and administration of contracts. No employee, officer, or agent shall participate in the selection, award, or administration of a contract supported by Federal funds if a real or apparent conflict of interest would be involved. Such a conflict would arise when the employee, officer, or agent, any member of his or her immediate family, his or her partner, or an organization which employs or is about to employ any of the parties indicated herein, has a financial or other interest in the firm selected for an award. The officers, employees, and agents of the recipient shall neither solicit nor accept gratuities, favors, or anything of monetary value from contractors, or parties to subagreements. However, recipients may set standards for situations in which the financial interest is not substantial or the gift is an unsolicited item of nominal value. The standards of conduct shall provide for disciplinary actions to be applied for violations of such standards by officers, employees, or agents of the recipient.

§ 3019.43 Competition.

All procurement transactions shall be conducted in a manner to provide, to the maximum extent practical, open and free competition. The recipient shall be alert to organizational conflicts of interests as well as noncompetitive practices among contractors that may restrict or eliminate competition or otherwise restrain trade. In order to ensure objective contractor performance and eliminate unfair competitive advantage, contractors that develop or draft specifications, requirements, statements of work, invitations for bids and/or requests for proposals shall be excluded from competing for such procurements. Awards shall be made to the bidder or offeror whose bid or offer is responsive to the solicitation and is most advantageous to the recipient, price, quality and other factors considered. Solicitations shall clearly set forth all requirements that the bidder or offeror shall fulfill in order for the bid or offer to be evaluated by the recipient. Any and all bids or offers may be rejected when it is in the recipient's interest to do so.

§ 3019.44 Procurement procedures.

(a) All recipients shall establish written procurement procedures. These procedures shall provide for, at a minimum, that paragraphs (a)(1), (a)(2), and (a)(3) of this section apply.

(1) Recipients avoid purchasing unnecessary items.

(2) Where appropriate, an analysis is made of lease and purchase alternatives to determine which would be the most economical and practical procurement for the Federal Government.

(3) Solicitations for goods and services provide for all of the following:

(i) A clear and accurate description of the technical requirements for the material, product or service to be procured. In competitive procurements, such a description shall not contain features which unduly restrict competition.

(ii) Requirements which the bidder/offeror must fulfill and all other factors to be used in evaluating bids or proposals.

(iii) A description, whenever practicable, of technical requirements in terms of functions to be performed or performance required, including the range of acceptable characteristics or minimum acceptable standards.

(iv) The specific features of "brand name or equal" descriptions that bidders are required to meet when such items are included in the solicitation.

(v) The acceptance, to the extent practicable and economically feasible, of products and services dimensioned in the metric system of measurement.

(vi) Preference, to the extent practicable and economically feasible, for products and services that conserve natural resources and protect the environment and are energy efficient.

(b) Positive efforts shall be made by recipients to utilize small businesses, minority-owned firms, and women's business enterprises, whenever possible. Recipients of Federal awards shall take all of the following steps to further this goal.

(1) Ensure that small businesses, minority-owned firms, and women's business enterprises are used to the fullest extent practicable.

(2) Make information on forthcoming opportunities available and arrange time frames for purchases and contracts to encourage and facilitate participation by small businesses, minority-owned firms, and women's business enterprises.

(3) Consider in the contract process whether firms competing for larger contracts intend to subcontract with small businesses, minority-owned firms, and women's business enterprises.

(4) Encourage contracting with consortiums of small businesses, minority-owned firms and women's business enterprises when a contract is too large for one of these firms to handle individually.

(5) Use the services and assistance, as appropriate, of such organizations as the Small Business Administration and the Department of Commerce's Minority Business Development Agency in the solicitation and utilization of small businesses, minority-owned firms and women's business enterprises.

(c) The type of procuring instruments used (e.g., fixed price contracts, cost reimbursable contracts, purchase orders, and incentive contracts) shall be determined by the recipient but shall be appropriate for the particular procurement and for promoting the best interest of the program or project involved. The "cost-plus-a-percentage-of-cost" or "percentage of construction cost" methods of contracting shall not be used.

(d) Contracts shall be made only with responsible contractors who possess the potential ability to perform successfully under the term and conditions of the proposed procurement. Consideration shall be given to such matters as contractor integrity, record of past performance, financial and technical resources or accessibility to other necessary resources. In certain circumstances, contracts with certain parties are restricted by agencies' implementation of E.O.s 12549 and 12689, "Debarment and Suspension."

(e) Recipients shall, on request, make available for the Federal awarding agency, pre-award review and procurement documents, such as request for proposals or invitations for bids, independent cost estimates, etc., when any of the following conditions apply.

(1) A recipient's procurement procedures or operation fails to comply with the procurement standards in the Federal awarding agency's implementation of this part.

(2) The procurement is expected to exceed the small purchase threshold fixed at 41 U.S.C. 403(11) (currently $25,000) and is to be awarded without competition or only one bid or offer is received in response to a solicitation.

(3) The procurement, which is expected to exceed the small purchase threshold, specifies a "brand name" product.

(4) The proposed award over the small purchase threshold is to be awarded to other than the apparent low bidder under a sealed bid procurement.

(5) A proposed contract modification changes the scope of a contract or increases the contract amount by more than the amount of the small purchase threshold.

§ 3019.46 Cost and price analysis.

Some form of cost or price analysis shall be made and documented in the procurement files in connection with every procurement action. Price analysis may be accomplished in various ways, including the comparison of price quotations submitted, market prices and similar indicia, together with discounts. Cost analysis is the review and evaluation of each element of cost to determine reasonableness, allocability and allowability.

§ 3019.46 Procurement records.

Procurement records and files for purchases in excess of the small purchase threshold shall include the following at a minimum:

(a) Basis for contractor selection,

(b) Justification for lack of competition bids or offers are not obtained, and

(c) Basis for award cost or price.

§ 3019.47 Contract administration.

A system for contract administration shall be maintained to ensure contractor conformance with the terms, conditions and specifications of the contract and to ensure adequate and timely follow up of all purchases. Recipients shall evaluate contractor performance and document, as appropriate, whether contractors have met the terms, conditions and specifications of the contract.

§ 3019.48 Contract provisions.

The recipient shall include, in addition to provisions to define a sound and complete agreement, the following provisions in all contracts. The following provisions shall also be applied to subcontracts.

(a) Contracts in excess of the small purchase threshold shall contain contractual provisions or conditions that allow for administrative, contractual, or legal remedies in instances in which a contractor violates or breaches the contract terms, and provide for such remedial actions as may be appropriate.

(b) All contracts in excess of the small purchase threshold shall contain suitable provisions for termination by the recipient, including the manner by which termination shall be effected and the basis for settlement. In addition, such contracts shall describe conditions under which the contract may be terminated for default as well as conditions where the contract may be terminated because of circumstances beyond the control of the contractor.

(c) Except as otherwise required by statute, an award that requires the contracting (or subcontracting) for construction or facility improvements shall provide for the recipient to follow its own requirements relating to bid guarantees, performance bonds, and payment bonds unless the construction

contract or subcontract exceeds $100,00. For those contracts or subcontracts exceeding $100,000, the Federal awarding agency may accept the bonding policy and requirements of the recipient, provided the Federal awarding agency has made a determination that the Federal Government's interest is adequately protected. If such a determination has not been made, the minimum requirements shall be as follows.

(1) A bid guarantee from each bidder equivalent to five percent of the bid price. The "bid guarantee" shall consist of a firm commitment such as a bid bond, certified check, or other negotiable instrument accompanying a bid as assurance that the bidder shall, upon acceptance of his bid, execute such contractual documents as may be required within the time specified.

(2) A performance bond on the part of the contractor for 100 percent of the contract price. A "performance bond" is one executed in connection with a contract to secure fulfillment of all the contractor's obligations under such contract.

(3) A payment bond on the part of the contractor for 100 percent of the contract price. A "payment bond" is one executed in connection with a contract to assure payment as required by statute of all persons supplying labor and material in the execution of the work provided for in the contract.

(4) Where bonds are required in the situations described herein, the bonds shall be obtained from companies holding certificates of authority as acceptable sureties pursuant to 31 CFR part 223, "Surety Companies Doing Business with the United States."

(d) All negotiated contracts (except those for less than the small purchase threshold) awarded by recipients shall include a provision to the effect that the recipient, the Federal awarding agency, the Comptroller General of the United States, or any of their duly authorized representatives, shall have access to any books, documents, papers and records of the contractor which are directly pertinent to a specific program for the purpose of making audits, examinations, excerpts and transcriptions.

(e) All contracts, including small purchases, awarded by recipients and their contractors shall contain the procurement provisions of Appendix A to this part, as applicable.

Reports and Records

§ 3019.50 Purpose of reports and records.

Sections 3019.51 through 3019.53 set forth the procedures for monitoring and reporting on the recipient's financial and program performance and the necessary standard reporting forms. They also set forth record retention requirements.

§ 3019.51 Monitoring and reporting program performance.

(a) Recipients are responsible for managing and monitoring each project, program, subaward, function or activity supported by the award. Recipients shall monitor subawards to ensure subrecipients have met the audit requirements as delineated in Section 3019.26.

(b) The Federal awarding agency shall prescribe the frequency with which the performance reports shall be submitted. Except as provided in paragraph (f) of this section, performance reports shall not be required more frequently than quarterly or, less frequently than annually. Annual reports shall be due 90 calendar days after the grant year; quarterly or semi-annual reports shall be due 30 days after the reporting period. The Federal awarding agency may require annual reports before the anniversary dates of multiple years awards in lieu of these requirements. The final performance reports are due 90 calendar days after the expiration or termination of the award.

(c) If inappropriate, a final technical or performance report shall not be required after completion of the project.

(d) When required, performance reports shall generally contain, for each award, brief information on each of the following.

(1) A comparison of actual accomplishments with the goals and objectives established for the period, the findings of the investigator, or both. Whenever appropriate and the output of programs or projects can be readily quantified, such quantitative data should be related to cost data for computation of unit costs.

(2) Reasons why established goals were not met, if appropriate.

(3) Other pertinent information including, when appropriate, analysis and explanation of cost overruns or high unit costs.

(e) Recipients shall not be required to submit more than the original and two copies of performance reports.

(f) Recipients shall immediately notify the Federal awarding agency of developments that have a significant impact on the award-supported activities. Also, notification shall be given in the case of problems, delays, or adverse conditions which materially impair the ability to meet the objectives of the award. This notification shall include a statement of the action taken or contemplated, and any assistance needed to resolve the situation.

(g) Federal awarding agencies may make site visits, as needed.

(h) Federal awarding agencies shall comply with clearance requirements of 5 CFR part 1320 when requesting performance data from recipients.

§ 3019.52 Financial reporting.

(a) The following forms or such other forms as may be approved by OMB are authorized for obtaining financial information from recipients.

(1) SF–269 or SF–269A, Financial Status Report.

(i) Each Federal awarding agency shall require recipients to use the SF–269 or SF–269A to report the status of funds for all nonconstruction projects or programs. A Federal awarding agency may, however, have the option of not requiring the SF–269 or SF–269A when the SF–270, Request for Advance or Reimbursement, or SF–272, Report of Federal Cash Transactions, is determined to provided adequate information to meet its needs, except that a final SF–269 or SF–269A shall be required at the completion of the project when the SF–270 is used only for advances.

(ii) The Federal awarding agency shall prescribe whether the report shall be on a cash or accrual basis. If the Federal awarding agency requires accrual information and the recipient's accounting records are not normally kept on the accrual basis, the recipient shall not be required to convert its accounting system, but shall develop such accrual information through best estimates based on an analysis of the documentation on hand.

(iii) The Federal awarding agency shall determine the frequency of the Financial Status Report for each project or program, considering the size and complexity of the particular project or program. However, the report shall not be required more frequently than quarterly or less frequently than annually. A final report shall be required at the completion of the agreement.

(iv) The Federal awarding agency shall require recipients to submit the SF–269 or SF–269A (an original and no more than two copies no later than 30 days after the end of each specified reporting period for quarterly and semi-annual reports, and 90 calendar days for annual and final reports. Extensions of reporting due dates may be approved by the Federal awarding agency upon request of the recipient.

(2) SF–272, Report of Federal Cash Transactions.

(i) When funds are advanced to recipients the Federal awarding agency shall require each recipient to submit the SF–272 and, when necessary, its continuation sheet, SF–272a. The Federal awarding agency shall use this report to monitor cash advanced to recipients and to obtain disbursement information for each agreement with the recipients.

(ii) Federal awarding agencies may require forecasts of Federal cash requirements in the "Remarks" section of the report.

(iii) When practical and deemed necessary, Federal awarding agencies may require recipients to report in the "Remarks" section the amount of cash advances received in excess of three days. Recipients shall provide short narrative explanations of actions taken to reduce the excess balances.

(iv) Recipients shall be required to submit not more than the original and two copies of the SF–272 15 calendar days following the end of each quarter. The Federal awarding agencies may require a monthly report from those recipients receiving advances totaling $1 million or more per year.

(v) Federal awarding agencies may waive the requirement for submission of the SF–272 for any one of the following reasons:

(A) When monthly advances do not exceed $25,000 per recipient, provided that such advances are monitored through other forms contained in this section;

(B) If, in the Federal awarding agency's opinion, the recipient's accounting controls are adequate to minimize excessive Federal advances; or

(C) When the electronic payment mechanisms provide adequate data.

(b) When the Federal awarding agency needs additional information or more frequent reports, the following shall be observed.

(1) When additional information is needed to comply with legislative requirements, Federal awarding agencies shall issue instructions to require recipients to submit such information under the "Remarks" section of the reports.

(2) When a Federal awarding agency determines that a recipient's accounting system does not meet the standards in § 3019.21, additional pertinent information to further monitor awards may be obtained upon written notice to the recipient until such time as the system is brought up to standard. The Federal awarding agency, in obtaining this information, shall comply with report clearance requirements of 5 CFR part 1320.

(3) Federal awarding agencies are encouraged to shade out any line item on any report if not necessary.

(4) Federal awarding agencies may accept the identical information from the recipients in machine readable format or computer printouts or electronic outputs in lieu of prescribed formats.

(5) Federal awarding agencies may provide computer or electronic outputs to recipients when such expedites or contributes to the accuracy of reporting.

§ 3019.53 Retention and access requirements for records.

(a) This section sets forth requirements for record retention and access to records for awards to recipients. Federal awarding agencies shall not impose any other record retention or access requirements upon recipients.

(b) Financial records, supporting documents, statistical records, and all other records pertinent to an award shall be retained for a period of three years from the date of submission of the final expenditure report or, for awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report, as authorized by the Federal awarding agency. The only exceptions are the following.

(1) If any litigation, claim, or audit is started before the expiration of the 3-year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

(2) Records for real property and equipment acquired with Federal funds shall be retained for 3 years after final disposition.

(3) When records are transferred to or maintained by the Federal awarding agency, the 3-year retention requirement is not applicable to the recipient.

(4) Indirect cost rate proposals, cost allocations plans, etc. as specified in paragraph (g) of this section.

(c) Copies of original records may be substituted for the original records if authorized by the Federal awarding agency.

(d) The Federal awarding agency shall request transfer of certain records to its custody from recipients when it determines that the records possess long term retention value. However, in order to avoid duplicate recordkeeping, a Federal awarding agency may make arrangements for recipients to retain any records that are continuously needed for joint use.

(e) The Federal awarding agency, the Inspector General, Comptroller General of the United States, or any of their duly authorized representatives, have the right of timely and unrestricted access to any books, documents, papers, or other records of recipients that are pertinent to the awards, in order to make audits, examinations, excerpts, transcripts and copies of such documents. This right also includes timely and reasonable access to a recipient's personnel for the purpose of interview and discussion related to such documents. The rights of access in this paragraph are not limited to the required retention period, but shall last as long as records are retained.

(f) Unless required by statute, no Federal awarding agency shall place restrictions on receipts that limit public access to the records of recipients that are pertinent to an award, except when the Federal awarding agency can demonstrate that such records shall be kept confidential and would have been exempted from disclosure pursuant to the Freedom of Information Act (5 U.S.C. 552) if the records had belonged to the Federal awarding agency.

(g) Indirect cost rate proposals, cost allocations plans, etc. Paragraphs (g)(1) and (g)(2) of this section apply to the following types of documents, and their supporting records: indirect cost rate computations or proposals, cost allocation plans, and any similar accounting computations of the rate at which a particular group of costs is chargeable (such as computer usage chargeback rates or composite fringe benefit rates).

(1) If submitted for negotiation. If the recipient submits to the Federal awarding agency or the subrecipient submits to the recipient the proposal, plan, or other computation to form the basis for negotiation of the rate, then the 3-year retention period for its supporting records starts on the date of such submission.

(2) If not submitted for negotiation. If the recipient is not required to submit to the Federal awarding agency or the subrecipient is not required to submit to the recipient the proposal, plan, or other computation for negotiation purposes, then the 3-year retention period for the proposal, plan, or other computation and its supporting records starts at the end of the fiscal year (or other accounting period) covered by the proposal, plan, or other computation.

Termination and Enforcement

§ 3019.60 Purpose of termination and enforcement.

Sections 3019.61 and 3019.62 set forth uniform suspension, termination and enforcement procedures.

§ 3019.61 Termination.

(a) Awards may be terminated in whole or in part only if paragraphs (a)(1), (a)(2) or (a)(3) of this section apply.

(1) By the Federal awarding agency, if a recipient materially fails to comply with the terms and conditions of an award.

(2) By the Federal awarding agency with the consent of the recipient, in which case the two parties shall agree upon the termination conditions, including the effective date and, in the case of partial termination, the portion to be terminated.

(3) By the recipient upon sending to the Federal awarding agency written notification setting forth the reasons for such termination, the effective date, and, in the case of partial termination, the portion to be terminated. However, if the Federal awarding agency determines in the case of partial termination that the reduced or modified portion of the grant will not accomplish the purposes for which the grant was made, it may terminate the grant in its entirety under either paragraphs (a)(1) or (2) of this section.

(b) If costs are allowed under an award, the responsibilities of the recipient referred to in § 3019.71(a), including those for property management as applicable, shall be considered in the termination of the award, and provision shall be made for continuing responsibilities of the recipient after termination, as appropriate.

§ 3019.62 Enforcement.

(a) *Remedies for noncompliance.* If a recipient materially fails to comply with the terms and conditions of an award, whether stated in a Federal statute, regulation, assurance, application, or notice of award, the Federal awarding agency may, in addition to imposing any of the special conditions outlined in § 3019.14, take one or more of the following actions, as appropriate in the circumstances.

(1) Temporarily withhold cash payments pending correction of the deficiency by the recipient or more severe enforcement action by the Federal awarding agency.

(2) Disallow (that is, deny both use of funds and any applicable matching credit for) all or part of the cost of the activity or action not in compliance.

(3) Wholly or partly suspend or terminate the current award.

(4) Withhold further awards for the project or program.

(5) Take other remedies that may be legally available.

(b) *Hearings and appeals.* In taking an enforcement action, the awarding agency shall provide the recipient an opportunity for hearing, appeal, or other administrative proceeding to which the recipient is entitled under any statute or regulation applicable to the action involved.

(c) *Effects of suspension and termination.* Costs of a recipient resulting from obligations incurred by the recipient during a suspension or after termination of an award are not allowable unless the awarding agency expressly authorizes them in the notice of suspension of termination or subsequently. Other recipient costs during suspension or after termination which are necessary and not reasonably avoidable are allowable if paragraphs (c)(1) and (c)(2) of this section apply.

(1) The costs result from obligations which were properly incurred by the recipient before the effective date of suspension or termination, are not in anticipation of it, and in the case of a termination, are noncancellable.

(2) The costs would be allowable if the award were not suspended or expired normally at the end of the funding period in which the termination takes effect.

(d) *Relationship to debarment and suspension.* The enforcement remedies identified in this section, including suspension and termination, do not preclude a recipient from being subject to debarment and suspension under E.O.s 12549 and 12689 and the Federal awarding agency implementing regulations (see § 3019.13).

Subpart D—After-the-Award Requirements

§ 3019.70 Purpose.

Sections 3019.71 through 3019.73 contain closeout procedures and other procedures for subsequent disallowances and adjustments.

§ 3019.71 Closeout procedures.

(a) Recipients shall submit, within 90 calendar days after the date of completion of the award, all financial, performance, and other reports as required by the terms and conditions of the award. The Federal awarding agency may approve extensions when requested by the recipient.

(b) Unless the Federal awarding agency authorizes an extension, a recipient shall liquidate all obligations incurred under the award not later than 90 calendar days after the funding period or the date of completion as specified in the terms and conditions of the award or in agency implementing instructions.

(c) The Federal awarding agency shall make prompt payments to a recipient for allowable reimbursable costs under the award being closed out.

(d) The recipient shall promptly refund any balances of unobligated cash that the Federal awarding agency has advanced or paid and that is not authorized to be retained by the recipient for use in other projects. OMB Circular A–129 governs unreturned amounts that become delinquent debts.

(e) When authorized by the terms and conditions of the award, the Federal awarding agency shall make a settlement for any upward or downward adjustments to the Federal share of costs after closeout reports are received.

(f) The recipient shall account for any real and personal property acquired with Federal funds or received from the Federal Government in accordance with §§ 3019.31 through 3019.37.

(g) In the event a final audit has not been performed prior to the closeout of an award, the Federal awarding agency shall retain the right to recover an appropriate amount after fully considering the recommendations on disallowed costs resulting from the final audit.

§ 3019.72 Subsequent adjustments and continuing responsibilities.

(a) The closeout of an award does not affect any of the following.

(1) The right of the Federal awarding agency to disallow costs and recover funds on the basis of a later audit or other review.

(2) The obligation of the recipient to return any funds due as a result of later refunds, corrections, or other transactions.

(3) Audit requirements in § 3019.26.

(4) Property management requirements in §§ 3019.31 through 3019.37.

(5) Records retention as required in § 3019.53.

(b) After closeout of an award, a relationship created under an award may be modified or ended in whole or in part with the consent of the Federal awarding agency and the recipient, provided the responsibilities of the recipient referred to in § 3019.73(a), including those for property management as applicable, are considered and provisions made for continuing responsibilities of the recipient, as appropriate.

§ 3019.73 Collection of amounts due.

(a) Any funds paid to a recipient in excess of the amount to which the recipient is finally determined to be entitled under the terms and conditions of the award constitute a debt to the

Federal Government. If not paid within a reasonable period after the demand for payment, the Federal awarding agency may reduce the debt by:

(1) Making an administrative offset against other requests for reimbursements.

(2) Withholding advance payments otherwise due to the recipient.

(3) Taking other action permitted by statute.

(b) Except as otherwise provided by law, the Federal awarding agency shall charge interest on an overdue debt in accordance with 4 CFR Chapter II, "Federal Claims Collection Standards."

Appendix A—Contract Provisions

All contracts, awarded by a recipient including small purchases, shall contain the following provisions as applicable:

1. *Equal Employment Opportunity*—All contracts shall contain a provision requiring compliance with E.O. 11246, "Equal Employment Opportunity," as amended by E.O. 11375, "Amending Executive Order 11246 Relating to Equal Employment Opportunity," and as supplemented by regulations at 41 CFR part 60, "Office of Federal Contract Compliance Programs, Equal Employment Opportunity, Department of Labor."

2. *Copeland "Anti-Kickback" Act (18 U.S.C. 874 and 40 U.S.C. 276c)*—All contracts and subgrants in excess of $2000 for construction or repair awarded by recipients and subrecipients shall include a provision for compliance with the Copeland "Anti-Kickback" Act (18 U.S.C. 874), as supplemented by Department of Labor regulations (29 CFR part 3, "Contractors and Subcontractors on Public Building or Public Work Financed in Whole or in Part by Loans or Grants from the United States"). The Act provides that each contractor or subrecipient shall be prohibited from inducing, by any means, any person employed in the construction, completion, or repair of public work, to give up any part of the compensation to which he is otherwise entitled. The recipient shall report all suspected or reported violations to the Federal awarding agency.

3. *Davis-Bacon Act, as amended (40 U.S.C. 276a to a–7)*—When required by Federal program legislation, all construction contracts awarded by the recipients and subrecipients of more than $2000 shall include a provision for compliance with the Davis-Bacon Act (40 U.S.C. 276a to a–7) and as supplemented by Department of Labor regulations (29 CFR part 5, "Labor Standards Provisions Applicable to Contracts Governing Federally Financed and Assisted Construction"). Under this Act, contractors shall be required to pay wages to laborers and mechanics at a rate not less than the minimum wages specified in a wage determination made by the Secretary of Labor. In addition, contractors shall be required to pay wages not less than once a week. The recipient shall place a copy of the current prevailing wage determination issued by the Department of Labor in each solicitation and the award of a contract shall be conditioned upon the acceptance of the wage determination. The recipient shall report all suspected or reported violations to the Federal awarding agency.

4. *Contract Work Hours and Safety Standards Act (40 U.S.C. 327–333)*—Where applicable, all contracts awarded by recipients in excess of $2000 for construction contracts and in excess of $2500 for other contracts that involve the employment of mechanics or laborers shall include a provision for compliance with Sections 102 and 107 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 327–333), as supplemented by Department of Labor regulations (29 CFR part 5). Under Section 102 of the Act, each contractor shall be required to compute the wages of every mechanic and laborer on the basis of a standard work week of 40 hours. Work in excess of the standard work week is permissible provided that the worker is compensated at a rate of not less than 1½ times the basic rate of pay for all hours worked in excess of 40 hours in the work week. Section 107 of the Act is applicable to construction work and provides that no laborer or mechanic shall be required to work in surroundings or under working conditions which are unsanitary, hazardous or dangerous. These requirements do not apply to the purchases of supplies or materials or articles ordinarily available on the open market, or contracts for transportation or transmission of intelligence.

5. *Rights to Inventions Made Under a Contract or Agreement*—Contracts or agreements for the performance of experimental, developmental, or research work shall provide for the rights of the Federal Government and the recipient in any resulting invention in accordance with 37 CFR part 401, "Rights to Inventions Made by Nonprofit Organizations and Small Business Firms Under Government Grants, Contracts and Cooperative Agreements," and any implementing regulations issued by the awarding agency.

6. *Clean Air Act (42 U.S.C. 7401 et. seq.) and the Federal Water Pollution Control Act (33 U.S.C. 1251 et seq.)*, as amended—Contracts and subgrants of amounts in excess of $100,000 shall contain a provision that requires the recipient to agree to comply with all applicable standards, orders or regulations issued pursuant to the Clean Air Act (42 U.S.C. 7401 et seq.) and the Federal Water Pollution Control Act as amended (33 U.S.C. 1251 et seq.). Violations shall be reported to the Federal awarding agency and the Regional Office of the Environmental Protection Agency (EPA).

7. *Byrd Anti-Lobbying Amendment (31 U.S.C. 1352)*—Contractors who apply or bid for an award of $100,000 or more shall file the required certification. Each tier certifies to the tier above that it will not and has not used Federal appropriated funds to pay any person or organization for influencing or attempting to influence an officer or employee of any agency, a member of Congress, officer or employee of Congress, or an employee of a member of Congress in connection with obtaining any Federal contract, grant or any other award covered by 31 U.S.C. 1352. Each tier shall also disclose any lobbying with non-Federal funds that takes place in connection with obtaining any Federal award. Such disclosures are forwarded from tier to tier up to the recipient.

8. *Debarment and Suspension (E.O.s 12549 and 12689)*—All parties doing business with the Department of Agriculture should consult the Department's regulations for debarment and suspension found at 7 CFR 3017. No contract shall be made to parties listed on the General Services Administration's List of Parties Excluded from Federal Procurement or Nonprocurement Programs in accordance with E.O.s 12549 and 12689, "Debarment and Suspension." This list contains the names of parties debarred, suspended, or otherwise excluded by agencies, and contractors declared ineligible under statutory or regulatory authority other than E.O. 12549. Contractors with awards that exceed the small purchase threshold shall provide the required certification regarding its exclusion status and that of its principal employees.

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federal register

Thursday
August 24, 1995

Part III

Department of Transportation

Federal Aviation Administration

14 CFR Chapter I
Review of Existing Rules; Proposed Ruie

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Chapter I

[Docket No. 28311]

Review of Existing Rules

AGENCY: Federal Aviation Administration, DOT.

ACTION: Proposed Regulatory Review Program; Request for comments.

SUMMARY: To make the regulatory process more responsive to the needs of the public and regulated industry, the FAA has included in its strategic plan to undertake periodic reviews of its existing regulations. This document sets forth the Federal Aviation Administration's (FAA) plan to perform future reviews and solicits comments.

DATES: Comments concerning this program must be received on or before November 22, 1995.

ADDRESSES: Send comments on this notice in triplicate, to: Federal Aviation Administration, Office of Chief Counsel, Attention: Rules Docket (AGC–200), Docket No. 28311, 800 Independence Avenue, SW., Washington, DC, 20591, or faxed to (202) 267–7257. Comments also may be submitted via the Internet to nprmcmts@mail.hq.faa.gov.

FOR FURTHER INFORMATION CONTACT: Chris A. Christie, Director, Office of Rulemaking, 800 Independence Ave., SW., Washington, DC 20591, telephone (202) 267–9677.

SUPPLEMENTARY INFORMATION: In recent years, the FAA has conducted several regulatory reviews.

On January 10, 1994, the FAA published in the **Federal Register** (59 FR 1362) a notice that it was initiating a short-term regulatory review in response to a recommendation from the President's National Commission to Ensure a Strong Competitive Airline Industry. The notice requested each commenter to limit himself/herself in identifying only the top three issues/regulations/or problems that needed attention. In response to this notice, the FAA received more than 400 comments from 184 commenters. The agency reviewed, analyzed, published a summary and disposition of all comments, and revised its regulatory agenda based on them.

Similarly, in early 1992, pursuant to an Executive Order issued by then-President Bush, the Department of Transportation (DOT) and each of its modal administrations reviewed all existing regulations. Following a solicitation for public comments published in the **Federal Register** (57 FR 4744, February 7, 1992), the FAA received more than 300 comments from 30 commenters. The agency reviewed the Federal Aviation Regulations taking into consideration the comments received and revised its regulatory agenda and priorities accordingly.

Our experience with the above two reviews has shown that there is great value in obtaining public input to the agency's regulatory agenda and priorities regardless of whether such input is an affirmation of the direction the agency is going or an indication of a need to alter course. A public agency must keep itself informed of public need as well as the impact its activities have on those regulated. For the reasons stated, the FAA would like to continue to obtain public input on its regulatory agenda and priorities. Accordingly, the agency intends to, on a periodic basis, request public comments for the purpose of assistance in determining its future regulatory agenda and priorities. In both the 1992 and 1994 efforts, the agency determined the public deserved some type of response by the agency to its comments. As a result, in each case, the FAA published a summary of the comments received with an agency disposition of each comment. The summary, analysis, and disposition proved to be resource intensive. Since the agency's resources are limited, the expenditure of resources in such reviews must be kept under control if they are not to have a negative impact on our efforts to keep regulations current. In addition, rulemaking actions normally require anywhere from 18 to 36 months to complete. For these reasons, the FAA proposes to hold such reviews every 3 years, and as in the 1994 review limit the commenters input to the three issues he/she considers most urgent.

FAA Plan for Periodic Regulatory Reviews

Beginning January 1997, and every 3 years thereafter, the FAA proposes to conduct comprehensive regulatory reviews. The review will be initiated with a published announcement in the **Federal Register** inviting the public to identify those regulations, issues, or subject areas that should be reviewed by the FAA. In order to focus on those areas of greatest interest and to effectively manage agency resources, commenters will be expected to limit their input to the three issues they consider most urgent. The FAA will review the issues addressed by the commenters against its regulatory agenda and rulemaking program efforts, and adjust its regulatory priorities consistent with its statutory authority and responsibilities.

At the end of this process, the FAA will publish a summary and general disposition of the comments and indicate, where appropriate, how its regulatory priorities will be adjusted.

Comments Invited

The FAA is currently soliciting comments on this periodic regulatory review plan. Specifically, the FAA would like to receive comment on:

1. The frequency of the reviews (i.e., every 3 years);
2. The method for concluding the review (publication of a document containing the summary and disposition of comments received); and
3. Limiting each commenter in identifying the three most important issues or areas that he/she believes are appropriate for attention.

The FAA seeks comments on the above issues to facilitate the adoption of a continuing regulatory review process that is responsive to concerns raised by the public, assists the agency in setting its priorities for future regulatory action, and considers available regulatory resources.

Issued in Washington, DC, on August 18, 1995.

Anthony J. Broderick,

Associate Administrator for Regulation and Certification.

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federal register

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August 24, 1995

Part IV

Federal Reserve System

Department of the Treasury
31 CFR Part 103
Bank Secrecy Act Regulations; Final Rule and Proposed Rule

Federal Reserve System

12 CFR Part 219
Reimbursement for Providing Financial Records; Recordkeeping Requirements for Certain Financial Records; Final Rule

Department of the Treasury

31 CFR Part 103
Bank Secrecy Act Regulations; Final Rule and Proposed Rule

FEDERAL RESERVE SYSTEM

[Docket No. R–0807]

DEPARTMENT OF THE TREASURY

31 CFR Part 103

RIN 1506–AA16

Amendment to the Bank Secrecy Act Regulations Relating to Recordkeeping for Funds Transfers and Transmittals of Funds by Financial Institutions

AGENCY: Board of Governors of the Federal Reserve System; Department of the Treasury.

ACTION: Joint final rule; delay of effective date.

SUMMARY: On January 3, 1995, the Financial Crimes Enforcement Network (FinCEN) of the Department of the Treasury (Treasury) and the Board of Governors of the Federal Reserve System (Board) jointly published a final rule that requires enhanced recordkeeping related to certain funds transfers and transmittals of funds by financial institutions, effective January 1, 1996. (60 FR 220). The Treasury and the Board have delayed the effective date of the joint final rule until April 1, 1996, because of the uncertainty by financial institutions as to their responsibilities under the joint final rule with respect to international transfers pending final action on proposed amendments to the rule, which are published elsewhere in today's **Federal Register**.

EFFECTIVE DATES: Effective August 24, 1995, the effective date of the joint final rule published on January 3, 1995, at 60 FR 220, is delayed until April 1, 1996.

FOR FURTHER INFORMATION CONTACT:

Treasury: Roger Weiner, Assistant Director, 202/622–0400; Stephen R. Kroll, Legal Counsel, 703/905–3534; or Nina A. Nichols, Attorney-Advisor, 703/905–3598, FinCEN.

Board: Louise L. Roseman, Associate Director, 202/452–2789; Gayle Brett, Manager, Fedwire Section, 202/452–2934; Division of Reserve Bank Operations and Payment Systems; Oliver Ireland, Associate General Counsel, 202/452–3625; or Elaine Boutilier, Senior Counsel 202/452–2418, Legal Division, Board of Governors of the Federal Reserve System. For the hearing impaired only, Telecommunication Device for the Deaf (TDD), Dorothea Thompson, 202/452–3544.

The effective date of the joint final rule published by the Board and Treasury at 60 FR 220, January 3, 1995, is delayed for three months from January 1, 1996 to April 1, 1996.

In concurrence:

By the Board of Governors of the Federal Reserve System, August 17, 1995.

William W. Wiles,

Secretary to the Board.

By the Department of the Treasury,
Dated: July 31, 1995.

Stanley E. Morris,

Director, Financial Crimes Enforcement Network.

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BILLING CODES: 6210–01–P, 4820–03–P

FEDERAL RESERVE SYSTEM

12 CFR Part 219

[Regulation S; Docket No. R–0807]

Reimbursement for Providing Financial Records; Recordkeeping Requirements for Certain Financial Records

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule; delay of effective date.

SUMMARY: On January 3, 1995, the Board of Governors of the Federal Reserve System (Board) published a final rule that established Subpart B of Regulation S (60 FR 231), which cross-references the substantive provisions of a joint rule adopted by the Board and the Department of the Treasury on the same day. The joint rule requires enhanced recordkeeping related to certain funds transfers and transmittals of funds by financial institutions. The Board and the Department of the Treasury have delayed the effective date of the joint final rule until April 1, 1996, because of the uncertainty by financial institutions as to their responsibilities under the joint final rule with respect to international transfers pending final action on proposed amendments to the rule, which are published elsewhere in today's **Federal Register**. Because Subpart B of Regulation S relies on the joint final rule for its substantive provisions, its effective date is also delayed until April 1, 1996.

EFFECTIVE DATES: Effective August 24, 1995, the effective date of the final rule published on January 3, 1995, at 60 FR 231, is delayed until April 1, 1996.

FOR FURTHER INFORMATION CONTACT: Louise L. Roseman, Associate Director, 202/452–2789; Gayle Brett, Manager, Fedwire Section, 202/452–2934; Division of Reserve Bank Operations and Payment Systems; Oliver Ireland, Associate General Counsel, 202/452–3625; or Elaine Boutilier, Senior Counsel 202/452–2418, Legal Division, Board of Governors of the Federal Reserve System. For the hearing impaired only, Telecommunication Device for the Deaf (TDD), Dorothea Thompson, 202/452–3544.

The effective date of the final rule published by the Board at 60 FR 231, January 3, 1995, is delayed for three months from January 1, 1996, to April 1, 1996.

By the Board of Governors of the Federal Reserve System, August 17, 1995.

William W. Wiles,

Secretary to the Board.

[FR Doc. 95–20843 Filed 8–23–95; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF THE TREASURY

31 CFR Part 103

RIN 1506–AA17

Amendment to the Bank Secrecy Act Regulations Relating to Orders for Transmittals of Funds by Financial Institutions

AGENCY: Financial Crimes Enforcement Network, Treasury.

ACTION: Final rule; delay of effective date.

SUMMARY: In January 1995, the Department of the Treasury (Treasury), through its Financial Crimes Enforcement Network (FinCEN), adopted a final rule (60 FR 234, January 3, 1995) requiring financial institutions that transmit funds to include in transmittal orders certain information (the travel rule). On the same date, Treasury, through FinCEN, and the Board of Governors of the Federal Reserve System (the Board) jointly adopted a final rule (60 FR 220, January 3, 1995) requiring financial institutions to obtain and retain certain information about parties to transmittals of funds (the joint rule). In response to requests from the banking industry, Treasury and the Board have issued proposed amendments to the joint rule, and Treasury has proposed conforming amendments to the travel rule (see documents published elsewhere in today's **Federal Register**). In order to provide financial institutions subject to the rules sufficient time to adapt their funds transmittal systems to comply with the rules as they are proposed to be amended, the effective date of the travel rule is hereby delayed from January 1, 1996 to April 1, 1996. The effective date of the joint rule has also

been delayed from January 1, 1996 to April 1, 1996 (see document published elsewhere in today's **Federal Register**).

EFFECTIVE DATES: Effective August 24, 1995, this document delays the effective date of the final rule published at 60 FR 234, January 3, 1995, until April 1, 1996.

FOR FURTHER INFORMATION CONTACT: Roger Weiner, Assistant Director, Office of Compliance and Enforcement, 202/622–0400; Nina A. Nichols, Attorney-Advisor, Office of Legal Counsel, 703/905–3598.

The effective date of the final rule issued by Treasury and published at 60 FR 234, January 3, 1995, is delayed for three months, from January 1, 1996 to April 1, 1996.

Dated: July 31, 1995.

Stanley E. Morris,

Director, Financial Crimes Enforcement Network.

[FR Doc. 95–20844 Filed 8–23–95; 8:45 am]

BILLING CODE 4820–03–P

FEDERAL RESERVE SYSTEM

[Docket No. R–0888]

DEPARTMENT OF THE TREASURY

31 CFR Part 103

RIN 1506–AA16

Amendment to the Bank Secrecy Act Regulations Relating to Recordkeeping for Funds Transfers and Transmittals of Funds by Banks and Other Financial Institutions

AGENCY: Department of the Treasury; Board of Governors of the Federal Reserve System.

ACTION: Joint proposed rule.

SUMMARY: In January 1995, the Financial Crimes Enforcement Network (FinCEN) of the Department of the Treasury (Treasury) and the Board of Governors of the Federal Reserve System (Board) jointly published a final rule that requires enhanced recordkeeping related to certain funds transfers and transmittals of funds by financial institutions (the joint rule). Also in January 1995, the Treasury adopted a companion rule, known as the travel rule, that requires financial institutions to include in transmittal orders certain information that must be maintained under the joint rule. The joint rule sets forth definitions of terms used in both rules. The original effective date of these rules was January 1, 1996. Subsequent to adoption of these rules, several banks have expressed concerns to the Treasury and the Board that compliance with the joint rule and the travel rule would be complicated if the parties to an international transfer were defined differently in the Bank Secrecy Act regulations than they are defined in the Uniform Commercial Code Article 4A. The Treasury and the Board have proposed amendments to the joint rule's definitions and technical conforming changes to the substantive provisions of the joint rule to conform the meanings of the definitions of the parties to an international transfer to their meanings under Article 4A of the Uniform Commercial Code. These proposed amendments are intended to reduce confusion of banks and nonbank financial institutions as to the applicability of the joint rule and the travel rule and to reduce the cost of complying with the rules' requirements. The Treasury and the Board believe that the proposed amendments will not have a material adverse effect on the rules' usefulness in law enforcement investigations and proceedings. The proposed amendments should not affect a bank's responsibilities under the rules with respect to domestic funds transfers. Due to the uncertainties resulting from these proposed amendments, the Treasury and the Board have delayed the effective date of the joint rule; a document delaying the effective date of the final joint rule until April 1, 1996, is published elsewhere in today's **Federal Register**.

DATES: Comments must be submitted on or before September 25, 1995.

ADDRESSES: Each comment should be sent separately to both the Treasury and the Board at the following addresses:

Treasury: Office of Regulatory Policy and Enforcement, Financial Crimes Enforcement Network, Department of the Treasury, 2070 Chain Bridge Road, Vienna, VA 22182, Attention: Funds Transfer NPRM. Comments may be inspected between 10:00 a.m. and 4:00 p.m. at the Treasury Library, located in room 5030, 1500 Pennsylvania Avenue, N.W., Washington, D.C. Persons wishing to inspect the comments submitted should request an appointment at the Treasury Library, 202/622–0990.

Board: Comments, which should refer to Docket No. R–0888, may be mailed to Mr. William W. Wiles, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue, N.W., Washington, D.C. 20551. Comments also may be delivered to Room B–2222 of the Eccles building between 8:45 a.m. and 5:15 p.m. weekdays, or to the guard station in the Eccles Building courtyard on 20th Street N.W. (between Constitution Avenue and C Street) at any time. Comments may be inspected in Room MP–500 of the Martin Building between 9:00 a.m. and 5:00 p.m. weekdays, except as provided in 12 CFR 261.8 of the Board's Rules Regarding Availability of Information.

FOR FURTHER INFORMATION CONTACT:

Treasury: Roger Weiner, Assistant Director, 202/622–0400; Stephen R. Kroll, Legal Counsel, 703/905–3534; or Nina A. Nichols, Attorney-Advisor, 703/905–3598, FinCEN.

Board: Louise L. Roseman, Associate Director, 202/452–2789; Gayle Brett, Manager, Fedwire Section, 202/452–2934; Division of Reserve Bank Operations and Payment Systems; Oliver Ireland, Associate General Counsel, 202/452–3625; or Elaine Boutilier, Senior Counsel, 202/452–2418, Legal Division, Board of Governors of the Federal Reserve System. For the hearing impaired only, Telecommunication Device for the Deaf (TDD), Dorothea Thompson, 202/452–3544.

SUPPLEMENTARY INFORMATION:

I. Background

The statute generally referred to as the Bank Secrecy Act (BSA) (Pub. L. 91–508, codified at 12 U.S.C. 1829b and 1951–1959, and 31 U.S.C. 5311–5330) authorizes the Secretary of the Treasury to require financial institutions to keep records and file reports that the Secretary determines have a high degree of usefulness in criminal, tax, or regulatory investigations or proceedings. The authority of the Secretary to administer the BSA has been delegated to the Director of FinCEN. The BSA was amended by the Annunzio-Wylie Anti-Money Laundering Act of 1992 (Pub. L. 102–550), which authorizes the Treasury and the Board to prescribe regulations to require maintenance of records regarding domestic and international funds transfers. The Treasury and the Board are required to promulgate jointly, after consultation with state banking supervisors, recordkeeping requirements for international funds transfers by depository institutions and nonbank financial institutions. The Treasury and the Board are required to consider the usefulness of recordkeeping rules for international funds transfers in criminal, tax, or regulatory investigations or proceedings and the effect of such rules on the cost and efficiency of the payments system. The Treasury and the Board are authorized to promulgate regulations for domestic funds transfers by depository institutions. The Treasury, but not the Board, is authorized to promulgate recordkeeping and reporting requirements for domestic funds transfers by nonbank financial institutions.

In January 1995, the Treasury and the Board jointly published enhanced recordkeeping requirements related to certain funds transfers and transmittals of funds by banks and other financial institutions, in accordance with the BSA (60 FR 220, January 3, 1995). At the same time, the Treasury adopted a companion rule, known as the travel rule, that requires financial institutions to include in transmittal orders certain information that must be retained under the joint rule (60 FR 234, January 3, 1995). The joint rule sets forth definitions of terms used in both rules. These rules were scheduled to become effective on January 1, 1996.

II. Industry Concerns Regarding Definition of Parties to an International Funds Transfer

Subsequent to adoption of these rules, several large banks as well as bank

counsel have advised the Treasury and the Board that compliance with the joint rule and the travel rule would be complicated if the parties to an international funds transfer were defined differently in the joint rule than they are in the Uniform Commercial Code Article 4A (UCC 4A). Under the joint rule adopted in January, the first U.S. bank office that handles an incoming international funds transfer is defined as the originator's bank.[1] Under UCC 4A and the Board's Regulation J governing Fedwire transfers (12 CFR Part 210, subpart B), which incorporates UCC 4A, if the U.S. bank receives a payment order from a foreign bank and executes a corresponding payment order to a subsequent receiving bank, the first U.S. bank would be deemed an intermediary bank rather than the originator's bank. Large banks that regularly process international funds transfers believe that substantial confusion would result from defining the parties to an international funds transfer for the purposes of the BSA rules differently from the manner in which they are defined under UCC 4A.

In addition to the confusion created by defining the parties to an international funds transfer in a manner that is not consistent with the roles of the parties as defined by UCC 4A, several banks have indicated that they believe the difference between the BSA and the UCC 4A definitions may cause certain problems in the application of the joint rule and the travel rule to international funds transfers. The following chart depicts a hypothetical funds transfer that serves to illustrate the operational issues raised by the industry representatives if the first U.S. bank in an incoming international funds transfer were deemed to be the originator's bank and the last U.S. bank in an outgoing international funds transfer were deemed to be the beneficiary's bank:

Parties to transfer	Definitions of bank and FI parties to transfer limited to US offices (rule published in January 1995)	Definitions that conform to UCC 4A meanings (proposed amended rule)
German Company		Originator/Transmittor.
German Bank 1		Originator's bank/Transmittor's FI.
German Bank 2	Originator/Transmittor	Intermediary bank/Intermediary FI.
New York Bank 1	Originator's bank/Transmittor's FI	Intermediary bank/Intermediary FI.
New York Bank 2	Intermediary bank/Intermediary's FI	Intermediary bank/Intermediary FI.
California Bank	Beneficiary's bank/Recipient's FI	Intermediary bank/Intermediary FI.
Japanese Bank	Beneficiary/Recipient	Beneficiary's bank/Recipient's FI.
Japanese Company		Beneficiary/Recipient.

In this transfer, a German company instructs its bank (German Bank 1) to send a dollar payment to Japanese Bank for credit to a Japanese company. German Bank 1 forwards the payment instructions to its correspondent, German Bank 2. German Bank 2 sends the payment instructions via SWIFT to its New York correspondent, New York Bank 1. New York Bank 1 executes a payment order via CHIPS to New York Bank 2. New York Bank 2 forwards the payment order via Fedwire to California Bank. California Bank sends the payment order via SWIFT to Japanese Bank, which credits the account of the Japanese company.

III. Definitions Under Joint Rule as Published in January 1995

Under the joint rule as adopted in January, German Bank 2 is defined as the originator (transmittor) of the transfer, because it is the sender of the first payment order[2] in a funds transfer and New York Bank 1 is defined as the originator's bank (transmittor's financial institution). Japanese Bank 1, which is neither a bank nor a financial institution under the BSA definitions, is defined as the beneficiary and California Bank is defined as the beneficiary's bank. In the example, New York Bank 1 as originator's bank would be subject to the following requirements under the joint rule:

A. *Obtain and retain the name and address of German Bank 2 (the originator) (103.33(e)(1)(i)).* New York Bank 1 generally would have a record of the name and address of German Bank 2, which in virtually all cases would be an accountholder at New York Bank 1. In the rare case in which German Bank 2 is not an established customer of New York Bank 1, New York Bank 1 would be required to obtain this information.

B. *Have the capability to retrieve the record of the funds transfer by name or account number of German Bank 2 (103.33(e)(4)).* All financial institutions are currently subject to the general retrievability requirements under section 103.38(d), which states that all records required to be retained under 31 CFR Part 103 ". . . shall be filed or stored in such a way as to be accessible within a reasonable time, taking into consideration the nature of the record, and the amount of time expired since the record was made." While the requirements of the joint rule emphasize the need for an originator's bank to have the capability to retrieve funds transfer records by name or account number of the originator, the bank would nonetheless have to have the capability to retrieve these records if it were deemed to be an intermediary bank.

C. *Comply with the verification requirements if German Bank 2 is not an established customer (103.33(e)(2)).* If German Bank 2 were not an established customer of New York Bank 1 (a situation that would occur only rarely), New York Bank 1 would have to comply with the joint rule's verification requirements. This would require manual intervention in what is generally a highly automated process, and the Treasury and the Board do not believe that the resulting information would be highly useful to law enforcement.

In addition, under the travel rule, the originator's bank and each intermediary bank (if the information is received from the sender) would be required to:

D. *Include the name, address, and account number of German Bank 2 in the payment order it executes (103.33(g)*

[1] The originator's bank is defined as "the receiving bank to which the payment order of the originator is issued if the originator is not a bank, or the originator if the originator is a bank." (103.11(w)) A receiving bank is defined as "the bank to which the sender's instruction is addressed." (103.11(aa)) As the definition of bank is limited to an "agent, agency, branch or office within the United States" (103.11(c)), a receiving bank must be a U.S. banking office, and therefore the originator's bank is the first U.S. banking office to handle the transfer.

[2] A payment order is defined as "an instruction of a sender to a receiving bank. . . ." (31 CFR 103.11(y)) As noted above, a receiving bank is defined as "the bank to which the sender's instruction is addressed." Because the BSA rules limit the definition of bank to an office within the United States, the instruction of a sender to the first U.S. banking office is defined as the first payment order.

(1) and (2)). New York Bank 1 typically would include in the payment order it executes the SWIFT Bank Identification Code (BIC) or CHIPS Universal Identifier (UID) of German Bank 2 (the originator), rather than German Bank 2's name, address, and account number. The Treasury believes that use of a widely-used industry code, such as a BIC, UID, or routing number, to identify the transmittor constitutes compliance with the travel rule requirement to include the name, address, and account number of the transmittor in subsequent payment orders.

Information pertaining to German Bank 2 may not be retained in all subsequent payment orders, however, because German Bank 2 generally would be identified as the instructing bank, rather than the originator's bank, in the CHIPS message sent by New York Bank 1. While the identification of the bank included in the originator's bank field generally is retained in subsequent payment orders, the identification of the bank in the instructing bank field may change in subsequent payment orders.[3]

California Bank, as beneficiary's bank, would be required under the joint rule to (1) retain the information contained in the payment order sent by New York Bank 2 (103.33(e)(1)(iii)); (2) have the capability to retrieve the record of the funds transfer by name or account number of Japanese Bank (103.33(e)(4)); and (3) comply with the verification requirements if Japanese Bank is not an established customer (103.33(e)(3)).

IV. Effect of Proposed Amendment

If New York Bank 1 and California Bank in the example above were considered to be intermediary banks instead of the originator's bank and beneficiary's bank, respectively, under the BSA rules, they would be required under the joint rule to retain a copy of the payment order they accept (103.33(e)(1)(ii)). As noted above, while there is no specific retrievability requirement under the joint rule for intermediary banks, under 103.38(d) information retained must be "accessible." Under the travel rule, New York Bank 1 would be required to include in its payment order to New York Bank 2 only the information pertaining to the transmittor and other transfer information that it received from German Bank 2 (103.33(g)(2)). Similarly, New York Bank 2 and California Bank, as other intermediary banks in the funds transfer, would be required to include this information in the payment orders they execute if received in the payment orders they accepted.

Treatment of New York Bank 1 and California Bank as intermediary banks addresses the concerns of industry representatives. Under current industry practice, banks generally would be in compliance with the recordkeeping, retrievability, and travel rule requirements for intermediary banks. The Treasury and the Board do not believe that identifying the banks in an international transfer in the same manner as they are defined in UCC 4A will reduce the usefulness of the information to law enforcement, *provided* that intermediary banks comply with the requirements of 103.38(d). As part of the 36-month review of the effectiveness of the joint rule and the travel rule, Treasury will monitor the experience of law enforcement in obtaining from intermediary banks information retained pursuant to the joint rule.

V. Corresponding Changes Affecting Nonbank Financial Institutions

The example reviewed above involves banks, as banks have raised concerns with the differences between the definitions of the parties to international funds transfers in the joint rule and UCC 4A. Financial institutions other than banks have not raised operational concerns with the Treasury and the Board on this matter. The Treasury and the Board believe, however, that nonbank financial institutions that conduct international transmittals of funds may have similar compliance concerns. Accordingly, the proposed amendments to the joint rule include modifications that correspond to the changes that apply to banks.

VI. Request for Comment

The Treasury and the Board request comment on proposed amendments to the definitions that make the roles of the parties to an international funds transfer consistent under the BSA rules and under UCC 4A and that make parallel changes to the definitions of the parties to an international transmittal of funds. The proposed amendments include expansion of the definitions of beneficiary's bank, originator's bank, payment order, receiving bank, receiving financial institution, recipient's financial institution, transmittal order, transmittor, and transmittor's financial institution to include both domestic and foreign institutions. The Treasury and the Board have also proposed technical conforming changes to the joint rule to clarify that only bank and financial institution offices located within the United States are subject to the joint rule's requirements.

These amendments should reduce confusion with respect to the interpretation of the rules and should facilitate compliance with the rules' requirements. Moreover, the Treasury and the Board do not believe that these proposed amendments will increase the cost of compliance with the rules' requirements for those banks and nonbank financial institutions that have prepared to comply with the rules under the assumption that the first U.S. banking office in an international transfer is subject to the originator's bank responsibilities.

In addition, the Treasury and the Board have revised section 103.33(e)(6) by deleting the word "domestic" prior to the word "bank" and prior to the words "broker or dealer in securities." These changes have no material effect on the scope of the exclusions set forth in this section as the word "bank" is defined to be limited to offices located within the United States and the term "broker or dealer in securities" is limited to brokers registered with the Securities and Exchange Commission.[4]

VII. Paperwork Reduction Act

The collection of information required by the joint final rule whose amendment is proposed in this notice was submitted by the Treasury to the Office of Management and Budget in accordance with the requirements of the Paperwork Reduction Act (44 U.S.C. 3504(h)) under control number 1505–0063. (See, 60 FR 227 (January 3, 1995)) The collection is authorized, as before, by 12 U.S.C. 1829b and 1959 and 31 U.S.C. 5311–5330.

The changes to the joint final rule proposed in this document will eliminate information collection requirements that were required by the joint final rule. Therefore, no additional Paperwork Reduction Act submissions are required.

[3] Banks often define the parties to an international transfer in the SWIFT, CHIPS, and Fedwire formats differently than the parties are defined in the BSA rules as adopted in January. These formats have fields for the identification of the originator's bank, the instructing bank, the sender bank (the bank that sends the transfer through SWIFT, CHIPS, or Fedwire), the receiver bank, the intermediary bank, and the beneficiary's bank. The first U.S. or foreign bank in a transfer is generally identified in the message format as the originator's bank; the bank that immediately precedes the sender bank (if different than the originator's bank) is identified as the instructing bank. For transfers that are sent through a large number of receiving banks, the identification of instructing bank may change from payment order to payment order.

[4] The Treasury has also proposed companion amendments to the travel rule. See document elsewhere in today's **Federal Register**.

VIII. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Treasury and the Board hereby certify that these proposed amendments to the joint final rule will not have a significant economic impact on a substantial number of small entities. The proposed amendments eliminate uncertainty as to the application of the joint final rule and reduce the cost of complying with the joint rule's requirements. Furthermore, the proposed amendments affect international funds transfers and transmittals of funds, which are handled almost exclusively by large institutions. Accordingly, a regulatory flexibility analysis is not required.

IX. Executive Order 12866

The Treasury finds that these proposed amendments to the joint rule are not "significant" for purposes of Executive Order 12866. The modifications should reduce the cost of compliance with the joint rule and the travel rule. The Treasury believes that these proposed rule changes will not affect adversely in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. These proposed revisions create no inconsistencies with, nor do they interfere with actions taken or planned by other agencies. Finally, these proposed revisions raise no novel legal or policy issues. A cost and benefit analysis therefore is not required.

X. Unfunded Mandates Reform Act of 1995 Statement

Section 202 of the Unfunded Mandates Reform Act of 1995, Public Law 104–4 (Unfunded Mandates Act), signed into law on March 22, 1995, requires that an agency prepare a budgetary impact statement before promulgating a rule that includes a federal mandate that may result in expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year. The Treasury has determined that it is not required to prepare a written budgetary impact statement for the proposed amendments, and has concluded that the proposed amendments are the most cost-effective and least burdensome means of achieving the stated objectives of the rule.

List of Subjects in 31 CFR Part 103

Administrative practice and procedure, Banks, banking, Brokers, Currency, Foreign banking, foreign currencies, Gambling, Investigations, Penalties, Reporting and recordkeeping requirements, Securities.

Amendment

For the reasons set forth in the preamble, 31 CFR Part 103 is proposed to be amended as set forth below:

PART 103—FINANCIAL RECORDKEEPING AND REPORTING OF CURRENCY AND FOREIGN TRANSACTIONS

1. The authority citation for Part 103 is revised to read as follows:

Authority: 12 U.S.C. 1829b and 1951–1959; 31 U.S.C. 5311–5330.

2. Section 103.11 is amended by revising paragraphs (e), (w), (y) introductory text, (aa), (bb), (dd), (kk) introductory text, (ll), and (mm) to read as follows:

§ 103.11 Meaning of terms.

* * * * *

(e) *Beneficiary's bank.* The bank or foreign bank identified in a payment order in which an account of the beneficiary is to be credited pursuant to the order or which otherwise is to make payment to the beneficiary if the order does not provide for payment to an account.

* * * * *

(w) *Originator's bank.* The receiving bank to which the payment order of the originator is issued if the originator is not a bank or foreign bank, or the originator if the originator is a bank or foreign bank.

* * * * *

(y) *Payment order.* An instruction of a sender to a receiving bank, transmitted orally, electronically, or in writing, to pay, or to cause another bank or foreign bank to pay, in a fixed or determinable amount of money to a beneficiary if:

* * * * *

(aa) *Receiving bank.* The bank or foreign bank to which the sender's instruction is addressed.

(bb) *Receiving financial institution.* The financial institution or foreign financial agency to which the sender's instruction is addressed. The term receiving financial institution includes a receiving bank.

* * * * *

(dd) *Recipient's financial institution.* The financial institution or foreign financial agency identified in a transmittal order in which an account of the recipient is to be credited pursuant to the transmittal order or which otherwise is to make payment to the recipient if the order does not provide for payment to an account. The term recipient's financial institution includes a beneficiary's bank, except where the beneficiary is a recipient's financial institution.

* * * * *

(kk) *Transmittal order.* The term transmittal order includes a payment order and is an instruction of a sender to a receiving financial institution, transmitted orally, electronically, or in writing, to pay, or cause another financial institution or foreign financial agency to pay, a fixed or determinable amount of money to a recipient if:

* * * * *

(ll) *Transmittor.* The sender of the first transmittal order in a transmittal of funds. The term transmittor includes an originator, except where the transmittor's financial institution is a financial institution or foreign financial agency other than a bank or foreign bank.

(mm) *Transmittor's financial institution.* The receiving financial institution to which the transmittal order of the transmittor is issued if the transmittor is not a financial institution or foreign financial agency, or the transmittor if the transmittor is a financial institution or foreign financial agency. The term transmittor's financial institution includes an originator's bank, except where the originator is a transmittor's financial institution other than a bank or foreign bank.

* * * * *

3. In § 103.33, paragraphs (e) introductory text, (e)(1)(i) introductory text, (e)(1)(ii), (e)(1)(iii), (e)(6)(i)(A) through (e)(6)(i)(G), (e)(6)(ii), (f) introductory text, (f)(1)(i) introductory text, (f)(1)(ii), (f)(1)(iii), (f)(6)(i)(A) through (f)(6)(i)(G) and (f)(6)(ii) are revised to read as follows:

§ 103.33 Records to be made and retained by financial institutions.

* * * * *

(e) *Banks.* Each agent, agency, branch, or office located within the United States of a bank is subject to the requirements of this paragraph (e) with respect to a funds transfer in the amount of $3,000 or more:

(1) *Recordkeeping requirements.* (i) For each payment order that it accepts as an originator's bank, a bank shall obtain and retain either the original or a microfilm, other copy, or electronic record of the following information relating to the payment order:

* * * * *

(ii) For each payment order that it accepts as an intermediary bank, a bank shall retain either the original or a microfilm, other copy, or electronic record of the payment order.

(iii) for each payment order that it accepts as a beneficiary's bank, a bank shall retain either the original or a microfilm, other copy, or electronic record of the payment order.

* * * * *

(6) *Exceptions.* * * *

(i) * * *

(A) A bank;

(B) A wholly-owned domestic subsidiary of a bank chartered in the United States;

(C) A broker or dealer in securities;

(D) A wholly-owned domestic subsidiary of a broker or dealer in securities;

(E) The United States;

(F) A state or local government; or

(G) A federal, state or local government agency or instrumentality; and

(ii) Funds transfers where both the originator and the beneficiary are the same person and the originator's bank and the beneficiary's bank are the same bank.

(f) *Nonbank financial institutions.* Each agent, agency, branch, or office located within the United States of a financial institution other than a bank is subject to the requirements of this paragraph (f) with respect to a transmittal of funds in the amount of $3,000 or more:

(1) *Recordkeeping requirements.* (i) For each transmittal order that it accepts as a transmittor's financial institution, a financial institution shall obtain and retain either the original or a microfilm, other copy, or electronic record of the following information relating to the transmittal order:

* * * * *

(ii) For each transmittal order that it accepts as an intermediary financial institution, a financial institution shall retain either the original or a microfilm, other copy, or electronic record of the transmittal order.

(iii) for each transmittal order that it accepts as a recipient's financial institution, a financial institution shall retain either the original or a microfilm, other copy, or electronic record of the transmittal order.

* * * * *

(6) *Exceptions.* * * *

(i) * * *

(A) A bank;

(B) A wholly-owned domestic subsidiary of a bank chartered in the United States;

(C) A broker or dealer in securities;

(D) A wholly-owned domestic subsidiary of a broker or dealer in securities;

(E) The United States;

(F) A state or local government; or

(G) A federal, state or local government agency or instrumentality; and

(ii) Transmittals of funds where both the transmittor and the recipient are the same person and the transmittor's financial institution and the recipient's financial institution are the same broker or dealer in securities.

In concurrence:

By the Board of Governors of the Federal Reserve System, August 17, 1995.

William W. Wiles,

Secretary to the Board.

Dated: July 31, 1995.

By the Department of the Treasury.

Stanley E. Morris,

Director, Financial Crimes Enforcement Network.

[FR Doc. 95–20842 Filed 8–23–95; 8:45 am]

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DEPARTMENT OF THE TREASURY

31 CFR Part 103

RIN 1506–AA17

Amendment to the Bank Secrecy Act Regulations Relating to Orders for Transmittals of Funds by Banks and Other Financial Institutions

AGENCY: Financial Crimes Enforcement Network, Treasury.

ACTION: Proposed rule.

SUMMARY: In January 1995, the Financial Crimes Enforcement Network (FinCEN) of the Department of the Treasury (Treasury) and the Board of Governors of the Federal Reserve System (the Board) jointly adopted a final rule (the joint rule) requiring financial institutions to collect and retain certain information pertaining to transmittals of funds. At the same time, FinCEN adopted a final rule (the travel rule) that required financial institutions to include in transmittal orders certain information collected under the joint rule. Both the travel rule and the joint rule were to become effective on January 1, 1996. In response to industry concerns about the application of the joint rule and the travel rule to transmittals of funds involving foreign financial institutions, Treasury and the Board today are proposing amendments to the joint rule that conform the definitions of the parties to transmittals of funds to definitions found in Article 4A of the Uniform Commercial Code (see document published elsewhere in today's Federal Register). This document proposes amendments to the travel rule that are necessary to reflect the amended definitions in the joint rule. These proposed amendments to the travel rule also make the exceptions applicable for the joint rule applicable for the travel rule. To provide financial institutions sufficient time to complete their compliance programs for both rules, the effective dates of the joint rule and the travel rule are delayed until April 1, 1996 (see documents published elsewhere in today's Federal Register).

DATES: Comments are due by September 25, 1995.

ADDRESSES: Comments should be in writing and addressed to: Office of Regulatory Policy and Enforcement, Financial Crimes Enforcement Network, Department of the Treasury, 2070 Chain Bridge Road, Vienna, VA 22182, *Attention*: Transmittal of Funds NPRM. Comments may be inspected between 10:00 a.m. and 4:00 p.m. at the Treasury Library, located in room 5030, 1500 Pennsylvania Avenue, N.W., Washington, D.C. Persons wishing to inspect the comments submitted should request an appointment at the Treasury Library, 202/622–0990.

FOR FURTHER INFORMATION CONTACT: Roger Weiner, Assistant Director, Office of Compliance and Enforcement, 202/622–0400; Nina A. Nichols, Attorney-Advisor, Office of Legal Counsel, 703/905–3598.

SUPPLEMENTARY INFORMATION:

Background

The statute generally referred to as the Bank Secrecy Act (Titles I and II of Pub. L. 91–508, codified at 12 U.S.C. 1829b and 1951–1959, and 31 U.S.C. 5311–5330), authorizes the Secretary of the Treasury (the Secretary), *inter alia*, to require financial institutions to keep records and file reports that the Secretary determines have a high degree of usefulness in criminal, tax, or regulatory investigations or proceedings, and to implement counter-money laundering programs and compliance procedures. The Secretary's authority to administer the Bank Secrecy Act has been delegated to the Director of FinCEN.

Section 1515 of the Annunzio-Wylie Anti-Money Laundering Act of 1992 (Title XV of Pub. L. 102–550 (Annunzio-Wylie)), codified at 12 U.S.C. 1829b(b), amended the Bank Secrecy Act (1) to require the Secretary and the Board jointly to promulgate, after consultation with state banking supervisors, recordkeeping requirements for international funds transfers by depository institutions and nonbank financial institutions; and (2) to authorize the Secretary and the Board jointly to promulgate regulations for domestic funds transfers by depository institutions. Section 1517(a) of Annunzio-Wylie, codified at 31 U.S.C. 5318(g) and (h), authorizes the Secretary, *inter alia*, to require financial institutions to carry out anti-money laundering programs. See 31 U.S.C. 5318(h)(1).

In January 1995, Treasury and the Board jointly adopted a rule (the joint rule) that imposed recordkeeping requirements with respect to transmittals of funds by banks and other financial institutions (60 FR 220, January 3, 1995). Treasury also adopted a rule (the travel rule) requiring financial institutions (including banks) to include in transmittal orders certain information collected under the joint rule (60 FR 234, January 3, 1995). The joint rule contained definitions of the terms used in both rules. These rules were to become effective on January 1, 1996.

Subsequent to publication of the joint rule and the travel rule, it became apparent that there was confusion within the banking industry about the application of the rules to transmittals of funds involving foreign financial institutions. Several banks and bank counsel advised Treasury and the Board that compliance with the rules was complicated by the fact that the joint rule definitions of parties to funds transfers differed from the definitions in Article 4A of the Uniform Commercial Code (UCC 4A). Because a financial institution's obligations under the joint and travel rules depend upon its role in a particular transmittal of funds, the differences between the Bank Secrecy Act regulations definitions and UCC 4A definitions have material operational consequences.

Definitions of Parties to International Transfers

The joint rule, when read together with other definitions found in the Bank Secrecy Act regulations at 31 CFR 103.11, limits the definition of the term "bank" to offices located within the U.S.; thus, a foreign bank could not be an originator's bank, intermediary bank or beneficiary's bank. In a transfer from a foreign bank to a U.S. bank (an inbound transfer), the foreign bank would be the originator and the U.S. bank would be the originator's bank. UCC 4A, however, does not restrict the definition of a bank in this way; therefore, applying UCC 4A definitions to an inbound transfer, the foreign bank would be an originator's (or intermediary) bank and the U.S. bank would be an intermediary (or beneficiary's) bank.

The joint rule added definitions of financial institutions that correspond to the UCC 4A definitions used for banks—*e.g.*, transmittor's financial institution, intermediary financial institution, recipient's financial institution. These definitions resulted in further confusion because the Bank Secrecy Act regulations also limit the definition of "financial institution" to offices located in the U.S.

One other source of confusion is the overlap among the terms used to refer to banks and financial institutions. In general, the travel rule obligations apply equally to banks and to nonbank financial institutions, because the terms used for financial institutions include the terms used to refer to banks. The travel rule imposes obligations only on transmittors' financial institutions and intermediary financial institutions;

these terms include originators' banks and intermediary banks.[1]

Industry Concerns About Application of the Travel Rule

The following hypothetical transmittal of funds (illustrated on the accompanying chart) illustrates the differences between the effect of the travel rule as published and its effect following the proposed amendments to the definitions in the joint rule. In this transfer, German Company instructs its bank, German Bank 1, to send a dollar payment to Japanese Bank 2 for credit to Japanese Company. German Bank 1 forwards the payment instructions to its correspondent, German Bank 2. German Bank 2 sends the payment instructions via SWIFT to its New York correspondent, New York Bank 1. New York Bank 1 executes a transmittal order via CHIPS to New York Bank 2. New York Bank 2 forwards the transmittal order via Fedwire to California Bank. California Bank sends the transmittal order via SWIFT to its correspondent, Japanese Bank 1. Japanese Bank 1 forwards the transmittal order to Japanese Bank 2, which credits the account of Japanese Company.

Parties to transfer	Definitions of financial institutions limited to U.S. offices (travel rule adopted in January 1995)	Definitions are parallel to UCC 4A definitions of banks (proposed amended travel rule)
German Company.	.....	Transmittor.
German Bank 1.	.....	Transmittor's FI.
German Bank 2.	Transmittor .	Intermediary FI.
New York Bank 1.	Transmittor's FI.	Intermediary FI.
New York Bank 2.	Intermediary FI.	Intermediary FI.
California Bank.	Recipient's FI.	Intermediary FI.
Japanese Bank 1.	Recipient	Intermediary FI.
Japanese Bank 2.	.....	Recipient's FI.
Japanese Company.	.....	Recipient.

[1] In limited circumstances, a beneficiary's bank will also have travel rule obligations. If the recipient's financial institution is not a bank, then the bank that sends a transmittal order to the recipient's financial institution will be a beneficiary's bank *and* an intermediary financial institution subject to the requirements of 103.33(g)(2).

Obligations Under the Travel Rule as Adopted

The middle column of the chart reflects the roles of the parties to this transmittal under the rules as adopted in January 1995. The travel rule imposes the following obligations:

1. New York Bank 1, as the transmittor's financial institution, must include in the transmittal order to New York Bank 2 the name, address and account number of German Bank 2 (the transmittor) (103.33(g)(1)(i)-(ii)). New York Bank 1 would typically include German Bank 2's SWIFT Bank Identification Code (BIC) or its CHIPS Universal Identifier (UID) rather than its name, address and account number; however, Treasury believes that a widely-used industry code, such as a BIC, UID or routing number, would comply with the requirements, so long as the financial institution's name, address and account number can be readily derived from its industry code.

In addition, New York Bank 1 would have to include, if received, information about Japanese Bank 1 (the recipient) and California Bank (the recipient's financial institution) (103.33(g)(1)(v)-(vi)).

2. New York Bank 2, as an intermediary financial institution, must include in its transmittal order to California Bank the name, address and account number of German Bank 2 (the transmittor), if New York Bank 2 receives this information.

This requirement raises significant operational concerns, because as a matter of ordinary business practice, German Bank 2 would be identified as the "instructing bank" in the order received by New York Bank 2, and would not be identified in the order executed by New York Bank 2. While the bank identified in the originator's bank field generally is retained in subsequent transmittal orders, the identification in the instructing bank field may change, and the information may not be passed on to the next receiving financial institution.

New York Bank 2 must also include information on New York Bank 1 as the transmittor's financial institution (103.33(g)(1)(vii)). Again, New York Bank 1 would be identified as the instructing bank in the transmittal order executed by New York Bank 2, but the information might be dropped from subsequent transmittal orders.

New York Bank 2 would also have to include, if received, the identity of California Bank (the recipient's financial institution) and Japanese Bank 1 (the recipient) (103.33(g)(2)(v)-(vi)).

3. California Bank, as the recipient's financial institution, is not subject to travel rule requirements.

Effect of Proposed Amendments

In response to banking industry concerns, Treasury and the Board have proposed amendments to the joint rule that will conform the definitions of banks that are parties to funds transfers to the definitions found in UCC 4A and that will change the definitions of the terms applicable to financial institutions so that their meanings are parallel to the definitions in UCC 4A. (See document published elsewhere in today's **Federal Register.**)

The third column of the accompanying chart reflects the effect of the proposed amendments for compliance with the travel rule. When the definitions applicable to financial institutions are conformed to the definitions in UCC 4A, all of the U.S. banks in the hypothetical transfer are treated as intermediary financial institutions. As an intermediary financial institution, rather than a transmittor's financial institution, New York Bank 1 is not required under the travel rule to pass on the specified information unless it actually receives it from German Bank 2.

More importantly, the redefinition of the parties to the transmittal means that the information that must be passed on pertains to German Company (the transmittor), German Bank 1 (the transmittor's financial institution), Japanese Bank 2 (the recipient's financial institution) and Japanese Company (the recipient). These definitions are more in accord with the economic reality of the transaction and with current industry practice, and the information required is more likely to be included in the transmittal orders.

With respect to the transmittal from California Bank, Treasury does not believe that the requirements placed on the U.S. bank in an outbound transfer significantly increase the cost of complying with the travel rule. Although California Bank, as an intermediary financial institution, would have to include information in its transmittal order to Japanese Bank 1, this information would typically be included as a matter of standard practice. Furthermore, California Bank would not have the verification obligations that it has as a beneficiary's bank. When considered in combination with the proposed amendments to the joint rule, Treasury believes that there is an overall reduction in burden.

Effect on Law Enforcement; Ongoing Review

Treasury believes that these proposed changes, while reducing the burden of compliance, will maintain the usefulness for law enforcement of the information passed on in transmittal orders pursuant to the travel rule. While the requirement placed on an intermediary financial institution is limited to information that it receives, the information passed on should be of greater use because it will pertain to the true transmittor and recipient in the transaction. Furthermore, the financial institutions that must be identified will more likely be ones with which the transmittor and recipient have account relationships. Under the rule adopted in January, transmittor's financial institutions and intermediary financial institutions may not be required to pass along information pertaining to these parties when a transmittal involves a foreign financial institution.

Under the proposed amendments, an intermediary financial institution will be required to pass on information to a receiving financial institution even when the receiving financial institution is located outside the U.S. Treasury believes that in the interests of international cooperation in law enforcement, and recognizing the use for illicit purposes of the global payments system, there is a law enforcement benefit to this requirement. In addition to the potential availability of information that is forwarded to foreign financial institutions, this rule lays a foundation for international cooperation in setting standards for improving law enforcement efforts while imposing a minimal administrative burden on financial institutions.

As stated in the joint and travel rules when they were adopted, Treasury will monitor the effectiveness of the rules to assess their usefulness to law enforcement and their effect on the cost and efficiency of the payments system. Within 36 months of April 1, 1996, Treasury will review the effectiveness of the travel rule and will consider making any appropriate modifications.

Addition of Exceptions

This proposed rule also proposes the addition of new § 103.33(g)(3), which incorporates exceptions to the joint rule that appear in §§ 103.33(e)(6) and 103.33(f)(6). Those sections provide that a transmittal of funds is not subject to the requirements of the joint rule if the parties to the transmittal are both banks or brokers and dealers in securities, or their subsidiaries, or government entities, or if the transmittor and recipient are the same person and the transmittal involves a single bank or broker/dealer. These exceptions apply to the travel rule as well.

Request for Comment

These proposed amendments to the travel rule specify that the requirements of the travel rule apply only to financial institution offices that are located within the U.S. Treasury requests comments on these proposed amendments, and comments on the effect on the travel rule of the proposed amendments to the joint rule.

Executive Order 12866

Treasury finds that these proposed amendments to a final rule are not a significant rule for purposes of Executive Order 12866. The final rule is not anticipated to have an annual effect on the economy of $100 million or more. It will not affect adversely in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities. It creates no inconsistencies with, nor does it interfere with actions taken or planned by other agencies. Finally, it raises no novel legal or policy issues. A cost and benefit analysis is therefore not required.

Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act, Treasury hereby certifies that these proposed amendments to the final rule will not have a significant economic impact on a substantial number of small entities. The proposed amendments eliminate uncertainty as to the application of the final rule and reduce the cost of complying with the rule's requirements. Accordingly, a regulatory flexibility analysis is not required.

Paperwork Reduction Act

The collection of information required by the final rule whose amendment is proposed in this document was submitted by the Treasury to the Office of Management and Budget in accordance with the requirements of the Paperwork Reduction Act (44 U.S.C. 3504(h)) under control number 1505–0063. See 60 FR 237 (January 3, 1995). The collection is authorized, as before, by 12 U.S.C. 1829b and 1959 and 31 U.S.C. 5311–5330.

The changes to the final rule proposed in this document will eliminate information collection requirements that were required by the final rule. Therefore no additional Paperwork Reduction Act submissions are required.

Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995, Public Law 104–4 (Unfunded Mandates Act), signed into law on March 22, 1995, requires that an agency prepare a budgetary impact statement before promulgating a rule that includes a federal mandate that may result in expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year. Treasury has determined that it is not required to prepare a written budgetary impact statement for the proposed amendments, and has concluded that the proposed amendments are the most cost-effective and least burdensome means of achieving the stated objectives of the rule.

List of Subjects in 31 CFR Part 103

Administrative practice and procedure, Banks, banking, Brokers, Currency, Foreign banking, foreign currencies, Gambling, Investigations, Penalties, Reporting and recordkeeping requirements, Securities.

Amendment

For the reasons set forth in the preamble, 31 CFR Part 103 is proposed to be amended as set forth below:

PART 103—FINANCIAL RECORDKEEPING AND REPORTING OF CURRENCY AND FOREIGN TRANSACTIONS

1. The authority citation for Part 103 continues to read as follows:

Authority: 12 U.S.C. 1829b and 1951–1959; 31 U.S.C. 5311–5330.

2. In § 103.33, paragraphs (g) introductory text and (g)(1) introductory text are revised and paragraph (g)(3) is added to read as follows:

§ 103.33 Records to be made and retained by financial institutions.

* * * * *

(g) Any transmittor's financial institution or intermediary financial institution located within the United States shall include in any transmittal order for a transmittal of funds in the amount of $3,000 or more, information as required in this paragraph (g):

(1) A transmittor's financial institution shall include in a transmittal order, at the time it is sent to a receiving financial institution, the following information:

* * * * *

(3) Exceptions. The requirements of this paragraph (g) shall not apply to transmittals of funds that are listed in paragraphs (e)(6) or (f)(6) of this section.

Dated: July 31, 1995.

Stanley E. Morris,

Director, Financial Crimes Enforcement Network.

[FR Doc. 95–20845 Filed 8–23–95; 8:45 am]

BILLING CODE 4820–03–P

federal register

Thursday
August 24, 1995

Part V

Department of the Interior

Bureau of Indian Affairs

Proclaiming Certain Lands as Reservation for the Pueblo of Acoma and the Makah indian Tribes; Notices

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Proclaiming Certain Lands as Reservation for the Pueblo of Acoma Indian Tribe

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of Reservation Proclamation.

SUMMARY: The Assistant Secretary—Indian Affairs proclaimed 291.84 acres, more or less, as an addition to the reservation of the Pueblo of Acoma Indian Tribe of New Mexico on August 11, 1995. This notice is published in the exercise of authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs by 209 DM 8.3A.

FOR FURTHER INFORMATION CONTACT: Alice A. Harwood, Bureau of Indian Affairs, Division of Real Estate Services, Chief, Branch of Technical Services, MS–4522/MIB/Code 220, 1849 C Street, NW., Washington, DC 20240, telephone (202) 208–3604.

SUPPLEMENTARY INFORMATION: A proclamation was issued on August 11, 1995, according to the Act of June 18, 1934 (48 Stat. 986; 25 U.S.C. 467), for the tracts of land described below. The land was proclaimed to be an addition to and part of the Pueblo of Acoma Indian Reservation for the exclusive use of Indians on that reservation who are entitled to reside at the reservation by enrollment or tribal membership.

Cibola County, New Mexico

Lots 3 and 4 and the South half of the Northwest quarter (S½NW¼) of Section 4, Township 8 North, Range 9 West, New Mexico Principal Meridian, Cibola County, New Mexico, containing 131.84 acres, more or less,

and

The West half of the Northwest quarter (W½NW¼) and the West half of the Southwest quarter (W½SW¼) of Section 28, Township 9 North, Range 9 West, New Mexico Principal Meridian, Cibola County, New Mexico, containing 160 acres, more or less.

Title to the land described above is conveyed subject to any valid existing easements for public roads, highways, public utilities, pipelines, and any other valid easements or rights-of-way now on record.

Dated: August 11, 1995.

Ada E. Deer,

Assistant Secretary—Indian Affairs.

[FR Doc. 95–20509 Filed 8–23–95; 8:45 am]

BILLING CODE 4310–02–P

Proclaiming Certain Lands as Reservation for the Makah Indian Tribe

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of Reservation Proclamation.

SUMMARY: The Assistant Secretary—Indian Affairs proclaimed 1,989.35 acres, more or less, as an addition to the reservation of the Makah Indian Tribe of Washington on August 11, 1995. This notice is published in the exercise of authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs by 209 DM 8.3A.

FOR FURTHER INFORMATION CONTACT: Alice A. Harwood, Bureau of Indian Affairs, Division of Real Estate Services, Chief, Branch of Technical Services, MS–4522/MIB/Code 220, 1849 C Street, NW., Washington, DC 20240, telephone (202) 208–3604.

SUPPLEMENTARY INFORMATION: A proclamation was issued on August 11, 1995, according to the Act of June 18, 1934 (48 Stat. 986; 25 U.S.C. 467), for the tracts of land described below. The land was proclaimed to be an addition to and part of the Makah Indian Reservation for the exclusive use of Indians on that reservation who are entitled to reside at the reservation by enrollment or tribal membership.

Clallam County, Washington

Parcel A:

Government Lots 1, 2 and 3, and the Northwest Quarter of the Southeast Quarter (NW¼SE¼), and the North Half of the Southwest Quarter (N½SW¼), the South Half of the Southeast Quarter (S½SE¼), and the South Half of the Southwest Quarter (S½SW¼), the Northeast Quarter of the Southeast Quarter (NE¼SE¼) of Section 17, Township 32 North, Range 15 West, Willamette Meridian, Clallam County, Washington, containing 359.47 acres, more or less.

Parcel B:

All the Northwest Quarter (NW¼) and all the Southeast Quarter (SE¼) of Section 20, Township 32 North, Range 15 West, Willamette Meridian, Clallam County, Washington, containing 320.00 acres, more or less.

Parcel C:

All the Northwest Quarter (NW¼) of Section 28, Township 32 North, Range 15 West, Willamette Meridian, Clallam County, Washington, containing 160.00 acres, more or less.

Parcel D:

All the Southeast Quarter (SE¼) and all the Southwest Quarter (SW¼) of Section 29, Township 32 North, Range 15 West, Willamette Meridian, Clallam County, Washington, containing 320.00 acres, more or less.

Parcel E:

The Southeast Quarter of the Northwest Quarter (SE¼NW¼) and all of the Southeast Quarter (SE¼), and the East Half of the Southwest Quarter (E½SW¼) and the West Half of the Northeast Quarter (W½NE¼) in Section 30, Township 32 North, Range 15 West, Willamette Meridian, Clallam County, Washington, containing 360.00 acres, more or less.

Parcel F:

All of the North Half (N½) of Section 32, Township 32 North, Range 15 West, Willamette Meridian, Clallam County, Washington, containing 320.00 acres, more or less.

Parcel G:

Governments Lots 3 and 4, and the North Half of the Southwest Quarter (N½SW¼) of Section 33, Township 32 North, Range 15 West, Willamette Meridian, Clallam County, Washington, containing 149.88 acres, more or less.

Title to the lands described above is conveyed subject to any valid existing easements for public roads, highways, public utilities, pipelines, and any other valid easements or rights of way now on record.

Dated: August 11, 1995.

Ada E. Deer,

Assistant Secretary—Indian Affairs.

[FR Doc. 95–20510 Filed 8–23–95; 8:45 am]

BILLING CODE 4310–02–P

federal register

Thursday
August 24, 1995

Part VI

Pension Benefit Guaranty Corporation

29 CFR Part 2606, et al.
Missing Participants; Proposed Rule

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Parts 2606, 2616, 2617, and 2629

RIN 1212–AA81

Missing Participants

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Proposed rule.

SUMMARY: The Pension Benefit Guaranty Corporation is proposing a regulation to implement the new missing participants program under section 4050 of the Employee Retirement Income Security Act of 1974. Section 4050 applies to single-employer defined benefit plans distributing benefits in accordance with the standard termination procedures of Title IV.

DATES: Comments must be received by October 10, 1995.

ADDRESSES: Comments should be mailed to the Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW., Washington, DC 20005–4026, or delivered to suite 340 at that address. Written comments will be available for public inspection at the PBGC's Communications and Public Affairs Department, suite 240 at the same address.

FOR FURTHER INFORMATION CONTACT: Harold J. Ashner, Assistant General Counsel, or Deborah C. Murphy, Attorney, Office of the General Counsel, suite 340, Pension Benefit Guaranty Corporation, 1200 K Street NW., Washington, DC 20005–4026; 202–326–4024 (202–326–4179 for TTY and TDD).

SUPPLEMENTARY INFORMATION: When a fully-funded single-employer defined benefit pension plan terminates, the plan administrator must provide each participant and beneficiary with his or her benefit by purchasing an annuity from an insurer or paying a lump sum. Although in most cases the plan administrator can find all participants and beneficiaries, the plan administrator sometimes cannot do so.

Plan administrators provide benefits to persons who cannot be located by purchasing annuities from insurers or, in some limited cases, depositing funds in financial institutions. In certain instances, an insurer may not provide an annuity, or a financial institution may decline to accept the funds. A person who later comes forward may have difficulty locating his or her benefit.

Section 4050, which applies after final regulations go into effect, requires the plan administrator to distribute the benefits of a person who cannot be located by purchasing an annuity from an insurance company or paying funds to the PBGC. The PBGC will search for participants and beneficiaries for whom funds are paid to the PBGC, and pay benefits to those who are located (or their survivors). Participants and beneficiaries may also contact the PBGC to get the name of the insurance company from which an annuity was purchased or to obtain their benefits from the PBGC.

This proposed rule implementing section 4050 applies to plans undergoing standard terminations and to plans undergoing distress terminations that are sufficient for guaranteed benefits and close out under the standard termination rules.

The Administration has proposed extending the missing participants program to terminating defined contribution plans and to terminating defined benefit plans not covered by Title IV. This proposed rule addresses only the enacted program for terminating defined benefit plans covered by Title IV.

Diligent Search

A plan administrator must conduct a "diligent search" for a missing participant before paying the benefit to the PBGC. (The term "missing participant" includes beneficiaries as well as participants, and may include alternate payees under a qualified domestic relations order.)

A search is a diligent search only if:

- The plan administrator asks any known beneficiaries of the missing participant for the missing participant's address; and
- The plan administrator uses a commercial locator service.

The plan administrator must undertake the search at or after the beginning of the plan termination process, and in a manner reasonably expected to permit timely distributions to located participants and beneficiaries. A plan administrator may use additional search methods, such as the Internal Revenue Service's letter forwarding program for those attempting to locate missing individuals, or mailing correspondence to the missing participant's last known address with a request to the post office for an address correction.

Payments to the PBGC (Designated Benefit)

Amount

A plan administrator that does not purchase an annuity for a missing participant must pay to the PBGC an amount (the "designated benefit") representing the value of the missing participant's plan benefit. The method for determining the amount to be paid depends mainly on the plan's provisions.

If under the plan the missing participant would be paid a mandatory lump sum distribution—*e.g.*, because the single sum value does not exceed $3,500—the plan administrator pays the amount of the mandatory lump sum to the PBGC.

If the missing participant would not receive a mandatory lump sum under the plan, but the value of the missing participant's benefit is *de minimis (i.e.*, the benefit has a value of $3,500 or less) under the "missing participant lump sum assumptions", the plan administrator pays that value.

For the remaining missing participants, the plan administrator determines whether the missing participant can elect an immediate lump sum under the plan as of the "deemed distribution date" selected by the plan administrator (generally between the distribution date for non-missing participants and the end of the permitted distribution period). If not, the plan administrator pays the value of the missing participant's benefit calculated under the "missing participant annuity assumptions."

If the missing participant can elect a lump sum, the plan administrator pays an amount equal to the greater of the lump sum using plan assumptions or the value of the benefit using the missing participant annuity assumptions.

PBGC Assumptions and Calculation Methods

Certain relevant information, such as the future marital status of a missing participant or whether the missing participant is still alive, is not available to the plan administrator. The PBGC has developed a number of simplifying assumptions to deal with these and other issues under the missing participants program. These assumptions take into account the value of the various benefits the missing participant (or his or her beneficiary) could receive under the plan. The PBGC invites public comment on these assumptions.

The actuarial assumptions used under the missing participants program are based on the lump sum and annuity assumptions in the PBGC's single-employer valuation regulation (29 CFR Part 2619). (The PBGC intends to propose new assumptions for valuing lump sums and the final missing

participant regulations may reflect those changes.) However, the mortality tables and loading charges in the valuation regulation are modified and the "most valuable benefit" is used instead of the benefit at the expected retirement age.

For a missing participant whose benefit is in pay status, the most valuable benefit is the benefit in pay status. For a participant whose benefit is not in pay status, the plan administrator assumes the participant is married to a spouse the same age, and the participant's qualified joint and survivor annuity under the plan is valued at each age between the participant's earliest early retirement age and the participant's normal retirement age to find the most valuable benefit. For a beneficiary whose benefit is not in pay status, the plan administrator assumes the beneficiary is not married, and the beneficiary's automatic form of benefit under the plan is valued at each age between the deceased participant's earliest early retirement age and the participant's normal retirement age to find the most valuable benefit.

Several special rules apply, including rules for when there are employee contributions to the plan or distributions of residual assets to missing participants.

Benefit Payments by the PBGC

If a plan administrator pays an amount to the PBGC for a missing participant, and the missing participant (or his or her beneficiary or estate) later contacts the PBGC or is located through the PBGC search process, the PBGC provides benefits as described below. (If a plan administrator purchases an annuity for a missing participant, and the missing participant (or his or her beneficiary or estate) later contacts the PBGC, the PBGC advises the person of the identity of the insurance company that issued the annuity.)

Automatic Lump Sums

The PBGC pays a lump sum to a located missing participant if the plan would have paid the missing participant a mandatory lump sum. The lump sum equals the amount paid to the PBGC plus interest.

If, unknown to the plan administrator, the missing participant died before the deemed distribution date, and if the plan so provides, the PBGC pays the lump sum to the missing participant's beneficiary or estate. If the missing participant dies on or after the deemed distribution date, the PBGC pays the lump sum to the missing participant's estate.

Similar rules apply when, although a mandatory lump sum would not be paid to the missing participant under the plan, the PBGC could pay a *de minimis* lump sum under the guaranteed benefit program because the value of the benefit was $3,500 or less under the missing participant lump sum assumptions. In this case, however, the participant or beneficiary may decline the *de minimis* lump sum and elect to receive an equivalent annuity to the extent that participants and beneficiaries in the PBGC's guaranteed benefits program have that option.

Annuities

In other cases the PBGC pays the benefit in the forms available under the guaranteed benefits program. If the missing participant is a participant and is alive, the form is typically a qualified joint and survivor annuity or, for unmarried participants, a single life annuity. A living missing participant's annuity equals the annuity that can be purchased with the amount the plan administrator paid to the PBGC (minus the loading charge) using the missing participant annuity assumptions in effect at the deemed distribution date. A missing participant whose benefit was in pay status before becoming missing receives back payments and continuation of the original benefit.

A missing participant who could have received an immediate lump sum as of the deemed distribution date under the plan may elect a lump sum payment from the PBGC (after obtaining any required spousal consent). The lump sum equals the amount paid to the PBGC plus interest.

If the missing participant is a participant and dies before receiving benefits from the PBGC, the PBGC pays the missing participant's surviving spouse (unless the spouse has properly waived the benefit) a preretirement survivor annuity, based on a joint and 50 percent survivor annuity that is the actuarial equivalent of the amount paid to the PBGC (minus the loading charge). A beneficiary of such a deceased missing participant who was in pay status receives the benefit the beneficiary would have received under the plan, including, where appropriate, back payments.

A beneficiary of a missing participant who died before the deemed distribution date may establish that he or she is the proper beneficiary under the plan, or that he or she would have received benefits in a different form, at a different time, or in a different amount. If the beneficiary establishes this to the PBGC's satisfaction, the beneficiary will receive the revised benefit. However, the total actuarial value as of the deemed distribution date of all benefits payable will be limited to the designated benefit.

A spouse or other beneficiary of a deceased missing participant may elect a lump sum equivalent of the survivor annuity if the missing participant could have elected a lump sum under the plan.

Guaranteed Benefit

If a missing participant or his or her beneficiary establishes, to the PBGC's satisfaction, that the designated benefit paid to the PBGC was less than the amount that should have been paid as a designated benefit, the PBGC will increase the benefit to reflect the correct designated benefit or, if less, the value of the guaranteed benefit.

Procedural Requirements

The plan administrator pays the designated benefits to the PBGC by the time the post-distribution certification (PDC) required under the PBGC's plan termination regulation is due. (Interest is assessed if the payment is late.) At the same time, the plan administrator must give the PBGC certifications and information about all missing participants, as required by new Schedule MP and its instructions, which are set forth as an addendum to this proposed rule document.

Special rules are provided for missing participants who are discovered to be missing shortly before the deemed distribution date ("recently-missing participants") and for participants who are located late in the process ("late-discovered participants").

The PBGC has discretion to return to the plan administrator the designated benefit of a missing participant found within 30 days after the PBGC receives the designated benefit. The plan administrator will then distribute the benefit under the plan to that individual.

The PBGC will review compliance with the missing participant program as part of its standard termination audits. The six-year recordkeeping requirement that applies generally to plan records associated with the termination process (§§ 2616.9 and 2617.10) applies to missing participant records.

Paperwork Reduction Act

The collection of information requirements contained in the proposed regulation on missing participants, and the forms and instructions to be used under the missing participants program, have been submitted to the Office of Management and Budget for review under section 3504(h) of the Paperwork Reduction Act of 1980. The PBGC needs the information submitted by plan

administrators of terminating single-employer plans to identify, for missing participants whose benefits are annuitized, the insurance companies that are to provide their benefits; to attempt to locate missing participants for whom benefits are paid to the PBGC and to pay their benefits; and to monitor and audit compliance with all applicable requirements.

The PBGC estimates that it will take an average of 2.46 hours to comply with the collection of information requirements under the proposed regulation and, based on its experience with trusteed plans, that about 500 plans will be required to comply each year. Accordingly, the estimated burden of the collection of information is 1,230 hours.

Copies of the proposed forms and instructions are set forth as an addendum to this proposed rule document. Comments on the paperwork provisions of the proposed rule and on the forms and instructions should be mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for the Pension Benefit Guaranty Corporation, Washington, DC 20503. Comments may address (among other things)—

- Whether the proposed collection of information is needed for the proper performance of the PBGC's functions and will have practical utility;
- The accuracy of the PBGC's estimate of the burden of the proposed collection of information;
- Enhancement of the quality, utility, and clarity of the information to be collected; and
- Minimizing the burden of the collection of information on respondents through the use of automated collection techniques (or other forms of information technology) or in other ways.

In particular, the PBGC invites suggestions regarding procedures for submitting some or all of the required information electronically.

Compliance With Rulemaking Guidelines

The PBGC has determined that this action is not a "significant regulatory action" under the criteria set forth in Executive Order 12866 because the rule will not have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866.

The PBGC certifies under section 605(b) of the Regulatory Flexibility Act that this regulation will not have a significant economic impact on a substantial number of small entities. Pension plans with fewer than 100 participants have traditionally been treated as small plans. Plan administrators of terminating plans of all sizes already have a duty to determine the amounts of all benefits, to attempt to locate all persons entitled to benefits, and to annuitize or provide cash accounts for those who cannot be found. The primary effect of this regulation is to substitute a formal procedure involving the PBGC for the informal procedures already being followed. The PBGC does not expect the standardization of these procedures to have a significant effect on plan administrators' burdens. Accordingly, sections 603 and 604 of the Regulatory Flexibility Act do not apply.

List of Subjects

29 CFR Part 2606

Employee benefit plans, Pension insurance, Pensions, Administrative practice and procedure.

29 CFR Parts 2616, 2617, and 2629

Employee benefit plans, Pension insurance, Pensions, Reporting and recordkeeping requirements.

In consideration of the foregoing, the PBGC proposes to amend 29 CFR chapter XXVI as follows.

1. Part 2629 is added to subchapter C to read as follows:

PART 2629—MISSING PARTICIPANTS

Sec.

Authority: 29 U.S.C. 1302(b)(3), 1350.

§ 2629.1 Purpose and scope.

(a) *Purpose.* This part prescribes rules for distributing benefits under a terminating plan to any individual whom the plan administrator has not located when distributing benefits under § 2617.28(c) of this chapter.

(b) *Scope.* This part applies to a plan if the plan's deemed distribution date (or the date of other payments made in accordance with § 2629.12) is in a plan year beginning on or after the effective date of this part.

§ 2629.2 Definitions.

For purposes of this part:

(a) *Act* means the Employee Retirement Income Security Act of 1974, as amended.

(b) *Code* means the Internal Revenue Code of 1986, as amended.

(c) *Deemed distribution date* means the date selected by the plan administrator of a terminating plan that is on or after the date when all benefit distributions have been made under the plan except for distributions to missing participants whose designated benefits are paid to the PBGC, but not later than the last day of the period in which distribution may be made under § 2616.29(a) or 2617.28(a) of this chapter (whichever applies).

(d) *Designated benefit* means the amount payable to the PBGC for a missing participant pursuant to § 2629.5.

(e) *Designated benefit interest rate* means the rate of interest applicable to underpayments of guaranteed benefits by the PBGC under § 2623.11(d) of this chapter.

(f) *Guaranteed benefit form* means, with respect to a benefit, the form in which the PBGC would pay a guaranteed benefit to a participant or beneficiary in the PBGC's program for trusteed plans under parts 2613 and 2621 of this chapter (treating the deemed distribution date as the date of plan termination for this purpose).

(g) *Late-discovered participant* means a participant or beneficiary entitled to a distribution under a terminating plan whom the plan administrator locates before the plan administrator pays the individual's designated benefit to the PBGC (or distributes the individual's benefit by purchasing an irrevocable commitment from an insurer) and not more than 90 days before the deemed distribution date.

(h) *Missing participant* means a participant or beneficiary entitled to a distribution under a terminating plan whom the plan administrator has not located as of the date when the plan administrator pays the individual's designated benefit to the PBGC (or distributes the individual's benefit by purchasing an irrevocable commitment from an insurer). In the absence of proof of death, individuals not located are presumed living.

(i) *Missing participant annuity assumptions* means the interest rate assumptions and actuarial methods (using the interest rates for annuity valuation in Appendix B to part 2619 of this chapter) for valuing a benefit to be paid by the PBGC as an annuity under part 2619 of this chapter, applied—

(1) As if the deemed distribution date were the date of plan termination;

(2) Using unisex mortality rates that are a fixed blend of 50 percent of the male mortality rates and 50 percent of the female mortality rates from the 1983 Group Annuity Mortality Table as prescribed in Rev. Rul. 95–6, 1995–4 IRB 22, January 23, 1995 (Internal Revenue Bulletins are available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402);

(3) Without using the expected retirement age assumptions in Subpart D to part 2619 of this chapter; and

(4) By adding $300 for each missing participant as an adjustment (loading) for expenses (instead of the adjustment for expenses provided for in § 2619.49(a)(4) of this chapter).

(j) *Missing participant forms and instructions* means PBGC Forms 501 and 602, Schedule MP thereto, and related forms, and their instructions.

(k) *Missing participant lump sum assumptions* means the interest rate assumptions and actuarial methods (using the interest rates for lump sum valuations in Appendix B to part 2619 of this chapter) for valuing a benefit to be paid by the PBGC as a lump sum under part 2619 of this chapter, applied—

(1) As if the deemed distribution date were the date of plan termination;

(2) Using mortality assumptions for healthy lives only (from Table I of Appendix A to part 2619 of this chapter, substituting x+1 for x); and

(3) Without using the expected retirement age assumptions in Subpart D to part 2619 of this chapter.

(l) *Pay status* means, with respect to a benefit, that, as of the deemed distribution date, one or more benefit payments have been made or would have been made except for administrative delay or a waiting period.

(m) *Post-distribution certification* means the post-distribution certification required by § 2616.29(b) or 2617.28(h) of this chapter.

(n) *Plan administrator* means the administrator as defined in section 4001(a)(1) of the Act.

(o) *Recently-missing participant* means a participant or beneficiary entitled to a distribution under a terminating plan whom the plan administrator discovers to be missing on or after the 90th day before the deemed distribution date.

(p) *Unloaded designated benefit* means the designated benefit reduced by $300.

§ 2629.3 Method of distribution for missing participants.

The plan administrator of a terminating plan shall distribute benefits for each missing participant by—

(a) Purchasing an irrevocable commitment from an insurer in accordance with § 2617.28(c) or § 2616.29(a)(1) of this chapter (whichever is applicable); or

(b) Paying the PBGC a designated benefit in accordance with §§ 2629.4 through 2629.6 (subject to the special rules in § 2629.12).

§ 2629.4 Diligent search.

(a) *Search required.* A plan administrator shall make a diligent search for each missing participant whose designated benefit is paid to the PBGC. The search shall be made before the payment is made.

(b) *Diligence.* A search is a diligent search only if the plan administrator—

(1) Begins the search at or after the time when notices of intent to terminate are issued and carries on the search in such a manner that if the individual is found, distribution to the individual can reasonably be expected to be made on or before the deemed distribution date (or, in the case of a recently-missing participant, on or before the 90th day after the deemed distribution date);

(2) Makes inquiry of any plan beneficiaries and alternate payees of the missing participant whose names and addresses are known to the plan administrator; and

(3) Engages a commercial locator service to search for the missing participant.

§ 2629.5 Designated benefit.

(a) *Amount of designated benefit.* The amount of the designated benefit shall be the amount determined under paragraph (a)(1), (a)(2), (a)(3), or (a)(4) of this section (whichever is applicable) or, if less, the amount that could be provided under the plan to the missing participant in the form of a single sum in accordance with section 415 of the Code.

(1) *Mandatory lump sum.* The designated benefit of a missing participant required under a plan to receive a mandatory lump sum as of the deemed distribution date shall be the lump sum payment that the plan administrator would have distributed to the missing participant as of the deemed distribution date.

(2) *De minimis lump sum.* The designated benefit of a missing participant not described in paragraph (a)(1) of this section whose benefit is not in pay status and whose benefit has a *de minimis* actuarial present value ($3,500 or less) as of the deemed distribution date under the missing participant lump sum assumptions shall be such value.

(3) *No lump sum.* The designated benefit of a missing participant not described in paragraph (a)(1) or (a)(2) of this section who, as of the deemed distribution date, cannot elect an immediate lump sum under the plan shall be the actuarial present value of the missing participant's benefit as of the deemed distribution date under the missing participant annuity assumptions.

(4) *Elective lump sum.* The designated benefit of a missing participant not described in paragraph (a)(1), (a)(2), or (a)(3) of this section shall be the greater of the amounts determined under the methodologies of paragraph (a)(1) or (a)(3) of this section.

(b) *Assumptions.* When the plan administrator uses the missing participant annuity assumptions or the missing participant lump sum assumptions for purposes of determining the designated benefit under paragraph (a) of this section, the plan administrator shall value the most valuable benefit, as determined under paragraph (b)(1) of this section, using the assumptions described in paragraph (b)(2) or (b)(3) of this section (whichever is applicable).

(1) *Most valuable benefit.* For a missing participant whose benefit is in pay status, the most valuable benefit is the benefit in pay status. For a missing participant whose benefit is not in pay status, the most valuable benefit is the benefit payable at the age on or after the deemed distribution date (beginning with the participant's earliest early retirement age and ending with the participant's normal retirement age) for which the present value as of the deemed distribution date is the greatest. The present value as of the deemed

distribution date with respect to any age is determined by multiplying:

(i) The monthly (or other periodic) benefit payable under the plan; by

(ii) The present value (determined as of the deemed distribution date using the missing participant annuity assumptions) of a $1 monthly (or other periodic) annuity beginning at the applicable age.

(2) *Participant.* A missing participant who is a participant, and whose benefit is not in pay status, is assumed to be married to a spouse the same age, and the form of benefit that must be valued is the qualified joint and survivor annuity benefit that would be payable under the plan. If the participant's benefit is in pay status, the form and beneficiary of the participant's benefit are the form of benefit and beneficiary of the benefit in pay status.

(3) *Beneficiary.* A missing participant who is a beneficiary, and whose benefit is not in pay status, is assumed not to be married, and the form of benefit that must be valued is the survivor benefit that would be payable under the plan. If the beneficiary's benefit is in pay status, the form and beneficiary of the beneficiary's benefit are the form of benefit and beneficiary of the benefit in pay status.

(4) *Examples.* See Appendix A for examples illustrating the provisions of this section.

(c) *Missed payments.* In determining the designated benefit, the plan administrator shall include the value of any payments that were due before the deemed distribution date but that were not made.

(d) *Payment of designated benefits.* Payment of designated benefits shall be made in accordance with § 2629.6 and shall be deemed made on the deemed distribution date.

§ 2629.6 Payment and required documentation.

(a) *Time of payment and filing.*

(1) *General rule.* The plan administrator shall pay designated benefits, and file the information and certifications (of the plan administrator and the plan's enrolled actuary) specified in the missing participant forms and instructions, by the time the post-distribution certification is due (determined in accordance with §§ 2616.7(a) and 2617.8(a) of this chapter). Except as otherwise provided in the missing participant forms and instructions, the plan administrator shall submit the designated benefits, information, and certifications with the post-distribution certification.

(2) *Recently-missing participants.* In the case of a recently-missing participant, the plan administrator shall pay the designated benefit by the time the amended post-distribution certification is due under paragraph (a)(2)(ii) of this section. Except as otherwise provided in the missing participant forms and instructions—

(i) *Payment.* The plan administrator shall submit the designated benefit with the amended post-distribution certification described in paragraph (a)(2)(ii) of this section; and

(ii) *Filing.* If the diligent search is not complete when the plan administrator submits the filing described in paragraph (a)(1) of this section, the plan administrator shall indicate this in that filing and submit an amended filing (including an amended post-distribution certification) within 120 days after the deemed distribution date.

(3) *Late-discovered participants.* When it is impracticable for the plan administrator to include complete and accurate final information on a late-discovered participant in a timely post-distribution certification, the plan administrator shall submit an amended post-distribution certification within 120 days after the deemed distribution date in accordance with the missing participant forms and instructions.

(b) *Interest on late payments.* If the plan administrator does not pay a designated benefit by the time specified in paragraph (a) of this section, the plan administrator shall pay interest as assessed by the PBGC for the period beginning on the deemed distribution date and ending on the date when the payment is received by the PBGC. Interest will be assessed at the rate provided for late premium payments in § 2610.7 of this chapter.

(c) *Supplemental information.* Within 30 days after the date of a written request from the PBGC, a plan administrator required to provide the information and certifications described in paragraph (a) of this section shall file supplemental information, as requested, for the purpose of verifying designated benefits and determining benefits to be paid by the PBGC under this part.

(1) *Information mailed.* Supplemental information filed under this paragraph (c) is considered filed on the date of the United States postmark stamped on the cover in which the information is mailed, if—

(i) The postmark was made by the United States Postal Service; and

(ii) The information was mailed postage prepaid, properly addressed to the PBGC.

(2) *Information delivered.* When the plan administrator sends or transmits the information to the PBGC by means other than the United States Postal Service, the information is considered filed on the date it is received by the PBGC. Information received on a weekend or Federal holiday or after 5:00 p.m. on a weekday is considered filed on the next regular business day.

§ 2629.7 Benefits of missing participants—in general.

(a) *If annuity purchased.* If a plan administrator distributes a missing participant's benefit by purchasing an irrevocable commitment from an insurer, and the missing participant (or his or her beneficiary or estate) later contacts the PBGC, the PBGC will inform the person of the identity of the insurer and the relevant policy number.

(b) *If designated benefit paid.* If the PBGC locates or is contacted by a missing participant for whom a plan administrator paid a designated benefit to the PBGC (or his or her beneficiary or estate), the PBGC will pay benefits in accordance with §§ 2629.8 through 2629.10 (subject to the limitations and special rules in §§ 2629.11 and 2629.12).

(c) *Examples.* See Appendix B for examples illustrating the provisions of §§ 2629.8 through 2629.10.

§ 2629.8 Automatic lump sum.

This section applies to a missing participant whose designated benefit was determined under § 2629.5(a)(1) (mandatory lump sum) or § 2629.5(a)(2) (de minimis lump sum).

(a) *General rule.*

(1) *Benefit paid.* The PBGC will pay a single sum benefit equal to the designated benefit plus interest at the designated benefit interest rate from the deemed distribution date to the date on which the PBGC pays the benefit.

(2) *Payee.* Payment shall be made—

(i) To the missing participant, if located;

(ii) If the missing participant died before the deemed distribution date, and if the plan so provides, to the missing participant's beneficiary or estate; or

(iii) If the missing participant dies on or after the deemed distribution date, to the missing participant's estate.

(b) De minimis annuity alternative. If the guaranteed benefit form for a missing participant whose designated benefit was determined under § 2629.5(a)(2) (de minimis lump sum) (or the guaranteed benefit form for a beneficiary of such a missing participant) would provide for the election of an annuity, the missing participant (or the beneficiary) may elect to receive an annuity. If such an election is made—

(1) The PBGC will pay the benefit in the elected guaranteed benefit form, beginning on the annuity starting date

elected by the missing participant (or the beneficiary), but not before the later of the date of the election or the earliest date on which the missing participant (or the beneficiary) could have begun receiving benefits under the plan; and

(2) The monthly (or other periodic) benefit paid will be actuarially equivalent to the designated benefit, i.e., each benefit payment will equal the designated benefit divided by the present value (determined as of the deemed distribution date under the missing participant lump sum assumptions) of a $1 monthly (or other periodic) annuity beginning on the annuity starting date.

§ 2629.9 Annuity or elective lump sum—living missing participant.

This section applies to a missing participant whose designated benefit was determined under § 2629.5(a)(3) (no lump sum) or § 2629.5(a)(4) (elective lump sum) and who is living on the date as of which benefits commence.

(a) *Missing participant whose benefit is not in pay status.* The PBGC will pay the benefit of a missing participant whose benefit is not in pay status as follows.

(1) *Time and form of benefit.* The PBGC will pay the missing participant's benefit in the guaranteed benefit form, beginning on the annuity starting date elected by the missing participant (but not before the later of the date of the election or the earliest date on which the missing participant could have begun receiving benefits under the plan).

(2) *Amount of benefit.* The PBGC will pay a monthly (or other periodic) benefit that is actuarially equivalent to the unloaded designated benefit, i.e., each benefit payment will equal the unloaded designated benefit divided by the present value (determined as of the deemed distribution date under the missing participant annuity assumptions) of a $1 monthly (or other periodic) annuity beginning on the annuity starting date.

(b) *Missing participant whose benefit is in pay status.* The PBGC will pay the benefit of a missing participant whose benefit is in pay status as follows.

(1) *Time and form of benefit.* The PBGC will pay the benefit in the form that was in effect, beginning when the missing participant is located.

(2) *Amount of benefit.* The PBGC will pay the monthly (or other periodic) amount of the benefit that was in pay status, plus a lump sum equal to the payments the missing participant would have received under the plan, plus interest on the missed payments (at the plan rate up to the deemed distribution date and thereafter at the designated benefit interest rate) to the date as of which the PBGC pays the lump sum.

(c) *Payment of lump sum.* If a missing participant whose designated benefit was determined under § 2629.5(a)(4) (elective lump sum) so elects, the PBGC will pay his or her benefit in the form of a single sum. This election is not effective unless the missing participant's spouse consents (if such consent would be required under section 205 of the Act). The single sum equals the designated benefit plus interest (at the designated benefit interest rate) from the deemed distribution date to the date as of which the PBGC pays the benefit.

§ 2629.10 Annuity or elective lump sum—deceased missing participant.

This section applies to a beneficiary of a deceased missing participant whose designated benefit was determined under § 2629.5(a)(3) (no lump sum) or § 2629.5(a)(4) (elective lump sum) and whose benefit is not payable under § 2629.9.

(a) *If missing participant died with benefit not in pay status.*

(1) *General rule.*

(i) *Beneficiary.* The PBGC will pay a benefit to the surviving spouse of a missing participant who is a participant and whose benefit is not in pay status (unless the surviving spouse has properly waived a benefit in accordance with section 205 of the Act).

(ii) *Form and amount of benefit.* The PBGC will pay the survivor benefit in the form of a single life annuity. Each benefit payment will equal 50% of the quotient that results when the unloaded designated benefit is divided by the present value (determined as of the deemed distribution date under the missing participant annuity assumptions, and assuming that the missing participant survived to the deemed distribution date) of a $1 monthly (or other periodic) joint and 50% survivor annuity in the form described in § 2619.49(f)(1) of this chapter beginning on the annuity starting date.

(iii) *Time of benefit.* The PBGC will pay the survivor benefit beginning at the time elected by the surviving spouse (but not before the later of the date of the election or the earliest date on which the surviving spouse could have begun receiving benefits under the plan).

(2) *If missing participant died before deemed distribution date.* Notwithstanding the provisions of paragraph (a)(1) of this section, if a beneficiary of a missing participant who died before the deemed distribution date establishes to the PBGC's satisfaction that he or she is the proper beneficiary or would have received benefits under the plan in a form, at a time, or in an amount different from the benefit paid under paragraph (a)(1)(ii) or (a)(1)(iii) of this section, the PBGC will make payments in accordance with the facts so established, but only in the guaranteed benefit form.

(3) *Elective lump sum.* Notwithstanding the provisions of paragraphs (a)(1) and (a)(2) of this section, if the beneficiary of a missing participant whose designated benefit was determined under § 2629.5(a)(4) (elective lump sum) so elects, the PBGC will pay his or her benefit in the form of a single sum. The single sum will be equal to the actuarial present value (determined as of the deemed distribution date under the missing participant annuity assumptions) of the death benefit payable on the annuity starting date, plus interest (at the designated benefit interest rate) from the deemed distribution date to the date as of which the PBGC pays the benefit.

(b) *If missing participant died with benefit in pay status.*

(1) *Beneficiary.* The PBGC will pay benefits to the beneficiary (if any) of the benefit that was in pay status.

(2) *Form and amount of benefit.* The PBGC will pay a monthly (or other periodic) amount equal to the monthly (or other periodic) amount, if any, that the beneficiary would have received under the form of payment in effect, plus a lump sum payment equal to the payments the beneficiary would have received under the plan subsequent to the missing participant's death and prior to the date as of which the benefit is paid under paragraph (b)(4) of this section, plus interest on the missed payments (at the plan rate up to the deemed distribution date and thereafter at the designated benefit interest rate) to the date as of which the benefit is paid under paragraph (b)(4) of this section.

(3) *Lump sum payment to estate.* The PBGC will make a lump sum payment to the missing participant's estate equal to the payments that the missing participant would have received under the plan for the period prior to the missing participant's death, plus interest on the missed payments (at the plan rate up to the deemed distribution date and thereafter at the designated benefit interest rate) to the date as of which the benefit is paid under paragraph (b)(4) of this section. Notwithstanding the preceding sentence, if a beneficiary of a missing participant other than the estate establishes to the PBGC's satisfaction that the beneficiary is entitled to the

lump sum payment, the PBGC will pay the lump sum to such beneficiary.

(4) *Time of benefit.* The PBGC will pay the survivor benefit when the beneficiary is located.

§ 2629.11 Limitations.

(a) *Exclusive benefit.* The benefits provided for under §§ 2629.8 through 2629.10 shall be the only benefits payable by the PBGC to missing participants or to beneficiaries based on the benefits of deceased missing participants.

(b) *Limitation on benefit value.* The total actuarial present value of all benefits paid with respect to a missing participant under §§ 2629.8 through 2629.10, determined as of the deemed distribution date, shall not exceed the missing participant's designated benefit.

(c) *Guaranteed benefit.* If a missing participant or his or her beneficiary establishes to the PBGC's satisfaction that the benefit under §§ 2629.8 through 2629.10 (based on the designated benefit actually paid to the PBGC) is less than the minimum benefit in this paragraph (c), the PBGC shall instead pay the minimum benefit. The minimum benefit shall be the lesser of:

(1) The benefit as determined under the PBGC's rules for paying guaranteed benefits in trusteed plans under parts 2613 and 2621 of this chapter (treating the deemed distribution date as the date of plan termination for this purpose); or

(2) The benefit based on the designated benefit that should have been paid under § 2629.5.

(d) *Limitation on annuity starting date.* A missing participant (or his or her survivor) may not elect an annuity starting date after the later of—

(1) The required beginning date under section 401(a)(9) of the Code; or

(2) The date when the missing participant (or the survivor) is located.

§ 2629.12 Special rules.

(a) *Late-discovered participants.* The plan administrator of a plan that terminates with one or more late-discovered participants shall (after issuing notices to each such participant in accordance with §§ 2616.22 and 2616.27 or 2617.22 and 2617.23 of this chapter (whichever apply)), distribute each such late-discovered participant's benefit within the period described in § 2616.29(a) or 2617.28(a) of this chapter (whichever applies) if practicable or (if not) as soon thereafter as practicable, but not more than 90 days after the deemed distribution date.

(b) *Missing participants located quickly.* Notwithstanding the provisions of §§ 2629.8 through 2629.10, if the PBGC or the plan administrator locates a missing participant within 30 days after the PBGC receives the missing participant's designated benefit, the PBGC may in its discretion return the missing participant's designated benefit to the plan administrator, and the plan administrator shall treat the missing participant like a late-discovered participant.

(c) *Qualified domestic relations orders.* Plan administrators and the PBGC shall take the provisions of qualified domestic relations orders (QDROs) under section 206(d)(3) of the Act into account in determining designated benefits and benefit payments by the PBGC, including treating an alternate payee under an applicable QDRO as a missing participant or as a beneficiary of a missing participant, as appropriate, in accordance with the terms of the QDRO. For purposes of calculating the amount of the designated benefit of an alternate payee, the plan administrator shall use the assumptions for a missing participant who is a beneficiary under § 2629.5(b).

(d) *Employee contributions.*

(1) *Mandatory employee contributions.* Notwithstanding the provisions of § 2629.5, if a missing participant's contributions were mandatory (within the meaning of section 4044(a)(2) of the Act), the missing participant's designated benefit shall not be less than the sum of the missing participant's mandatory contributions and interest to the deemed distribution date at the plan's rate or the rate under section 204(c) of the Act (whichever produces the greater amount).

(2) *Voluntary employee contributions.*

(i) *Applicability.* This paragraph (d)(2) applies to any employee contributions that were not mandatory (within the meaning of section 4044(a)(2) of the Act) to which a missing participant is entitled in connection with the termination of a defined benefit plan.

(ii) *Payment to PBGC.* A plan administrator, in accordance with the missing participant forms and instructions, shall pay the employee contributions described in paragraph (d)(2)(i) of this section (together with any earnings thereon) to the PBGC, and shall file Schedule MP with the PBGC, by the time the designated benefit is due under § 2629.6. Any such amount shall be in addition to the designated benefit and shall be separately identified.

(iii) *Payment by PBGC.* In addition to any other amounts paid by the PBGC under §§ 2629.8 through 2629.10, the PBGC shall pay any amount paid to it under paragraph (d)(2)(ii) of this section, with interest at the designated benefit interest rate from the date of receipt by the PBGC to the date of payment by the PBGC, in the same manner as described in § 2629.8 (automatic lump sums), except that if the missing participant died before the deemed distribution date and there is no beneficiary, payment shall be made to the missing participant's estate.

(e) *Residual assets.* The PBGC shall determine, in a manner consistent with the purposes of this part and section 4050 of the Act, how the provisions of this part shall apply to any distribution, to participants and beneficiaries who cannot be located, of residual assets remaining after the satisfaction of benefit liabilities in connection with the termination of a defined benefit plan. The deadline for payment of residual assets for a missing participant and for submission to the PBGC of a Schedule MP (or an amended Schedule MP) is the 30th day after the date on which all residual assets have been distributed to all participants and beneficiaries other than missing participants for whom payment for residual assets is made to the PBGC.

(f) *Sufficient distress terminations.* In the case of a plan undergoing a distress termination (under section 4041(c) of the Act) that is sufficient for at least all guaranteed benefits and that distributes its assets in the manner described in section 4041(b)(3) of the Act, the benefit assumed to be payable by the plan for purposes of determining the amount of the designated benefit under § 2629.5 shall be limited to the Title IV benefit (as defined in § 2616.2 of this chapter).

(g) *Similar rules for later payments.* If the PBGC determines, upon audit of a plan termination, that one or more persons should receive benefits (which may be in addition to benefits already provided) in order for a termination to be valid, and one or more of such individuals cannot be located, the PBGC shall determine, in a manner consistent with the purposes of this part and section 4050 of the Act, how the provisions of this part shall apply to such benefits.

Appendix A—Examples of Designated Benefit Determinations for Missing Participants Under § 2629.5

The calculation of the designated benefit under § 2629.5 is illustrated by the following examples.

Example 1. Plan A provides that any participant whose benefit has a value at distribution of $1,750 or less will be paid a lump sum, and that no other lump sums will be paid. P, Q, and R are missing participants.

(1) As of the deemed distribution date, the value of P's benefit is $1,700 under plan A's assumptions. Under § 2629.5(a)(1), the plan

administrator pays the PBGC $1,700 as P's designated benefit.

(2) As of the deemed distribution date, the value of Q's benefit is $3,700 under plan A's assumptions and $3,200 under the missing participant lump sum assumptions. Under § 2629.5(a)(2), the plan administrator pays the PBGC $3,200 as Q's designated benefit.

(3) As of the deemed distribution date, the value of R's benefit is $3,400 under plan A's assumptions, $3,600 under the missing participant lump sum assumptions, and $3,450 under the missing participant annuity assumptions. Under § 2629.5(a)(3), the plan administrator pays the PBGC $3,450 as R's designated benefit.

Example 2. Plan B provides for a normal retirement age of 65 and permits early commencement of benefits at any age between 60 and 65, with benefits reduced by 5 percent for each year before age 65 that the benefit begins. The qualified joint and 50 percent survivor annuity payable under the terms of the plan requires in all cases a 16 percent reduction in the benefit otherwise payable. The plan does not provide for elective lump sums.

(1) M is a missing participant who separated from service under plan B with a deferred vested benefit. M is age 50 at the deemed distribution date, and has a normal retirement benefit of $1,000 per month payable at age 65 in the form of a single life annuity. M's benefit as of the deemed distribution date has a value greater than $3,500 using either plan assumptions or the missing participant lump sum assumptions. Accordingly, M's designated benefit is to be determined under § 2629.5(a)(3).

(2) For purposes of determining M's designated benefit, M is assumed to be married to a spouse who is also age 50 on the deemed distribution date. M's monthly benefit in the form of the qualified joint and survivor annuity under the plan varies from $840 at age 65 (the normal retirement age) ($1,000×(1−.16)) to $630 at age 60 (the earliest retirement age) ($1,000×(1−5×(.05))×(1−.16)).

(3) Under § 2629.5(a)(3), M's benefit is to be valued using the missing participant annuity assumptions. The select and ultimate interest rates on Plan B's deemed distribution date are 7.50 percent for the first 20 years and 5.75 percent thereafter. Using these rates and the blended mortality table described in the definition of "missing participant annuity assumptions" in § 2629.2(i)(2), the plan administrator determines that the benefit commencing at age 60 is the most valuable benefit (*i.e.*, the benefit at age 60 is more valuable than the benefit at ages 61, 62, 63, 64 or 65). The present value as of the deemed distribution date of each dollar of annual benefit (payable monthly as a joint and 50 percent survivor annuity) is $5.4307 if the benefit begins at age 60. (In accordance with § 2619.49(d)(5), the mortality of the spouse during the deferral period is ignored.) Thus, without adjustment (loading) for expenses, the value of the benefit beginning at age 60 is $41,056 (12×$630×5.4307). The designated benefit is equal to this value plus an expense adjustment of $300, or a total of $41,356.

Appendix B—Examples of Benefit Payments for Missing Participants Under §§ 2629.8 Through 2629.10

The provisions of §§ 2629.8 through 2629.10 are illustrated by the following examples.

Example 1. Participant M from Plan B (see Example 2 in Appendix A of this part) is located. M's spouse is ten years younger than M. M elects to receive benefits in the form of a joint and 50 percent survivor annuity commencing at age 62.

(1) M's designated benefit was $41,356. The unloaded designated benefit was $41,056. As of Plan B's deemed distribution date (and using the missing participant annuity assumptions), the present value per dollar of monthly benefit (payable monthly as a joint and 50 percent survivor annuity commencing at age 62 and reflecting the actual age of M's spouse) is $4.7405. Thus, the monthly benefit to M at age 62 is $722 ($41,056 / (4.7405×12)). M's spouse will receive $361 (50 percent of $722) per month for life after the death of M.

(2) If M had instead been found to have died on or after the deemed distribution date, and M's spouse wanted benefits to commence when M would have attained age 62, the same calculation would be performed to arrive at a monthly benefit of $361 to M's spouse.

Example 2. Participant P is a missing participant from Plan C, a plan that allows elective lump sums upon plan termination. Plan C's administrator pays a designated benefit of $10,000 to the PBGC on behalf of P, who was age 30 on the deemed distribution date.

(1) P's spouse, S, is located and has a death certificate showing that P died after the deemed distribution date with S as spouse. S is the same age as P, and would like survivor benefits to commence immediately, at age 55. S's benefit is the survivor's share of the joint and 50 percent survivor annuity which is actuarially equivalent, as of the deemed distribution date, to $9,700 (the unloaded designated benefit).

(2) The select and ultimate interest rates on Plan C's deemed distribution date were 7.50 percent for the first 20 years and 5.75 percent thereafter. Using these rates and the blended mortality table described in § 2629.2(i)(2), the present value as of the deemed distribution date of each dollar of annual benefit (payable monthly as a joint and 50 percent survivor annuity) is $2.4048 if the benefit begins when S and P would have been age 55. Thus, the monthly benefit to S commencing at age 55 is $168 (50 percent of $9,700 / (2.4048×12)). Since P could have elected a lump sum upon plan termination, S may elect a lump sum. S's lump sum is the present value as of the deemed distribution date (using the missing participant annuity assumptions) of the monthly benefit of $168, accumulated with interest at the designated benefit interest rate to the date paid.

PART 2606—RULES FOR ADMINISTRATIVE REVIEW OF AGENCY DECISIONS

2. The authority citation for part 2606 continues to read as follows:

Authority: 29 U.S.C. 1302(b)(3),

3. In § 2606.1, paragraph (b)(8) is amended by removing the word "and"; paragraph (b)(9) is amended by removing the period at the end of the paragraph and adding in its place "; and"; and a new paragraph (b)(10) is added to read as follows:

§ 2606.1 Purpose and scope.

* * * * *

(b) *Scope.* * * *

* * * * *

(10) Determinations—

(i) That the amount of a participant's or beneficiary's benefit under section 4050(a)(3) of the Act has been correctly computed based on the designated benefit paid to the PBGC under section 4050(b)(2) of the Act, or

(ii) That the designated benefit is correct, but only to the extent that the benefit to be paid does not exceed the participant's or beneficiary's guaranteed benefit.

* * * * *

§ 2606.51 [Amended]

4. Section 2606.51 is amended by removing the words "§ 2606.1(b)(5) through (9)" and adding in their place the words "§ 2606.1(b)(5) through (10)".

PART 2616—DISTRESS TERMINATIONS OF SINGLE-EMPLOYER PLANS

PART 2617—STANDARD TERMINATIONS OF SINGLE-EMPLOYER PLANS

5. The authority citations for parts 2616 and 2617 are revised to read as follows:

Authority: 29 U.S.C. 1302(b)(3), 1341, 1344, 1350.

§ 2616.2, § 2617.2 [Amended]

6. In §§ 2616.2 and 2617.2, the definition of date of distribution is amended by removing the period at the end of paragraph (2); adding in its place a semicolon; and adding after the semicolon the words "except that date of distribution means the deemed distribution date in the case of a designated benefit paid to the PBGC, or a benefit provided after the deemed distribution date to a late-discovered participant, in accordance with part 2629 of this chapter (dealing with missing participants)."

§ 2616.7, § 2617.8 [Amended]

7. In §§ 2616.7 and 2617.8, paragraph (b) is amended by removing the words "Any document" and adding in their place the words "Except as may otherwise be provided in applicable forms and instructions, any document".

§ 2616.29, § 2617.28 [Amended]

8. Paragraph (b) of § 2616.29 and paragraph (h) of § 2617.28 are amended by adding at the end of § 2616.29(b) and § 2617.28(h) the words "The plan administrator shall be considered to have satisfied this requirement if, in accordance with § 2629.11 of this chapter, the plan administrator timely files an amended post-distribution certification that otherwise satisfies all applicable requirements."

9. In § 2617.28, paragraph (c) is amended by adding at the end a new sentence to read as follows:

§ 2617.28 Closeout of plan.

* * * * *

(c) *Method of distribution.* * * * The plan administrator shall comply with part 2629 of this chapter (dealing with missing participants), if applicable.

* * * * *

Issued in Washington, DC, this 21st day of August, 1995.

Martin Slate,

Executive Director, Pension Benefit Guaranty Corporation.

Addendum (Draft forms and instructions for Part 2629)

(Note: A draft of the missing participant forms and instructions follows. These forms and instructions will not appear in the Code of Federal Regulations.)

BILLING CODE 7708-01-P

DRAFT DRAFT

FILING INSTRUCTIONS FOR SCHEDULE MP

MISSING PARTICIPANTS PACKAGE

PAPERWORK REDUCTION ACT NOTICE

The PBGC needs the information required by Schedule MP to administer the Missing Participants Program. Section 4050 of the Employee Retirement Income Security Act of 1974, as added by the Retirement Protection Act of 1994, established the Missing Participants Program to assist plan administrators in closing out plans and to help participants in these plans secure their benefits. The PBGC will use the information to direct missing participants to the appropriate insurance company; to locate and pay missing participants for whom benefits were paid to the PBGC; and to monitor and audit compliance. You are required to provide this information pursuant to section 4050 and 29 CFR Part 2629.

The PBGC estimates that it will take an average of 2.46 hours per plan to complete and file Schedule MP (including attachments). The actual time will vary depending on the circumstances in a given case.

Comments concerning the accuracy of this time estimate or suggestions pertaining to the forms should be addressed to Pension Benefit Guaranty Corporation, Office of the General Counsel, Suite 340, 1200 K Street, NW., Washington, DC 20005-4026, and Office of Management and Budget, OIRA, Attention Desk Officer -- PBGC, New Executive Office Building, (1212-____), Washington, DC 20503.

TABLE OF CONTENTS

I. INTRODUCTION

Pursuant to the Retirement Protection Act of 1994, the PBGC has established a Missing Participants Program for single-employer defined benefit pension plans subject to Title IV of ERISA. This program will help terminating plans distribute missing participants' benefits and help missing participants receive their benefits. A *missing participant* is a participant, beneficiary or alternate payee entitled to a distribution under a terminating plan whom the plan administrator has not located as of the date the plan administrator pays the individual's designated benefit to the PBGC (or distributes the individual's benefit by purchasing an irrevocable commitment from an insurer). In the absence of proof of death, individuals not located are presumed living.

The new rules generally apply to plans that make a final distribution of assets in plan years beginning on or after [effective date of 29 CFR Part 2629].

A plan administrator must distribute the benefits of a missing participant by purchasing an irrevocable commitment from an insurance company or paying the value of the missing participant's benefit to the PBGC after making a diligent search for the participant. The new program applies to distributions in a standard plan termination, and to distributions in a distress plan termination in which assets are sufficient to provide all guaranteed benefits.

The new Missing Participants Program requires a few changes in the way that plans with missing participants complete the Post-Distribution Certification (Form 501 or 602). (See Part V of these instructions for changes to the Post-Distribution Certification.) These changes do not affect plans without missing participants.

The plan administrator of a plan with a missing participant must file a Schedule MP with the Post-Distribution Certification and pay the PBGC the value of benefits payable to any missing participant for whom the plan administrator did not purchase an irrevocable commitment. The Schedule MP includes the information the PBGC needs to identify and locate missing participants; to compute and pay benefits; and to direct individuals for whom the plan purchased annuities to the appropriate insurance company.

II. GENERAL INSTRUCTIONS FOR SCHEDULE MP

A. Plans Required to File

The plan administrator of a single-employer plan covered by Title IV that is terminating in a standard termination or in a distress termination in which plan assets are sufficient to provide all guaranteed benefits must file Schedule MP if the plan has any missing participants. The requirement applies to plans with a "deemed distribution date" (or a distribution of residual assets to missing participants or a distribution pursuant to a PBGC audit of a plan termination) in a plan year beginning on or after [effective date of 29 CFR Part 2629]. (See definition of "deemed distribution date" in instructions for line 2a below.)

B. What and When to File and Pay

1. What to File and Pay. You must file Schedule MP, including Attachment A (Annuity Purchase Information) and Attachment B (Individual Information), as applicable. You must file Attachment A (or provide the specified information on a separate page) if the plan purchased an irrevocable commitment for one or more missing participants. You must file a separate Attachment B for each missing participant for whom you pay amounts to the PBGC. You must send the PBGC payment for these amounts, together with a payment

voucher. Write the plan's EIN/PN and the PBGC Case Number on your check. You may use photocopies or other facsimilies of the forms, but signatures must be original.

2. When to File and Pay.

a. In general. The filing due date for the Schedule MP (including attachments) is the same as for the Post-Distribution Certification. The Schedule MP is considered filed on the date received by the PBGC. A payment to the PBGC (including the payment voucher) is considered filed on the date the PBGC receives it at the lockbox address in C.2 below.

b. Due Dates for Later Filings. You must file a Schedule MP (including applicable attachment(s) or payment), marked as amended if a Schedule MP was previously filed, in the following cases shown in the table below.

(If a later Schedule MP reports payment of designated benefits to the PBGC or purchase of annuities for benefit liabilities, it must be accompanied by an amended Post-Distribution Certification reflecting these additional distributions.)

Table of Due Dates for Later Filings of Schedule MP

Reason for Later Filing:	The Schedule MP must be filed no later than --
(1) Residual assets owed after the deemed distribution date for a person who is a missing participant at the time residual assets are payable.	30 days after the plan administrator has distributed residual assets to all participants and beneficiaries entitled to them (other than missing participants for whom payment of residual assets is made to PBGC).
(2) Payment to the PBGC or purchase of annuities for a recently-missing participant.	120 days after the deemed distribution date.
(3) Payment to the PBGC or purchase of annuities for participants and beneficiaries who cannot be located, pursuant to an audit of the plan termination.	The date specified by the PBGC in connection with the audit.

C. Where to File and Pay

1. Where to File. You must file the Schedule MP (including any required attachments) with the Post-Distribution Certification. You should mail them to:

Pension Benefit Guaranty Corporation
Standard Processing and Control Branch
1200 K Street, NW Suite 930
Washington, DC 20005-4026

2. Where to Pay. Send payment for designated benefits, voluntary employee contributions in a separate account, or residual assets, with a completed payment voucher to the lockbox address below. (Send one check for the plan, not separate checks for each participant.)

[LOCKBOX ADDRESS]

D. Questions, Problems, Copies of Forms

If you have questions about this form, the revised instructions for the Post-Distribution Certification, or other questions about the Missing Participants Program, please contact:

Pension Benefit Guaranty Corporation
Administrative Review and Technical Assistance Branch
1200 K Street, NW Suite 930
Washington, DC 20005-4026
Telephone: (202) 326-4000
Hearing impaired persons may telephone (202) 326-4179.

These phone numbers are not toll-free, and the PBGC cannot accept collect calls.

You can receive copies of the forms by contacting the Pension Benefit Guaranty Corporation's Case Operations and Compliance Division at the same address and telephone numbers above.

E. Recordkeeping Requirements

The plan administrator is required to retain records supporting the calculation of designated benefits or other amounts paid to PBGC for six years after the date a Post-Distribution Certification or amended Post-Distribution Certification is filed.

III. LINE-BY-LINE INSTRUCTIONS FOR SCHEDULE MP

NOTE: When filing an amended Schedule MP, enter only the plan identification information (Lines 1a-1c) and the additional information being reported.

2. Missing Participant Information

b. Number of missing participants for whom amounts are paid to the PBGC. Enter the total number of missing participants for whom amounts are being paid to the PBGC concurrent with this filing. If the Schedule MP is an amended filing, enter only the number of participants for whom you are paying amounts to the PBGC concurrent with the amended filing. Enter zero if you are paying no amounts to the PBGC.

c. Deemed distribution date. The deemed distribution date is a date the plan administrator of a terminating plan selects. You may select any date on or after the date when all benefit distributions have been made (except for distributions to missing participants whose designated benefits are to be paid to the PBGC), provided the date is not later than the last day of the period in which distribution may be made under the PBGC's standard termination regulation (29 CFR § 2617.28(a)) or the PBGC's distress termination regulation

(29 CFR § 2616.29(a)), whichever applies.

Note: If you are distributing residual assets and have made no other distributions to missing participants, enter "00/00/00."

3. Amounts Paid to the PBGC

Note: The amounts entered in each of lines 3a, 3b, and 3c should be the sum of the amounts on lines 2a, 2b, and 2c, respectively, of Attachment B (Individual Information).

IV. INSTRUCTIONS FOR ATTACHMENT B (INDIVIDUAL INFORMATION)

General Instructions

File Attachment B (Individual Information) with the Schedule MP (or amended Schedule MP) for each missing participant (participant, spouse or other beneficiary, or alternate payee) for whom you send payment to the PBGC.

LINE-BY-LINE INSTRUCTIONS FOR ATTACHMENT B

NOTE: When filing an amended Attachment B, enter only the plan name and case number, the individual's name and Social Security number, and the additional information being reported.

2. Amount Paid to the PBGC

a. Designated benefit. The amount and category of the designated benefit are determined under 29 CFR §§ 2629.5 and 2629.12. (If you are not paying a designated benefit to the PBGC, enter zero and do not check a category.)

b. Other amounts. Other amounts you are paying to the PBGC are determined under 29 CFR § 2629.12. (If you are not paying other amounts to the PBGC, enter zero.)

Note for lines 3 - 5: A missing participant had entered *pay status* as of the deemed distribution date if, as of that date, one or more benefit payments had been made or would have been made except for administrative delay. A beneficiary is considered in pay status if the payments to the beneficiary would have commenced automatically without an election upon the participant's death.

3. Participant Who is Missing and Had Not Entered Pay Status

a. Automatic form of benefit for participant not in pay status. Enter the benefit form that would be payable to the participant on retirement. Provide the forms for both married and unmarried participants, regardless of the participant's last-known marital status. Enter a code from the Table of Benefit Forms on page 6 below and fill in the relevant information.

4. Beneficiary or Alternate Payee Who is Missing and Had Not Entered Pay Status

a. Form of benefit for a beneficiary or alternate payee not in pay status. Enter the benefit form payable to the beneficiary or alternate payee (as applicable). Enter a code from the Table

of Benefit Forms on page 6 below and fill in the relevant information.

5. Missing Participant Who Is In Pay Status

Line 5 applies to a participant, beneficiary, or alternate payee who entered pay status before the deemed distribution date.

a. Form of benefit for a missing participant in pay status. Enter the benefit form that was in pay status as of the first missed payment. Enter a code from the Table of Benefit Forms on page 6 below and fill in the relevant information.

Table of Benefit Forms

Benefit Form Code	Benefit Form Applicable to Missing Participant See 29 CFR Part 2619 for definitions of benefit forms 1 - 8 listed below.
1	Life annuity payable periodically 29 CFR § 2619.44(c)
2	Annuity certain payable periodically 29 CFR § 2619.44(d)
3	Annuity certain and continuous 29 CFR § 2619.44(e)
4	Temporary life annuity 29 CFR § 2619.44(f)
5	Joint and survivor annuity (contingent basis) 29 CFR § 2619.44(i)
6	Annuity certain and joint and survivor (contingent basis) thereafter 29 CFR § 2619.44(l)
7	Single life cash refund annuity 29 CFR § 2619.44(m)
8	Installment refund annuity 29 CFR § 2619.44(n)
9	Single sum
10	Other benefit form Use the space provided on Attachment B to describe the benefit form that is payable with respect to the missing participant. Include, as applicable, the percentage of the missing participant's monthly benefit amount that is payable to each beneficiary on the missing participant's death, the period during which the missing participant's benefit is payable, the period during which each beneficiary's benefit is payable, and any other provisions that distinguish the benefit form. For example, in the case of a step-down benefit, state when and by how much the benefit is reduced.

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6. Employee Contributions

a-c. Mandatory Employee Contributions. Report mandatory employee contributions that fund a portion of the missing participant's accrued benefit under the plan and interest thereon to the deemed distribution date.

Note: The designated benefit amount reported on line 2a must be no less than the amount of mandatory employee contributions plus interest to the deemed distribution date (line 6c).

7. Residual Assets

a. Residual Assets. Enter the amount of any residual assets allocable to the participant in accordance with section 4044(d) of ERISA and the PBGC's regulation on Allocation of Assets (29 CFR Part 2618) (and earnings thereon to the date you pay PBGC). If no residual assets are being paid concurrent with this filing, enter $0. If residual assets will be paid later, see instructions for amended filings under "What and When to File" on page 2 above.

V. CHANGES TO POST-DISTRIBUTION CERTIFICATION (Forms 501 and 602)

A. Changes to Line-by-Line Instructions

Note: Line references are to Form 501. Line numbers are the same on Form 602, except where noted.

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4. Date of Distribution

Substitute the following for the existing instruction:

Enter the date on which the distribution of assets was completed for participants other than (1) missing participants for whom designated benefits are paid to the PBGC, (2) late-discovered participants for whom distribution has not been made, and (3) recently missing participants for whom distribution has not been made.

5b. Were participants and beneficiaries provided with the name and address of the insurer(s) no later than 45 days before the date of distribution? (Line 6b on Form 602)

Add the following at the end of the existing instruction:

Check "Yes" if you provided the name and address of the insurer(s) no later than 45 days before the date of distribution to each individual (other than a missing participant) for whom an annuity was purchased.

6. Were you able to locate all participants? (Line 7 on Form 602)

Substitute the following for the existing instruction:

For benefit distributions in plan years beginning on or after [effective date of 29 CFR Part 2629], if you are not able to locate a participant or beneficiary, you must either purchase an irrevocable commitment from an insurer for that participant or beneficiary or pay the missing participant's benefit to the PBGC.

If the plan has a missing participant, check "Yes" on line 6a (line 7a on Form 602), skip line 6b (line 7b on Form 602), and submit a Schedule MP with the Post-Distribution Certification.

7a. Has a copy of the annuity contract, certificate, or written notice been provided to each participant and beneficiary receiving benefits in the form of irrevocable commitments? (Line 8a on Form 602)

Add the following at the end of the existing instruction:

Enter "Yes" if you provided a copy of the annuity contract, certificate, or written notice to each individual (other than a missing participant) for whom an annuity was purchased.

10. Summary of distribution of benefit liabilities

Add the following at the end of the existing instruction:

Include annuities purchased for missing participants in "Annuities"; designated benefits paid to the PBGC in "Rollovers"; and recently-missing participants and late-discovered participants for whom distributions are not complete when the Post-Distribution Certification is sent in "No distribution."

If there are any recently-missing participants or late-discovered participants in the "No distribution" category, mark the top of the first page of the Post-Distribution Certification: "PRELIMINARY - Recently-Missing Participant," "PRELIMINARY - Late-Discovered Participant," or both, as applicable.

The plan administrator will have to file an amended Post-Distribution Certification to report distributions for these individuals.

B. Amended Filings. The plan administrator must file an amended Post-Distribution Certification to report distributions to participants and beneficiaries or payments to the PBGC not included in the original Post-Distribution Certification. The amended Post-Distribution Certification must be filed no later than 120 days after the deemed distribution date.

If you file an amended Post-Distribution Certification, mark "Amended" at the top. Complete lines 1 - 4 and report on the form only information about the distributions made since the original Post-Distribution Certification was filed.

If you report any payment to the PBGC or purchase of annuities for a missing participant, you must file with the amended Post-Distribution Certification a Schedule MP (including any applicable attachments). If you are making a payment to the PBGC, send the payment and payment voucher to:

[LOCKBOX ADDRESS]

DRAFT DRAFT

SCHEDULE MP (to PBGC Forms 501 and 602)

Plan Administrators must file the Schedule MP with Form 501 or 602 if a plan has purchased irrevocable commitments for one or more missing participants or is paying amounts to PBGC for one or more missing participants. (See page 2 of instructions for plans required to file Schedule MP.)

Check here if you previously filed a Schedule MP for this plan ___

1. Plan Identification Information

a. Plan Name _____

b. EIN/PN _____ c. PBGC Case No. _____

2. Missing Participant Information

a. Number of missing participants for whom irrevocable commitments purchased ___

b. Number of missing participants for whom amounts are paid to PBGC ___

c. Deemed distribution date ___/___/___

3. Amounts Paid to PBGC

a. $_____ Total designated benefits

b. $_____ Other amounts payable for missing participants (see instructions)

c. $_____ Total amount paid to PBGC (line 3a + line 3b)

-- DO NOT SEND PAYMENT WITH THIS FORM. SEND PAYMENT TO PBGC'S LOCKBOX WITH MISSING PARTICIPANT PAYMENT VOUCHER --

Certifications

Plan Administrator Certification

I, the Plan Administrator, certify that:

I have conducted a diligent search for all missing participants for whom I am paying amounts to PBGC (see definition of "diligent search" in 29 CFR § 2629.4).

To the best of my knowledge and belief, the information contained in this filing is true, correct, and complete.

In making this certification, I recognize that knowingly and willfully making false, fictitious, or fraudulent statements to the PBGC is punishable under 18 U.S.C. 1001.

Plan administrator name/title _____

_____

Company _____

Address _____

_____

Phone number _____

_____

Plan administrator signature and date

Enrolled Actuary Certification

(Not required if all benefits for all missing participants are distributed through the purchase of irrevocable commitments from an insurer)

I, the Enrolled Actuary, certify that:

To the best of my knowledge and belief, the actuarial information contained in this filing is true, correct, and complete and the designated benefits and/or other amounts payable for missing participants have been calculated in accordance with applicable provisions of ERISA and the regulations thereunder.

In making this certification, I recognize that knowingly and willfully making false, fictitious, or fraudulent statements to the PBGC is punishable under 18 U.S.C. 1001.

Enrolled actuary name _____

Enrolled actuary ID# _____

Company _____

Address _____

_____

Phone number _____

_____

Enrolled Actuary signature and date

DRAFT ATTACHMENT A DRAFT

Annuity Purchase Information

Complete Attachment A (or submit the required information on a separate page) and ettach to Schedule MP if the plan purchesed irrevocable commitments from an insurer for one or more missing participants. If any missing participant's annuity certificate number is not eveilable, report it to the PBGC when it becomes evailable. If irrevocable commitments were purchased from more than one insurer, please complete e separate sheet for each insurer.

Plan Name _____ PBGC Case No. _____

Check here if you previously filed an Attachment A for this plan ___

Insurance Company Information

Name of insurer _____
(Name must be the full officiel name of record)

Address of insurer _____

_____

Insurence company contact name _____ Phone No. _____

Policy number _____

List of Annuitized Missing Participants

	Name	Social Security No.	Date of Birth
1.	Missing Participant_____	_____	__/__/__
	Spouse or other beneficiary		
	_____	_____	__/__/__
	Certificate Number _____		
2.	Missing Participant_____	_____	__/__/__
	Spouse or other beneficiary		
	_____	_____	__/__/__
	Certificate Number _____		
3.	Missing Participant_____	_____	__/__/__
	Spouse or other beneficiary		
	_____ _____	_____	__/__/__
	Certificate Number _____		
4.	Missing Participant_____	_____	__/__/__
	Spouse or other beneficiary		
	_____	_____	__/__/__
	Certificate Number _____		
5.	Missing Participant_____	_____	__/__/__
	Spouse or other beneficiary		
	_____	_____	__/__/__
	Certificate Number _____		

(Continue on a separate page, if necessary, and identify plan name, PBGC case no. and insurer et the top of the page.)

DRAFT ATTACHMENT B DRAFT

Individual Information

Complete Attachment B and attach to Schedule MP for each missing participant for whom an amount is paid to PBGC.

Plan Name _____ PBGC Case No. _____

Check here if you previously filed an Attachment B for this individual ___

1. **Identification of Missing Participant**

a. Name _____ b. Social Security No. _____

c. Last-known address _____

d. Maiden name (if different) _____ Other name(s) ever used _____

e. Date of birth ___/___/___ · f. Sex: Male____ Female_____

g. Status (check one) (1) Participant ____ (2) Spouse or other beneficiary ____ (3) Alternate payee ____
Spouse ☐ Other ☐ (Attach copy of QDRO)

2. **Amounts Paid to PBGC**

a. $_____ Designated Benefit
Missing participant's designated benefit category:
(check no more than one from items (1) - (4))

____ (1) Mandatory lump sum ____ (2) De minimis lump sum
____ (3) No lump sum ____ (4) Elective lump sum

b. $_____ Other amounts paid, if any (line 6f + line 7a)

c. $_____ Total (line 2a + line 2b)

3. For a participant who is missing and had not entered pay status as of the deemed distribution date, complete the following:

a. Automatic form of retirement benefit payable with respect to the participant under the plan.

Married participant:

Code from table on page 6 in instructions: ☐	_____ % Survivor percentage
	_____ # of Monthly payments in period certain
If you entered code 10, "Other benefit form," describe the form below:	$_____ Fixed sum (use only for codes 7 & 8)
Other:	

Unmarried participant:

Code from table on page 6 in instructions: ☐	_____ % Survivor percentage
	_____ # of Monthly payments in period certain
If you entered code 10, "Other benefit form," describe the form below:	$_____ Fixed sum (use only for codes 7 & 8)
Other:	

b. Participant's earliest early retirement date (or the deemed distribution date, if later). ___/___/___

c. Did the participant and last-known spouse waive the QPSA provided under the plan? Yes___ No___ N/A___
(If yes, attach a copy of the waiver and skip questions 4d and 4e below.)

d. Last-known spouse's name _____ Social Security No. _____
(if applicable)

e. Spouse's earliest possible QPSA annuity starting date under the plan (or deemed distribution date, if later). ___/___/___
(If the QPSA is payable immediately upon the participant's death, enter the deemed distribution date.)

4. For a beneficiary or alternate payee who is missing and had not entered pay status as of the deemed distribution date, complete the following:

a. Form of benefit to which the beneficiary or alternate payee is entitled.

Code from table on page 6 in instructions: ☐	____ % Survivor percentage
	____ # of Monthly payments in period certain
If you entered code 10, "Other benefit form," describe the form below:	$____ Fixed sum (use only for codes 7 & 8)
Other:	

b. Earliest date the beneficiary or alternate payee could commence receiving benefits (or the deemed distribution date, if later). ___/___/___

5. For a participant, beneficiary, or alternate payee who is missing and had entered pay status as of the deemed distribution date, complete the following:

a. Form of benefit that was in pay status. (Attach a copy of form election, if any.)

Code from table on page 6 in instructions: ☐	____ % Survivor percentage
	____ # of Monthly payments in period certain
	$____ Fixed sum (use only for codes 7 & 8)
If you entered code 10, "Other benefit form," describe the form below:	___/___/___ Date of first missed monthly payment
	$____ Amount of first missed monthly payment
	____ % Plan interest rate for missed payments
Other:	

b. Name of missing participant's beneficiary or beneficiaries, if any. (Attach a copy of designation form, if any.)

1. _____ Name — _____ Relationship to missing participant (e.g., spouse, daughter, estate, etc.)

2. _____ Name — _____ Relationship to missing participant

6. Employee Contributions

Complete lines a, b and c if part of the missing participant's designated benefit is attributable to mandatory employee contributions.

a. $_____ Mandatory employee contributions

b. $_____ Interest credited to the deemed distribution date

c. $_____ Total (line 6a + 6b)

Complete lines d, e and f if any additional amount is being paid to PBGC for voluntary employee contributions held in a separate account.

d. $_____ Voluntary employee contributions

e. $_____ Earnings credited to the date sent to PBGC

f. $_____ Total (line 6d + 6e)

7. Residual Assets

a. Residual plan assets $_____

b. Date residual assets are sent to PBGC

___/___/___

8. Attached Documents

Check and attach the following documents as applicable:

___(a) Waiver of Qualified Pre-retirement Survivor Annuity (QPSA)
___(b) Election of optional benefit form
___(c) Designation(s) of beneficiary
___(d) Qualified Domestic Relations Order (QDRO)

DRAFT DRAFT

MISSING PARTICIPANTS PAYMENT VOUCHER

**PAYMENT OF DESIGNATED BENEFITS,
VOLUNTARY EMPLOYEE CONTRIBUTIONS IN SEPARATE ACCOUNT,
OR RESIDUAL ASSETS**

Plan Administrator Contact:

Name _____ **Telephone** _____

Plan Name _____
(as it appears on the Post-Distribution Certification)

EIN/PN _____ **PBGC Case Number** _____

Amount Enclosed $_____ **Check No.** _____
(Enter the plan's EIN/PN and PBGC Case No. on the check)

Date Schedule MP was sent to the PBGC ___/___/___

SEND TO: Pension Benefit Guaranty Corporation
[LOCKBOX ADDRESS]

[FR Doc. 95–21065 Filed 8–23–95; 8:45 am]
BILLING CODE 7708–01–C

federal register

Thursday
August 24, 1995

Part VII

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 201, et al.
Prescription Drug Product Labeling; Medication Guide Requirements; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201, 208, 314, and 601

[Docket No. 93N–0371]

RIN 0910–AA37

Prescription Drug Product Labeling; Medication Guide Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: Inadequate access to appropriate patient information is a major cause of inappropriate use of prescription medications, resulting in serious personal injury and related costs to the health care system. The Food and Drug Administration (FDA) believes that it is essential that patients receive information accompanying dispensed prescription drugs. This information must be widely distributed and be of sufficient quality to promote the proper use of prescription drugs. Therefore, FDA is proposing performance standards that would define acceptable levels of information distribution and quality, and to assess supplied information according to these standards. Preliminary evidence suggests recent increases in the distribution of privately-produced patient medication information with dispensed prescriptions. Unfortunately, estimated distribution rates indicate that significant portions of patients do not receive information with their medications. FDA analyses also indicate that there is a high variability in the quality of this information. FDA believes that, with greater encouragement and clear objectives, the private sector will substantially improve the quality and distribution of patient information. Therefore, in concert with Healthy People 2000, FDA is proposing that private sector initiatives meet the goal of distributing useful patient information to 75 percent of individuals receiving new prescriptions by the year 2000 and 95 percent of individuals receiving new prescriptions by the year 2006. FDA is proposing two alternative approaches to help ensure that these goals (performance standards) are achieved. FDA would periodically evaluate and report on achievement of these goals. If the goals are not met in the specified timeframes, FDA would either (1) Implement a mandatory comprehensive Medication Guide program, or (2) seek public comment on whether the comprehensive program should be implemented or whether, and what, other steps should be taken to meet patient information goals. Regardless of the approach chosen, a mandatory Medication Guide program limited to instances where a product poses a serious and significant public health concern requiring immediate distribution of FDA-approved patient information would be implemented within 30 days of publication of a final rule based on this proposal. FDA believes that substantial health care cost savings can be realized by ensuring that consumers obtain the inherent benefits of proper use of prescription drugs, and by reducing the potential for harm caused by inappropriate drug use by the patient.

DATES: Comments by November 22, 1995.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Louis A. Morris, Center for Drug Evaluation and Research (HFD–240), Food and Drug Administration, 5600 Fishers Lane Rockville, MD 20857, 301–594–6828.

SUPPLEMENTARY INFORMATION:

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I. Introduction

As the Federal agency responsible for the proper labeling of prescription drug and biological products, FDA believes that patient information accompanying these products is essential. It is paradoxical that products as potentially hazardous as prescription medications are often dispensed with little more than a "use as directed" statement printed on the container label. Considerably less dangerous products, such as foods and over-the-counter (OTC) drugs, contain extensive usage labeling. Many OTC drugs also contain detailed warning labeling. Further, food labeling serves to warn at-risk individuals of potentially harmful ingredients. For example, people with phenylketonuria need to know what foods contain phenylalanine. Similarly, people with diabetes need to know about sugar content and people with high blood pressure need to know about sodium content.

FDA believes that improved dissemination of accurate, thorough and understandable information about prescription drug products is necessary to fulfill patients' need and right to be informed. Regardless of any other effects of such information, FDA believes that the direct educational benefits are sufficient to justify a requirement that such information be disseminated.

The use of drug and biological products often entails complex risk-benefit deliberations by prescribers. Yet, there is often little or no information shared with patients about the treatment's potential outcomes (i.e., its risks and benefits). In contrast, even simple surgical procedures, often posing

less severe risks to the patient, routinely require detailed patient consent prior to instituting the procedure. Improved education will enhance patients' ability to understand the benefits and risks of treatment. This will help patients interact more fully with health care professionals, thereby enabling patients to take a more active role in their own health care.

FDA also believes that improved patient education will improve adherence with prescribed regimens, decreasing unnecessary physician visits and hospitalizations, and will give patients the information they need to make truly informed decisions about the drugs they take. Demographics suggest an increasing need for better information and counseling about drugs. As the population ages, a greater proportion will rely heavily on prescription drugs.

It has been over a decade since FDA withdrew regulations mandating patient package inserts (PPI's) for prescription drugs. (PPI's are leaflets containing information about a drug product's benefits, risks, and directions for use.) At that time, the agency stated that mandatory requirements were unnecessary because the goal of improved patient education could be achieved through private sector initiatives. During this period, numerous voluntary programs designed to improve patient knowledge were launched, many with direct support from FDA and virtually all with FDA encouragement. In addition, FDA has asked certain manufacturers to include patient labeling for a few prescription drugs, where FDA believed that it was essential that patients were directly informed about the products' risks and limitations.

In the decade following withdrawal of the PPI regulations, FDA conducted research to evaluate the progress made by the voluntary programs. This research has shown minimal progress in improving the distribution of prescription drug information to patients.

However, very recently there have been new and encouraging signs that a greater percentage of patients are now receiving written information with their prescriptions. Many State Boards of Pharmacy expanded the offer to counsel requirement of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) to include all patients, instead of only Medicaid recipients. Developments in computer technology have permitted pharmacies more effectively to store and generate written documents for patients. As a result, there appears to be a sharp increase in the number of patients receiving computer-generated information along with their medication.

FDA is encouraged by this recent trend and hopes that: (1) It continues so that eventually the vast majority of Americans will receive this vital information, and (2) the information dispensed will be sufficiently accurate, thorough, and understandable for patients to properly use and monitor their treatment.

Therefore, in concert with goals established by the Public Health Service's Healthy People 2000, FDA is proposing performance standards for the distribution and quality of voluntary written prescription drug information dispensed to patients. Achievement of these performance standards would indicate that there is no need for Federal regulations for a comprehensive mandatory patient information program. Failure to achieve these performance standards would indicate that a federally-mandated comprehensive patient information program is necessary to meet patients' prescription drug information needs. In this document, FDA is proposing for public comment two alternative approaches that could be used to encourage achievement of performance standards for quality and distribution of patient prescription drug information, and to ensure that those products that pose a serious and significant public health concern include FDA-approved patient labeling. If the private sector fails to attain the performance standards in the specified timeframes, both alternatives would ultimately result in a regulation that would require that FDA-approved patient labeling be prepared and dispensed to patients, along with new prescriptions, for most prescription drug products used primarily on an outpatient basis. The alternatives are described in detail in section VIII. of this document.

FDA will continue to monitor and evaluate progress toward the standards for a 5- to 11-year period. During this time, FDA will continue to work with and encourage private sector efforts to educate patients. It is FDA's hope and belief that a renewed partnership to encourage voluntary distribution of prescription drug information, coupled with feedback and accountability, is the best mechanism for achieving the goal of improved patient information.

Currently, although numerous sources of prescription drug information suitable for distribution to patients have been developed, sizeable proportions of patients have not received adequate written information. With the advent of patient information software and installation of computer systems in pharmacy outlets, FDA believes that acceptable levels of patient information can result from voluntary efforts if three important conditions are instituted. First, there must be clearly established and attainable goals. Second, there must be sufficient incentives to achieve these goals. Third, for selected products, which cannot be marketed for safe and effective use unless patients receive clear warnings and directions, patient labeling (Medication Guides) must be required.

To promote responsibility and accountability, FDA is proposing performance standards for both the distribution and quality of written information. Performance standards would permit the flexibility demanded by an ever-changing, complex, and diverse distribution system for product information, while ensuring consistency in the application of standards.

Performance standards would result in less burdensome requirements on drug manufacturers and dispensers, the flexible adaptation of product information requirements into broader patient education programs, and increased utilization of technology to improve storage and distribution of information. They would further encourage a partnership approach so that health care providers, drug manufacturers, patient/consumer groups, and the public sector can work cooperatively to provide essential information to patients. If these standards are met, a comprehensive program of FDA-approved patient labeling would not be required. If these clearly defined and achievable performance standards are not met within a reasonable time period, FDA will institute steps to help ensure that the standards will be achieved.

During the hearings that led to the withdrawal of the 1980 PPI regulations, promises were made by representatives of the pharmaceutical, medical, and pharmacy communities that if FDA withdrew the PPI regulations, the private sector would develop a variety of systems that would meet the goals of the proposed PPI program. These promises have not yet been fulfilled. In the withdrawal notice, FDA promised to monitor periodically and evaluate progress made in providing patients with necessary prescription drug information. However, the withdrawal notice did not contain specified goals or a time frame for evaluating progress toward these goals.

While FDA understands and accepts that the development of grassroots programs will necessarily take longer than a mandatory program, FDA

believes that the continuation of an open-ended promise without a clear time frame for judging success is unacceptable. Therefore, FDA intends to articulate clear distribution and quality goals and maintain a specific timetable for judging success. During this time, FDA will only require FDA-approved patient labeling for certain drugs for which patient information will greatly facilitate safe and effective product use.

FDA has found that there are certain prescription drugs for which patient information is integral to the very marketing of the products. For these products, patient information is essential to assure that the drug can be used with acceptable levels of risk. Historically, PPI's have been instituted by independent regulations (e.g., estrogen products, oral contraceptives) or on a voluntary basis by the manufacturer (e.g., Accutane, Halcion, Proscar, Metformin). FDA has concluded that PPI's were essential for specific drug products based upon the existence of significant and possibly life-threatening drug effects about which patients must be warned in order to understand the risks they are undertaking by using the product or how to minimize those risks (e.g., by carefully monitoring their response to treatment for signs of adverse drug effects). These considerations are based upon a broad safety analysis that includes the indication for the product, the existence of alternative treatments, and the potential for patient information to increase the margin of safety in using the product.

While FDA has usually successfully relied upon the good will and voluntarism of prescription drug manufacturers to institute PPI's when needed, there have been occasions where manufacturers have refused to include such information. For example, although one manufacturer of a particular drug agreed to include a PPI when new information was uncovered about the possibly fatal interaction of this product with certain other products, the manufacturer of a similar product in the same therapeutic class, for which the same drug-interaction warning applied, did not agree to provide patients with a PPI.

As the agency has done with estrogens and oral contraceptive drug products, FDA could rely on notice and comment rulemaking to require patient labeling when necessary. However, it takes a significant amount of time to propose and finalize such regulations. Therefore, FDA is proposing rules that would require patient labeling (Medication Guides) for certain products that pose a serious and significant public health concern requiring immediate distribution of FDA-approved patient information.

II. Regulatory Background

A. Brief History of Patient Labeling Initiatives and the 1980 Final Rule on Patient Package Inserts

Since 1968, FDA has occasionally required that labeling written in nontechnical language be distributed to patients whenever certain prescription drugs were dispensed. Generally, FDA required distribution of such patient information to alert patients of adverse reactions associated with the drug product or to provide information about the product's use, contraindications, precautions, and effectiveness. Examples of such patient-oriented labeling include patient warnings on isoproterenol inhalation drug products (see 33 FR 8812, June 18, 1968), oral contraceptive drug products (see 35 FR 9001, June 11, 1970, and 43 FR 4212, January 31, 1978), estrogenic drug products (see 42 FR 37636, July 22, 1977), and patient labeling requirements for progestational drug products (see 43 FR 47198, October 13, 1978). (FDA has also approved patient labeling as part of the labeling requirements for certain individual drug products. These products include Roferon, Introna, Nicoderm, Nicorette, Rogaine, Halcion, Norplant System, Proscar, Accutane, and others.)

During the 1970's, FDA also began evaluating the usefulness of patient labeling for prescription drug products generally, and studied ways to present the information to patients. FDA discussed patient labeling issues with interested and potentially affected persons, reviewed scientific literature about patients' needs and desires for patient labeling, conducted research projects to evaluate existing and model patient labeling pieces, and reviewed existing methods for communicating drug information to patients (44 FR 40016 at 40018–40025, July 6, 1979, and 45 FR 60754 at 60755–60758, September 12, 1980). FDA also published a notice in the **Federal Register** of November 7, 1975 (40 FR 52075), soliciting public comments to assist the agency in formulating a policy on patient labeling.

As a result of these initiatives, in the **Federal Register** of July 6, 1979 (44 FR 40016), FDA issued a proposed rule to require PPI's for prescription drug products. The proposal would have required manufacturers or distributors to prepare PPI's for their drug products. Persons dispensing the drug products would be required to distribute the PPI's to patients. The PPI would be in nontechnical language, would not be promotional in tone or content, would be based primarily on the approved professional labeling, and:

> * * * would contain both a summary of the information about the product and more detailed information that identifies the product and the person responsible for the labeling, the proper uses of the product, circumstances under which it should not be used, serious adverse reactions, precautions the patient should take when using the product, information about side effects, and other general information about the proper uses of prescription drug products.

(44 FR 40016 at 40025).

The 1979 proposed rule would have required PPI's to be distributed to the patient with the drug product except in limited situations, such as those where the patient was legally incompetent or when institutionalized.

The 1979 proposal generated approximately 1,500 comments. Generally, consumers favored the proposed PPI program, but many licensed practitioners, pharmacists, and drug manufacturers opposed it. Those in favor of a mandatory PPI program contended that it would: (1) Promote patient understanding of and adherence to drug therapy; (2) permit the patient to avoid interactions with other drugs or foods; (3) prepare the patient for possible side effects; (4) inform the patient of positive and negative effects from the use of the drug product; (5) permit the patient to share in the decision to use the drug product; (6) enhance the patient/licensed practitioner relationship; and (7) provide the pharmacist and licensed practitioner with a basis for discussing the use of a prescription drug product with the patient. Those opposed to the program contended that it would: (1) Encourage self-diagnosis and the transfer of prescription drug products between patients; (2) produce adverse reactions in patients through suggestion; (3) affect adversely the liability of drug manufacturers, licensed practitioners, and pharmacists; (4) interfere with the patient/licensed practitioner relationship; (5) impose unnecessary burdens on manufacturers and pharmacists; and (6) increase the cost of prescription drug products and health care in general.

After considering the comments, in the **Federal Register** of September 12, 1980 (45 FR 60754), FDA published a final rule that established requirements and procedures for the preparation and distribution of PPI's. FDA concluded that there was ample evidence that PPI's can significantly improve the quality of health care obtainable from using prescription drugs. The agency

explained that PPI's can reduce the potential for harm to patients resulting from prescription drug use by enhancing patient compliance with prescribed regimens and by decreasing inappropriate drug use. In addition, PPI's can increase patient knowledge about prescription drugs, thereby promoting their optimal use.

The 1980 final rule required PPI's for human prescription drug products, and, as in the 1979 proposed rule, required manufacturers and distributors of prescription drug products to prepare PPI's for their drug products. The 1980 final rule required distributors and dispensers to distribute the PPI's to patients receiving a new prescription, but did not require PPI distribution for prescription drug refills or where the patient's licensed practitioner specifically directed that the PPI not be given to the patient (unless the patient specifically requested it). The 1980 final rule required a PPI to be written in nontechnical language, be based primarily on the approved professional labeling for the drug product, and contain: (1) The drug product's established name or, for a licensed biological product, proper name; (2) a summary of the information about the drug product; (3) a statement about the proper use of the drug product, identifying its indications for use; (4) information which the patient should provide the health practitioner before taking the drug, including the circumstances under which the drug product should not be used; (5) a statement of serious adverse reactions and potential safety hazards; (6) caution statement(s) that patients should observe, including statements about risks to pregnant women, nursing mothers, and pediatric patients; (7) a statement of the risks, if any, to the patient of developing a tolerance to or dependence on the drug; (8) a statement of what the patient should do in case of overdose or missed doses; (9) a statement of clinically significant, frequently recurring, possible side effects; (10) information about the safe and effective use of prescription drug products; and (11) information about the drug product's manufacturer, packer, or distributor, special storage instructions, and the PPI's date (45 FR 60754 at 60781–60782).

Under the 1980 final rule, manufacturers, distributors, or dispensers would provide PPI's to "practitioners, pharmacists, other dispensers and consumers" in "sufficient numbers" to permit a party to provide a PPI to each patient receiving a drug product. However, the 1980 final rule also permitted distributors and dispensers to prepare and use their own PPI's. The 1980 final rule also contained provisions that would require health care institutions to make PPI's available to patients upon the patient's request, after notification of availability. It would not have required PPI's for patients receiving emergency treatment.

The 1980 final rule provided printing specifications, and stated that FDA might prepare and make guideline PPI's available for specific drugs or drug classes. In the **Federal Register** of September 12, 1980 (45 FR 60785), FDA issued draft guideline PPI's for 10 drugs or drug classes. The 10 drugs or drug classes were: Ampicillin, benzodiazepines, cimetidine, clofibrate, digoxin, methoxsalen, propoxyphene, phenytoin, thiazide, and warfarin. FDA intended to implement PPI's for these 10 drugs or drug classes over a 3-year period, after which the agency would evaluate the program's results before applying the requirements to additional drugs. FDA stated that, although there was ample evidence of the value of PPI's in helping patients use drug products safely and effectively, additional studies were needed to confirm the costs of a mandatory, nationwide PPI program, to determine whether those costs were reasonable in terms of the benefits the program provides, and also to verify the best way to convey to consumers information about prescription drug products. In the **Federal Register** of November 25, 1980 (45 FR 78516), FDA announced that the PPI requirements would be effective on May 25, 1981, for cimetidine, clofibrate, and propoxyphene. In the **Federal Register** of January 2, 1981 (46 FR 160), the agency announced that the requirements for ampicillin and phenytoin would be effective on July 1, 1981. FDA issued final PPI's for these five drugs. The agency did not establish an effective date for the remaining five drugs.

B. The Stay of Effectiveness for the 1980 Final Rule and Its Subsequent Revocation

On February 17, 1981, the President issued Executive Order 12291 (see 46 FR 13193, February 19, 1981). Section 2 of the Order required each Federal agency to adhere to certain principles in promulgating new regulations and reviewing existing regulations. Given this Executive order, the Department of Health and Human Services and FDA decided to review the 1980 final rule. In the **Federal Register** of April 28, 1981 (46 FR 23739), the agency stayed the effective date for the 1980 final rule because it had received numerous comments stating that PPI's would be unnecessarily burdensome, costly, and inconsistent with Executive Order 12291. In the same issue of the **Federal Register**, FDA stayed the effective date of the PPI's. FDA indicated that further review of the PPI program was necessary. On September 30 and October 1, 1981, the agency held public meetings on the PPI program. The meetings reviewed FDA's administrative record of the PPI program and the results of a 3-year study conducted for FDA by the Rand Corp. on PPI's of various styles and formats.

On the basis of its review, in the **Federal Register** of February 17, 1982 (47 FR 7200), FDA proposed to revoke the 1980 final rule. The agency stated that:

> The goals of providing patients with information about prescription drugs can be reached more effectively and efficiently by cooperating with health professionals and others in both the public and private sector to expand upon current initiatives in patient education.

FDA reiterated its belief that informing patients about their prescription drug products would significantly improve the quality of their health care, and established a Committee on Patient Education to coordinate efforts to educate consumers about prescription drugs and to help private sector initiatives. However, the agency believed that private sector initiatives would be more effective than a mandatory PPI program and should be encouraged (see 47 FR 7200 at 7201).

In the **Federal Register** of September 7, 1982 (47 FR 39147), the agency issued a final rule that revoked the PPI regulations. The revocation was based, for the most part, on a decision to permit voluntary private sector initiatives for distributing patient information to proceed before a determination was made whether to impose a mandatory program. The preamble to the final rule listed several private sector programs underway at that time: (1) The National Council on Patient Information and Education (NCPIE)—a national consortium of health professionals, trade representatives, consumer groups, and Government agencies formed to encourage, coordinate, and promote private patient education efforts; (2) the American Medical Association (AMA) distributed Patient Medication Instruction (PMI) sheets—drug information leaflets to be handed out by licensed practitioners at the time of prescribing; (3) the American Society of Hospital Pharmacists, now known as the American Society of Health-Systems Pharmacists (ASHP), designed publications and audiovisual

presentations to assist hospital and retail pharmacists in providing drug information to patients; (4) the United States Pharmacopeial Convention, Inc. (USP), published several consumer guides to prescription drugs; (5) the American Association of Retired Persons (AARP) provided package inserts with prescriptions filled by its mail-order pharmacy service; (6) Doubleday, Inc., published a consumer's compendium of drug therapy, which included tear-out sheets about specific diseases; and (7) many retail pharmacies provided pamphlets, posters, and books on prescription drugs to pharmacy customers (47 FR 39147 at 39151). Some of these programs and others are discussed in detail below.

In the preamble to the final rule FDA stated:

> * * * Although the agency realizes that consumer groups generally supported the PPI pilot program, it believes that as the voluntary systems emerge, consumers will receive not only an adequate supply of prescription drug information from a variety of sources, but should receive more information about more drugs than would have resulted from a mandatory system. FDA also believes that the current regulatory environment demands that these various private sector efforts be given the opportunity to demonstrate that they can meet consumers' needs as well, if not better than, a government program.

(47 FR 39147 at 39153).

FDA indicated that, although it was revoking the 1980 regulation, it intended to work closely with the private sector and with other public sector agencies to identify and implement methods of providing information about prescription drugs to consumers, to promote patient education, to monitor changes in patient awareness of drug information, and to develop and evaluate the effectiveness of information dissemination activities. As mentioned above, FDA announced that it was forming a Committee on Patient Education to coordinate efforts to educate consumers about prescription drugs and to serve as a catalyst for private sector initiatives. Specifically, the committee was established to: (1) Evaluate existing patient information systems as well as new ones; (2) encourage the formation of, and serve as a liaison for, outside organizations that are or want to become active in patient information systems; (3) provide guidance and serve as a clearinghouse for firms that want to draft prescription drug information; (4) alert consumers and health professionals to the usefulness and availability of prescription drug information; and (5) identify the need for patient information in the use of other FDA-regulated products. FDA also indicated that it would be conducting surveys of consumers and health care professionals to evaluate the availability of adequate patient information on a nationwide basis. FDA stated that it will assess this information "over the next several years." FDA also noted: "The agency believes it would be counterproductive to the development of private initiatives for it to develop and publicly announce a course of action it might take should these private initiatives not materialize" (47 FR 39147 at 39152).

III. The Continuing Need for Prescription Drug Information

A. Continuing Problems of Lack of Adherence and Preventable Adverse Drug Reactions

FDA's proposal and final rule extensively reviewed the literature relating to patient adherence (also known as compliance) with medication regimens. FDA cited two literature reviews, and completed its own review of 50 studies, and concluded that noncompliance rates averaged from 30 percent to 50 percent. FDA also concluded that improved communication could contribute to improving compliance rates. Written information was necessary not only to improve adherence rates, but to inform patients about precautions, contraindications, and adverse drug reactions, leading to better knowledge about: (1) Using drugs properly, (2) monitoring reactions to medications for signs of possible problems, and (3) raising issues with licensed practitioners and other health professionals to improve communications about medication. (The term "licensed practitioner" in this document refers to individuals licensed, registered, or otherwise permitted to prescribe drug products in the course of their professional practice.)

The literature published since 1982 continues to support the conclusion that patient education can contribute to the prevention of disease, successful results in treatment, and reduction in medical costs. However, the need for drug information, education, and counseling exceeds the current supply, both in quantity and quality, and much of the available information fails to reach patients who need it, when they need it, and in the form they need it (Ref. 1). Although there is a wide variety of sources, the information that actually reaches most patients is focused primarily on how to use the medication, with little precautionary or adverse drug information obtained by most patients (Ref. 2). FDA believes that standard drug information, when combined with counseling from a prescribing practitioner, pharmacist, or other health professional should significantly increase patients' knowledge about the prescription drugs they are taking, and thereby make prescription drugs safer and more effective for consumer use.

The literature on patient compliance since 1982 continues to demonstrate a significant lack of medication adherence. For example, a 1990 report by NCPIE found that about one-third of patients fail to take their prescribed medications (Ref. 3). An overview of patient compliance studies reveals that about one-half of prescribed medications fail to produce the intended therapeutic effect because of improper use (Ref. 4). Studies examining compliance rates in specific patient populations suggest that parental noncompliance with drug therapy prescribed for their children exceeds 50 percent (Ref. 5) and noncompliance in the elderly ranges from 26 percent to 59 percent (Ref. 8).

Patient noncompliance with prescribed drug regimens can be directly related to therapeutic failure. For example, missed doses of antiglaucoma medications may lead to optic nerve damage and blindness. Missed doses of antiarrhythmic medications may lead to arrhythmia and cardiac arrest. Missed doses of antihypertensive drug products may lead to rebound hypertension that is sometimes worse than if no medication was taken at all. Missed doses of antibiotics may lead to recurrent infection and also may contribute to the emergence of antibiotic-resistant microorganisms (Ref. 9).

In addition to addressing problems of adherence, patient information is also necessary to improve drug use by forewarning patients about precautions to take to avoid adverse drug reactions. Further, forewarning is necessary to improve the patient's ability to monitor reactions to treatment to ensure both that the drug is working and that it is not causing adverse reactions.

A 1990 report by the Office of the Inspector General found that the process of patient education can save time by reducing calls or visits to the licensed practitioner or pharmacist and reducing the number of hospitalizations that are due to a patient's failure to follow his or her prescribed drug regimen (Ref. 17). For example, increased visits to the licensed practitioner may be required if the patient's condition does not improve because of noncompliance with his or her drug regimen. If the licensed practitioner is unaware of the

noncompliance, he or she may increase the patient's dosage or prescribe additional medicine that may be unnecessary and possibly dangerous. Or if the patient's condition fails to improve, the licensed practitioner may order additional diagnostic tests or unnecessary treatments.

Adverse drug reactions also are a continuing problem for the health care system. Adverse drug reactions occur in 20 percent of ambulatory patients (Ref. 10), and 2 percent to 5 percent of hospital admissions are attributed to drug-related illness (Ref. 10). The case/fatality rate from drug-induced disease in hospitalized patients is 2 percent to 12 percent (Ref. 10). Iatrogenic admissions to medical wards continue to be a costly result of improper use of prescription drugs.

At a psychiatric service of a Veterans' Administration hospital, 41 admissions over a 4-month period were reviewed for drug-related problems (Ref. 12). Two percent of admissions were determined to be due to drug side effects.

Charts of 293 patients admitted over the course of 1 year to a family medicine inpatient service were reviewed, showing 15.4 percent of admissions to be drug related (Ref. 13). Six percent of admissions for the most frequent type of drug-related admissions were for adverse drug reactions.

Adverse drug reactions among older Americans are even more frequent. In one study, researchers analyzed 463 charts of geriatric outpatients (Ref. 14), revealing 107 notations of adverse drug reactions in the charts of 97 patients (21 percent). Twelve patients were hospitalized as a direct result of an adverse drug reaction. In another study (Ref. 8) of 315 geriatric hospitalizations, 16.8 percent of admissions were determined to be related to adverse drug reactions. The hospital charge for these admissions was $224,542.

Some proportion of adverse drug reactions will occur regardless of how carefully patients follow their therapeutic regimens. Although it is difficult to estimate the proportion of adverse drug reactions and associated health care costs that can be attributed to nonoptimal patient adherence, there are some data relevant to this issue. In one study, 834 admissions to a hospital medical service were reviewed for iatrogenic disease, and 4 percent were determined to be drug-related (Ref. 11). Of these, 54 percent were classified as potentially avoidable, including, for example, overdoses and adverse reactions that evolved slowly enough that had the problems been reported earlier, treatment alterations could have been made in ambulatory care settings. In an earlier study of a sample of 1,000 patients in a community practice, it was determined that 55 percent of the adverse drug reactions experienced were unnecessary and potentially preventable (Ref. 84).

In addition, a 1990 meta-analysis of seven studies that looked at the association between hospital costs and admissions for problems specifically caused by noncompliance (strictly defined as overuse, underuse, or erratic use) indicates that adverse drug reactions caused by noncompliance constitute costly consequences for the health care system. This analysis estimated that 5.3 percent of annual hospital admissions, costing $8.5 billion in 1986, were a direct result of drug treatment noncompliance (Ref. 15).

B. The Benefits of Patient Information

1. Written Information Increases Patient Knowledge and Satisfaction

Patients who receive written information about their medications derive increased personal benefits from the information. The most widely documented of these is increased knowledge.

Industry experts, practitioners, and consumers agree that patients must have some basic information about prescription drugs to adhere successfully to their prescribed drug therapy. Many studies have tested whether the dissemination of written material increases patient knowledge and understanding. For example, a 1983 study of FDA's PPI for benzodiazepines concluded that the PPI effectively conveyed written drug information to patients, and that knowledge and comprehension varies according to the patient's age, years of education, and reading environment (Ref. 58). In this study, patients who received written patient information scored higher on a knowledge and comprehension test than those who received no written information, and those who completed the test at home scored higher than those who completed it at the pharmacy.

It is clear that patients who receive written materials about medications have increased knowledge about the use and effects of the medications (Refs. 38, 42, 44, 47, 48, 52, 53, and 59 through 61). In particular, patients who receive written information show more knowledge about side effects (Refs. 46, 47, 48, 52, and 58), and are better able to attribute adverse reactions to the medications they are taking (Ref. 62). They can more easily discriminate adverse reactions attributable to the medication from other clinical events (Ref. 63).

Patients who receive written information about their medications are more likely to make healthy lifestyle changes (Ref. 60). They are also more satisfied with their treatment (Refs. 33, 42, 47, and 53). In a review of the literature, one author suggests that provision of written materials may help patients cope with illnesses over time, as their modes of coping evolve and the corresponding need for information changes (Ref. 38).

When presented with written information about their medications, the vast majority of patients read it, particularly if it is the initial prescription (Refs. 38, 40, and 44). Reading may be thorough or superficial (Ref. 45). Patients report reading the printed information when receiving the first prescription and refills (Ref. 40), and they may read the materials more than once (Ref. 46).

2. Written Materials About Medications Can Increase Patient Compliance

Even more critical to the health care system, studies of the effects of providing written medication information to patients demonstrate that the result can be increased compliance with the treatment regimen (Refs. 38, 47, and 48). For example, in one study, outpatients who received a patient information leaflet along with their penicillin prescription were tested against patients who received no information at all. Researchers found that a significantly lower proportion of patients who received the patient information omitted doses than those who did not receive the information (Ref. 47). Similarly, researchers concluded that providing written information to patients with antibiotic prescriptions resulted in significant improvement in drug taking behavior and in knowledge about the therapy prescribed (Ref. 48). In a study of psychiatric patients, those receiving written information were more compliant in their medication regimens than those not receiving it, and patients receiving both written and oral information were the most compliant (Ref. 7). In another study, patients receiving both written and oral information about their medications were more compliant than those given no information (Ref. 49). Providing written information has also resulted in fewer patients stopping treatment (Ref. 50). The results of increased compliance may be fewer deaths and lower overall costs of treatment, due to fewer requirements for hospitalizations and

nursing home admissions (Refs. 4 and 57).

In a broad review of the effects of written information, Ley (Ref. 36) concluded that most of the studies examined found positive effects resulting from the provision of written information to patients. Out of 32 studies examining effects on knowledge, 97 percent found increases; of the 25 studies examining compliance, 60 percent found increases; and in 7 studies examining therapeutic benefit, 57 percent found increases.

It should be noted that "compliance" represents a broad range of behaviors that are difficult to measure (Ref. 51). Several studies that have sought to measure the effects of written information have failed to find compliance improved by written information (Ref. 44, 52 through 55). However, in a critical review of the methodologically rigorous studies of interventions to improve compliance, Haynes et al. (Ref. 56) concluded that compliance with short-term treatments can be improved by clear instructions, including written information, as well as by other interventions. Compliance with long-term treatments is more difficult to achieve; no single intervention has been shown to be effective on its own. Rather, improved compliance with long-term regimens requires a combination of interventions, including clear instructions enhanced by written information.

3. Written Patient Information Does Not Have Negative Consequences

There has been speculation about the potential adverse effects of providing information about medications to patients. However, the studies suggest that written information does not increase reports of adverse events (Refs. 38, 42, 44, 45, 48, 52, 53, 62 and 91), nor does oral information (Ref. 65). Two studies that appear to indicate the opposite are flawed. In one case, the authors admit that the written information given to patients was inadequate (Ref. 52) and, in the other, statistical analyses were performed by combining control and experimental groups inappropriately (Ref. 50). A study of psychiatric patients was inconclusive on this point (Ref. 66).

Studies do not show evidence of decreased compliance as a result of written information (Refs. 52 and 66) or evidence of increased anxiety levels (Ref. 60).

4. Relative Effectiveness of Oral and Written Patient Information

Studies examining the relative effectiveness of printed and oral medication information are scarce. However, one study shows that provision of printed information is more effective in increasing patients' knowledge than oral information, and that a combination of the two is best. The authors believe that written materials, particularly those containing information about side effects, may be more effective and timely and less alarming to patients than oral information because most side effects do not occur until after the medication has been taken for a while (Ref. 67). One author suggests that written information should be used to supplement oral instructions that should be tailored to meet the particular beliefs, concerns, and expectations of the individual patient (Ref. 38).

One meta-analysis of the literature, published in 1983 by the Pharmaceutical Manufacturers Association (PMA) (Ref. 68), merits special attention because it purports to demonstrate that PPI's about drugs have almost no effect in improving knowledge or compliance. After careful review of this analysis, FDA has concluded that the methodology was flawed and should not be relied upon with regard to the effects of written drug information on compliance. The details of the study and FDA's analysis of its methodology follow.

In 1983, PMA funded a grant to assess the literature regarding mechanisms for improving patients' knowledge and use of prescription drugs. The authors performed a meta-analysis of studies selected from the patient education/compliance literature. They examined eight different strategies to improve patient knowledge and use of prescription drugs: Counseling, group education, behavior modification, counseling plus materials, materials alone, memory aids, counseling plus memory aids, and PPI's. The authors concluded that seven of the strategies improved patient knowledge and use by 24 percent to 72 percent; however, PPI's had practically no effect in improving patient knowledge or compliance. They concluded that PPI's were an ineffective tool to improve patients' knowledge about or use of medication.

FDA staff reviewed the meta-analysis and found its conclusions to be unsupported by the analysis performed by its authors. There are major definitional and methodological problems with the authors' analysis.

First, the inclusion criteria used were not rigorously followed. Following Kanouse, et al. (Ref. 69), the authors of the meta-analysis defined PPI's as "standardized leaflets which accompany a prescription drug as it is dispensed to the patient and which are designed to inform patients about a drug's actions, indications, and proper use, and to alert them about risks, necessary precautions, and possible side effects." However, as a practical matter, the authors sorted studies meeting this definition into two analytical groups ("materials" and "PPI's"). They placed studies in the PPI category if the authors of that study called the leaflets "PPI's" as opposed to "written" information. The "materials" group included studies that did not designate the written materials as PPI's.

Second, the PMA authors used a different analytical procedure for the PPI section of their analysis than for the remaining sections. Selecting test and control groups for the meta-analysis is a vital aspect of this type of analysis because it seeks to estimate the effect size of the difference between these groups. For all but a few studies examined in the meta-analysis, a group of subjects that received an intervention (e.g., counseling) was compared to a group that did not receive the intervention (e.g., no counseling). However, for the PPI analysis in 27 of the 28 studies examined, the test group was compared to a group that received an alternative version of that PPI. Thus, for PPI's, the authors compared intervention to intervention rather than intervention to control.

The 27 PPI studies included in the meta-analysis were from FDA-funded studies that had been conducted by the Rand Corp. These Rand studies examined 12 different formats for communicating information to patients for each of three drugs: erythromycin (an antibiotic), flurazepam (a sleeping pill), and estrogens (for postmenopausal symptoms). The Rand studies included no-intervention control groups for erythromycin and flurazepam. For estrogens, the Rand study included a control group composed of patients receiving the FDA-approved PPI for estrogens. Citing incompatibility of the data offered by Rand with meta-analytical procedures, the authors of the PMA-funded study selected the intervention group that they believed should have performed worst (i.e., was less sound educationally) to serve as the control group.

The authors of the Rand studies concluded that PPI's lead to reliable gains in drug knowledge. This conclusion directly contradicts the PMA meta-analysis conclusion that was based primarily on Rand study results. The Rand studies were designed only to compare the effects of variations in style of information presentation within PPI's. Each of the PPI's studied by Rand

was highly similar in content and varied only in format or style. Therefore, the selection of one of the intervention groups to serve as a control by PMA researchers was inappropriate and obfuscated differences Rand researchers observed and reported.

IV. Patient Education Programs Instituted Since 1982

A. NCPIE's Coordinating Function

As described in FDA's final rule that revoked mandated PPI's (47 FR 39147), the major coordinating body for private sector organizations has been NCPIE. NCPIE is a voluntary organization comprised of approximately 370 member organizations representing health care professionals, consumer groups, voluntary health organizations, pharmaceutical manufacturers, Government agencies, and other health-related groups. Since its inception in 1982, NCPIE has engaged in numerous activities to improve the delivery of communication of prescription drug information to patients and consumers. For example, NCPIE has coordinated broad scale public service advertising campaigns targeted at improving medication use among older Americans and children, sponsors an annual national conference on prescription medicine information and education, has targeted reports on drug use in population segments (elderly, pediatric, women), sponsors "Talk About Prescriptions Month" every October, and creates and distributes educational materials such as the "Brown Bag Review Kit," in support of the National Brown Bag Medicine Review Program, which NCPIE developed with support from the Administration on Aging. NCPIE has also compiled a directory of drug information, citing numerous patient education resources. These include drug leaflet programs; specialized pamphlets, newsletters, etc., which are directed to improving use of specific drugs; books for patients and health professionals; high-tech or other automated videos, telephone, and computer software; interactive-computer kiosks, and other audiovisual instructional aids; compliance reminder systems, aids, and devices; program guides to set up educational systems; and other patient information and education systems.

B. Pharmaceutical Industry Programs

In the past decade, the pharmaceutical industry has developed and distributed drug information to consumers, both directly and through health professionals.

In the early 1980's, these programs provided health professionals with leaflets or booklets describing various disease processes and medications that might be used to treat these conditions (Ref. 20). In recent years, the industry has begun to prepare numerous additional materials, ranging from simple brochures to elaborate patient education kits and programs. Currently, the great majority of pharmaceutical products prescribed to patients have some patient materials developed as well.

Recently, pharmaceutical companies have begun the development of relatively comprehensive patient support programs. Several such programs have been developed, including the following: Alliance Program, Good Start Program, Patient Support Program, Wellspring Service, Partners Program, Growing with Humatrope, The Patient at Heart, Stay in Control, HealthQuest, Unique Patient Support Program, Clinical Experience Program, CardiSense, Hands on Health, Seasons, Care Kits, Asthma Management Program, Total Lifestyle Connection, and Dialogue. These programs provide a consistent flow of information to patients initiated on therapy for the target drugs. They provide information about the product as well as information about the disease and lifestyle modifications necessary for treatment. As promotional labeling or advertising, these materials necessitate the inclusion of labeling information and must meet other regulatory standards.

In the mid-1980's, the pharmaceutical industry began to direct advertisements to the consumer to promote certain prescription drugs. These advertisements have taken many different forms. "Help-seeking" advertisements encourage consumers to seek professional assistance for certain conditions, but do not promote a particular product. Reminder advertisements merely mention a product and its dosage form but give no other suggestions or representations of how the product is to be used or its benefits. Institutional advertisements describe the pharmaceutical company and the work it is doing.

There has also been a significant increase in consumer-directed advertisements that directly promote a prescription drug product or group of products and discuss in detail product risks and benefits. Direct-to-consumer advertising (DTCA) has been placed in consumer magazines or newspapers for several products, including Actigall, Cardizem CD, Claritin, Cognex, Estraderm, Felbatol, Habitrol, Hismanal, Mevacor, Minitran, N.E.E. 1/35, Neurontin, Nicoderm, Nicorette, Nicotrol, Norplant System, Ortho Novum 777, Premarin, Proscar, Prostep, Rogaine, Seldane and Seldane-D, and Transderm Scōp. FDA reviews DTCA for these products to ensure that they are not false or misleading and are in fair balance. However, FDA acknowledges that the rules that govern the regulation of advertising focus primarily on advertising geared towards health professionals.

Although individual advertising materials disseminated to consumers may meet regulatory standards in that they are in fair balance and are not false or misleading, FDA remains concerned that the overall practice of DTCA will have cumulative effects of providing patients with information based primarily on promotional materials furnished by the pharmaceutical industry, and that this promotional focus will result in problematic overall perceptions of prescription drugs. For example, it would not benefit the public health for consumers to perceive prescription drugs—i.e., potentially dangerous medicines—as relatively nonserious, or for consumers to believe that nonprofessionals are competent to make skilled therapeutic decisions. FDA believes that the availability of quality patient information will help to counter any unbalanced perceptions of prescription drugs promoted to the consumer.

C. Patient Information Supplier Programs

During the past 10 years, numerous health professional and consumer associations and private sector organizations have initiated programs to educate drug consumers about their prescriptions. FDA has worked to support these programs through staff support, expert review, and evaluating research.

1. Major Associn Programs

a. *AMA.* In 1982, the AMA initiated a program to encourage licensed practitioner distribution of written patient medication information (PMI's). AMA's PMI sheets were designed to provide licensed practitioners with written drug information they could give to a patient at the time a medication is prescribed. Each PMI consists of a single sheet of paper, printed on both sides, containing information about the specific drug or drug class. The instructions are designed to improve the effectiveness of drug therapy, to reduce the risk of adverse drug reactions, and to reinforce communication between patient and licensed practitioner. Specific PMI's are

based on the drug information leaflets produced by the USP, which are revised to conform to the PMI format and are then subjected to additional review by the AMA and other medical consultants. Currently, there are 101 drug titles, including classes and individual drugs, offered through the PMI program. This provides coverage of over 1,700 of the most widely prescribed drugs.

Available sales data indicated a recent downturn in the use of PMI's. While over 84,000 pads (each consisting of 50 sheets) were sold between July 1, 1987, and June 30, 1988, a steady annual decline in unit sales resulted in a sales figure of approximately 47,500 the 1993 fiscal year.

b. *AARP pharmacy service.* The AARP Pharmacy Service program, Medication Information Leaflets for Seniors (MILS), addresses the special drug information needs of the elderly. AARP requires its pharmacies to include the drug information leaflets with the original and first refill mail-order prescription for each patient. AARP designed the leaflets in consultation with FDA and geriatric experts. The leaflets cover between 80 percent and 85 percent of all drugs dispensed by AARP pharmacies.

In addition to its printed materials, AARP also conducts seminars concerning the safe and effective use of prescription and over-the-counter drugs, and the special health care needs of the elderly. For example, AARP advises its members how to prepare for an office visit, what information to share with the licensed practitioner and pharmacist, what information to get about each drug prescribed, and how to organize a system for taking medicines.

c. *Other association programs.* Several other voluntary health organizations have been involved in the development and delivery of health information to patients. These programs are described in the NCPIE Directory (Ref. 18). Some of the organizations that have developed programs include:

(1) American Association of Family Physicians (AAFP): the DUET program (recently discontinued program providing abstracts for photocopying and distribution);

(2) American Dental Association: DDIS (Dental Drug Information Series)—distribute leaflets;

(3) American Academy of Pediatrics: Patient Medication Instruction Sheets—distribute leaflets;

(4) American Society of Health-Systems Pharmacists: Several programs, such as MEDTEACH—software program, Medication Teaching Manual—book, Drug Information Service—health professional reference book.

2. Selected Private Sector Programs

In addition to these associations, several private sector information suppliers have developed programs to communicate drug information to the patient, including the following.

a. *USP.* USP has developed a drug information data base and prepares written information. Both the data base and prepared medication leaflets are used in many patient information programs. For example, USP distributes drug information leaflets, which can be personalized for the organization, to State pharmaceutical associations, chain and independent pharmacies, and large institutions.

USP also produces the "USP Dispensing Information, Advice for the Patient" publication as part of its 3-volume "USP Dispensing Information" (USP DI) series. The "Advice for the Patient" publication contains monographs that provide general information (such as information that the patient should tell his or her licensed practitioner, nurse, or pharmacist before using the drug product, proper use of the drug product, storage conditions, precautions, and adverse reactions) about drug products. These monographs form the basis of the USP's Patient Drug Education Leaflet program and other programs, such as the National Association of Retail Druggists' (NARD) Patient Information Leaflet program. USP DI Patient Education Leaflets are currently available from USP as preprinted, English-language leaflets for the 88 drugs or families of drugs most frequently used in ambulatory care. USP also publishes full text, easy-to-read leaflets. In addition, abstracts from the USP DI are available to health care providers who wish to institute their own patient education leaflet programs. These abstracts are stored on a data base, may be personalized for the health care provider, and are available in both English and Spanish.

b. *Medi-Span, Inc.* Medi-Span, Inc., has developed a drug education data base consisting of patient-oriented information about prescription and OTC medications. Drug information is both product and dosage form specific. Programming by the user or computer software vendor and integration into the pharmacy, medical records or patient care software package allows health professionals to print a customized counseling sheet for the particular drug product.

Medi-Span, Inc., also produces a stand-alone MS–DOS software version of their patient drug information which allows printing of a customized patient counseling message for prescription and OTC medications. This software does not require programming by a software vendor and is marketed to home health care agencies, retail pharmacies, consultant pharmacists, physician offices, drug information centers, and small hospital pharmacies. The software allows for selected sections of the product information to be printed.

D. Continuing FDA Encouragement

Since the withdrawal of the PPI regulations, every FDA Commissioner and HHS Secretary has urged private sector health professionals to be more active in counseling patients about their medications. In 1992, Commissioner Kessler and several other senior FDA staff renewed this call for private sector health professional medication counseling, reinforced by the provision of written information. Professional journals published several articles publicizing FDA's renewed interest in increasing the provision of written information to patients (Refs. 92 and 93). In addition, several speeches were delivered to communicate similar messages. For example:

(1) On March 16, 1992, at the Opening General Session of the Annual Meeting of the American Pharmaceutical Association (APhA), the Commissioner challenged pharmacists to renew their commitment to patient education. After taking note of the House of Delegates' newly adopted position that "makes pharmacists responsible for initiating pharmacist-patient dialogue," the Commissioner reviewed the benefits of patient information and the key role pharmacists play as gatekeepers.

(2) In his address in June of 1992 at the Biannual Meeting of the American Nurses Association, the Commissioner asserted that patients are eager to learn more about medications they are taking and that nurses should step up their efforts to instruct patients on how to take their medications properly.

(3) At the National Association of Chain Drug Stores (NACDS) Pharmacy Conference in the summer of 1992, the Commissioner emphasized that pharmacists are ideally suited to take the lead in the patient education effort because of their training and unique position in the health care system. He also stated that it is inconceivable that a patient could leave the pharmacy with a new prescription medication and not have written advice about how to get the maximum benefit from their medication.

(4) At the USP Open Conference on Patient Education in September 1992,

the Deputy Commissioner for External Affairs stated that in order to make patient education more effective, all health professionals need to become more involved and invested in the process. She stated that the question should no longer be "Should I counsel?" but "What should I say?"

(5) In May 1993, at the NCPIE Annual Conference, the Deputy Commissioner for External Affairs once again challenged health professionals to do a better job of communicating with patients. She also predicted that the patient education message would become more critical as we approve drugs with much more complex risk/benefit profiles. Further, she stated that patients must understand the risks and limitations of the products so that they can use the drugs properly.

In addition, professional staff from FDA's Office of Health Affairs, Office of Consumer Affairs, Office of Policy, and the Center for Drug Evaluation and Research have researched and analyzed patient information and challenged pharmacists, physicians, and nurses to renew their commitment to patient education. At the same time, through speeches, participation at professional meetings, site visits, and articles in professional journals, these agency staff have renewed and amplified the agency effort to promote communication to patients about their medications.

V. Evaluation of Progress

As mentioned earlier, in the revocation of the 1980 mandatory PPI regulation, FDA indicated that it would be conducting surveys to evaluate the availability of adequate patient information. This section discusses FDA surveys and other available data that assess the effectiveness of the private sector initiatives in providing patient medication information.

A. FDA Surveys of Oral and Written Patient Information

FDA sponsored national telephone surveys of patient receipt of information about new prescriptions in 1982, 1984, and 1992 (Refs. 22, 23, and 24, respectively). In each survey year, researchers collected data from approximately 1,000 patients who had received a new prescription for either themselves or a family member during the 4 weeks before the interview. Researchers asked respondents about their experiences at the licensed practitioner's office and the pharmacy, and whether they had gained any drug knowledge independent of those experiences. In an effort to establish patient drug education trends, the latter report (Ref. 24) compares data collected from the surveys over the past 10 years.

1. Experiences at the Licensed Practitioner's Office

a. *Oral counseling.* When asked whether they received any prescription drug counseling at the licensed practitioner's office, approximately 66 percent of patients in each year answered affirmatively. The surveys asked patients about five specific drug counseling topics: (1) Directions regarding how much medication to take, (2) directions regarding how often to take the medication, (3) information about refills, (4) precautions, and (5) adverse reaction information. Researchers found no meaningful change in the percentage of patients whose licensed practitioner voluntarily instructed them how much or how often to take their medication. Slightly over half of the respondents in each year received instructions without questioning their licensed practitioner. Researchers discovered a small gain in counseling about precautionary information, from 26 percent in 1982 to 33 percent in 1984; the level remained at 33 percent with no increase experienced between 1984 and 1992. For counseling about adverse reactions, the rate measured increased from 23 percent (in 1982 and 1984) to 29 percent in 1992. Less than 5 percent of respondents, in each of the three surveys, received any additional counseling other than directions for use, refills, precautionary and adverse reaction information.

The rate at which patients question their licensed practitioners about their prescriptions has also remained low over the past 10 years; only between 2 percent and 3 percent ask for directions regarding the correct use of their prescriptions and 4 percent to 6 percent ask for refill, precaution, and adverse reaction information. When researchers examined both spontaneous counseling and spontaneous questioning, the only meaningful gain in licensed practitioner-patient communication was in the area of adverse drug reaction counseling. However, even though this rate increased from 27 percent to 35 percent, only slightly more than one-third of patients receive any counseling regarding possible adverse drug reactions.

b. *Written information.* A comparison of the three surveys reveals an increase in licensed practitioner dissemination of written drug information, from 5 percent in 1982, to 9 percent in 1984, to 14 percent in 1992. Seventy-five percent of the 1992 respondents who received written information said that they received an instruction sheet, 55 percent of which were preprinted, and 39 percent of which were printed at the licensed practitioner's office. Overall, approximately 5 percent of all participants in the 1992 survey received a personalized, computer-generated brochure or sheet to instruct them about their prescription medications.

2. Experiences at the Pharmacy

a. *Oral counseling.* During the past 10 years, fewer pharmacists, and more pharmacy clerks or cashiers, are distributing prescriptions to patients at the pharmacy counter. In 1992, 43 percent of consumers received their prescription from the pharmacist, and 41 percent received their prescription from a clerk. However, even though the number of pharmacists distributing drugs to consumers has decreased, the amount of counseling has increased.

Respondents were questioned about the same five areas of counseling at the licensed practitioners' office. There has been an increase in pharmacist counseling in four out of the five prescription education areas that were tested. In 1992, 32 percent of the patients said that their pharmacist instructed them about how much or how often to take their medicine, as compared to between 20 percent and 23 percent in 1982 and 1984. Similarly, there was an increase in refill and precautionary counseling. The rate for refills increased from 12 percent in 1982 to 18 percent in 1992, and for precautions from 8 percent in 1982 to 21 percent in 1992. Adverse drug reaction counseling decreased in 1984 to 9 percent, from 16 percent in 1982. It has increased since 1984, to 13 percent, but remains below the 1982 level.

Although research indicated gains in pharmacist counseling in four of five areas covered, analysis of the percentage of patients who obtain counseling about any of the topics covered indicates that this percentage has remained stable over the years. This suggests that patients obtaining counseling at the pharmacy are more likely to obtain a broader overview of topic coverage.

The percentage of patients who question their pharmacists has increased from 2 percent in 1982 to 5 percent in 1984 to the 7 percent to 9 percent range in 1992. The largest gain was made in the area of patients questioning their pharmacists about adverse drug reactions.

Data indicate that the type of verbal information that pharmacists are most likely to give reinforces the licensed practitioner's instructions on how often and how much medicine to take. In other words, although the data indicate

an increase in pharmacist counseling, patients are receiving redundant information. On the other hand, the increase in patient-initiated questioning resulted in patients receiving information at the pharmacy that they had not received at the licensed practitioner's office.

b. *Written information.* Respondents were asked if they received any written information furnished with the medicines aside from the label information on the medication container. The percentage of respondents answering affirmatively has increased over the three surveys. Specifically, 32 percent of patients reported receiving written drug information in 1992 as compared to 26 percent in 1984 and 16 percent in 1982. The type of additional information ranged from sticker labels affixed to the container to brochures and information sheets. Examining the particular form of information provided in the 1992 survey indicated that, overall, 23 percent of subjects reported receiving informational brochures or instructions (more than brief sticker labels).

FDA's 1992 survey also revealed changes in how written material is prepared. Technological advances, most notably in the use of personal computers, led to an increase in the dissemination of computer-generated information. Overall, 12 percent of patients in the 1992 survey received a computer-generated information sheet at the pharmacy.

3. Ten-Year Trends in Information Distribution

The data from these surveys do not indicate any sweeping changes in the nature or frequency of information disseminated either by licensed practitioner or pharmacist. However, the data do indicate some discernible trends.

Consumers are more likely to receive oral instructions for use and information about precautions and adverse reactions related to their medicines today than they were 10 years ago. In addition, patients are more likely to receive some form of written prescription information today, especially at the pharmacy, than they were 10 years ago. There have been some gains in all categories of information disseminated at the pharmacy, except adverse reaction information. However, a broader analysis indicates that the gains made in patient counseling are attributable to an increase in the number of categories of information disseminated, not to an increase in the number of patients who receive counseling. Finally, despite overall gains in health professionals' counseling and disseminating written information, over three-fourths of all patients in the 1992 survey received no substantial written prescription information. Further, data from the 1992 survey indicate that when a drug is initially prescribed and dispensed, approximately half of all patients receive no forewarning of possible adverse reactions that they may experience from their medications.

B. Other Literature About Oral and Written Patient Information

1. Patients Continue to Want Written Information

In the 1979 PPI proposal, FDA reviewed five studies in which consumers were asked about their desire to obtain additional information about their prescriptions. Three of the studies specifically addressed patients' desire to obtain printed information about their medication. The studies indicated that the majority of patients who were provided written information with their medication (oral contraceptive users or those in an experimental test of a PPI for Thiazide drugs) wanted to obtain written information for additional drugs (86 percent to 97 percent wanted this additional information). The third study simply asked consumers if they thought it was important for printed patient information to be provided with prescription drugs. Sixty-four percent responded affirmatively.

Studies completed after 1979 continue to support the previous trends that indicate that patients want to know more about their medications, especially the risks, and that people would like to receive written information with their prescriptions. A 1982 AARP survey of people over age 45 indicated that 60 percent of respondents would like to receive written information with their medication. The majority of respondents indicated that their licensed practitioner or pharmacist did not provide written information.

A national survey conducted in 1984 by the Columbia Broadcasting System also indicated that labels on medication and inserts would be useful for obtaining information about safety and potential adverse reactions (83 percent and 74 percent) as well as effectiveness (60 percent and 64 percent) (Ref. 25). Subjects in the survey were asked to rate 27 categories of information about medication in terms of their perceived knowledge about that category and how important it would be to know about that aspect of information. The perceived knowledge gap (i.e., the difference between ratings of knowledge and perceived importance) for safety and efficacy of medication was 50 percent (i.e., 27 percent of the sample believed that they were well-informed about the safety and efficacy of medications and 77 percent believed that it was important to be well-informed about this aspect of medication information).

Another study, conducted by the President's Commission for the Study of Ethics in Medicine and Biomedical and Behavioral Research (Ref. 26), found that both licensed practitioners and members of the public believed that patients should be informed about the potential adverse reactions of medical treatment. The survey also indicated that patients and licensed practitioners alike believed that this information should be delivered spontaneously, without patients having to ask for the information. The majority of the general population surveyed (64 percent) also asserted that they should be informed of serious risks regardless of how likely the risk was to occur.

Other studies, both in this country and abroad, consistently show that patients want more information about their drugs (Refs. 29, 38, 42, and 43), including information about precautions and interactions (Ref. 33). In one study, when asked whether they want information orally, in writing, or both, more patients preferred to have both (45 percent) than preferred only written information (21 percent) or only oral information (30 percent) (Ref. 43).

2. Limitations of Current Patient Counseling Efforts

The literature since 1982 demonstrates that patients need and want additional information about their medications. Studies have shown that licensed practitioners and pharmacists often do not provide information about drugs to patients (Refs. 27, 28, and 29), including information about side effects (Refs. 29 through 32), precautions, and interactions (Ref. 33).

A study published in 1987 revealed that, while over 90 percent of the patients interviewed had received some information about their drug treatment from licensed practitioners, nurses, or pharmacists, only 32 percent received counseling regarding adverse reactions (Ref. 29), even though another study showed that patients rate information about precautions, drug interactions, and adverse reactions as most important (Ref. 33). Only 14 percent of patients in the 1987 study received written information, despite the fact that 74 percent said that written instructions would be valuable. Despite the great demand for information, however, only one-third of the patients in this study

questioned their licensed practitioners about their treatment (Ref. 29).

Two FDA-sponsored studies, one of consumers and one of physicians and pharmacists, reveal that the professional and consumer groups have substantially different perceptions of the type and amount of information provided by licensed practitioners, as well as the intensity of patients' demand for drug information. Eighty-eight percent of licensed practitioners surveyed believed their patients were well or adequately informed about the purpose and use of their prescriptions. However, patients revealed that only 26 percent received oral information about side effects from licensed practitioners' offices (11 percent from pharmacies) and only 32 percent of patients reported receiving oral precaution information from licensed practitioners' offices (16 percent from pharmacies). Approximately 60 percent received information about how and when to take the medications from licensed practitioners and about 25 percent from pharmacists (Ref. 34).

Licensed practitioners may find it difficult to counsel patients because they are not comfortable in the role of counselor (Ref. 32) or because medical records do not always contain the information necessary for them to provide appropriate counseling for individual patients (Ref. 35). For example, a study that monitored charts of patients who had been prescribed amiodarone found that only 14 percent of the charts documented patient education concerning photosensitivity which can be controlled, at least partially, with a sunscreen (Ref. 31). In another study, researchers reviewed the charts of hospital patients who had been prescribed benzodiazepines. Fifty-seven percent of the charts failed to show whether the patient used alcohol, even though the introduction of alcohol could result in a life-threatening interaction (Ref. 35).

When licensed practitioners do provide counseling, information on side effects is often omitted (Ref. 29), and side effect information, if given, usually relates to the most frequent, rather than the most serious, side effects (Ref. 30).

Even if counseling is provided, patients may not remember the information that is given. In a review of primarily pre-1983 research on this issue, one author notes that it is well established that patients forget much of what they are told during medical consultations (Ref. 36).

Pharmacists, as well as licensed practitioners, often fail to provide information about medications. In a 1993 nationwide survey of 2,000 consumers, a substantial proportion of respondents stated that their pharmacists did not regularly tell them how to take their medications or advise them of possible adverse reactions (Ref. 37). Almost half of the consumers said they were not told how to take their medicine. Almost 30 percent reported that their pharmacist never warns them of common adverse reactions that are bothersome although not necessarily serious. Nearly half of the consumers responded that their pharmacist never told them about serious adverse reactions for which they should contact their licensed practitioner. The author of this study notes that these results conflict with a survey of pharmacists, conducted by two pharmacist associations, in which 89 to 98 percent of pharmacists reported that they orally counsel their patients (Ref. 37). The disparity between these two surveys may suggest that pharmacists and consumers have different perceptions about the quality and quantity of counseling provided by pharmacists. The results of a 1992 Wisconsin Statewide survey of pharmacy patients are consistent with the nationwide consumer survey. In this study of persons who recalled the time their last new prescription was filled, 53 percent had not received any oral consultation from their pharmacists, and 23 percent had not received consultation from their prescribers. Nineteen percent received no consultation from either pharmacists or prescribers. For new and refill prescriptions combined, 60 percent reported receiving no oral information from pharmacists and 26 percent reported none from prescribers. The authors cited comparable findings in other studies (Ref. 27).

These results are similar to responses given in a 1985 survey, in which pharmacists reported having provided oral counseling for 52 percent of patients with new prescriptions and for 18 percent of those with refill prescriptions. The authors concluded that pharmacists provide oral and written information selectively to patients and this information is usually not complete. They suggest increased counseling and the provision of comprehensive leaflets about the medication (Ref. 28).

3. Elderly Patients Have Special Information Needs

In a review of the literature, one author demonstrates that elderly patients, who are prone to forget or to be confused, and who may be taking several medications, require special attention when drug information is given (Ref. 38). Research indicates that 23 percent of nursing home admissions are attributable to noncompliance with drug therapy, in part because a gap exists in elderly patients' understanding of proper medication use (Ref. 4). They frequently do not remember to take their medications and report receiving little information about their medications (Ref. 41). One study concluded that, because almost 75 percent of elderly patients could not remember receiving oral instructions regarding potential adverse reactions, and only 14 percent claimed to have received any written information, the elderly require special medication education that includes both oral counseling and written reinforcement (Ref. 52).

C. The Adequacy of Currently Available Written Information

Patients report reading written information when they receive it (Ref. 38). However, currently available written material often is inadequate. Even when written information is provided to patients, the material may not be expressed appropriately to communicate the important information (Ref. 39), and patients often fail to understand the written materials (Refs. 38 and 40). In addition, written materials often take the form of auxiliary labels (Ref. 28) that offer a few directives with no explanation or background information to improve comprehension and retrieval of the message.

However, with the trend in pharmacy toward computer automation of label-making and record keeping, there has also been an increase in electronically-available patient drug information designed to be given out with dispensed prescriptions. FDA reviewed patient drug information from eight independent sources that provide information on electronic media designed to be used by retail pharmacists as an aid to patient counseling at the time of drug dispensing. These sources were the American Society of Health-Systems Pharmacists, Clinical Reference Systems, Ltd., Facts and Comparisons, First Data Bank, Medi-Span, Inc., Medi*CHEX, Inc., Pharmex, and the U.S. Pharmacopeia. The accuracy and comprehensiveness of the patient information for three drugs was determined by an assessment of consistency with the approved labeling. The specificity of the information communicated was judged on the basis of whether the directions for use were clear and whether the risk information conveyed the significance of the risk, how to recognize negative

consequences, and the proper response to take should they occur.

Patient information was gathered from each source for three drugs: Oral alprazolam (a benzodiazepine), oral amoxicillin (a penicillin), and oral enalapril (an angiotensin converting enzyme (ACE) inhibitor). Only four of the eight sources produced drug-specific information for the three drugs chosen; the other four sources produced therapeutic class information.

FDA's review found substantial differences between sources in the quality of information provided. One source included no mention of indication for any of the three drugs studied. Only two of the eight sources mentioned both of alprazolam's approved indications (i.e., anxiety disorder and panic disorder). On the other hand, the sources that provided general benzodiazepine information mentioned uses that are not approved for alprazolam, including the treatment of insomnia, muscle spasm, convulsive disorders, and symptoms of alcohol withdrawal.

Only two of eight sources mentioned either of alprazolam's contraindications (i.e., known sensitivity to a benzodiazepine or acute narrow angle glaucoma). Side effect/risk information tended to be highly general and nonspecific; the significance of the risks was often minimized and the serious, but rare risks were often missing. For alprazolam, all information providers included the common side effects of drowsiness and dizziness, but four failed to mention any risk incurred when alprazolam is taken during pregnancy and none of them described the risk itself (either a birth defect when taken during the first trimester or withdrawal symptoms in the child at birth). Unlabeled side effect information ("wormlike movements, tongue protrusions, chewing motions, and lip smacking") were reported for alprazolam by some sources; none of these effects appear in its label.

Only two of the eight sources mentioned amoxicillin's only contraindication (previous allergic reaction to any of the penicillins). Only two of the eight warned the patient to be aware of symptoms that may signal a superinfection with mycotic or bacterial pathogens.

None of the eight sources mentioned the contraindications for the use of enalapril, i.e., allergic reactions or swelling (angioedema) on previous treatment with similar drugs. Two of the sources failed to warn the patient about symptoms of angioedema, a potentially deadly allergic reaction. Of the six including such symptoms (i.e., swelling of face, extremities, eyes, lips, tongue or difficulty in swallowing or breathing), only one advised the patient experiencing such symptoms to take no more drug and to seek medical attention immediately.

The analysis did not assess the accuracy of important and relevant information not derived from the approved labeling. The most common types of such information were: (1) Directions for what to do in case of a missed dose, (2) proper storage conditions, (3) directions for what to do in case of accidental ingestion or overdose, (4) directions for when to take the drug with respect to meal times. However, there was little consistency between sources in inclusion of this information. For example, different sources gave opposing directions for handling missed doses and for when to take the product in relation to mealtimes.

The lack of specificity and contextual information found in information from some of these systems is of special concern. Research examining the effectiveness of warning labels points to the need for warning messages to include sufficient context to explain to users why they should take certain actions or precautions or pay attention to certain aspects of the product. Standards for warning labels indicate that, in addition to being conspicuous and understandable to the targeted population, labels need to get the reader's attention (e.g., by use of a signal word), and disclose the potential danger, why it is important to avoid the danger, and specific instructions regarding how to avoid it.

Research on warnings provided in consumer-directed advertisements for prescription drugs indicate that general warnings (e.g., see your doctor) do not give consumers a sufficient understanding of the risks inherent in product use. Consumers interpret advice to consult a health care professional as "general reassurance" that the condition is under sufficient treatment, rather than that "specific vigilance" is needed to protect the consumer from product risks (Ref. 94). Therefore, nonspecific advice to consult with the health care professional may be insufficient as a means of communicating risk information.

Searches through a frequently-used patient medication information data base for products with boxed warnings in the approved labeling (generally indicating an extremely serious warning) revealed a general lack of the kind of information that would allow the reader to understand the reason for or significance of the warning. For example, despite Hismanal's boxed warning concerning life-threatening heart arrhythmias that may occur on use with common prescription antibiotics and antifungals, the advice given was simply to check with the doctor or pharmacist before taking any new medicine, either prescription or over-the-counter. The information for Seldane-D, which has the same boxed warning, added the names of the drugs that cause the interactions. Neither specified that a potential outcome of mixing these drugs is a fatal heart attack.

D. Recent Changes in Pharmacy Provision of Patient Information

The most recently analyzed FDA survey of patient receipt of medication information was conducted at the end of 1992, immediately prior to the implementation date of the 1990 Omnibus Budget Reconciliation Act (OBRA '90) (Ref. 70). OBRA '90 requires pharmacists to offer to counsel Medicaid recipients. Guidelines and requirements for how to implement this statute have been issued by individual states. Many states expanded the covered population to include all patients. In addition, several pharmacy organizations, individual pharmacies, and drug store chains have been implementing their own policy regarding prescription drug counseling.

In recent meetings, FDA staff informally discussed the issue of patient education with representatives from consumer, medical professional, pharmacy, pharmaceutical industry, and patient information provider groups, including the National Consumer League, AARP, NCPIE, AMA, AAFP, ASHP, APhA, NARD, NACDS, Pharmaceutical Research and Manufacturers Association (PhRMA), USP, and Medi-Span. In many of these discussions, representatives suggested that the implementation of OBRA '90, although focused on oral counseling, had also significantly affected the distribution of written information.

Several of these groups also recently conducted surveys to describe pharmacist behavior and perceptions concerning printed patient information. According to a 1993 NARD survey of its members, 92 percent of independent retail pharmacists responding to the survey reported that they provide printed patient drug information. NACDS determined that 95 percent of responding drug store chains reported having a printed patient information program in place in 1994.

However, these estimates do not allow specification of the type of printed patient information available.

Manufacturer-supplied promotional brochures, as well as leaflets that accompany drug products in unit-of-use packaging (e.g., oral contraceptive patient labeling) and short labels designed to stick onto prescription vials would be included in the broad definition of printed patient information. These surveys were not designed to examine these distinctions.

The Research Institute of Pharmaceutical Sciences of the University of Mississippi School of Pharmacy conducted surveys of chain and independent drug stores in the spring of 1994. In one survey, 77 percent of the pharmacy manager respondents reported using printed patient information supplied by commercial vendors; 64 percent reported using printed patient information from pharmaceutical manufacturers; and 17 percent reported using printed patient information from nonprofit associations. In a separate survey, 93 percent of responding community pharmacists indicated that they used printed patient information. However, only 54 percent of pharmacists indicated that they give out printed patient information with at least 75 percent of all new prescriptions dispensed, and only 37 percent give out printed patient information with at least 95 percent of all new prescriptions dispensed. Sixty-eight percent of the pharmacists indicated that computerized patient information was available in their pharmacy. However, on average, the computerized patient information was reported being accessed for patient counseling purposes an average of 86 times per week. In contrast, the average number of prescriptions dispensed per day was 131, suggesting that, even though available, patient information systems are not being fully utilized.

However, there is preliminary evidence that the rates of prescription drug information received by patients has increased substantially in the past 2 years, based on comparison with the 32 percent of respondents in the 1992 FDA survey who reported receipt of any written information in addition to the label on the container, and the 23 percent who reported receiving "longer" information sheets and brochures (not including sticker labels). The new evidence comes from two recent patient surveys.

First, in July 1994, patients/caregivers who obtained a prescription from a pharmacy within the past 6 months were surveyed for the National Association of Boards of Pharmacy (Ref. 95). In this survey, 64 percent of respondents said that they received printed materials about their medication from the pharmacy. However, these data cannot be examined further as a function of how much of this percentage represents short "sticker label" information and how much represents "longer" information sheets and brochures. Second, a repeat of the FDA patient information survey was conducted in December 1994 and January 1995, with data collection cofunded by the Health Care Financing Administration. Preliminary data from this survey also support the occurrence of an increase in distribution of written information to patients; 58 percent of patients reported receiving some form of written information at the pharmacy. The rate of dissemination of "longer" information (more than sticker labels) was 55 percent.

VI. Relationship To International Activities

On March 31, 1992, the European Community (EC) adopted a Directive requiring its member States to refuse an application to place a medicinal product for human use on the market if the product's user package leaflet did not comply with the Directive (Ref. 71). The EC based its mandatory leaflet program on the desirability of uniform labeling among member countries and on consumer protection. The Directive states that the leaflets are necessary in order to ensure that medicinal products are used correctly on the basis of full and comprehensible information.

A user package leaflet must accompany all human drug products unless the manufacturer includes the required leaflet information on the outer or immediate packaging. The EC leaflet must include the following information:

(1) *Identification of the product*—Name of the product, active and excipient ingredients, and pharmaceutical form;

(2) *Therapeutic indications*—All therapeutic indications are to be listed unless the authorities find that the listing of certain indications would have serious disadvantages for the patient;

(3) *Information necessary before taking the product*— Contraindications, appropriate precautions for use, and special warnings, which must include categories for children, breast-feeding women, the elderly, and patients with special pathological conditions;

(4) *Instructions for proper use*—Dosage, method and frequency of administration, any limitations on duration of treatment, action to be taken in case of overdose, action to be taken in case of missed doses, and risk of withdrawal, if any;

(5) *Description of possible undesirable effects under ordinary use*—Including the action to be taken if the patient experiences an adverse reaction, with mandatory language directing the patient to contact his or her licensed practitioner if the patient experiences any effect not listed on the leaflet;

(6) *Expiration*—Including a warning not to use after expiration, instructions on proper storage, and description of visible signs of deterioration, if any; and

(7) *Last revision date of the leaflet.*

The user package leaflet may contain pictograms or symbols, but may not include language or symbols that the authorities regard as promotional. The language must be clear and understandable, the print must be clearly legible, and the leaflet must be offered in the official languages of the country where the product is placed on the market.

The Directive requires authorities to refuse a marketing application if the product's leaflet does not comply with the Directive. All changes to any contents of the leaflet that are covered by the Directive, except for information relating to the summary of characteristics, must be submitted to the authorities for approval. The authorities may exempt a drug product from the Directive if the product is not intended to be delivered to the patient for self-administration. Enforcement provisions allow the authorities to withdraw a medicinal product from the market until its leaflet complies with the Directive.

The Commission of the European Communities is directed to publish guidelines concerning:

(1) Special warnings for certain categories of medicinal products; (2) required information relating to self-medication; (3) legibility; (4) methods to identify and authenticate medicinal products; and (5) the list of excipients that must be featured on the labeling and the manner in which they must be indicated.

Countries were directed to take whatever measures necessary to comply with the Directive before January 1, 1993. The members were directed to implement the Directive after January 1, 1994. In other words, any application to place a medicinal product for human use on the market or to renew a marketing authorization after January 1, 1994, must include a user package leaflet that complies with the Directive.

Both the EC's leaflet program and FDA's proposed patient information program share the same patient education goal of increasing the safe and effective use of prescription drugs. Both patient information efforts should provide basic information about product

identification, directions for use, indications, adverse drug reactions, and precautions. Both programs also require that medication information for patients be written in understandable language, be devoid of promotional material, and be legibly printed. Both FDA and the EC recognize that the role of the printed leaflet is to reinforce the counseling that patients receive from health care professionals.

VII. Options Considered

FDA considered several alternative approaches that might remedy the problems associated with inadequate communication of prescription drug information to patients. From the literature reviewed, it was evident that a multifaceted, broad-based medication labeling and education program is needed that has as its central component the communication of information between health professionals and patients.

At a minimum, understandable information about medications should be supplied with new prescriptions for most products used without direct medical supervision. Written information should be designed to complement and reinforce oral counseling by prescribers and dispensers and achieve the overall objective of enhancing patient understanding and use of medications.

FDA examined a number of possible approaches in its consideration of how best to achieve the desired objectives of enhancing patient understanding and use of medications. After extensive deliberation and consultation with concerned consumer groups, pharmaceutical industry and pharmacy groups, and patient information suppliers, and careful consideration of the regulatory options, FDA determined that a combination of regulatory and voluntary efforts would take best advantage of available expertise and resources. Recent increases in pharmacy distribution of private-supplier patient medication information were strongly factored into FDA's analysis.

The remainder of this section describes the various alternative approaches considered, along with their advantages and disadvantages, in terms of how they address two components of such systems: the content of patient information and the distribution system involved. A major difference in the alternatives is the extent of FDA's role in determining the content of patient information. FDA's statutory obligation is to ensure that prescription drugs and biological products are labeled properly to encourage appropriate use. Traditionally, this has meant that FDA approves, on a word-by-word basis, labeling (i.e., package inserts) for prescription medications. This requires extensive resources for review and negotiation, and consequently would be associated with slower implementation. In contrast, deferral of the responsibility for reviewing content to private sector sources means that there is no assurance that patients would not receive inaccurate, incomplete, overly promotional or misleading information.

The alternatives also differ with regard to how patient information would be distributed. The last five approaches presented focus solely on the distribution of materials; they do not address content at all.

A. Continuation of the Status Quo

Should FDA decide to take no specific action, it would continue to require patient labeling only for carefully selected drugs. Production and distribution of patient information materials would depend primarily on the private sector.

This system has the advantage of allowing the self-correcting activities of an open marketplace to produce a wide variety of materials. Economic burdens are placed on manufacturers, health care providers, and dispensers only to the extent to which they wish to participate voluntarily or are compelled to do so because of other laws or regulations.

The disadvantage of this approach is that it has been in effect for over a decade and has not adequately improved the flow of information to patients. FDA has conducted and analyzed three surveys in the last decade to evaluate the degree to which the private sector has disseminated information to patients. Despite a variety of private sector programs and an increasing recognition that patients need and have a right to information about their medicines, a sizeable proportion of patients still receive no substantial written information. Further, initial evaluations indicate that written information currently disseminated varies widely in quality.

B. No Prior FDA Review

Under this option, the content of patient information would not be subject to prior review and approval by FDA. However, FDA would establish general requirements for this information. Under one form of this option, individuals preparing such information would be required to submit copies to FDA for review at the time of initial dissemination. Upon review, if FDA objected to any of the information, it would request that the information be revised to meet FDA requirements.

FDA would also require either that manufacturers supply dispensers with this information or that dispensers obtain or create such information and supply it to patients at the time of prescription dispensing.

This alternative has the advantage of an extremely rapid implementation period. Compliance with such a requirement would ensure that virtually all products would be covered within a very short period of time. If the system was imposed upon dispensers, the dispenser could easily choose a single system that would impose as small a regulatory burden as possible. Further, as multiple labeling systems would be developed, the dispenser would have the option of utilizing several systems simultaneously (selecting a different sheet for each product from among the differing systems) or selecting from among several systems to choose the best system to meet the needs of patients.

The major disadvantage of this approach was discussed above. Specifically, FDA's experience with the review of promotional materials issued by manufacturers (which utilizes a similar post-distributional review system), as well as its review of current patient information systems, suggests that considerable rewriting would be necessary to ensure consistency with professional labeling, nonpromotional tone, and lay language. This would also mean that patients might receive inadequate or misleading information until revisions could be effected. There would be considerable inefficiencies in the application of FDA resources because the same information would need to be reviewed for each of the systems submitted.

Despite these disadvantages, FDA has decided to propose a form of this general approach as the primary component of the selected option. It is discussed in more detail in section VIII. of this document.

C. FDA-Approved Patient Information

This approach defines both content and distributional requirements for Medication Guides, which would be FDA-approved patient information for most prescription drug products. Product sponsors would be required to prepare Medication Guides and to submit them to FDA for review and approval.

Prior FDA review of content has the advantage of ensuring that the information is consistent with information provided to health professionals, is nonpromotional, and is

written in lay language. A uniform format would allow patients to find needed information easily and increase their ability and willingness to use the information. Prior FDA review, however, has the disadvantage of taking a long time to implement because of limited resources. FDA has estimated that this approach would not be fully implemented for 10 years. In addition, mandated content does not allow for flexibility in the marketplace. For example, changes to content could not easily be made to account for changes in the state of knowledge about a product or the way in which it is customarily used.

Distribution of Medication Guides would also be required. Dispensers would be required to provide a Medication Guide to each patient receiving an applicable prescription drug. Manufacturers would be required to provide the dispenser with "the means" to ensure distribution. Distribution would be required with new prescriptions and on patient request when receiving a refill. Also considered, but rejected because of the associated major increase in distribution costs, was the option of requiring distribution with all (new and refill) prescriptions.

The advantage of this distribution system is that it would ensure that all patients receive written information about their medications. The disadvantage of this system is that drug dispensers, i.e., pharmacists, would need to store printed Medication Guides or generate computerized versions in the pharmacy. Even assuming that computer-generated Medication Guides quickly became the norm, it would take time to solve the logistical problem of integrating information from many different manufacturers into a system usable at the pharmacy level.

D. Distribution-Focused Approaches

These options do not address the content of patient information. They only describe different systems for distributing patient information.

1. Unit-of-Use Packaging

This approach would require that patient information be distributed in "unit-of-use" packaging. In this form of packaging, products are prepackaged in standardized amounts that can be dispensed directly to patients without the need for pharmacists to count out the specific number of tablets, capsules, etc., prescribed. The prescription label simply is applied to the unit-of-use package before dispensing to the patient. This type of packaging is currently used for certain prescription drug products dispensed in the United States (e.g., oral contraceptives, creams and lotions) and for most prescription drug products dispensed in Western Europe and in other parts of the world.

The advantage of unit-of-use packaging is that minimal time is needed for the dispenser to retrieve, verify, and dispense patient information. Except for packaging failures, prepackaging ensures that the patient will receive medication information with each product dispensed.

The disadvantage of unit-of-use packaging is that it requires more space for shipping and storing than other forms of packaging. Although the technology for unit-of-use packaging exists, it would be very costly for manufacturers to add unit-of-use packaging to already existing product lines. Wholesalers and retailers would need to increase space to store these products.

2. Reference Book At Dispensing Site

This distribution system would require that there be a looseleaf book located near where medications are dispensed. The book would contain a compilation of patient information leaflets, kept up-to-date by an individual at the site. Patients would be able to find the page(s) within the book that described their medication(s) and read the information during the time they were waiting for their prescription(s) or at any other time the book was not being used.

The advantage of this system is that it would reduce the burden on the dispenser of having to distribute a leaflet to each patient. Because the information would be read at the pharmacy, there would be a health professional present to answer any questions patients might have after reading the material.

There are several disadvantages of such a system. It does not provide patients with information that can be taken home for reading and rereading when patients were ready to take their medication. The system would not be viable for patients who do not pick up their own medication. Mail-order pharmacies would need to utilize alternative information systems. The system also requires patients to "affirmatively seek," as opposed to "passively receive," labeling information. Although this additional search process appears to be minimal, some patients would need help finding the particular pages where their medication was listed, space would need to be set aside in the pharmacy for such a book, and unless patients were guaranteed privacy, there could be considerable barriers to obtaining information for those concerned about this issue.

3. Interactive Computer Technology

Using available technology, computer systems could be placed in pharmacies or physicians' offices to allow patients to view patient information and print copies if desired. These "information kiosks" could also contain additional information, for example, suggestions for lifestyle changes or general information about how to use medications wisely.

The advantage of such a system is that only minimal direct input from the health professional would be needed. It would be available to anyone wishing to use it, and it could supply patients with additional information. The interactive technology allows the information to be focused on a particular patient's needs. The distribution system's location would also ensure that health professionals would be nearby to answer questions.

The disadvantage of this system is that not all patients would receive information about their prescribed medications. Only those patients with the time, skills, and assertiveness to seek out the information actively would benefit. This could be a particular problem for elderly patients who obtain a disproportionately high number of prescriptions, because they may be intimidated by computer technology.

4. Distributing a Book to Consumers

Under this distribution system, each household in the country would be provided a book of drug information. The book would be printed each year and mailed to each household or delivered to prescription dispensing sites where they could be obtained by a member of each household that requests a copy. The advantage of such a system is that it permits a once-a-year distribution of drug information, as opposed to the distribution on a continuous basis for each new prescription dispensed. It also provides patients with a convenient storage system for compiling patient information sheets.

The disadvantage of such a system is that it is extremely inefficient and costly. The book itself would be quite voluminous (the most conservative estimate is over 1,000 pages) and therefore costly to produce, distribute, and store. If provided without charge, one would expect consumers to be quite liberal in requesting copies, resulting in numerous copies within individual households; this would be both wasteful

and costly. If the book was to be sold, it would provide a financial barrier for people who could not afford to pay its price. It would need to be updated yearly at least, quarterly at best, to provide up-to-date information about new and already approved medications.

5. Telephone Counseling

This distribution option would require that manufacturers, pharmacists, or the Federal Government establish telephone numbers to be staffed by health professionals to answer questions about medications and to send out patient information upon request. Patients could listen to recordings on a number of topics, speak with pharmacists about their prescribed medications, and/or request that written information be mailed or faxed.

The advantage of such a system is that patients could obtain highly specific feedback and interact more fully with a health professional. If a single telephone number was established, patients could call it for "one-stop health information shopping." The system could be self-supporting if patients were charged for the service (e.g., via a 900 telephone exchange). Technicians and health professionals would not have to spend time dispensing individual patient information leaflets.

The disadvantages of such a system are that only those patients who call the number would receive the necessary information. Research has shown that it is difficult for patients to ask questions without having sufficient background about the medication (as would be provided by information provided with dispensed medications). Unless the patient requests a copy of an information leaflet, this alternative does not ensure that patients will receive complete and balanced information (e.g., information about product risks). Charging for the information would be a barrier for those who could not afford the telephone call.

VIII. Proposed Options and Implementation

FDA is proposing regulations that would require manufacturers to provide pharmacists and other authorized dispensers with the means to distribute FDA-approved Medication Guides for their products to help ensure that patients receive adequate information about their prescription drugs. However, FDA is proposing two alternative approaches to how FDA could defer immediate implementation of a comprehensive Medication Guide program for most outpatient drug and biological products. These alternatives are explained in detail in this section.

Regardless of the alternative chosen, FDA is also proposing regulations that would require FDA-approved Medication Guides for products that pose a serious and significant public health concern requiring immediate distribution of FDA-approved patient information. For these products, the regulations would become effective 30 days following publication of the final rule. FDA anticipates that about 10 products or product classes would require such patient labeling each year.

On some occasions, FDA has found it necessary to require that patient labeling be prepared by the manufacturer for distribution with the product because the agency believed that it was in the best interest of the public health for patients to be informed about the product's risks and benefits. In these instances, the agency believes that the risks associated with using the product should be carefully assessed in light of the product's potential benefits for the individual patient. How the information is specifically presented to the patient is particularly important to assure that the patient understands the risks and consequences, including the significance of proper adherence to directions.

FDA intends to use the following criteria to determine what products or classes should be considered for FDA-approved Medication Guides as products that pose a serious and significant public health concern that requires immediate distribution of FDA-approved patient information. FDA seeks comments on the appropriateness of these criteria for selecting products for which FDA-approved patient labeling could be required.

(a) Products for which patient labeling could help prevent serious adverse effects. In these cases, the patient labeling would inform patients about other products or foods which could interact with the labeled product, certain activities (e.g., exposure to the sun, driving) which would increase patient risk, or specific early warning signals indicative of serious adverse effects (e.g., leg pains that could signal a blood clot).

(b) Products that have significant risks about which the patient should be made aware.

(c) Products that pose risks in particular patient populations (e.g., pregnant women, geriatric patients, pediatric patients).

(d) Products for which patient adherence is crucial to either the safety or efficacy of therapy with the product, and for which patient labeling would help increase adherence.

In considering these criteria, FDA may also take into account how many patients use the product. FDA also intends to obtain public input, either through advisory committee deliberations or other public forums, concerning the specific products or classes the agency feels should have FDA-approved Medication Guides. FDA would notify affected manufacturers by letter if and when one of their products is identified as posing a serious and significant public health concern that requires immediate distribution of FDA-approved patient information, and would give the manufacturer sufficient time to produce a draft Medication Guide for agency review.

Application for approval of a Medication Guide would be made via one of two processes, depending on whether the product is already being marketed or is in clinical development, pending approval. FDA believes that in some cases a product already would be on the market when a determination is made that the product poses a serious and significant public health concern requiring immediate distribution of FDA-approved patient information. It is often the case that once a product is used widely in the general population, additional side effects, drug interactions or other effects may be discovered that were not identified during clinical trials of the product. For these products, the manufacturer would submit a labeling supplement to the product's New Drug Application (NDA). In some cases a serious or significant public health concern may arise during drug development, prior to approval. Under these circumstances, the agency may determine that the benefits outweigh the risks, and will approve the product, only if patients are made aware of the potential risks. For these products, the manufacturer would submit a draft Medication Guide as part of the product's NDA.

The agency does not believe that the requirement of a sponsor to prepare a Medication Guide for distribution with the product would pose an undue burden on the sponsor or slow down the approval process. Since patient labeling would be based on the professional labeling, both types of labeling can be developed simultaneously. The Information for Patients section of the professional labeling is already being used by many sponsors to include the kind of information that would be appropriate for inclusion in Medication Guides. However, the agency seeks comments concerning how development of patient labeling could affect approval time or place an undue burden on sponsors.

A. Alternative Approaches

Under Alternative A, implementation of FDA's proposed regulations for a comprehensive Medication Guide program would be deferred if predetermined standards for the distribution of useful patient information are met through voluntary programs within specified timeframes. The agency would periodically evaluate attainment of the performance standards. Proposed performance standards, timeframes and the evaluation process are discussed in detail in this section.

Under Alternative B, FDA would only finalize the Medication Guide program for products that pose a serious and significant public health concern requiring immediate distribution of FDA-approved patient information. The comprehensive program, as it relates to other outpatient products, would not be finalized at this time. Instead, the agency would incorporate the performance standards into a guidance document. The agency would also evaluate, as under Alternative A, whether these performance standards are met in the specified timeframes. If they are not met, FDA would seek public comment on whether the comprehensive Medication Guide program, as proposed in this document, should be finalized and implemented, or whether, and what, other steps should be taken to meet the patient information goals.

B. Performance Standards

The remainder of this section discusses proposed performance standards for assessing the effectiveness of voluntary programs in achieving patient education goals, how performance will be judged against these standards, and how the results of such evaluations will be publicly communicated. It is FDA's intention to work with the private sector to develop reasonable standards that will protect and promote consumer understanding of the directions, uses, and risks of medications, and also to provide periodic feedback so that progress can be monitored and corrective action taken.

As used in this section, the following terms are defined as follows:

"Goal"—the broad objective to be sought. For example, Healthy People 2000 specifies the broad goal that 75 percent of patients should receive useful information.

"Standard or performance standard"—the basic requirement that will be used to judge the degree to which progress has been made toward achieving the specified goals.

"Components"—if there are multiple parts or dimensions upon which performance standards must be judged, the components are an enumeration of each of the parts of a standard. FDA has proposed seven components to the useful information performance standard.

"Criteria"—for each of the components of a performance standard, the basis upon which judgments will be made to determine if the component has been successfully achieved. In this section, FDA lists the seven proposed components of usefulness and describes the criteria that will be used to judge whether each component has been met.

1. Overall Goal

The Public Health Services's (PHS) Healthy People 2000 enumerates a variety of goals which are intended to focus public and private resources on specific and achievable outcomes. Recently, PHS proposed the addition of a new objective, 12.7: "Increase to at least 75 percent the proportion of people who receive useful information verbally and in writing for new prescriptions from prescribers or dispensers."

This objective recognizes the need for both oral and written information to be given to patients along with new prescriptions. The distribution rate of 75 percent is clearly delineated. However, the goal does not specify what standards should be applied to determine whether dispensed information is "useful."

FDA believes that useful information must be informative and usable by patients to be deemed acceptable for meeting this goal. In section VIII.B.3. of this document, FDA further delineates proposed performance standards that may be used to judge the usefulness of written patient information.

2. Distribution

As the performance standard for distribution of patient information for the year 2000, FDA is proposing to use the Healthy People 2000 goal that at least 75 percent of people receiving new prescriptions are given useful written patient information. In addition, for the year 2006, FDA proposes that the distribution standard be increased such that 95 percent of people who receive new prescriptions also receive useful written patient information.

Generally, FDA envisions that the fulfillment of these standards would entail the distribution of printed information. However, with advancing technology, the development of disease management systems, and the distribution of medication through new distribution channels (e.g., mail-order pharmacies), new technologies may be developed that fulfill the purposes of this standard without requiring paper-based materials. To permit applicability of these standards to a changing patient information landscape, FDA is proposing the following as a definition of receipt of patient information: With new prescriptions, patients must receive permanent, fully portable, and easily accessible media that describe the prescription drug product.

The person who receives the information would be either the patient for whom the product was prescribed or the patient's designee. The information would have to be given to the patient at the dispensing site without the patient's having to actively search for or select the information. The information could be physically handed to the patient or placed in a bag with the prescription in order to meet the distribution standard. However, information that requires patients to select from a display or requires a phone call or return of a postcard would not meet the standard. Permanency of the media means that the information can be repeatedly referenced and can be stored by the patient for future use. Fully portable media means that persons obtaining prescriptions can physically carry the information with them. Easily accessible media means that the information is in a form that can be expected to be readily accessed by patients. Information in the form of a leaflet or brochure would meet the distribution standard, as would an auditory device that plays the message each time a button is pressed. Audiotapes, computer disks, videotapes or other media could potentially meet the standard if the distributor can be assured that the patient has all the devices necessary in his or her residence to use the media distributed.

3. Useful Information

In specifying a performance standard for useful patient information, FDA believes that there are several components that must be taken into account. Each of these components must be satisfactory for FDA to determine that patient information is useful. The seven specific components proposed by FDA include scientific accuracy, consistency with a standard format, nonpromotional tone and content, specificity, comprehensiveness, understandable language, and legibility.

In the section below, FDA further defines each of these components. FDA invites comments on the appropriateness of these standards, components, and criteria proposed to judge overall usefulness of patient information.

FDA further wishes to acknowledge that the specifics of risk information disclosure specified in the performance standards described below may appear to be more detailed than are the specifics of benefits disclosure. FDA believes that it is important to communicate benefits information, as long as it is accurate and is not done in an excessively promotional fashion. FDA believes that the reader will infer many of the benefits of a prescription drug product from the disclosure of how the product is used (its indication). For example, if a product is described as being used to lower high blood pressure, the inference is that use of this medication will benefit the patient by lowering his or her blood pressure, along with reducing whatever additional heart-related risks are associated with uncontrolled elevated blood pressure. FDA also recognizes that benefits inferences that need to be made concerning treatment of certain conditions are more complex and may need to be more specifically defined for the patient. Further, some conditions are more severely debilitating than others. In some cases, it may be appropriate to include relatively more extensive information about the benefits, and to be more reassuring about the risks, of a product, especially when the benefit to risk ratio clearly favors use of the medication.

a. *Scientific accuracy.* (1) Accuracy would be judged by review of the materials for consistency with FDA-approved labeling. Approved uses may be summarized in lay terms (e.g., "treats certain heart problems") as opposed to enumerating specific medical indications. However, limitations should also be noted (e.g., "treats heart disorders" would not be acceptable). The content of certain patient information may be written to apply to classes of drugs containing products with different indications. In these instances, uses that do not apply to the entire class should be qualified (e.g., "some," or "certain" products treat * * *).

(2) Qualifications or limitations regarding the use of the product should be described. For example, if a product is approved for use in conjunction with a dietary or behavioral regimen, the patient information should include reference to such a regimen.

(3) Additional uses that have not been approved by FDA should only be referenced by a general statement (e.g., "may be used for other purposes as prescribed by your doctor"). Personalized information for individual patients relevant to such a use may be added by a health care provider as a matter of professional practice.

b. *Consistency with suggested format.* The order and headings used should follow those specified for Medication Guides in the final rule (see proposed § 208.22(e)).

c. *Nonpromotional tone and content.* (1) The language used should be educational in nature and avoid "puffery" or other promotional terminology. There should be a "fair balance" in the description of benefits and risks. The benefits should be described in terms of the uses and effects of the individual medication. Discussion of therapeutic options is acceptable. However, differences among therapies should not be described in terms of express or implied unbalanced comparisons of the advantages of the medication (excepting information supplied for informed consent purposes). For example, phrases such as "unlike other drugs * * * this drug * * *" may be perceived as promotional.

Advertising and labeling information directed to patients or consumers, distributed by or on behalf of pharmaceutical manufacturers, must meet the provisions of FDA regulations, including submission for FDA review.

(2) The information should not be misleading in terms of the description of individual drug effects or the overall impression conveyed. Misleading information would include the use of formatting techniques that emphasize benefits and de-emphasize risks.

d. *Specificity.* (1) The information provided should enable a patient to use the product correctly. Proper use includes not only directions for taking the medication, but also information about avoiding negative consequences. Information should also be included regarding proper monitoring of the impact of therapy by correctly interpreting physical reactions to the drug. This would include, for example, informing patients when to call their physician if they do not notice signs of improvement. Risk information should include sufficient detail for an average patient to understand the significance of the hazard described. For example, if a drug causes birth defects when taken in the second or third trimester of pregnancy, users should be expressly informed that the drug may cause birth defects if used after the third month of pregnancy. General references, such as "tell the doctor if you are pregnant," would be insufficient.

(2) Warnings denoting serious or life-threatening effects, even if rare, should be expressly described. This information should not be combined with other information in a fashion that reduces communication of its significance. Additional contextual information should be provided to help patients understand these important risks. This contextual information may include statements of the likelihood of occurrence, the reason why such effects may occur, how to prevent these effects, how to monitor for early warning signs, and/or what to do if such effects occur.

e. *Comprehensiveness.* (1) Information important for the patient to know should be covered in each of the sections of the suggested format. However, it need not be detailed or exhaustive. This would include information necessary for patients to use the drug correctly, to understand important limitations or precautions, and to know the risks that may be assumed by taking the drug.

(2) Long lists of common and infrequent side effects need not be included. The side effects mentioned should include rare, but serious effects as well as common ones. The side effects may be summarized in lay language (e.g., "blood problems") and need not be exhaustive. However, the presentation should not diminish communication of the potential hazard. Further, if long lists are included, they should not diminish the significance of major warnings or side effects.

f. *Understandable language.* (1) The information provided should be clearly written for the average person. FDA will not specify a reading level due to concerns about the validity of readability tests as applied to patient drug information. However, the principles of clear writing, as described in a variety of manuals (Refs. 85, 86, 87 and 88) should be followed. Technical terminology should be used only if the terminology is explained and use of the terminology would help the patient understand the material.

(2) Deletion or degradation of important risk, benefit, or directions for use information cannot be justified by the need for language simplification. Additional information, provided through both print and other media, can be used to help communicate to populations with literacy problems.

In general, the information should be likely to be understood by the ordinary individual under customary conditions. While it is clear that many patients will not be able to read English, FDA would not consider this ability as a factor in determining information adequacy. FDA would consider efforts by distributors to communicate with patients of low literacy as consistent with a determination of overall adequacy. Thus, distribution of otherwise

acceptable written materials that utilize simplified language, pictograms, or other communication techniques would be encouraged. Similarly, programs in foreign languages, braille, or other forms of written communication that meet the literacy and information processing needs and ability of selected patient populations would be encouraged.

g. *Legibility.* (1) The information presentation should permit an interested reader to discern the important information. Type size, white space, characters per inch, contrasting colors, and other graphic elements should provide sufficient legibility to enable a typical medication user to read the information. (Note that the typical medication user is often an elderly person with less than perfect vision.)

(2) The layout and graphic presentation should invite readership; interested patients should want to read the material. The graphic presentation should communicate that the material is usable, readable, and comprehensible. The layout should not convey the impression that the material is simply the "small print" presented for legal reasons and unnecessary to read. Nor should it convey the impression that the reader would be unable to understand the material because it is too "dense."

C. Evaluation

Since the revocation of the PPI regulation in 1982, FDA's evaluation of the extent of distribution of patient information has relied upon national telephone surveys of people who obtained new prescriptions for themselves or a family member at retail pharmacies. This form of research has the advantage of obtaining reports of recent experiences from a representative sample of subjects. The obtained data describe experiences related to obtaining prescription medicines at the pharmacy, licensed practitioner's office, and other self-selected sites. FDA intends to continue using this form of data collection to monitor progress toward meeting the information distribution standard. FDA will also collect and evaluate patient information to determine whether it meets the usefulness standard. FDA will evaluate attainment of these performance standards regardless of whether they are codified in the rule (as under Alternative A) or described in a guidance document (as under Alternative B).

1. Measurement of Distribution Rates

FDA anticipates conducting three iterations of these national surveys in the approximately 11 years following publication of the final rule. The first iteration will be conducted along with a concomitant "pharmacy shopping" survey, to validate distribution elements obtained by the national telephone survey. The second iteration will be conducted in approximately the year 2000. The distribution rates obtained from this iteration will be used to help determine whether the standard of useful information distribution that would result in continued deferral of further FDA action toward implementing (Alternative A) or finalizing and implementing (Alternative B) a comprehensive mandatory program has been met. Similarly, the third survey iteration will be conducted approximately 6 years later. Together with the results of FDA's evaluation of patient information usefulness, the distribution rates obtained from this final iteration will determine whether the standard of useful information distribution has been attained.

FDA encourages interested groups to sponsor similar distribution rate evaluations in the intervening years to achieve a more complete picture of the effectiveness of information distribution of the voluntary programs. FDA will make its methodology and survey questionnaire available to the public and will provide technical assistance to any party interested in using this procedure.

One major limitation of the survey is that patient reports obtained over the telephone cannot detail the type of information disseminated. Further, these reports rely on patient memory, which may be subject to distortions. Therefore, FDA will conduct a one-time-only pharmacy "shopping" survey to validate the telephone interviewing data related to the distribution of written information with dispensed new prescriptions. This will be a multiple city survey. Observers will pose as patients and fill prescriptions for a commonly used drug. The observers will collect written information disseminated to patrons. They will also record oral interactions with pharmacy personnel and the existence of collateral information available to patients.

Although FDA would also prefer to validate the reported data concerning oral and written information obtained at the licensed practitioner's office, there are numerous cost, methodological, and logistical barriers to a data collection of such size and complexity. FDA invites comments about the advisability of, and recommendations for how to accomplish, validating these data.

Data from the shopping survey will be analyzed in conjunction with a concomitant telephone survey to validate self-reported rates and to help understand the degree to which any reporting biases may influence the telephone survey results. The shopping survey will also obtain information about the use of various commercial information systems at pharmacies across the country. These data, along with obtainable industry-trend data, will be used to project national totals of the degree to which information is being disseminated to patients.

FDA will also collect sample patient information pieces from commercial suppliers. The initial data collection will occur immediately following publication of the final rule, with additional collections occurring at 2-year intervals. Sample information sheets will be obtained for commonly used medications. Rarely used medications (not in the top 500 most commonly prescribed) and medications for which patient information may be problematic (e.g., cancer chemotherapy, major psychotropic medications) will not be included in these samples.

FDA will estimate the extent to which each system is used nationally. FDA will also estimate the percentage of prescriptions delivered through other distribution channels (e.g., mail-order pharmacies, dispensing physicians) and the extent to which different patient information systems are used in these distribution channels.

2. Determination of Information Usefulness

FDA will determine the degree to which obtained samples of patient information meet the performance standard of useful information. The samples will be evaluated on each component, using the criteria described above. Each sample will be scored on each criterion, using "acceptable" and "not acceptable" cutoff points. As mentioned, FDA believes that for a particular information sheet to be judged as acceptable overall, it must receive an acceptable rating on each of the individual components. However, the agency solicits comments regarding this rule of operation.

In addition, FDA solicits comments regarding how many and what type of drug products should be included in the patient information review, and how each component of usefulness should be scored. FDA also intends to hold a Part 15 Hearing or other public forum where interested parties could provide recommendations and rationale for usefulness components, associated criteria, and ratings systems for patient information.

D. Feedback and Application of Standards

1. Reporting the Evaluation Results

Approximately every 2 years, FDA will issue a report on the overall acceptability of written information, including ratings on each of the components of usefulness. Newly updated distribution rates will also be reported in relevant years (i.e., with the first, third, and sixth information evaluations). In these years, the report will also provide oral counseling rates.

FDA intends to estimate the percentage of patients receiving useful information by multiplying the percentage of patients stating that they received written information in the national survey by the percentage of patient information sheets judged as useful (weighted by estimated distribution rates for the sheets and the overall usefulness rating for the sheets).

FDA plans to issue a report discussing the results of each survey. The report will be in sufficient detail to permit an analysis of the basis of the computed percentages. It will also describe the analysis of each information sheet's performance on each of the usefulness components.

2. Report Implications

If Alternative A is selected, FDA will continue to defer the implementation date for the full Medication Guide program (except for the section that requires Medication Guides for specific drugs which FDA has determined have serious and significant public health concerns requiring immediate distribution of FDA-approved patient information) if the third evaluation report indicates that 75 percent of patients receive useful information. FDA will continue to conduct these surveys every 2 years. If the sixth evaluation report indicates that 95 percent of patients receive useful information, FDA will propose revocation of the sections of the rule that provide for implementation of a comprehensive Medication Guide program.

If Alternative B is selected and the third evaluation report indicates that 75 percent of patients receive useful information, FDA would continue to leave unfinalized the proposal for a comprehensive Medication Guide program. If this goal is not met, FDA would seek public comment on whether the comprehensive Medication Guide program, as proposed in this document, should be finalized and implemented, or whether, and what, other steps should be taken to help ensure that the goal is met. A similar judgment will be made based on whether the sixth evaluation report indicates that 95 percent of patients receive useful information.

In extrapolating from sample statistics to population parameters, all measurement involves a certain degree of imprecision. An estimate of expected sampling error for a simple random sample of 1,000 would be approximately plus or minus 3 percentage points of the sample statistic. FDA is proposing to use a relatively inclusive plus or minus 5 percentage points as the acceptable error (confidence interval at $\alpha = .95$) for the standards for information distribution. Using this interval means that the year 2000 standard would be met if it was determined that between 70 percent and 80 percent of patients received useful information. The year 2006 standard would be met if it was determined that between 90 percent and 100 percent of patients received useful information. FDA requests comments concerning whether this is the most appropriate confidence interval to use.

Given the time necessary to implement an adequate patient information program, by either a mandatory program or a continuation of voluntary programs, FDA anticipates that the great majority of patients should receive useful patient information by approximately 10 years after the effective date of a final rule based on this proposal.

E. Medication Guide Program

The regulations set forth in this proposal describe a program that requires manufacturers to prepare FDA-approved patient labeling (Medication Guides) for their prescription drug products. The regulations specify the format and content for such information. They further specify that manufacturers must provide drug distributors and authorized dispensers with sufficient copies of these Medication Guides, or the means to produce sufficient copies, such that each patient receives a Medication Guide with dispensed new prescriptions and upon request with a refill.

Under Alternative A, in the event that the distribution and/or "useful" performance standards previously described are not met, the final regulation based on this proposal (mandatory program) would be fully implemented. An announcement of the institution of such a program would be issued concurrently with the third or the sixth evaluation report notice published in the Federal Register (no sooner than 5 years or, if the rule continues to be deferred after the third evaluation report, 11 years after the effective date of the final rule).

To implement this requirement, New Drug Application (NDA) applicants and holders would be required to submit draft Medication Guides for all submissions for new molecular entities (NME's) and for new indications for approved products. In addition, concurrent with an announcement that the regulations will be fully implemented, FDA would publish an implementation schedule. This schedule would require that application holders submit draft Medication Guides for specified NDA's. FDA envisions that such a schedule would be based upon the most frequently used products at the time. In order to avoid problems with uneven competitive requirements, FDA would also consider the simultaneous review of products within the same pharmacological or therapeutic category.

Once an innovator drug Medication Guide was approved, manufacturers of generic versions of the drug would also be required to prepare and distribute Medication Guides modeled after the innovator's approved Medication Guide.

Given the large number of drugs on the market, FDA envisions that it would take approximately 10 years to complete approval for the vast majority of Medication Guides. However, by implementing the Medication Guide requirement as a function of the most popularly used products first, a larger percentage of dispensed prescriptions would be covered.

Under Alternative B, if the distribution and/or "useful" performance standards are not met, FDA would seek comment on whether the proposal requiring a comprehensive Medication Guide program, as described in this document, should be finalized and implemented, or whether, and what, other steps should be taken by FDA to ensure that the patient information goals are met. Subsequent to this comment period, either the Medication Guide regulations proposed in this document would be finalized and implemented, or FDA would repropose a different approach to helping to ensure attainment of the specified goals.

IX. Conclusion

The long history of PPI's demonstrates that disagreements between the public and private sectors in determining the best approach for providing patient information have not served patients well. Since the issue was first discussed in the 1970's, virtually all interested parties have agreed that there is a critical need to better inform patients

about their medications. Most of those who opposed PPI's accepted the premise that patients needed to be better informed. However, opponents argued that the private sector could do a better job of educating patients if left unencumbered by Federal regulations. FDA came to the same conclusion and withdrew requirements for the program. In the ensuing decade, however, evaluations demonstrate that although many private sector programs have been initiated, their impact on patient education has been disappointingly low.

In the last 2 years, however, the increasing computerization of pharmacies together with OBRA '90 requirements have apparently contributed to an increase in the provision of oral and written patient information. However, FDA's review of popular commercial systems in use indicates that the quality of information provided is uneven. In the interests of encouraging a continuation of this distribution trend, and improving the value of the information to patients, FDA has concluded that both standard-setting activities and the addition of a strong incentive are appropriate and necessary.

Prior to developing this proposed rule, FDA met individually with representatives of the pharmacy, pharmaceutical industry, patient information producer, medical, and consumer communities. All of the represented constituencies at these meetings indicated that they wanted health professionals to provide patients with useful written prescription drug information.

As mentioned above, in addition to soliciting written comments, FDA intends to hold a Part 15 Hearing to solicit a broad range of views about how best to measure usefulness of individual patient information pieces. It should be clear to all parties, however, that FDA's concern is not with the distribution of pieces of paper, but with the education and empowerment of patients. Therefore, FDA intends to expand this dialogue to solicit new ideas and feedback about other aspects of this proposal, such as how medication adherence can be more effectively facilitated, and new ideas about how to communicate information to patients. FDA believes that presentations based upon research with patients and consumers will be especially important; thus, FDA will actively solicit such information. Developing systems that make maximal use of technology and can be flexibly adapted to all patients, thus providing useful and specific information, is the goal of FDA's broader commitment to improving patient information. This goal will take an active partnership to meet; it cannot be achieved by FDA alone.

Private sector efforts also will be needed to improve the basic mechanism through which patient education about prescription medicines occurs, i.e., oral counseling. In addition, programs are needed to stimulate discussions about medications by health care professionals when the medications are initially prescribed. Organizations that can help determine the best mechanism for health professionals to introduce and discuss patient medication information with patients would be vital to the success of the program.

Additional programs also will be needed to provide educational aids to patients with literacy problems to help them utilize medication information most effectively. These programs must be diverse and targeted to address the particular deficiencies causing the literacy problem.

Data from the recent survey "Adult Literacy in the United States" (Ref. 72) indicate that most of the individuals who perform at the lowest level of proficiency (from 66 to 75 percent) described themselves as able to read or write English "well" or "very well." They did not view themselves as deficient in any substantive fashion. It would be inappropriate for health care professionals to withhold information from patients merely on the premise that they may have some difficulty understanding the information. Even with basic skills, interested patients would be able to profit to some extent from the documents. With additional help, the vast majority of patients would be able to profit from improved information.

Of major importance to the success of improved patient information would be private suppliers or organizations that can help pharmacies, physicians' offices, and managed care organizations store, access, produce, and/or distribute medication information. Groups that can provide customized services to meet the individual needs of the vast array of authorized dispensers would be of great service to help this community meet the desired objectives. Such groups could expand the provision of other information, such as disease information or general information about using medicines safely, which would augment the educational benefit for patients.

FDA welcomes comments about these topics and remains dedicated to forging a medicine information delivery system that encourages, and does not retard, the development of innovative communication systems.

X. Description of the Proposed Rule

The proposed rule, if finalized, would require a Medication Guide for certain human prescription drug products, including biological products. The rule would require manufacturers to prepare and distribute, or provide the means for distributing, a Medication Guide that would accompany prescription drug products that patients receive and use on an outpatient basis without the direct supervision of a health care professional. Medication Guides would be distributed with all new prescriptions and with refills when requested by the patient.

Under Alternative A, the provisions in the proposed rule would be deferred for a majority of the prescription drug and biological products that otherwise would be affected in order to give voluntary efforts an opportunity to achieve specific goals of distribution of useful drug information within specified timeframes. The agency will measure the success of the voluntary efforts by establishing performance standards that measure both the distribution of patient medication information and information usefulness. The agency will conduct periodic evaluations to measure whether the performance standards are met and will issue reports of the findings. If the performance standards are not met by the end of each of two specified timeframes, the provisions of the rule would be implemented.

For products that pose a serious and significant public health concern requiring immediate distribution of patient information the provisions would be implemented 30 days following publication of the final rule.

Under Alternative B, FDA would also give voluntary efforts an opportunity to achieve the goals of distribution of useful information within specified timeframes. The difference, however, is that under this option the agency does not intend to finalize immediately the proposed performance standards, or the sections that defer implementation, in the form of a regulation. Instead, the agency intends to use the proposed performance standards as guidance for the private sector. If the performance standards are not met at the specified times, then the agency will seek public comment on whether a comprehensive Medication Guide program, as described in this proposal, should be finalized and implemented or whether, and what, other steps should be taken to meet the patient information goals.

For Alternative B, FDA, however, does intend to finalize the requirement for products that pose a serious and

significant public health concern requiring immediate distribution of FDA-approved patient information. This provision would be implemented 30 days following publication of the final rule.

To be of value, product information must be understandable to patients. The use of overly technical language may deter patients from reading important information. Therefore, the proposed rule would require that the Medication Guide be written in nontechnical language, be nonpromotional in tone or content, be based on the professional labeling for the drug product, and be presented in a uniform format.

The Medication Guide would contain a summary of the most important information about a drug product, including the approved uses for the product, circumstances under which the drug product should not be used, serious adverse reactions, proper use of the product, cautions related to proper use, and other general information.

Parties would be permitted to request an exemption for a particular drug product from any of the specific requirements of the proposed rule. The proposed rule would also permit the agency to exempt or defer certain drug products from the requirement of a Medication Guide.

The proposed rule would require manufacturers to provide directly, or supply the means to provide, sufficient numbers of the Medication Guide to the distributor or dispenser of a prescription drug product. The dispenser, in turn, would be required to provide the Medication Guide to the patient. FDA is proposing to exempt qualifying small retail pharmacy outlets from the requirement to dispense a Medication Guide, except for products packaged in unit-of-use containers and for products which the agency determines must be dispensed with a Medication Guide.

Specific provisions of the proposed rule are as follows:

A. Scope and Implementation

Proposed § 208.1(a) would limit the Medication Guide requirements to human prescription drug products, including biological drug products, administered primarily on an outpatient basis without the direct supervision of a health professional. FDA is proposing this limitation because, as discussed earlier in this preamble, the agency believes that patients generally seek and are ready to receive and understand information about their drug products after they have received them. The Medication Guide would serve as an at-home reference for patients when they are ready to self-administer products. The proposed rule requires that a Medication Guide be dispensed with new prescriptions, and with refills if requested by the patient. The proposed rule would not apply to prescription drug products administered in licensed practitioners' offices or institutional settings, such as hospitals, nursing homes, or other long-term care facilities, because FDA believes that the continuous presence of health professionals in these settings gives patients the opportunity to ask questions about their prescription drug products. The proposed rule also would not apply in emergency situations because FDA believes distribution of the Medication Guide in such situations would be impractical. FDA has also provided an exemption for small retail pharmacy outlets. Other dispensers which meet the small business criteria set forth in the regulations would also qualify for such an exemption.

Proposed § 208.1(b) defers the implementation of the Medication Guide provisions for all affected drug and biologic products, except for the § 208.1(d) products, until a determination is made by FDA that certain performance standards have not been met.

Proposed § 208.1(b)(1) would provide for the Medication Guide provisions for all but the § 208.1(d) products to be deferred if 75 percent of the patients receiving new prescription drugs or biologics covered under these provisions receive useful patient information 5 years from the effective date of the final rule. If this standard is met, FDA would continue to monitor the voluntary efforts for distributing patient information. As proposed in § 208.1(b)(2), if, after an additional 6 years, 95 percent of the patients receiving new prescription drugs or biologics covered under these provisions receive useful patient information, the Medication Guide provisions would continue to be deferred, except for the § 208.1(d) products.

As described in greater detail previously, the agency will evaluate both the distribution and usefulness of the information with regard to specific criteria. Proposed § 208.1(c) includes the seven proposed components of the usefulness standard. An extensive discussion of the specific criteria the agency proposes to use in evaluating achievement of the usefulness standard is found in section VIII. of this document. FDA is considering whether the details of these criteria should be restated in the codified language, and invites comment on this issue.

Under Alternative A, if both of the requirements in proposed § 208.1(b) are met, the provisions of this part would be deferred for all products except those that the agency determines pose a serious and significant public health concern requiring immediate distribution of patient information. In addition, under Alternative A, if both of the requirements in proposed § 208.1(b) are met, the agency intends, at that time, to initiate notice and comment rulemaking to revoke § 208.1(b)(1) and (b)(2).

As discussed previously, under Alternative B, the agency does not intend to finalize § 208.1(b) and (c) immediately. Rather, if the performance standards set forth in proposed § 208.1(b) and (c) are not met, the agency will again seek public comment on whether a comprehensive mandatory Medication Guide program, as described in this document, should be implemented or whether, and what, other steps should be taken to meet the goals.

Under both alternatives, proposed § 208.1(d) would allow FDA to require that FDA-approved Medication Guides be distributed with certain prescription drug products. See Section VIII. of this document for a discussion of the criteria that would be used to determine the types of products that may fall under § 208.1(d).

B. Definitions

Proposed § 208.3(a) would define "authorized dispenser" as an individual who may legally dispense prescription drug products. FDA believes that, in most instances, the authorized dispenser will be a pharmacist.

Proposed § 208.3(b) would define the phrase "dispense to patients" as the act of delivering a prescription drug product to a patient or an agent of the patient. Because the proposed rule would apply only to drug products dispensed on an outpatient basis without the direct supervision of health care professionals, proposed § 208.3(b) limits the scope of "dispensing." For instance, the definition of the phrase "dispense to patients" does not include the delivery of a nonprescription drug product.

Proposed § 208.3(c) would define "distribute" as "the act of delivering (other than by dispensing) a drug product to any person."

Proposed § 208.3(d) would define "distributor" as a person who distributes a drug product. FDA notes that its interpretation of a distributor has traditionally included repackers, and would do so here.

Proposed § 208.3(e) would define "licensed practitioner" as an "individual licensed, registered, or otherwise permitted by the jurisdiction in which the individual practices to prescribe drug products in the course of professional practice."

Proposed § 208.3(f) would define "manufacturer" as described in §§ 201.1 and 600.3(t) of this chapter.

Proposed § 208.3(g) would define "patient" as any individual with respect to whom a drug product is intended to be, or has been, used.

C. Content of a Medication Guide

Proposed § 208.20 would describe the content of a Medication Guide. As stated earlier, FDA believes that the information in a Medication Guide must be written in language that is easily understood by patients. To ensure that information in a Medication Guide provides a comprehensible and objective description of the drug product, proposed § 208.20(a)(1) would require that information be written in English, presented in lay language, and would prohibit the use of promotional language.

While FDA acknowledges that there is a significant minority of U.S. citizens who speak Spanish as their primary language, it hesitates to impose the additional burdens on manufacturers and dispensers that would result from requiring the availability of Medication Guides written in Spanish for these individuals. FDA also recognizes the many other population segments who do not speak English as their primary language. FDA requests comments concerning how it can most fairly and effectively communicate patient medication information to these populations.

Under proposed § 208.20(a)(2), the Medication Guide must be based on, and must not conflict with, the approved professional labeling for the drug product. The Medication Guide should, in general, provide a lay "translation" of those portions of the professional labeling that are important for effective consumer understanding and use of the product. This "translation" may include sufficient background information or context to facilitate consumer understanding. Proposed § 208.20(b) lists specific types of information that must be included in a Medication Guide. Under proposed § 208.20(b)(1), the Medication Guide would be required to identify the drug product brand name (e.g., trademark name or proprietary name), if any, and established name. If the product does not have an established name, the proposed rule would require that the drug product be designated by its active ingredients. In addition, the Medication Guide would include the phonetic spelling of the brand name or the established name, whichever name appears throughout the Medication Guide.

Because many people take a number of drug products, FDA believes that it is important that patients be easily able to match a drug product with the correct Medication Guide. Information could include the color, shape, markings, and, if applicable, the drug product's code imprint. There are a number of possible ways to provide this information including: (1) A separate identification section, (2) including the information in the personalized section (this optional section of the Medication Guide is explained later in the preamble to this proposal), or (3) providing preprinted stickers that would be placed on the appropriate Medication Guide by the dispenser. An example of one way to provide product identification information is displayed in the sample Medication Guides in Appendix C.

Proposed § 208.20(b)(2) would require a brief section concerning the most important aspects of taking the drug product. This would include the product's approved indications, especially important instructions for proper use of the drug, and any significant warnings, precautions, contraindications, serious adverse reactions, and potential safety hazards.

Proposed § 208.20(b)(3) would require the Medication Guide to contain a statement identifying the product's indications, that is, the uses identified in the indications and usage section of the approved professional labeling. The Medication Guide may summarize indications or omit rarely prescribed indications.

Proposed § 208.20(b)(4) would require the Medication Guide to identify the conditions under which the drug product is not to be used for its labeled indications, i.e., contraindications to the product's use. In nontechnical language, the labeling would describe the contraindications specified in the professional labeling for the drug product, reminding the patient, for example, to provide the licensed practitioner with relevant medical history or information about other drugs the patient is taking that may pose a significant contraindication. Contraindications to use may include a previous allergic reaction to the product, pregnancy, the patient's use of certain other medications, or a particular condition that might make the drug product less effective or dangerous.

Proposed § 208.20(b)(4) would also require inclusion of the steps the patient should take to remedy the situation should any of the listed circumstances apply. This may include consulting with his or her licensed practitioner before taking the drug, discontinuing use of the product, etc.

Proposed § 208.20(b)(5) would require the Medication Guide to describe precautions related to the proper use of the drug product. Under proposed § 208.20(b)(5)(i), these precautions would include activities the patient should avoid while taking the drug product, such as driving or sunbathing, and list other drugs, foods, or substances, including alcohol or tobacco products, the patient should avoid because they may interact with the drug product. The information would help patients use the drug product in a way that would promote its safety and effectiveness.

Under proposed § 208.20(b)(5)(ii), the Medication Guide must also contain a statement regarding the product's use in pregnant women. The statement must discuss any risks to the pregnant woman or the fetus. Proposed § 208.20(b)(5)(iii) through (b)(5)(vi) would also require the Medication Guide to contain, if appropriate, precautionary information about risks to a nursing infant, and any information on use and risks for pediatric, geriatric, or other identifiable patient populations.

Proposed § 208.20(b)(6)(i) would require the Medication Guide to list and describe adverse reactions associated with the use of the drug product that are serious or occur frequently. This information would be presented in a manner that would help patients understand and remember it. Material presented under this provision would restate, in nontechnical language, the information regarding the most significant warnings and adverse reactions specified in the professional labeling. In addition, where appropriate, the Medication Guide should inform the patient what to do if they occur.

Organizing and explaining adverse reaction information for different drug products may vary. For example, adverse reactions might be organized by the organ systems in which they occur, by their severity, by the frequency with which they occur, by a combination of these approaches, or by any other appropriate method that would provide patients with the information. In contrast to the professional labeling, which often contains an exhaustive list of associated adverse reactions, regardless of their frequency, the Medication Guide should only list those adverse reactions that are meaningful to

the patient, in terms of seriousness, and/or frequency.

Proposed § 208.20(b)(6)(ii) would require the Medication Guide to discuss the risks, if any, to the patient of developing a tolerance to or a dependence upon the drug product.

Proposed § 208.20(b)(7) would require information concerning the proper use of the drug product. Studies indicate that many patients do not take prescription drugs properly (Refs. 3 and 4). Consequently, proposed § 208.20(b)(7)(i) would require a statement stressing the importance of adhering to the dosing instructions. Under proposed § 208.20(b)(7)(ii), the Medication Guide would also contain any special instructions on how to administer the drug; for example, proper dosing intervals, whether the drug should be taken with food, or at a period of time before or after eating. For products such as inhalers, injectables, skin patches, and so on, that have special instructions for administration, these instructions should be referenced in the Medication Guide.

Proposed § 208.20(b)(7)(iii) would require a statement of what a patient should do in case of an overdose, i.e., contact the local poison control center or hospital emergency room. Since FDA notes that a significant number of patients fail to adhere to the dosing regimen, proposed § 208.20(b)(7)(iv) would require a statement of what a patient should do if the patient misses taking a scheduled dose.

Proposed § 208.20(b)(8) would also require the Medication Guide to contain general information about the safe and effective use of prescription drug products.

Patients may become concerned if their Medication Guide does not include the purpose for which their health professional prescribed the product. Therefore, proposed § 208.20(b)(8)(i) would require inclusion of the verbatim statement that "Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide." This statement would be juxtaposed with a statement encouraging the patient to discuss any questions or concerns about the drug product with a health professional.

Although health professionals understand that approved products may be prescribed for other than FDA-approved indications, patients typically do not possess this knowledge. Therefore, it is appropriate to advise them of this fact, and that they should bring any concerns they may have to the attention of a health professional. FDA believes that these disclosures provide the necessary context to ensure that patients will comprehend effectively medication information. The agency stresses, however, that such "contextual" disclosure is inappropriate for professional labeling, which is directed at health professionals who are already aware of their freedom to prescribe medicines as they see fit, as part of the practice of their profession.

FDA also notes that this statement is an acknowledgment about the use of medicines in general, not about any particular product. The agency will not sanction the use of this or similar statements concerning unapproved uses in promotional labeling and advertising for specific products.

Proposed § 208.20(b)(8)(i) would also require a statement noting that professional labeling for drug products may be available from the patient's authorized dispenser or licensed practitioner. Many individuals, including some pharmacists and licensed practitioners, erroneously believe that State or Federal law prohibits providing a drug product's professional package insert to patients. Moreover, the professional labeling for a drug product provides the most detailed and comprehensive information about prescription drug products and should be available to any patient upon request. Although the professional labeling for a drug product may be too technical for many patients to understand, patients should be encouraged to learn more about their medications and may seek to examine professional labeling. Authorized dispensers and licensed practitioners are able to answer questions about the professional labeling and thereby reduce the amount of confusion produced by its technical language.

Proposed § 208.20(b)(8)(ii) would require a statement informing the patient that the drug product has been prescribed for the sole purpose of treating the patient's condition and must not be used for other conditions or given to other persons. This statement is intended to caution against the dangers of self-diagnosis and lay diagnoses in general. A licensed practitioner prescribes a particular drug to treat a certain condition in a certain individual. Use of the drug by lay persons to treat another condition in the same individual may be, at best, ineffective and, at worst, directly hazardous to a patient's health or indirectly hazardous by delaying proper diagnosis and treatment. Use of the drug by another individual, without a professional evaluation of the individual's medical condition and history, could be life-threatening.

Section 208.20(b)(8)(iii) would require the manufacturer's, packer's, or distributor's name and address; or the name and address of the dispenser of the drug product; or for biological products, the name, address, and license number of the manufacturer. This information could assist the manufacturer or distributor and FDA in tracing and, if necessary, recalling the drug product. Furthermore, providing names and addresses would enable patients to contact a manufacturer or distributor if they have any questions about the drug product.

Section 208.20(b)(8)(iv) would require the date of the most recent revision to the Medication Guide. This will enable patients and authorized dispensers with multiple versions of a Medication Guide to determine which Medication Guide contains the most current information.

The contents of a Medication Guide may vary based on the product's dosage form, bioavailability, or extent of systemic exposure, as stated in the product's labeling. For example, some topical prescription drug products that are not systemically absorbed may not require a statement regarding the activities, drugs, foods, or other substances that a patient should avoid when taking the drug product, or information on risks from use of the drug product during pregnancy, labor, delivery, or nursing. FDA encourages manufacturers, distributors, and others who have questions on the preparation or content of their Medication Guide to contact FDA.

The Medication Guide shall be dispensed as approved by FDA without the inclusion of any additional information. However, authorized dispensers may, and are encouraged to, personalize the Medication Guide document by including, for example, the prescription number, the name, address, and/or telephone number of the authorized dispenser and/or licensed practitioner, and information personally identifying the patient and relevant demographic or medical information (that does not violate the patient's privacy). This information may precede or follow the required information in the Medication Guide, but in no instance should the information be more prominent or obscure any required information. Authorized dispensers and licensed practitioners are also permitted and encouraged to supply special instructions regarding the product's use directly before or following information in the Medication Guide.

D. Format for a Medication Guide

FDA believes that the Medication Guide should have a uniform format so

patients can become familiar with the type and location of specific information. The proposed rule would require the Medication Guide to contain identical section headings, a consistent order of information, the use of highlighting techniques, and a minimum type size.

A "shell" of the proposed uniform format is displayed in Appendix A of this document. FDA chose different drugs to illustrate the uniform format, and these examples may be found in Appendix B of this document. Examples of the Medication Guide using alternative formats are displayed in Appendix C of this document. FDA invites comment on these alternative formats. These Medication Guide models were prepared solely by FDA for illustrative purposes and do not represent approved labeling by the agency.

The proposed rule would allow the Medication Guide to reach consumers through a variety of methods, ranging from traditional preprinted inserts to state-of-the-art, computer-generated material. The agency recognizes that the level of information technology varies widely across the country. For instance, while most pharmacies are now equipped with computers, both the ability to access outside materials and the print quality of computer-generated documents can vary greatly. Thus, the proposed Medication Guide regulations are designed to accommodate these varying levels of technology and not hinder technological advances or improvements in the transmission of patient information.

Proposed § 208.22(a), would establish a minimum 10-point type size for the Medication Guide (1 point = 0.0138 inches). This requirement applies to all sections of the Medication Guide except the name and address of the manufacturer and the revision date. FDA believes that this type size is necessary to facilitate easy reading by elderly patients. However, as legibility is determined by additional graphic factors, proposed § 208.22(b) would require that the print be legible and clearly presented.

Additionally, FDA is proposing to amend the professional labeling regulation at 21 CFR 201.57, which requires the professional labeling to reprint, in its entirety, any patient labeling for a drug product. The proposed amendment would clarify that the 10-point minimum type size does not apply to any patient labeling or Medication Guide that is reprinted in the professional labeling.

FDA recognizes that the communication of important information requires graphic emphasis to highlight certain portions of the text. The graphic emphasis selected should be appropriate to the particular method of printing the Medication Guide. Thus, while multiple colors may be used for emphasis in preprinting the Medication Guide, the use of dot-matrix computers would require boldfacing, underlining, or some other highlighting method.

As stated earlier in the preamble, the agency acknowledges that there are many forms of commercially available, consumer-oriented medication information. To enable patients to recognize that the Medication Guide is the "official" patient labeling for a particular drug product, proposed § 208.22(c) would require every Medication Guide to contain the words "Medication Guide" prominently at the top of the first page of each Medication Guide. It would also require, at the bottom of the Medication Guide, the verbatim statement that "This Medication Guide has been approved by the U.S. Food and Drug Administration." Section 208.22(d) would require the brand and established name to be prominently displayed. The established name shall not be less than one-half the height of the brand name.

In order to organize the information in the Medication Guide, proposed § 208.22(e) would require that the content requirements listed in § 208.20 be placed under specified headings. These headings would also be placed in a specified order so that the patient can easily find the information. The proposed headings are in question form and would include:

(1) "What is the most important information I should know about (name of drug)?;"

(2) "What is (name of drug)?;"

(3) "Who should not take (name of drug)?;"

(4) "How should I take (name of drug)?;"

(5) "What should I avoid while taking (name of drug)?;"

(6) "What are the possible side effects of (name of drug)?"

The Medication Guides for certain drugs may require additional headings, e.g., "How should I store (name of drug)?" (See Ceclor for oral suspension draft Medication Guide in Appendix B of this document.)

The agency invites comments on alternative headings. Examples of alternative headings appear in the Medication Guide models published in Appendix C of this document.

In developing these model Medication Guide formats, FDA has reviewed the formats used in a variety of patient information leaflet systems and in patient information books. The agency has tentatively concluded that the preferred format is the one that provides consumers with questions about their medication and answers to these questions and that organizes the information in a way similar to the professional labeling. This will help manufacturers to prepare the Medication Guide and place information in a consistent section of the Medication Guide. Patients will obtain information that is consistent with professional labeling. FDA intends to evaluate this (and other possible) formats during the comment period for this proposal.

FDA recognizes that there are important differences between labeling directed toward professionals and the Medication Guide directed toward patients. The format for the Medication Guide should help emphasize the most important information the patient needs to know to use the drug product properly and to communicate with his or her health care professional. Major sections of the professional labeling, such as the Clinical Pharmacology section, that are useful to health care professionals, are not likely to be as useful to patients (although conclusions from that section, such as effects of food on absorption, may be important). Similarly, other information, such as complete lists of reported adverse reactions, may overwhelm the patient or obscure the most important information. Thus, to facilitate the communication of information to patients in a meaningful fashion, the Medication Guide will be expected to summarize and distill the contents of the professional labeling into terms that are more understandable and useful to the layperson. On the other hand, it is not expected that the Medication Guide will omit serious or potentially adverse consequences of using the medicine that are important for patients to know.

FDA will also permit the addition of "contextual" information, not included in the professional labeling, to help patients understand the labeling information despite their lack of background and training in medicine.

FDA is aware that excessive length may discourage use of Medication Guides and interfere with the communication of important messages. FDA will therefore attempt to limit the amount of information included in the Medication Guide, focusing on and emphasizing the most important information for the patient (e.g., by changes in typeface, use of white space or contrast, underlining). The Medication Guide samples reprinted in the appendices to this document

provide examples of how FDA believes a Medication Guide should be formatted, composed, and otherwise structured for the patient. In addition to inviting general comments on these formats, FDA invites comments on whether the Medication Guide should be printed on paper of a specific size and whether a page limit (e.g., two pages) is appropriate.

E. Distributing and Dispensing of a Medication Guide

The proposed rule is intended to ensure that consumers receive patient labeling information, but permits manufacturers, distributors, and dispensers to provide information in addition to that required under the proposed rule. The agency has designed the distribution and dispensing requirements to be flexible and to accommodate the increased use of computers and other technological advances in pharmacies.

Proposed § 208.24(a) would establish distribution requirements for drug products in finished dosage form that are packaged in large volume containers. Under the proposal, a manufacturer that ships a large volume container of a finished dosage form to a distributor or an authorized dispenser would be required to provide the Medication Guide in sufficient numbers, or the means to produce the Medication Guide in sufficient numbers to enable the authorized dispenser to provide a Medication Guide to each patient receiving the drug product.

The reference to the "means to produce the Medication Guide in sufficient numbers" signifies that a manufacturer is not limited to providing hard copies of the Medication Guide to its distributors and authorized dispensers. Instead, the manufacturer can satisfy its distribution requirements by giving distributors and authorized dispensers the "means" to produce the Medication Guide in sufficient numbers. For example, the manufacturer could provide computer software that enables the distributor or authorized dispenser to print the Medication Guide. However, FDA cautions that if a manufacturer elects to give distributors and authorized dispensers the "means" to produce the Medication Guide, it must give the individual distributor or authorized dispenser an effective means, including resources and materials, to produce the Medication Guide. In other words, FDA would not consider a manufacturer to have complied with its regulatory obligations if it gave incompatible software to a distributor or authorized dispenser or provided items that would require the distributor or authorized dispenser to purchase other machines, goods, or services in order to produce a Medication Guide.

For each drug product requiring a Medication Guide, proposed § 208.24(a)(2) would require manufacturers to place a label on each large volume container of finished dosage form instructing authorized dispensers to distribute the Medication Guide. This is necessary because FDA intends to phase in Medication Guide requirements, and authorized dispensers will need to know which drug products have required patient labeling and which ones do not yet have such requirements.

The proposed rule would establish similar requirements for distributors who provide drug products to authorized dispensers.

FDA recognizes the complexity of the drug distribution system and encourages the development of innovative methods to meet the requirements of this section. The agency intends to consult with interested parties so that distribution problems may be identified and solutions developed.

For drugs in unit-of-use containers, proposed § 208.24(c) would require the manufacturer and distributor to provide the Medication Guide with each package that is intended to be dispensed to patients. The agency notes that this requirement, if finalized, would be consistent with EC requirements on patient leaflets in unit-of-use packaging.

The proposed rule, at § 208.24(d), would also enable manufacturers and distributors to have other persons meet their distribution and dispensing requirements. For example, manufacturers could enter into a contract with a third party to provide the Medication Guide to distributors and dispensers. Such third party information systems already exist in other contexts; for example, the agency is aware that a third party vendor routinely collects and publishes drug identification information which poison control centers and other health organizations use to identify drug products.

Proposed § 208.24(e) would require, in the absence of an exemption under proposed § 208.26, that an authorized dispenser provide a Medication Guide to the patient (or the patient's agent) at the time a prescription drug product is dispensed under a new prescription, and when requested by the patient for refill prescriptions.

Section 510 of the act (21 U.S.C. 360) requires all persons engaged in the manufacture, preparation, propagation, compounding, or processing of a drug to register with FDA and provide the agency with a list of drug products in commercial distribution. Under section 510(g)(1) of the act, however, pharmacies which conform to local laws, which are regularly engaged in dispensing prescription drugs upon prescriptions of licensed practitioners, and which do not manufacture, prepare, propagate, compound, or process drugs for sale other than in the regular course of dispensing drugs at retail, are exempt from the registration and listing requirements. The preparation and/or distribution of Medication Guides by a pharmacy does not diminish this exemption. Accordingly, under proposed § 208.24(f), authorized dispensers are not subject to section 510 of the act solely because of an act performed by the authorized dispenser to comply with this regulation.

F. Exemptions and Deferrals

The regulatory requirements presented in proposed § 208.20 are intended to be exhaustive as to the content of Medication Guides. Nevertheless, FDA realizes that some requirements in proposed § 208.20 may be inapplicable, unnecessary, or contrary to a patient's best interests for a particular drug product. Accordingly, proposed § 208.26(a) would advise manufacturers to contact FDA if they believe that certain requirements are inapplicable, unnecessary, or contrary to the patient's best interest.

Proposed § 208.26(a) would also allow FDA to determine that certain information should be omitted from the Medication Guide for a particular drug product. This determination would occur at the time a Medication Guide was submitted as part of a marketing application. The agency may also, on its own initiative or in consultation with a manufacturer, determine that any or all of the Medication Guide requirements should be deferred or exempted for a specific drug product.

The agency expects that the Medication Guide will facilitate communication between the health professional and patient, thereby enhancing the proper use of prescription drug products and helping to reduce the incidence of noncompliance and adverse reactions. FDA emphasizes, however, that the Medication Guide is not intended to displace or substitute for professional judgment. A practitioner may feel that, in certain cases, a patient may be adversely affected by the contents of a Medication Guide.

Consequently, under proposed § 208.26(b), the authorized dispenser of a prescription drug product would not

be required to provide a Medication Guide to a patient if the licensed practitioner who prescribes the drug product directs that the Medication Guide be withheld. The agency believes that prescribers should not direct dispensers to routinely withhold a Medication Guide from patients but should do so only when it is in the best interests of the specific patient involved.

In addition, FDA believes that authorized dispensers, as a result of their personal contact with a specific patient or a patient's family, often have information relevant to a decision to withhold a Medication Guide for a specific product. For example, an elderly patient functioning at a relatively low level of awareness of his cancer may have been prescribed a product that provides only palliative care, or a schizophrenic patient may have been prescribed a clearly anti-psychotic drug. Under such circumstances, the patient, and the course of therapy, may be adversely affected by the contents of a Medication Guide. Under these circumstances, where there are significant concerns about potential adverse effects of a Medication Guide, FDA would permit authorized dispensers to use their professional judgment in determining whether a particular patient would be best served by withholding the Medication Guide for a particular product. However, such an action should be based on the professional judgment of the authorized dispenser in each specific situation, and Medication Guides should not routinely be withheld for specific drug classes or specific patient characteristics. The agency invites comments on how best to implement this exemption.

FDA notes that under proposed § 208.26(b), the authorized dispenser must provide the Medication Guide to any patient who requests one. In addition, FDA has determined that for particular products patient information should be provided to all patients. Section 208.26(b) therefore provides that this exemption does not apply if FDA determines that a Medication Guide for a particular product should be provided to all patients under all circumstances.

Proposed § 208.26(c) would permit manufacturers, distributors, or authorized dispensers to provide drug products without a Medication Guide in emergency situations and in cases where the manufacturer, distributor, or authorized dispenser has made a good faith effort to obtain a Medication Guide for the drug product, but does not have a Medication Guide available for the patient. The manufacturer, distributor, or authorized dispenser would be required to document its good faith effort to obtain a Medication Guide. This provision is intended to address those situations where the Medication Guide is unavailable and would not prohibit authorized dispensers from providing a prescription drug product to a patient. For example, if an authorized dispenser is utilizing computer-generated Medication Guides and the computer system breaks down, or if an authorized dispenser had exhausted its supply of the Medication Guide for a particular drug product and was unable to secure an additional supply of the Medication Guide, proposed § 208.26(c) would permit the authorized dispenser to provide the drug product to the patient without a Medication Guide.

Proposed § 208.26(d) would exempt certain authorized dispensers from the requirement, in § 208.24(e), to provide a Medication Guide directly to each patient when dispensing a prescription drug product. This proposed exemption would apply to retail pharmacy outlets or other dispensers which: (1) Dispense, on average during the previous calendar year, no more than 300 outpatient prescription drugs per week; (2) have gross annual sales of no more than $5.0 million or are part of a business entity (i.e., sole proprietorship, partnership, or corporation) that has gross annual sales of no more than $5.0 million; and (3) make available to patients a compilation of current Medication Guides for reading in the drug product dispensing area.

FDA is proposing this exemption because it has determined, based on the agency's regulatory impact analysis in section XII. of this document, that the proposed regulation would have a significant economic impact on the operations of many smaller retail pharmacy outlets. Many larger pharmacies—members of chain drug stores and pharmacies in large food/drug combination stores—have computerized systems that can be used in dispensing Medication Guides to patients. Smaller pharmacies, however, will generally need to purchase computer equipment or they will incur costs for lost time and storage space by using preprinted Medication Guides.

This proposed exemption would not apply to drugs dispensed in unit-of-use containers. In this situation, the impact of the proposed regulation on smaller pharmacies would be less because the drug product is individually prepared for the patient by the manufacturer, and already includes the Medication Guide.

In addition, the proposed exemption would not apply when the agency determines, for safety or other reasons, that a particular drug product must be dispensed with a Medication Guide. For example, FDA currently requires that patient labeling must be dispensed with Accutane to ensure its safe use, i.e., to warn patients about its association with birth defects.

Exempted pharmacies must maintain a current compilation of Medication Guides available for consumers to consult in an accessible area, such as near the counter or the patient counseling area.

This proposed exemption is intended to lessen the economic impact of complying with the proposed Medication Guide dispensing requirements for smaller pharmacies and other dispensers. FDA invites general comments on this exemption and specific comments on the proposed threshold level (300 prescriptions per week) and whether this proposed exemption should be permanent or merely extend the time necessary for smaller pharmacies to comply with the exemption, for example by providing a 10-year extension for small businesses to comply with the requirements.

G. Miscellaneous Amendments

The proposed rule would also amend the provisions pertaining to NDA's, product license applications (PLA's) and abbreviated new drug applications (ANDA's) and abbreviated antibiotic drug applications (AADA's) to require applicants to include a Medication Guide as part of their labeling. The agency intends to review the Medication Guide along with the proposed professional labeling for the drug product or review the Medication Guide as it would review any proposed labeling change for a drug product that requires prior approval. Although the Medication Guide program would be implemented gradually if the performance standards are not met, its requirements would ultimately apply to all prescription drug products that patients primarily self-administer without the direct supervision of a health care professional. Therefore, as labeling, the proposed rule would expressly require that the Medication Guide be submitted as part of an NDA, PLA, or ANDA.

For applicants with approved products, the proposed rule would amend the regulations governing supplemental applications to require applicants to obtain prior FDA approval of any change to a Medication Guide. FDA is proposing to require prior approval of such changes, including the addition of any warning or adverse reaction, or even minor editorial

changes. As stated earlier, the Medication Guide is directed to consumers who may be distracted or overwhelmed by excessive information. Consequently, the agency will attempt to ensure that the Medication Guide contains information that consumers should know and can understand.

XI. Legal Authority

The act (21 U.S.C. 321 *et seq.*) authorizes FDA to regulate the marketing of drug products so that the products are safe and effective for their intended uses and are properly labeled. In order to carry out the public health protection purposes of the act, FDA: (1) Monitors drug manufacturers and distributors to help make certain that drug products are manufactured and distributed under conditions that ensure their identity, strength, quality, and purity; (2) approves new drugs for marketing only if they have been shown to be safe and effective; and (3) monitors drug labeling and prescription drug advertising to help ensure that they provide accurate information about drug products.

A major part of FDA's efforts regarding the safe and effective use of drug products involves FDA's review, approval, and monitoring of drug labeling. Under section 502(a) of the act (21 U.S.C. 352(a)), a drug product is misbranded if its labeling is false or misleading in any particular. In addition, under section 505(d) and (e) of the act (21 U.S.C. 355(d) and (e)), FDA must refuse to approve an application and may withdraw the approval of an application if the labeling for the drug is false or misleading in any particular.

Section 201 of the act (21 U.S.C. 321), the "Definitions" section of the act, describes the concept of "misleading" in the context of labeling and advertising. Section 201(n) of the act (21 U.S.C. 321(n)) explicitly provides that in determining whether the labeling of a drug is misleading, there shall be taken into account not only representations or suggestions made in the labeling, but also the extent to which the labeling fails to reveal facts that are material in light of such representations or material with respect to the consequences which may result from use of the drug product under the conditions of use prescribed in the labeling or under customary or usual conditions of use.

These statutory provisions, combined with section 701(a) of the act (21 U.S.C. 371(a)), clearly authorize FDA to promulgate a regulation designed to ensure that patients using prescription drugs will receive information that is material with respect to the consequences which may result from the use of a drug product under its labeled conditions. This interpretation of the act and the agency's authority to require patient labeling for prescription drug products has been upheld. (See *Pharmaceutical Manufacturers Association* v. *Food and Drug Administration*, 484 F. Supp. 1179 (D. Del. 1980), *aff'd per curiam*, 634 F. 2d 106 (3rd Cir. 1980)).

For generic drug products, section 505(j)(2)(A)(v) of the act (21 U.S.C. 355(j)(2)(A)(v)) provides additional legal authority for a Medication Guide. Section 505(j)(2)(A)(v) of the act requires an ANDA to contain information to show that the proposed generic drug product's labeling is the same (with some exceptions) as that of the corresponding reference listed drug. Thus, because a Medication Guide is drug labeling, FDA proposes to require generic drug product manufacturers to develop a Medication Guide that is the same as the one for the reference listed drug, except for differences attributable to legal or regulatory requirements (such as uses protected by patent) or because the generic drug product and the reference listed drug are produced or distributed by different manufacturers. If an ANDA or AADA fails to contain such information, this failure may be grounds for refusing to approve the ANDA or AADA under section 505(j)(3)(G) of the act (21 U.S.C. 355(j)(3)(G)).

In addition, for biological products, section 351 of the Public Health Service Act (42 U.S.C. 262) authorizes the imposition of restrictions through regulations "designed to insure the continued safety, purity, and potency" (including effectiveness) of the products. Biological product licenses are to be "issued, suspended, and revoked as prescribed by regulations" (42 U.S.C. 262(d)(1); see 21 CFR 601.4 through 601.6). The requirements of this proposed regulation on Medication Guides are designed, in part, to insure the continued safe and effective use of licensed biological products. Therefore, the agency may refuse to approve PLA's, or may revoke already approved licenses, for biological products that do not comply with the requirements of the final rule on Medication Guides.

Based upon these authorities, the agency proposes to require manufacturers of prescription drug products, including biological products, to disclose information about their products in the form of patient labeling. Just as scientific standards for evaluating a drug product's safety and effectiveness and manufacturing practices have evolved since enactment of the act in 1938, standards for appropriate labeling for drug products must also change as data are compiled about the effects of labeling on patients' safe and effective use of drug products.

XII. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–345). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the principles set out in the Executive Order.

The distribution of useful patient information will result in significant consumer benefit, but may also entail costs to industry. Some of the regulatory alternatives examined by the agency entail potential regulatory costs well in excess of $100 million. Even though the selected option is estimated to have associated costs well below this amount, FDA has prepared a preliminary economic analysis in accordance with Executive Order 12866 and the Regulatory Flexibility Act.

This preliminary economic analysis evaluates the costs and benefits of implementing FDA's proposal. This proposal states that in the absence of continued voluntary efforts to provide useful information to patients who purchase prescription drug or biological products, manufacturers of these products will be required to prepare and distribute patient information labeling that will accompany any new prescriptions. The objective of the proposed rule is to improve public health by allowing patients to make more informed uses of their medications. FDA has found that patients often fail to adhere to medication regimens or to recognize signs and symptoms of both preventable and unpreventable adverse drug reactions. These failures frequently prolong recovery or even contribute to additional illnesses. Because patients who receive understandable information about their drug therapies are better able to benefit from their medications, FDA believes that implementation of the proposed regulations will significantly enhance the public health. Although many programs that offer patient prescription drug information currently exist, this proposal is expected to increase the use and quality of such information, and provide standards for

guiding and assessing the adequacy of voluntary programs.

FDA has proposed to institute a comprehensive program of FDA-approved patient information only if the private sector does not meet defined goals for the distribution and adequacy of patient information. These goals are both reasonable and attainable. It is FDA's hope that the voluntary programs will achieve the desired goals and that consequently a government-imposed program will not be required. However, this was FDA's hope in 1982 when the initial PPI regulations were withdrawn. To provide sufficient incentive to meet distribution and quality goals for written patient information, FDA is proposing two alternatives that could result in a comprehensive program requiring FDA-approved Medication Guides, but no sooner than 5 years from the effective date of the final rule.

To estimate the costs of such a regulation, we have prepared a worst-case analysis that assumes no increase in the current state of distribution and quality of dispensed patient information, assumed to be at about 50 percent. This worst-case estimate is that the program would have annual gross costs of approximately $56 million, assuming neither inflation nor discounting. Thus, FDA estimates that the cost of this regulation would range from zero (if distribution and quality standards would have been achieved despite the promulgation of this rule) to $56 million (if the current state of private sector issuance of patient information would have remained unchanged.)

The proposed labeling would take the form of patient information sheets, called Medication Guides. These sheets would accompany new prescriptions for outpatient human drug and biological products, and would also be available upon request for refill prescriptions.

If the regulation is implemented, Medication Guides would be developed by drug manufacturers. They would be approved by FDA and would contain information designed to increase patient awareness of the proper use of the accompanying products. These information sheets would be distributed to the patient at the time the prescription is dispensed at the retail pharmacy (or other dispensing outlet). While manufacturers would be responsible for ensuring that adequate information is available to the dispenser, the dispenser would ultimately provide the information to the patient at the time the prescription is filled. The agency has taken the burden of small, retail pharmacies into account, and exempted certain low-volume outlets from this proposal.

In 1980, the agency issued a similar regulatory proposal calling for PPI's, initially to cover 10 drugs and drug classes. That rule was revoked in 1982 to permit the private sector to implement information programs without Government intervention In the intervening years, FDA has conducted periodic surveys of patients who have obtained new prescriptions. FDA found in the latest survey that the proportion of patients receiving written drug information (other than the prescription label on the container) had increased from 16 percent in 1982 to 58 percent in 1994. Preliminary analyses of FDA's most recent survey indicate that 55 percent of patients obtain more substantial information than brief stickers.

Other surveys of the pharmacy sector have also shown gains in distribution of written information. A 1992 survey of retail pharmacies conducted by the University of Mississippi showed that 77 percent of all pharmacies distribute printed patient counseling information (Ref. 76). A 1994 Consumer Patient Counseling Survey conducted for the National Association of Boards of Pharmacy (Ref. 95) showed that 64 percent of all patients or caregivers stated that they received printed materials about the medication from the pharmacy.

The agency believes that the availability of patient information should continue to grow. While there is little doubt that patient information activities have increased since the 1980 PPI proposal, a sizeable proportion of the patient population remains underinformed. FDA believes that a regulatory process that encourages or augments private sector initiatives will best meet the needs of these underserved patients.

OBRA '90 currently requires that pharmacists offer counseling to patients who receive State-assisted services. Many States have extended OBRA's requirements to additional patients. Required counseling under OBRA is limited to oral, face-to-face counseling between the patient and the dispensing pharmacist. Written material may be used as an adjunct, but cannot be substituted for oral counseling. Numerous studies have shown that counseling is most effective in modifying behavior when achieved through a combination of oral and written media. Thus, FDA believes that Medication Guides, or other voluntary written information, will complement OBRA requirements and provide more effective and comprehensive patient counseling.

A. Affected Sectors

The economic effects of the proposed regulations, if implemented, will vary with the number of affected drug products, prescriptions, and retail pharmacies. The number of affected drug products will dictate the number of separate Medication Guides that will be developed, the number of prescriptions will dictate the number of Medication Guides that will be distributed, and the number of pharmacies will dictate the number of facilities that will maintain equipment to distribute Medication Guides. To determine an initial baseline for this analysis, the discussion that follows is based on the assumption that voluntary information programs will not meet the distribution and quality standards for voluntarily-supplied patient information, and that the Medication Guide program will therefore be fully implemented.

Medication Guides must be available for most prescription drug and biological products dispensed outside of institutional environments (such as hospitals and nursing homes). The agency envisions an implementation period of 10 years, so that early resources may be spent developing Medication Guides for therapies that may pose public health concerns, as well as for new products. Over time, however, this analysis assumes that all prescription products that are the subject of approved NDA's and ANDA's will be accompanied by Medication Guides. FDA examined currently marketed drug products and their historical rates of introduction to arrive at an estimated 3,350 separate drug products that will require separate Medication Guides, as shown in Table 1.

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Table 1

Numbers of Drug Products, Prescriptions, and Resultant Medication Guides

	Number
Model Products	461
Category Products	782
Generic Products	2,107
Guides Developed	3,350
	Number (in millions)
Total Prescriptions	2,186
Unit-of-Use Prescriptions	525
Pharmacy Prepared Prescriptions	1,661
Pharmacy Prepared New Prescriptions	914
Requested Refill Guides	83
Guides Dispensed	1,522

Sources: Drug Products from FDA Data
Prescriptions from NACDS; 1992

The 3,350 drug products will eventually require separate Medication Guides. To develop these, FDA estimates that companies will select "models" from already existing materials. These models would be updated by the manufacturer. Once a manufacturer has developed a model it would be submitted to FDA for approval. The approved Medication Guide will then serve as a model for other similar drugs within the same therapeutic category, saving additional developmental costs. FDA analysis indicates that 461 guides will serve as "innovator" or "model" Medication Guides. These can serve as models for 782 similar "category" products (within narrowly-defined therapeutic categories) which, in turn, can be copied on a word-for-word basis for 2,107 generic drugs.

About 2.2 billion prescriptions were dispensed from retail pharmacies during 1992, according to data included in the "Prescription Drug Marketing Simulation Model" developed by the NACDS (Ref. 75). The proposed regulation, if fully implemented, will require Medication Guides to accompany each new prescription, as well as be available upon request for refill prescriptions. For cost calculation purposes, FDA has assumed that prescriptions dispensed via unit-of-use packaging would include Medication Guides whether the prescriptions are new or refills. Since approximately 24 percent of all prescriptions, or 525 million prescriptions, are issued in unit-of-use packages, an additional 1,661 million prescriptions would need to be prepared by a pharmacist. Of these, FDA estimates that approximately 55 percent, or 914 million, would be for new prescriptions. FDA also estimates that 5 percent of the 1,661 on-site, pharmacy-prepared prescriptions, or 83 million, would be for patient requests for Medication Guides for refill prescriptions. Thus, as shown in Table 1, the agency estimates that if the proposal were fully implemented, Medication Guides would be issued for 525 million unit-of-use prescriptions, 914 million other new prescriptions, and 83 million refill prescriptions, for a total of 1,522 million Medication Guides. This would cover 70 percent of all prescriptions.

However, pharmacies consist of both commercial and noncommercial outlets. The NACDS (Ref. 75) included a distribution of pharmacy outlets by type. The agency has allocated these outlets into three categories: Independent pharmacies (up to three outlets that fill prescriptions), chain pharmacies (four or more outlets under the same management, including food outlets and mail-order companies), and noncommercial outlets (Health Maintenance Organizations (HMO's)), hospitals, ambulatory care units, and physician offices), as shown in Table 2. Average prescription volume by outlet type is derived from the NACDS survey. Independent, community pharmacies are estimated to average approximately 530 prescriptions per week, while an average chain pharmacy averages over 825 weekly prescriptions. Overall, the agency estimates that the typical pharmacy dispenses approximately 600 prescriptions per week.

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Table 2

Retail Outlets and Prescription Volume

	Number of Outlets	Annual Prescriptions (In Millions)	Percent Prescriptions	Average Weekly Prescriptions
Independent Outlets	32,499	896.4	41.0	530
Traditional Chains	20,193	791.5	36.2	754
Food/Drug Combos	4,291	153.0	7.0	686
General Merchandise	2,688	94.0	4.3	672
Deep Discounters	903	39.4	1.8	839
Mail Orders	34	131.2	6.0	74,208
Sub-Total -- Chains	28,109	1,209.1	55.3	827
SUB-TOTAL COMMERCIAL	60,608	2,105.5	96.3	668
HMO's	1,179	21.9	1.0	357
Hospitals	1,080	17.5	0.8	312
Physician Offices	5,500	28.4	1.3	99
Ambulatory Centers	3,000	13.1	0.6	84
Sub-Total -- Others	10,759	80.9	3.7	145
TOTAL OUTLETS	71,367	2,186.4	100.0	589

Source: NACDS; 1992

B. Gross Costs of Compliance

FDA estimated the regulatory costs of this proposed regulation by developing the costs for dispensing Medication Guides at a typical (600 prescriptions per week) pharmacy. These costs were divided by the number of dispensed Medication Guides to derive a cost per Medication Guide, as well as multiplied by the number of outlets to derive a total cost of compliance. While this methodology may overstate unit costs for large outlets and understate unit costs for small outlets, due to economies of scale, these effects would tend to balance in the aggregate.

Because voluntary efforts exist to provide patient information, and these efforts are expected to expand, the incremental costs of compliance are only those above the costs of providing patient information that would accrue in the absence of this proposal. The agency has initially assumed that 50 percent of all patients currently receive patient information. Thus, gross costs are reduced to account for current activities. If private sector initiatives continue to grow in the absence of this regulation, the actual incremental compliance costs will be even further reduced. In fact, if all affected pharmacies would voluntarily dispense adequate, written patient information, the incremental costs of this proposal would be zero. However, to develop a baseline for analysis, the agency has assumed that the current baseline of 50 percent compliance will remain constant throughout the study period. This strategy results in the most conservative (i.e., the highest possible) estimate of costs.

Costs to manufacturers include the cost of developing Medication Guides and submitting them for FDA review. Costs to pharmacies include the cost of printing and dispensing Medication Guides with prescriptions.

1. Manufacturers

The worst-case scenario would require manufacturers of new drugs to develop Medication Guides with no prior model or prototype, for example, for a newly approved drug in a new therapeutic class. According to Merck Pharmaceuticals, it took 6 months of calendar time to develop, test, and revise an FDA-approved PPI to accompany a recent new drug. FDA assumes that a totally new Medication Guide could be developed within this timeframe, and would require a total of 2 months of full-time effort by manufacturers. This effort would include scientific research associates, regulatory affairs officials, and legal/scientific reviewers. Assuming an annual average professional labor cost of $70,000, each model Medication Guide would cost industry between $11,000 and $12,000.

The majority of Medication Guides (those for which there are models in the same therapeutic class) would be very similar to their applicable model guides in content. FDA expects that the cost for developing these "category" Medication Guides should be less than half of the model development cost, or approximately $5,000.

Medication Guides for generic drugs should be virtually identical to the originator product's Medication Guide, except for the name, description, and patent-protected information. Therefore, FDA estimates that the cost of developing generic Medication Guides would be approximately one-tenth the cost of developing a category Medication Guide, or $500.

Total industry costs of developing Medication Guides, if voluntary efforts do not continue to grow, are found by multiplying the applicable development cost by the expected number of products shown in Table 1. By the 10th year of implementation, all products would have Medication Guides at a cost to industry of approximately $10.5 million for development. Given the proposed phase-in plan, the agency expects annual development costs to equal approximately $1.3 million by year 10. As new products continue to be marketed, FDA expects this equilibrium to be maintained.

According to data developed by FDA, approximately 24 percent of all prescriptions are dispensed in unit-of-use packaging. These prescriptions would require preprinted Medication Guides that would likely be included in the packaging provided by the manufacturer prior to shipping. Thus, 525 million preprinted Medication Guides will be required by the 10th year of implementation.

According to purchasers, the cost of preprinted patient information sheets is currently about $0.025 per page. These sheets include customized information such as company address, phone numbers, logo, and other information. A supplier of patient information sheets (USP) lists a price of $2.10 for a pad of 50 sheets ($0.042 per sheet), but the order form provides for substantial discounts for bulk orders. FDA has assumed a cost of $0.025 per preprinted patient information sheet, for a total annual printing cost of $13.1 million. The agency believes that current packaging technology would allow for insertion of Medication Guides into unit-of-use packaging with little additional cost.

Prescriptions in other than unit-of-use packaging will likely be dispensed with Medication Guides that are generated at the retail pharmacy via computer. Many of the technologies for transmitting automated information to retail pharmacies are already in place. Distributor-based electronic information networks offer nationwide computer ties designed to influence as well as facilitate pharmaceutical care. According to one industry analyst, "Nearly 95 percent of all pharmacies in the U.S. have at least some computer link to a point-of-sale system that allows them to participate in these point-of-sale networks." (Ref. 73).

Although a precise prediction of future technologies remains speculative, FDA believes that the current availability of computers in almost all pharmacies indicates that patient information would be available in an automated format.

A number of possibilities would be available for the distribution of automated data to pharmacies. Although each individual manufacturer could distribute data disks to all pharmacies purchasing their drugs, this approach would entail routine shipments of hundreds of thousands of data disks and require expensive recordkeeping systems to avoid sending duplicate disks. It is far more likely that conventional market forces would lead to more rational information systems.

Logical models for distributing computerized information data bases include the third parties that already accumulate and disseminate these data. Because the regulation will impose the initial responsibility for information distribution on manufacturers, yet the pharmacies will need to augment their computer systems, the precise outcome of these market forces is uncertain. However, there are several reasons to believe that competitive considerations would prompt manufacturers to coordinate with third party data bases for the distribution of Medication Guides.

First, several vendors, such as the USP, Medi-Span, Inc., and the ASHP, already provide computerized drug information data bases. Thus, comparable systems are already in place. Second, the responsiveness of the private sector to the demand for Government-mandated information has been vividly demonstrated by the proliferation of vendors of chemical data bases following the promulgation of the Occupational Safety and Health Administration's "Hazard Communication Standard." Finally,

pharmaceutical manufacturers would vigorously support the development of a data distribution network that reduces the costs of printing and shipping large volumes of paper. The initial mechanism could reasonably involve manufacturer price discounts, rebates, or other like incentives designed to encourage pharmacies to use commercial data bases.

For this preliminary study, the costs of disseminating computerized data are considered pharmacy costs, via the purchase of software and updates, although part of this burden may be passed back to the manufacturers or distributors through various incentive programs. Table 3 indicates that the total annual gross costs to manufacturers of preparing Medication Guides and printing those used in unit-of-use packages would be expected to reach $14.4 million, if the proposed regulation is fully implemented.

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Table 3

Gross Annual Compliance Costs for Manufacturing and Pharmacy Sectors (Millions of Dollars)

	Manufacturers Cost	Pharmacy Cost	Total Annual Cost	Percent of Annual Cost (%)
Guide Development	1.3		1.6	1
Printing Unit-of-Use	13.1		13.1	11
Computer Hardware		6.6	6.6	5
Computer Supplies		27.4	27.4	23
Computer Software		22.5	22.5	19
Storage		7.4	7.4	6
Time		42.8	42.8	35
Total	14.4	106.7	121.1	100

2. Pharmacies

FDA has estimated the costs for a typical pharmacy that dispenses 600 prescriptions per week to comply with the proposed regulation. These costs include hardware (including a computer with sufficient hard disk space and a dedicated printer), supplies, space, and time to retrieve and dispense the Medication Guide.

a. *Hardware.* An estimate of the required hard disk space to operate a drug information network was developed from current requirements of the MEDTEACH program offered by ASHP, which provides 427 drug monographs to customers in disk form (each monograph contains information similar to that envisioned in a Medication Guide). The installation program requires two disks and quarterly updates or revisions are offered to all users.

ASHP reports that the current program and data require 3.1 megabytes of hard disk space. A program accounting for 1,000 monographs would require 6 megabytes. Because the proposed regulations, if implemented, would require 3,350 specific Medication Guides, the required disk space would ultimately be almost 20 megabytes. Hard disks exceeding 400 megabytes are now common at a price of under $1.00 per megabyte, and the technology is steadily advancing. FDA foresees no difficulty in meeting the longer term requirements for computer disk space, at an average amortized annual cost of only $6.

Dedicated printers would be required to generate the large numbers of Medication Guides. Dot matrix printers can be purchased for about $300, and are assumed to have a useful life of 4 years, which results in an amortized cost per printer of $87 per year (at 6 percent interest). Laser printers are assumed to cost $1,000 and also have a 4-year useful life, yielding an amortized annual cost of $289 per printer.

FDA found that the relatively slower dot-matrix printers would be adequate for most outlets. The dispensing clerk or pharmacist would complete other filing or labeling activities while the printer was operating.

b. *Supplies.* On the assumption that each computer-generated Medication Guide would fill two pages, FDA estimates that dot-matrix printers would require ribbon replacement every 1,250 pages, or 625 Medication Guides. Dot-matrix ribbons are estimated to cost $8. In addition, office supply catalogs indicate that the cost of bulk computer paper ranges from less than $0.005 to $0.01 per page. This study uses $0.007 per page as a mid-point in this range for a cost of $0.014 per 2-page Medication Guide.

A typical pharmacy is estimated to dispense 600 prescriptions per week. Twenty-four percent of these prescriptions (144) are dispensed in unit-of-use packaging, so a total of 456 prescriptions per week may require site-generated Medication Guides. The proposed regulation requires Medication Guides to accompany new prescriptions (55 percent of the total) as well as be available upon request. Thus, 60 percent of the affected prescriptions are expected to be accompanied by Medication Guides. This represents about 275 per week, or 14,300 per year when fully implemented.

The typical pharmacy would then require 23 ribbon replacements per year (almost one ribbon every 2 weeks) for an annual cost of $184. In addition, 28,600 pages of computer paper would cost a pharmacy $200 per year. The gross annual cost of supplies for providing Medication Guides at a typical pharmacy is therefore estimated to equal $384.

c. *Software.* Several companies, including the USP and ASHP, currently sell computerized patient information disks to pharmacies. Although these packages have limited coverage, and typically contain data for only the 200 top-selling drugs, FDA believes that such organizations could rapidly compile and market comprehensive Medication Guide data bases. Based on current costs for these software and data packages, this study assumes an initial cost of $400 and quarterly updates of $50 each. When these costs are amortized over a 4-year period, the resultant annual cost to the pharmacy equals $315.

d. *Storage.* Using computers to print Medication Guides would also add costs for storage, because an additional printer and paper would require approximately 2 square feet within the prescription preparation area. For example, 1,000 sheets of paper may be stored in a stack of only 1.5 inches. Storage space would still be available below the preparation counter, so FDA assumes that potential displacement of equipment would be equal to 1 square foot of floor space.

The conventional means of obtaining the economic cost of a productive resource is to estimate the market price of that resource. An annual rental charge of $7.50 per square foot of pharmacy space was obtained from survey data contained in the 1992 Lilly Digest (Ref. 78). Alternative approaches note that, in the short run, added storage requirements could impose additional opportunity costs if the turnover of goods could not be increased elsewhere in the pharmacy, which suggests a cost of storage based on displaced sales. FDA believes that this method likely overstates regulatory costs, both from a societal perspective (because the loss in sales to any one outlet would be gained by another) and an individual outlet perspective (because the average return per square foot of space exceeds the marginal return). That is, outlets would minimize any burden by displacing lower return items. Nevertheless, FDA has derived the value of sales per square foot from the 1992 Lilly Digest of independent pharmacies, and has used an annual cost of $104 per pharmacy per square foot to account for annual storage costs to the typical pharmacy. (Annual sales per square foot of pharmacy equal $360, and pharmacies have an average 29 percent gross sales margin. Thus, $360 × .29 = $104).

e. *Time.* Computerized pharmacies would incur relatively low burdens of time, because Medication Guides would be printed as other labeling and dispensing activities were occurring. However, pharmacists would remain responsible for ensuring that the correct Medication Guide accompanies each prescription. FDA has assumed that a minimum of 5 seconds of pharmacist time would be needed to verify each selection. Since the annual number of Medication Guides per typical pharmacy would equal 14,300, a pharmacist would be expected to spend almost 20 hours per year verifying Medication Guides.

The 1992 Lilly Digest reported average hourly wage rates of $30 for pharmacist/proprietors. Using this as a basis, the total annual cost of time would equal $600 for the typical pharmacy.

Although it is possible that this patient information would cause returns of drugs and additional questions of pharmacists, FDA is unaware of any study that confirms this hypothesis. The agency's 1980 economic analysis cited a contracted survey that indicated that no additional pharmacist time was required to address these concerns (Ref. 62). FDA invites additional public comment and data on more recent experience.

f. *Total compliance costs to pharmacies.* The sum of the annual costs of printers, supplies, software, storage, and time equal almost $1,500 for the typical pharmacy when, and if, the proposed regulations are fully implemented. This equals almost $0.105 per pharmacy-printed Medication Guide. Table 3 contains the total gross annual costs for the pharmacy sector.

Total annual gross costs to the retail pharmacy sector will equal $106.7

million if this regulation is fully implemented. This amount is found by multiplying the cost per pharmacy by the 71,367 universe of outlets shown in Table 2.

3. Total Annual Gross Costs of Developing and Dispensing Medication Guides

The estimated annual gross costs of developing and issuing Medication Guides include the annual costs to manufacturers of developing Medication Guides, in general, and printing unit-of-use Medication Guides ($14.4 million), and the total annual cost to retail pharmacies of printing and dispensing Medication Guides ($106.7 million). Thus, the total gross annual compliance cost of this proposal is estimated to equal $121.1 million. The estimated average cost to distribute one Medication Guide, whether via unit-of-use packaging or printed at a retail pharmacy, equals $0.08. This reflects the higher cost of printing Medication Guides on-site as well as the lower cost of including Medication Guides with unit-of-use packaging.

This estimate does not take into account the existence of current voluntary patient information programs. It also assumes static technologies and prescription demand.

C. Incremental Compliance Costs

As discussed earlier, the agency has assumed that current voluntary programs account for 50 percent of the market. Such programs include retail pharmacies that currently provide patient information, manufacturers that provide mandated patient information for certain individual drug products and product classes, mail-order pharmacies that routinely provide this information, and general unit-of-use packaging. Given the current state of patient information, the agency expects that the cost of achieving compliance with this proposal, if no further gains in patient information occur, would be only 50 percent of the total gross costs. Thus, the annual incremental cost of this proposal is estimated to be a maximum of $60.5 million (including those Medication Guides dispensed in unit-of-use packages). If private patient information programs continue to increase, on their own, the incremental cost of any regulatory plan would be even lower. In addition, this estimate does not account for the agency's proposal to allow an exemption for small-volume pharmacies. The cost implications of this exemption are discussed in the following section.

D. Small Pharmacy Exemption

The Regulatory Flexibility Act requires Federal agencies to prepare a regulatory flexibility analysis if a proposed regulation is expected to have a significant impact on a substantial number of small entities. FDA believes that compliance with the requirements for Medication Guides could have a significant impact on the operations of many small, independent pharmacies. The agency therefore proposes to exempt from most of the Medication Guide requirements any retail outlet that dispenses an average of fewer than 300 prescriptions per week, as long as total company annual sales do not exceed $5.0 million.

1. Disproportionate Costs

Although pharmacies that dispense the largest volumes of prescriptions would incur the greatest absolute costs, small pharmacies would bear a proportionally higher burden. Based on the assumptions previously discussed, for a typical outlet dispensing 600 prescriptions per week, the average gross cost to provide a Medication Guide is $0.105. The cost for a small outlet dispensing only 200 prescriptions per week would total about $0.177. This disparity reflects the ability of larger outlets to spread the fixed annual regulatory costs (printer, storage, and software) over more prescriptions.

In some circumstances, regulatory costs can be imposed without inflicting noticeable change to the affected industry sectors. However, in recent years, independent community pharmacies have faced rapidly growing competitive pressure from new sources of retail prescriptions, especially mail-order companies and HMO's. A 1992 study prepared for the NACDS (Ref. 75) projected independent pharmacy's share of prescriptions to decrease from 41 percent to 29 percent during the 1990's. IMS America (Ref. 77) reports that since 1990, the number of independent retail pharmacies decreased by 15 percent.

In general, the profitability of retail pharmacies varies in direct proportion to sales volume. For example, a survey of independent pharmacists (Ref. 78) reports that a typical independent pharmacy earned income (combined pretax net store profit and proprietor/manager salary) of $88,000 during 1991. Figure 1 shows that very small independent pharmacies (fewer than 150 prescriptions per week) earned total pretax incomes of only 26 percent of the industry average. Independent pharmacies dispensing between 150 and 300 prescriptions per week earned total income of only 51 percent of the industry average. These limited profits suggest that it would be difficult for small outlets to finance additional regulatory costs.

FDA is aware of the economic problems of the small retail pharmacy and is reluctant to impose additional economic burdens on this sector. Since scant public health benefits would be lost by excluding the smallest pharmacies from the requirement to dispense Medication Guides, the agency proposes exempting these pharmacies from the proposed regulation.

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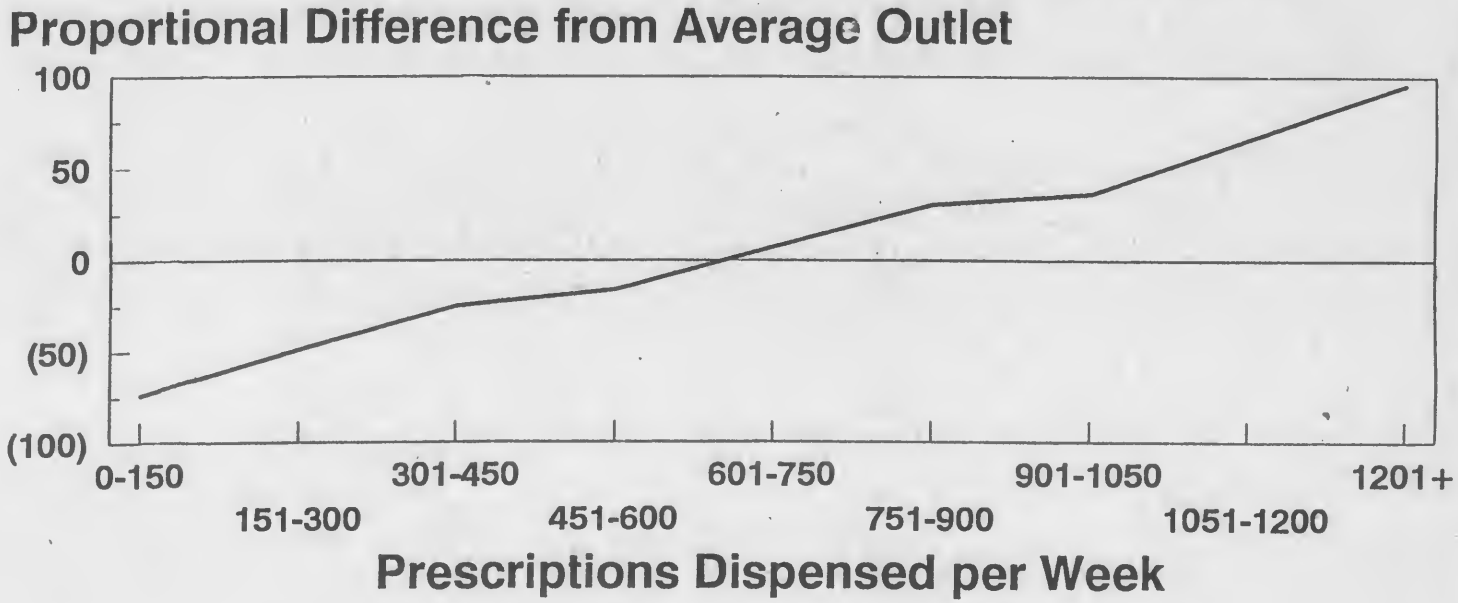
Figure 1

Total Pharmacy Income by Size for Independent Pharmacy Outlets



income equals net store profit plus salary of proprietor/manager. Source: 1992 Lilly Digest

2. Outlet Characteristics

To estimate the number of outlets that would be eligible for a small business exemption, FDA constructed a distribution of retail pharmacy outlets by prescription volume. This distribution was developed by merging data from two main sources: the 1992 Lilly Digest of Independent Pharmacies (Ref. 78) and an earlier NACDS study (Ref. 79). Although the Lilly Digest reported data for a self-selected sample of independent pharmacies, it provides the most detailed data available for that sector. The NACDS sampled all pharmacies with six or more outlets. Data are shown in Table 4.

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Table 4

Distribution of Pharmacy Outlets

By Dispensed Prescriptions per Week

	Number of Independents	Number of Chains	Sub-total–Number Commercial	Number of Others	Total Outlets
1-100	715	254	969	4,363	5,332
101-200	2,730	965	3,695	4,431	8,126
201-300	5,070	1,775	6,845	271	7,116
301-400	5,427	2,811	8,238	1,129	9,367
401-500	4,745	2,948	7,693	271	7,964
501-600	3,315	2,621	5,936	181	6,117
601-700	2,372	2,656	5,028	113	5,141
701-800	1,787	2,453	4,240	0	4,240
801-900	1,040	2,110	3,150	0	3,150
901-1000	975	1,933	2,908	0	2,908
1001-1100	975	1,630	2,605	0	2,605
1101-1200	910	1,331	2,241	0	2,241
1201+	2,438	4,622	7,060	0	7,060
Total	32,499	28,109	60,608	10,759	71,367

Independent data from 1992 Lilly Digest
Chain data (incl. other commercial) from NACDS

Because the methodology of these studies varied, FDA standardized the data by adjusting and interpolating between ranges to develop an outlet size distribution for the entire retail sector. The three defined categories of retail outlets were analyzed separately:

Independent Outlets—The 1992 Lilly Digest of independent pharmacies reports prescription volume in terms of prescriptions per day. FDA assumed that pharmacies were open an average of 12 hours a day, and calculated the dispensing days per week from reported weekly hours of operation per cohort. The establishments were then interpolated into cohorts of 100 weekly prescriptions.

Chain Outlets—A distribution of chain outlets was constructed from a May 1990 report entitled "An Assessment of Chain Pharmacies' Costs of Dispensing a Third Party Prescription" (Ref. 79) prepared for the NACDS. This report sampled all pharmacies with six or more outlets (including food/drug combinations, general merchandisers, discounters, etc.) and presented a volume distribution by units of annual prescriptions. The agency divided annual prescriptions by 52 to arrive at weekly rates, and again interpolated into cohorts of 100 weekly prescriptions. For the purposes of this analysis, mail-order pharmacies were considered chain outlets.

Other Outlets—Estimates for prescription volumes for other outlets were constructed separately. Hospitals and HMO's reported average weekly prescriptions of approximately 350 per week. Physician's offices and ambulatory care units averaged approximately 100 prescriptions per week. While outlets in this category account for 15 percent of all outlets, they account for less than 4 percent of all prescriptions, and most of these are distributed in unit-of-use packaging. The agency considers this sector to be minimally affected by this proposal and did not analyze its characteristics in detail.

Thus, the agency considered the small business impact on the 60,608 commercial, retail outlets that dispensed about 2.1 billion prescriptions per year. Approximately 54 percent of these outlets are independent while 46 percent are chain outlets.

Figure 2 illustrates the relationship between prescription volume and volume market share, and it shows that outlets dispensing 300 or fewer prescriptions per week account for almost 20 percent of all outlets. However, their dispensed prescriptions account for fewer than 6 percent of all prescriptions.

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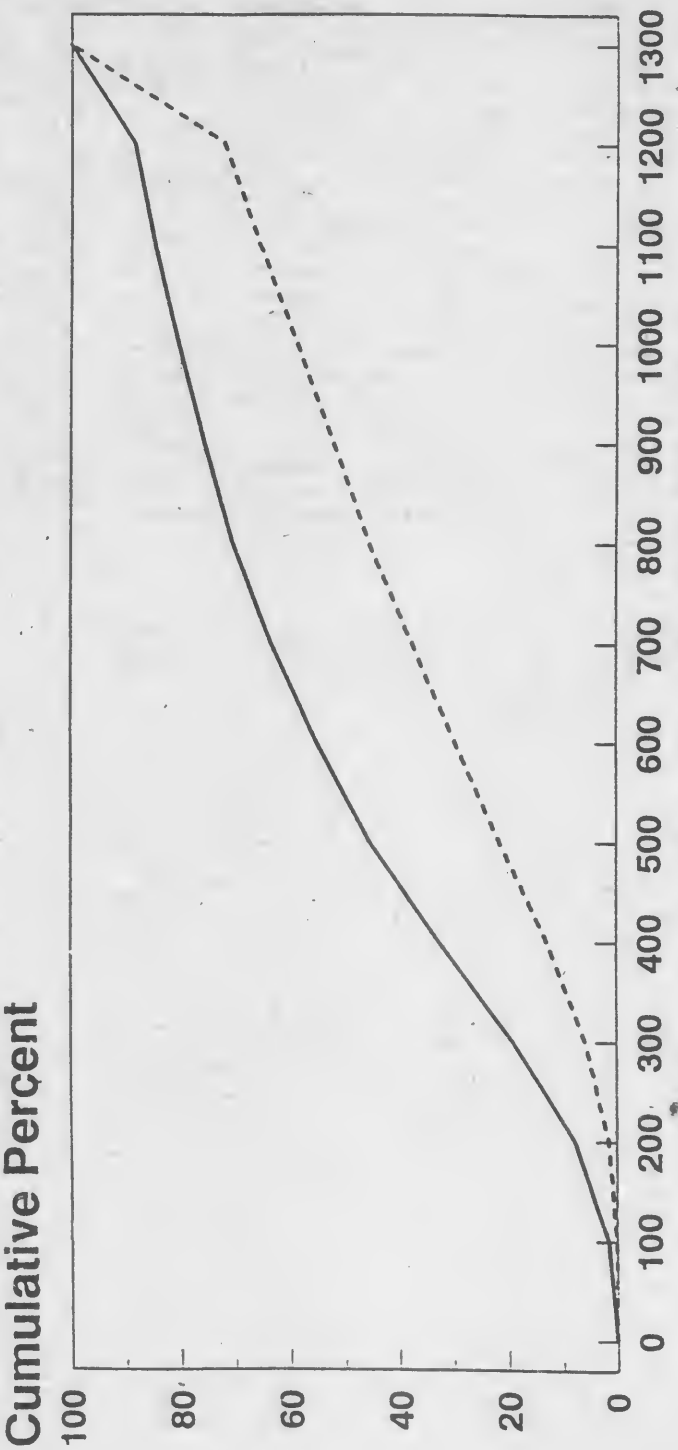
Figure 2



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3. Independent Outlets and Chain Outlets

Independent outlets are typically smaller than chain outlets. As indicated in Figure 3, over 2 percent of all independent pharmacies dispense fewer than 100 weekly prescriptions, while only 0.9 percent of all chain outlets are so small. Conversely, about 7.5 percent of all independent outlets dispense more that 1,200 weekly prescriptions while almost 17 percent of all chain outlets are that large. This results in chain outlets accounting for 26 percent of all outlets with fewer than 100 weekly prescriptions, but 66 percent of all outlets dispensing more than 1,200 weekly prescriptions.

Moreover, chain outlets earn more store revenue on nonpharmacy items. An annual survey conducted by the Drug Store News (Ref. 80) shows that prescription sales account for only 24 percent of total store sales in chain outlets, but 64 percent of sales in independent outlets. In comparison, a typical independent outlet that dispenses fewer than 300 weekly prescriptions has average annual gross revenues of less than $300,000. A typical chain outlet that dispenses the same number of prescriptions will have gross revenues of over $1 million. As the average chain operates 47 separate outlets, these data suggest that very few chain outlets would be eligible for the small business exemption.

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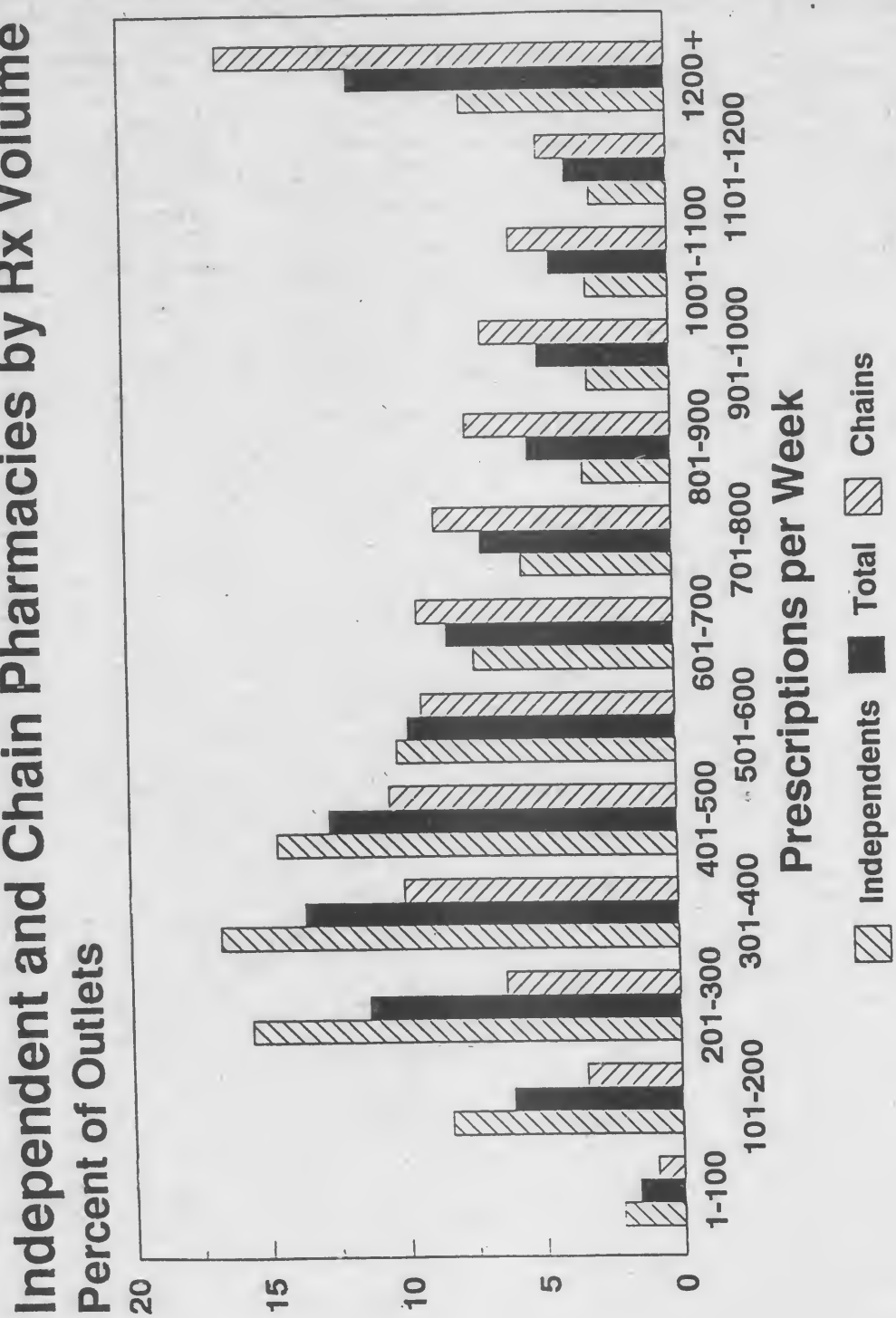
Figure 3



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4. Impact of Small Pharmacy Exemption

FDA proposes to exempt small pharmacies from the Medication Guide requirements if three conditions are met. The first two conditions are based on outlet characteristics. Based on distributions of prescription volume, a proposed outlet size limit of 300 prescriptions per week would exempt about 19 percent of all commercial pharmacies. However, the objective of the exemption is to minimize burdens on small business. Thus, company size, rather than outlet size alone, must be considered. FDA has adopted the Small Business Administration's limit of $5.0 million in annual company sales as an additional criterion for exemption. Thus, an outlet that is a subsidiary of a company with total sales of more than $5.0 million, regardless of sales at the specific outlet, would not qualify for the exemption.

Given these two criteria, FDA estimates that the proposed exemption would cover about 14 percent of all commercial outlets, primarily independent pharmacies. Altogether, these pharmacies dispense only about 4 percent of all prescriptions. Thus, although a substantial proportion of the smallest community pharmacies would be spared additional costs, the distribution of Medication Guides by outlets dispensing 96 percent of all prescriptions would be required. Moreover, since patients obtaining unit-of-use prescriptions would receive Medication Guides despite the small pharmacy exemption, it is likely that at least 97 percent of all new prescriptions would be accompanied by patient information.

The third condition is that exempted outlets make available a compilation of Medication Guides for reading in the dispensing or counseling area.

FDA calculates that this small pharmacy exemption would reduce the compliance costs of these proposed regulations to retail pharmacies by 7 percent, while having virtually no effect on manufacturers' costs. This would reduce the expected annual incremental regulatory cost of compliance to $56.3 million. Figure 4 displays these estimates for various exemption options for the retail pharmacy sector.

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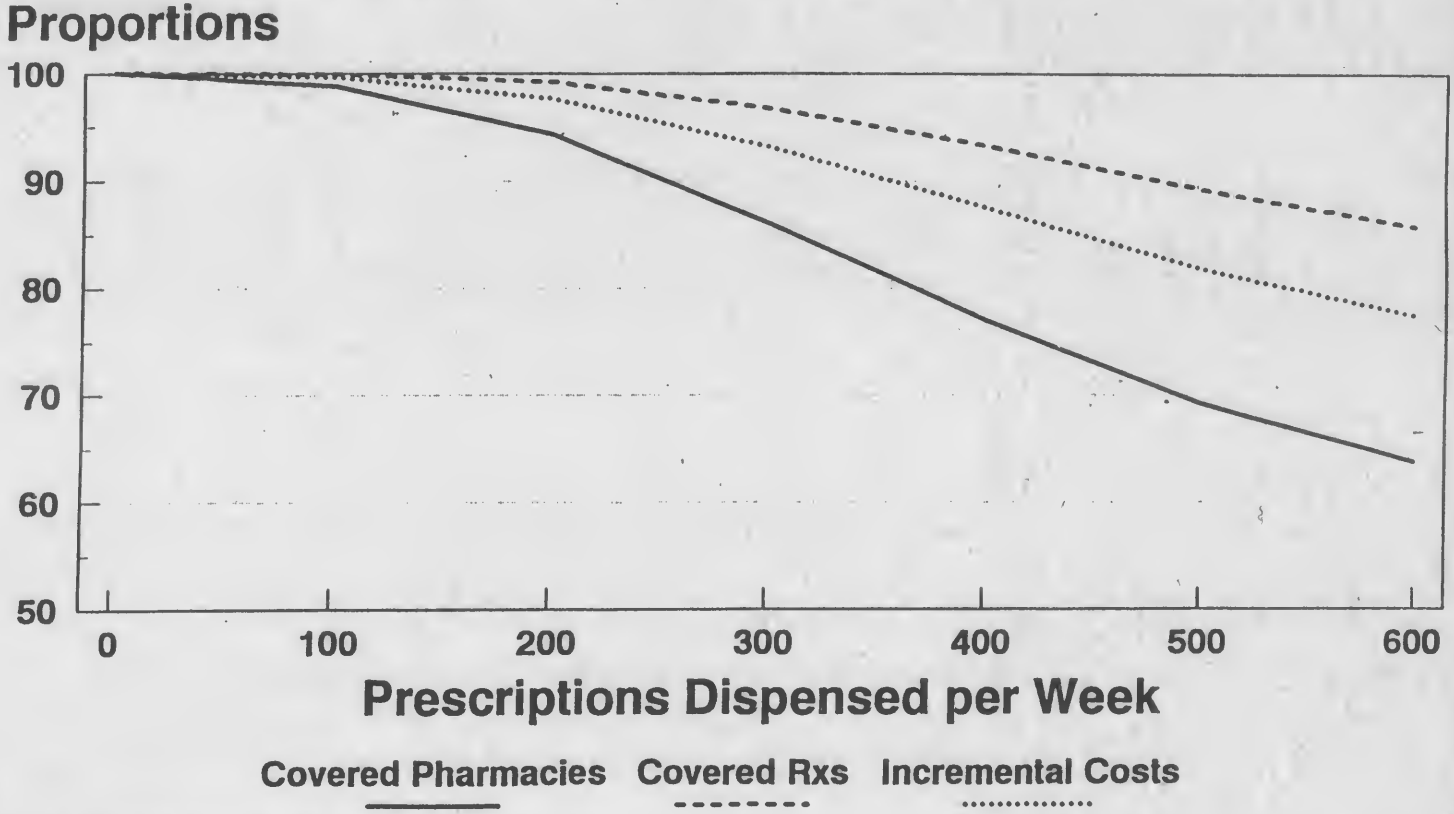
Figure 4

Effect of Exempting Pharmacies from Proposal

Options Based on Weekly Dispensed Prescriptions



Note: Includes $5.0 million Threshhold

E. Regulatory Options

Section VII. of this document discussed the advantages and disadvantages of several alternatives to the proposed regulations. The current section presents rough estimates of their potential costs.

Option A, *Continuation of the Status Quo,* would continue current practice. Under this option, FDA would continue to request patient information on an ad hoc basis for specific drug products. Some pharmacies would continue to purchase private product information systems from a variety of vendors for patient distribution, but they would continue to do so voluntarily. Thus, this option would impose no new incremental costs.

Option B, *No Prior FDA Review,* would require that patient information be dispensed with all drug products, but such information would not be approved by the agency prior to distribution. One form of this option reflects the proposed voluntary approach. Over time, compliance costs would approach those estimated for the proposed regulations.

Option C–1, *FDA-Approved Patient Information Available with New Prescriptions and Upon Request,* would require that a Medication Guide be provided with new prescriptions and upon request for refills. This is the proposed regulatory option only if voluntary information efforts are unsuccessful. As derived above, the annual incremental costs to the affected sectors are estimated to reach $56.3 million by the 10th year after implementation, assuming a small business exemption.

Option C–2, *FDA-Approved Patient Information Available with All Prescriptions,* would require that a Medication Guide be provided with both new and refill prescriptions. Although the cost per Medication Guide dispensed decreases slightly because fixed costs are distributed over more guides, the estimated annual incremental costs of compliance for this option are over 40 percent higher than if Medication Guides were only required for new prescriptions and on request for refills. The estimated annual incremental cost of this option is over $80 million.

Option D–1, *Unit-of-Use Packaging,* would require that all prescription drugs, together with Medication Guides, be dispensed in unit-of-use packaging. FDA does not have sufficient information to develop full cost estimates for this option, but believes the requirement would impose additional costs for both new packaging and increased storage space, while reducing product preparation costs. The following projections illustrate the potential magnitude for several of these categories.

The cost to manufacturers of developing and printing the Medication Guides to be enclosed in each drug package would reach about $50 million annually. In addition, the PMA estimated in 1979 that it would cost manufacturers between $25-$29 million to move to unit-of-use packaging. Updating that estimate to current dollars results in approximately $55 million. Moreover, there are about 67 percent more prescription products available today than in 1979, which would boost this estimate further.

Retail pharmacies and wholesalers would need to devote more storage space to unit-of-use drugs. Estimates from the United Kingdom suggest that this type of packaging may increase storage requirements by 40 percent (Ref. 73). A typical pharmacy uses about 500 square feet of floor space. If the 40 percent increment is representative, an annual rental fee of $7.50 per square foot would cost each pharmacy about $1,500. The total annual cost for retail storage would equal $107 million. FDA assumes that wholesalers would experience additional storage costs.

The reduced time for pharmacists to dispense unit-of-use products would offset some of these cost increases. Kaiser Permanente, for example, has estimated that unit-of-use packaging generates time and supply savings of between $0.50 to $1.00 per prescription, although they note that increased packaging costs offset about half of these savings. Other enterprises report lower savings (Ref. 73). FDA recognizes that strict requirements for unit-of-use packaging would have important consequences on these sectors and solicits additional public comment to allow the agency to understand better the associated costs and savings.

Option D–2, *Reference Book at Dispensing Site,* would require only that a book of Medication Guides be made available at the dispensing site. Under this option, manufacturers would continue to bear the same development costs, but the burden on retail pharmacies would be minimal. Even if the insertion of each new or revised Medication Guide into looseleaf binders took only 30 seconds, 200 to 300 annual revisions would entail annual incremental costs to pharmacies of over $2.2 million.

Option D–3, *Interactive Computer Technology,* would permit pharmacies to provide computer access to consumers in lieu of being handed a written Medication Guide. For example, consumers could be directed to a computer kiosk to retrieve automated information. If most consumers opted to print Medication Guides for new prescriptions, the annualized cost of this alternative per pharmacy might average about $100 for computer and printer equipment, $300 for software updates, and $400 for computer supplies. Further, the rental value of a 3 x 3 square foot cubicle in each pharmacy could add another $70 per year (or over $900 if displaced sales are used to value space). These assumptions imply a total annual incremental cost of about $38 million (about $70 million if displaced sales are used to value space).

Option D–4, *Distribution of Books to Consumers,* requires sending or distributing Medication Guide books to each household. The complete book would eventually include several thousand pages and is assumed to cost $5.00 to print. Consequently, if 50 percent of the nation's 95 million households received an annually updated book, the cost of printing would amount to $237.5 million. If the books were distributed from pharmacies, there would be additional costs for storage. If they were annually mailed to each consumer's residence, at a per book postal rate of approximately $2.00, this amounts to an additional $190 million.

Finally, FDA considered option D–5, *Telephone Counseling,* which would require manufacturers of prescription drug and biological products to provide patients with a number to access counseling via telephone. While FDA encourages manufacturers to provide this service voluntarily, the agency believes that this form of oral counseling should be considered an adjunct, not a replacement, for written information. One large, mail-order company reports that about 10 percent of its new prescription customers utilize a toll-free number. This percentage may be an upper-bound, however, when applied to retail outlets where pharmacists are available for counseling at the time of purchase. FDA estimates that if 5 to 10 percent of all new prescription purchases resulted in 3-minute telephone conversations, the annual cost of employing pharmacists to answer these calls would reach $82 to $164 million. In addition, the average telephone charges may equal about $0.30 per minute, adding $50 to $100 million in annual costs. Thus, the estimated incremental costs for this option range from $65 to $132 million.

F. Benefits

The primary objective of the proposed regulation is to enhance the nation's public health by allowing patients to make better use of their medications. FDA believes that the distribution of written prescription drug information to patients, when combined with licensed practitioner and/or pharmacist counseling, would accomplish this goal in two ways. First, it would reduce the incidence of therapeutic failures due to poor compliance with drug regimens. Second, it would decrease the number of preventable adverse drug reactions and preventable drug-drug and drug-food reactions. FDA believes that both outcomes are at least partly attainable with adequate patient knowledge. While there are no definitive studies that would allow FDA to develop precise measures of the present and future levels of these key health variables, this section presents the agency's best assessment of the expected values.

There is substantial literature on the extent of patient noncompliance with prescription drugs. Although a large number of national programs have been initiated to improve patient information and education, this research continues to demonstrate that noncompliance with prescription drug regimens remains a public health concern. A 1990 NCPIE report found that about one-third of patients fail to take their prescribed medications (Ref. 3). An overview of patient compliance studies found that rates of compliance for long-term therapy tend to converge to 50 percent (Ref. 4). Other studies examining the literature on compliance rates in discrete patient populations suggest that pediatric nonadherence to therapeutic regimens exceeds 50 percent (Ref. 5), noncompliance rates for unsupervised psychiatric outpatients range from 25 to 50 percent (Refs. 6 and 7), and noncompliance in the elderly ranges from 26 to 59 percent (Ref. 8). Therefore, FDA has concluded that current patient noncompliance rates range from 30 to 50 percent.

This research also provides evidence that patient noncompliance with prescribed drug regimens is directly related to therapeutic failure with serious health consequences, including blindness, cardiac arrest, and death (Refs. 9 and 10).

A 1990 Office of the Inspector General report found that the process of patient education can save time by reducing calls or visits to the licensed practitioner or pharmacist and by reducing the number of hospitalizations resulting from patients' failures to follow prescribed drug regimens (Ref. 17).

The economic burden to consumers and society of these preventable drug-related illnesses include the direct costs of additional or prolonged treatments by physicians or hospitals and the indirect costs of lost work-time, reduced productivity, and wasted expenditures on drugs whose efficacy is canceled or reduced by inappropriate or improper use. However, only a few studies have addressed the economic costs associated with drug noncompliance. More than 125,000 hospitalizations, and 20 million lost work-days (with lost earnings of $1.5 billion in 1984) were attributed to drug noncompliance related to cardiovascular disease (Ref. 15). A 1990 study of 315 elderly patients found that hospitalization costs totaled approximately $293,000 for all drug-related admissions (Ref. 8) (About $224,000 was attributable to adverse drug reactions and $77,300 for drug noncompliance.) A recent report (Ref. 81) by the Task Force for Compliance, a group of 22 major pharmaceutical companies, estimated that the annual economic costs of noncompliance exceed $100 billion. They attribute these costs to added hospital admissions ($25 billion), prescriptions ($8 billion), nursing home admissions ($5 billion), and lost productivity (over $50 billion).

The most comprehensive recent study employed a meta-analysis to measure the extent and direct costs of hospital admissions related to drug therapy noncompliance, using data on 2,942 hospital admissions from seven studies. Only published studies that met a strict definition of noncompliance (overuse, underuse, or erratic use) were included. The analysis found that 5.3 percent of annual hospital admissions, or 1.94 million admissions, were due to drug noncompliance, at a cost of $8.5 billion in 1986. The author noted that these results were similar to a 1974 Task Force on Prescription Drugs that estimated hospital costs of $3 billion in 1976 dollars for all drug-related admissions (Ref. 15).

As noted above, a precise quantitative measure of the benefits that would result from the increased availability of patient information is not possible, but FDA relied on the studies described above to develop an illustrative example of the potential magnitude of expected benefits. For its best estimate, FDA drew on the 1990 meta-analysis (Ref. 15) to assume that about 5 percent of the nation's 35 million annual hospital admissions are due to noncompliance with prescribed drug regimens. The average cost of each drug-related hospital admission is unknown, but the average cost for all inpatient hospital and physician services is estimated at almost $9,000 per admission (based on 1987 National Medical Expenditure Survey data, updated to 1993 by the Medical Care CPI). As shown in Table 5, the costs of these hospital admissions, based on an average 7-day stay, project to about $15.6 billion per year.

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Table 5

Annual Costs of Preventable Drug-Related Illness

	Number (Millions)	Incidence (Percent)	Unit Cost ($)	Total Cost (Mill. $)
NONCOMPLIANCE:				
Hospital Admissions	35	5.0	8,890	15,558
Unnecessary Rxs	60	5.0	20	60
Physician Visits	60	5.0	39	117
Sub-Total Non-Comp				15,735
ADVERSE REACTIONS:				
Hospital Admissions	35	1.4	8,890	4,387
TOTAL ANNUAL COST				20,122

No comparable studies examined the nonhospital-related costs of drug noncompliance. However, as stated above, FDA found that from 30 to 50 percent of all patients do not currently adhere to prescribed drug regimens. Because an estimated 150 million U.S. consumers use at least one prescription drug per year, about 60 million patients (150 million×40 percent) are at increased risk of added illness. FDA used this figure, together with an estimated incidence rate of 5 percent, to derive a conservative estimate of the percentage of the noncomplying population that would incur other direct medical costs, such as additional medications and physician visits. As shown, the total annual costs of noncompliance, including hospital admissions and other direct costs, are estimated to be about $15.7 billion.

In addition, adverse drug reactions continue to be a significant health problem. FDA believes that appropriate information can moderate these incidents by warning patients about necessary precautions and heightening their ability to understand and respond to adverse reactions. A review of the relevant research in this area indicates that the incidence of adverse drug reactions responsible for hospital admissions ranges from 0.3 to 16.8 percent (Refs. 8, 11, 12, 13, and 14). According to extrapolations from a sample of emergency rooms, approximately 5 percent of drug-related admissions were associated with adverse encounters with OTC drug products, and thus would not be affected by this proposal (Ref. 83). In addition, investigators have estimated that between 48 percent (Ref. 74) and 55 percent (Ref. 84) of all hospital admissions related to adverse reactions are preventable. Thus, using 50 percent as an estimate of preventable adverse reactions, the agency expects that approximately 47 percent (95 percent × 50 percent) of all hospital admissions associated with adverse drug reactions are potentially preventable by the distribution of quality patient information. This equals 1.4 percent of all hospital admissions. As shown in Table 5, these assumptions imply that the costs of preventable adverse drug reactions amount to about $4.4 billion per year. Moreover, although the incidence of adverse drug reactions in ambulatory patients has been reported at 20 percent (Ref. 48), FDA is still examining these data and has not derived estimates of the related costs. In sum, FDA finds that a partial tally of the direct medical costs associated with the additional or prolonged illnesses that result from both noncompliance with prescription drugs and preventable adverse drug reactions adds up to about $20.1 billion a year. Note that this estimate does not include the economic costs of lost productivity. As mentioned above, one pharmaceutical industry task force estimated the annual economic cost of noncompliance related to lost productivity as over $50 billion (Ref. 81).

The realized benefits of increased patient information will depend on the ensuing changes in patient behavior. Several studies since 1982 have found increases in compliance as a result of written information alone or in combination with oral counseling. The rate was as high as 79 percent in the case of a comprehensive patient education program that included additional features (Ref. 74), although in most cases there were more modest increases. Of the studies involving only written information, one found a 30 percent increase in compliance (Ref. 48) and another a 50 percent increase among patients taking penicillin, but no significant difference among patients taking nonsteroidal anti-inflammatory drugs (Ref. 47). Other studies using only written materials found no significant changes in compliance (Refs. 44 and 52). Two studies using both oral and written information showed increased compliance, with increases of 12 to 14 percent (Ref. 49) and 23 percent (Ref. 7). In another study, however, there was no significant effect of oral and written information on compliance (Ref. 66). These studies varied by type of patient, medication, and illness (chronic or acute), definition of compliance, length of therapy, and presence of noticeable symptoms. Such factors may explain the wide variation in the reported effects of written information on drug utilization behavior.

The agency does not anticipate that required patient information would avert the majority of the costs associated with drug-related illnesses. Even with current levels of patient information, significant levels of noncompliance still occur. However, the above studies indicate that understandable information has a significant impact on patient compliance and awareness. Although data are not available to present a precise forecast of the resulting health changes, the agency notes that the health costs described above imply that if patient information was to result in even a 10 percent reduction in adverse outcomes, this would result in benefits of $2 billion per year. A 5-percent improvement would produce annual benefits of $1 billion. Even a 1 percent reduction in these health care expenditures would more than offset the costs of these proposed regulations.

The agency notes that while these figures are only illustrative, it believes that the assumptions upon which they are based are conservative and that the projected range of benefits is reasonable. Moreover, this quantitative estimate does not account for the potential avoidance of catastrophic effects, such as avoidable death, permanent disability, or prolonged hospitalization. The costs of these more severe consequences, at even very low incidence rates, would be substantial.

G. Preliminary Conclusion

Given the enormous benefits in cost savings and improved health care of this program, FDA believes that the economic costs of these regulations are justified. The agency expects concerns to be raised during the comment period about the apparent imbalance in bearing the direct burden of the costs of these proposed regulations, especially as borne by drug manufacturers and retail pharmacies should preapproved Medication Guides be required.

The agency acknowledges that manufacturers would have the primary responsibility for providing required labeling for drug and biological products. FDA has recognized this concern in this proposal by requiring manufacturers to provide the means for the dispenser to generate a sufficient number of Medication Guides. However, as a practical matter, there is a strong possibility that the impact of the proposed patient labeling program, if fully implemented in the absence of satisfactory voluntary efforts, would place a greater share of the financial burden on the retail pharmacy sector rather than the manufacturer. The agency is soliciting guidance on how the costs of a required Medication Guide program could be allocated in a fair and reasonable fashion. Accordingly, in addition to the comments on the reasonableness of the estimates described above, the agency seeks comments on: (1) How manufacturers and pharmacies can share the costs of producing and dispensing Medication Guides; for example, by providing materials, computer support, subsidies, or in some other fashion; and (2) the role third-party intermediaries could play in interfacing between manufacturers and pharmacies, and how they could mitigate costs.

XIII. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) and (a)(11) that this action is of a type that does not

individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

XIV. Paperwork Reduction Act of 1980

This proposed rule contains information collections which have been submitted for approval to the Office of Management and Budget under the Paperwork Reduction Act of 1980. The title, description, and respondent description of the information collection are shown below, with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Medication Guide for Prescription Drug Products.

Description: The information collection requirements would impose reporting requirements on manufacturers and a recordkeeping requirement on dispensers. However, until at least the year 2000, this burden would only be required for a small subset of products that pose a serious and significant public health concern requiring immediate distribution of FDA-approved patient information. For these products, manufacturers would be required to develop Medication Guides and submit them to FDA for approval; dispensers would be required to document a good faith effort to obtain Medication Guides when their supply is low or depleted.

Description of Respondents: Businesses.

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

21 CFR section	Annual number of responses	Annual frequency	Average burden per response	Annual burden hours
208.26(c)	521	NA	30 min.	261
314.50 (c)(2)(i), (d)(5)(vi)(*b*), and (e)(2)(ii); and 601.2(a)	10	1	320 hrs.	3,200
314.70(b)(3)(ii)	20	1	160 hrs.	3,200
314.94 (a)(8)(i), (a)(8)(ii), (a)(8)(iii), and (a)(8)(iv); and 314.97	10	1	16 hrs.	160
Total				6,821

The agency has submitted a copy of this proposed rule to the Office of Management and Budget (OMB) for its review of these information collections. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to FDA's Dockets Management Branch (address above) and to the Office of Information and Regulatory Affairs, OMB, Washington, DC 20503.

XV. Federalism

Executive Order 12612, Federalism, is intended to "restore the division of governmental responsibilities between the national government and the States that was intended by the Framers of the Constitution and to ensure that the principles of federalism established by the Framers guide the Executive departments and agencies in the formulation and implementation of policies." Section 3(d)(3) of Executive Order 12612 states that, when national standards are required, agencies must consult appropriate State officials and organizations. Section 4(d) requires agencies that foresee any possible conflict between State laws and federally protected interests to consult, to the extent practicable, appropriate officials and organizations representing the States to avoid such conflict.

FDA is aware that several States have laws or regulations that require pharmacists to counsel patients on the use of prescription drug products. The agency does not believe its proposed rule on Medication Guides conflicts with such laws or regulations because the proposed rule would not affect any oral counseling requirement imposed by State laws or regulations. Nevertheless, the agency will continue to examine State laws for federalism purposes and invites comments from interested persons, particularly with respect to State initiatives to provide information on prescription drug products to patients.

XVI. References

The following information has been placed on display in the Dockets Management Branch (address above) where it may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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List of Subjects

21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 208

Drugs, Patient labeling, Reporting and recordkeeping requirements.

21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

21 CFR Part 601

Administrative practice and procedures, Biologics, Confidential business information.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that Chapter I of Title 21 of the Code of Federal Regulations be amended to read as follows:

PART 201—LABELING

1. The authority citation for 21 CFR part 201 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 508, 510, 512, 530–542, 701, 704, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 358, 360, 360b, 360gg-360ss, 371, 374, 379e); secs. 215, 301, 351, 361 of the Public Health Service Act (42 U.S.C. 216, 241, 262, 264).

2. Section 201.57 is amended by revising paragraph (f)(2) to read as follows:

§ 201.57 Specific requirements on content and format of labeling for human prescription drugs.

* * * * *

(f) * * *

(2) Information for patients: This subsection of the labeling shall contain information to be given to patients for safe and effective use of the drug, e.g., precautions concerning driving or the concomitant use of other substances that may have harmful additive effects. Any printed patient information or Medication Guide required under this chapter to be distributed to the patient shall be referred to under the "Precautions" section of the labeling and the full text of such patient information or Medication Guide shall be reprinted at the end of the labeling. The print size requirements for patient information or the Medication Guide set forth in § 208.22 of this chapter, however, do not apply to patient information or the Medication Guide that is reprinted in the professional labeling.

* * * * *

3. New part 208 is added to read as follows:

PART 208—MEDICATION GUIDE FOR PRESCRIPTION DRUG PRODUCTS

Subpart A—General Provisions

Sec.

Subpart B—General Requirements for a Medication Guide

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 510, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360, 371,

374); Sec. 351 of the Public Health Service Act (42 U.S.C. 262).

Subpart A—General Provisions

§ 208.1 Scope and implementation.

(a) This part sets forth requirements for patient labeling for human prescription drug products, including biological products. It applies only to those human prescription drug products administered primarily on an outpatient basis without direct supervision by a health professional. This part shall apply to new prescriptions and upon request by the patient for refill prescriptions. This part does not apply to prescription drug products administered in an institutional setting (such as hospitals, nursing homes, or other health care facilities), or in emergency situations.

(b) Except as provided in paragraph (d) of this section, the provisions of this part are deferred until a determination is made by FDA that either of the following performance standards has not been met:

(1) by (*insert date 5 years from the effective date of the final rule*), 75 percent of patients receiving new prescription drugs or biologics that are covered under these provisions receive useful patient information as described in paragraph (c) of this section, or

(2) by (*insert date 11 years from the effective date of the final rule*), 95 percent of the patients receiving new prescription drugs or biologics that are covered under these provisions receive useful patient information as described in paragraph (c) of this section.

(c) Determination of useful patient information will be based on scientific accuracy, consistency with the format in § 208.22, nonpromotional tone and content, specificity, comprehensiveness, understandable language, and legibility.

(d) This part shall apply without deferral to human prescription drug products and biological products that FDA determines pose a serious and significant public health concern requiring immediate distribution of FDA-approved patient information.

§ 208.3 Definitions.

For purposes of this part, the following definitions shall apply:

(a) *Authorized dispenser* means an individual licensed, registered, or otherwise permitted by the jurisdiction in which the individual practices to provide drug products on prescription in the course of professional practice.

(b) *Dispense to patients* means the act of delivering a prescription drug product to a patient or an agent of the patient either:

(1) By a licensed practitioner or an agent of a licensed practitioner, either directly or indirectly, for self-administration by the patient, or the patient's agent, or outside the licensed practitioner's direct supervision; or

(2) By an authorized dispenser or an agent of an authorized dispenser under a lawful prescription of a licensed practitioner.

(c) *Distribute* means the act of delivering, other than by dispensing, a drug product to any person.

(d) *Distributor* means a person who distributes a drug product.

(e) *Licensed practitioner* means an individual licensed, registered, or otherwise permitted by the jurisdiction in which the individual practices to prescribe drug products in the course of professional practice.

(f) *Manufacturer* means the manufacturer as described in §§ 201.1 and 600.3(t) of this chapter.

(g) *Patient* means any individual, with respect to whom a drug product is intended to be, or has been, used.

Subpart B—General Requirements for a Medication Guide

§ 208.20 Content of a Medication Guide.

(a) A Medication Guide shall meet all of the following conditions:

(1) The Medication Guide shall be written in English, in nontechnical language, and shall not be promotional in tone or content.

(2) The Medication Guide shall be based on, and shall not conflict with, the approved professional labeling for the drug product under § 201.57 of this chapter.

(b) A Medication Guide shall contain the following:

(1) The brand name (e.g., the trademark or proprietary name), if any, and established name. Those products not having an established name shall be designated by their active ingredients. The Medication Guide shall include the phonetic spelling of either the brand name or the established name, whichever is used throughout the Medication Guide.

(2) A summary section containing the drug product's approved indications, critical aspects of proper use, significant warnings, precautions, and contraindications, serious adverse reactions, and potential safety hazards.

(3) A section that identifies a drug product's indications for use. The Medication Guide may not identify an indication unless the indication is identified in the indications and usage section of the professional labeling for the product required under § 201.57 of this chapter.

(4) Information on circumstances under which the drug product should not be used for its labeled indication (its contraindications). The Medication Guide shall contain directions regarding what to do if any of the contraindications apply to a patient, such as contacting the licensed practitioner or discontinuing use of the drug product.

(5) A statement or statements of precautions the patient should take to ensure proper use of the drug, including:

(i) A statement that identifies activities (such as driving or sunbathing), and drugs, foods, or other substances (such as tobacco or alcohol) that the patient should avoid;

(ii) A statement of the risks to the mother and fetus from the use of the drug during pregnancy;

(iii) A statement of the risks of the drug product to a nursing infant;

(iv) A statement of pediatric indications, if any. If the drug product has specific hazards associated with its use in pediatric patients, a statement of the risks;

(v) A statement of geriatric indications, if any. If the drug product has specific hazards associated with its use in geriatric patients, a statement of the risks; and

(vi) A statement of special precautions, if any, that apply to the safe and effective use of the drug product in other identifiable patient populations.

(6)(i) A statement of the possible adverse reactions from the use of the drug product which are serious or occur frequently.

(ii) A statement of the risks, if any, to the patient of developing a tolerance to, or dependence on, the drug product.

(7) Information on the proper use of the drug product, including:

(i) A statement stressing the importance of adhering to the dosing instructions.

(ii) A statement describing any special instructions on how to administer the drug product.

(iii) A statement of what the patient should do in case of overdose of the drug product.

(iv) A statement of what the patient should do if the patient misses taking a scheduled dose of the drug product.

(8) General information about the safe and effective use of prescription drug products, including:

(i) The verbatim statement that "Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide" followed by a statement that the patient should ask the health professional about any concerns,

and a reference to the availability of professional labeling;

(ii) A statement that the drug product not be used for other conditions or given to other persons;

(iii) The name and place of business of the manufacturer, packer, or distributor, as required for the label of the drug product under § 201.1 of this chapter, or the name and place of business of the dispenser of the drug product or for biological products, the name, address, and license number of the manufacturer; and

(iv) The date, identified as such, of the most recent revision of the Medication Guide placed immediately after the last section.

§ 208.22 Format for a Medication Guide.

A Medication Guide shall be printed in accordance with the following specifications:

(a) The letter height or type size shall be no smaller than 10 points (1 point = 0.0138 inches) for all sections of the Medication Guide, except the manufacturer's name and address and the revision date.

(b) The Medication Guide shall be legible and clearly presented. Where appropriate, the Medication Guide shall also use boxes, bold or underlined print, or other highlighting techniques to emphasize specific portions of the text.

(c) The words "Medication Guide" shall appear prominently at the top of the first page of a Medication Guide. The verbatim statement "This Medication Guide has been approved by the U.S. Food and Drug Administration" shall appear at the bottom of a Medication Guide.

(d) The brand and established name shall be immediately below the words "Medication Guide." The established name shall be no less than one-half the height of the brand name.

(e) The Medication Guide shall use the following headings:

(1) "What is the most important information I should know about (name of drug)?"

(2) "What is (name of drug)?"

(3) "Who should not take (name of drug)?"

(4) "How should I take (name of drug)?"

(5) "What should I avoid while taking (name of drug)?"

(6) "What are the possible side effects of (name of drug)?"

§ 208.24 Distributing and dispensing a Medication Guide.

(a) For a large volume container of finished dosage form:

(1) Each manufacturer shall provide to each distributor to which it ships a large volume container of finished dosage form either:

(i) The Medication Guide in sufficient numbers; or

(ii) The means to produce the Medication Guide in sufficient numbers to permit the distributor to comply with paragraph (b) of this section.

(2) The label of each large volume container of finished dosage form shall instruct the authorized dispenser to provide a Medication Guide to each patient to whom the drug product is dispensed.

(b) Each manufacturer or distributor shall provide to each authorized dispenser to which it ships the drug product either:

(1) The Medication Guide in sufficient numbers; or

(2) The means to produce the Medication Guide in sufficient numbers to permit the authorized dispenser to provide the Medication Guide to each patient receiving a new prescription for a drug product or requesting a Medication Guide.

(c) For a drug product in a unit-of-use container, the manufacturer and distributor shall provide a Medication Guide with each package of the drug product that the manufacturer or distributor intends to be dispensed to patients.

(d) The requirements of this section can be met by the manufacturer or distributor or by any other person acting on behalf of the manufacturer or distributor. Nothing in this section prohibits a manufacturer or distributor from meeting the requirements with a Medication Guide printed by the distributor or authorized dispenser.

(e) Each authorized dispenser of a prescription drug product subject to this part shall, when the product is dispensed (to a patient or to a patient's agent), for new prescriptions and upon request by the patient for refill prescriptions, provide a Medication Guide directly to each patient (or to the patient's agent), unless an exemption applies under § 208.26.

(f) An authorized dispenser is not subject to section 510 of the Federal Food, Drug, and Cosmetic Act, which requires the registration of producers of drugs and the listing of drugs in commercial distribution solely because of an act performed by the authorized dispenser under part 208.

§ 208.26 Exemptions and deferrals.

(a) The Food and Drug Administration (FDA) on its own initiative or in response to a written request from an applicant, may exempt or defer any or all Medication Guide requirements on the basis that the requirement is inapplicable, unnecessary, or contrary to the patient's best interests. Requests from applicants should be submitted to the director of the FDA division responsible for reviewing the marketing application for the drug product, or for a biological product, to the application division in the office with product responsibility.

(b) If the licensed practitioner who prescribes a drug product, or the authorized dispenser who dispenses a drug product, determines that it is not in the patient's best interest to receive a Medication Guide because of significant concerns about the effect of a Medication Guide, the licensed practitioner may direct that the Medication Guide not be provided to the patient, or the authorized dispenser may withhold the Medication Guide. However, the authorized dispenser of a prescription drug product shall provide a Medication Guide to any patient who requests it when the drug product is dispensed regardless of any such direction by the licensed practitioner or the authorized dispenser. This exemption from providing a Medication Guide does not apply if FDA determines that a Medication Guide for a particular product should be provided to all patients under all circumstances.

(c) A Medication Guide is not required to be dispensed to patients in emergency situations or where the manufacturer, distributor, or authorized dispenser, after documenting a good faith effort to obtain a Medication Guide for the patient, does not have a Medication Guide available for the patient.

(d)(1) An authorized dispenser, as defined in § 208.3(a), shall be exempt from the dispensing requirements of § 208.24(e) when the following conditions are met:

(i) The authorized dispenser dispensed, in the previous calendar year, no more than an average of 300 outpatient prescription drug products per week; and

(ii) The authorized dispenser, or its business entity, has gross annual sales of no more than $5.0 million; and

(iii) The authorized dispenser makes available to patients a compilation of current Medication Guides for reading in the dispensing or counseling area.

(2) This exemption does not apply to a drug dispensed in a unit-of-use container or a drug which the agency determines must be dispensed with a Medication Guide.

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG OR AN ANTIBIOTIC DRUG

4. The authority citation for 21 CFR part 314 is revised to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 701, 704, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371, 374, 379e).

5. Section 314.50 is amended by revising the first and third sentences of the introductory text, paragraph (c)(2)(i), the first sentence of paragraph (d)(5)(vi)(*b*), paragraph (e)(2)(ii), and the fourth sentence in paragraph (k)(1) to read as follows:

§ 314.50 Content and format of an application.

Applications and supplements to approved applications are required to be submitted in the form and contain the information, as appropriate for the particular submission, required under this section. * * * An application for a new chemical entity will generally contain an application form, an index, a summary, five or six technical sections, case report tabulations of patient data, case report forms, drug samples, and labeling, including, if applicable, any Medication Guide required under part 208 of this chapter. * * *

* * * * *

(c) * * *

(2) * * *

(i) The proposed text of the labeling, including, if applicable, any Medication Guide required under part 208 of this chapter, for the drug, with annotations to the information in the summary and technical sections of the application that support the inclusion of each statement in the labeling, and, if the application is for a prescription drug, statements describing the reasons for omitting a section or subsection of the labeling format in § 201.57 of this chapter.

* * * * *

(d) * * *

(5) * * *

(vi) * * *

(*b*) The applicant shall, under section 505(i) of the act, update periodically its pending application with new safety information learned about the drug that may reasonably affect the statement of contraindications, warnings, precautions, and adverse reactions in the draft labeling and, if appropriate, any Medication Guide required under part 208 of this chapter. * * *

* * * * *

(e) * * *

(2) * * *

(ii) Copies of the label and all labeling for the drug product (including, if applicable, any Medication Guide required under part 208 of this chapter) for the drug product (4 copies of draft labeling or 12 copies of final printed labeling).

* * * * *

(k) * * *

(1) * * * Information relating to samples and labeling (including, if applicable, any Medication Guide required under part 208 of this chapter), is required to be submitted in hard copy. * * *

* * * * *

6. Section 314.70 is amended by revising paragraph (b)(3) to read as follows:

§ 314.70 Supplements and other changes to an approved application.

* * * * *

(b) * * *

(3) *Labeling.* (i) Any change in labeling, except one described in paragraphs (c)(2) or (d) of this section.

(ii) If applicable, any change to a Medication Guide required under part 208 of this chapter.

* * * * *

7. Section 314.94 is amended by revising paragraph (a)(8) to read as follows:

§ 314.94 Content and format of an abbreviated application.

* * * * *

(a) * * *

(8) *Labeling*—(i) *Listed drug labeling.* A copy of the currently approved labeling (including, if applicable, any Medication Guide required under part 208 of this chapter) for the listed drug referred to in the abbreviated new drug application, if the abbreviated new drug application relies on a reference listed drug.

(ii) *Copies of proposed labeling.* Copies of the label and all labeling for the drug product (including, if applicable, any Medication Guide required under part 208 of this chapter) for the drug product (4 copies of draft labeling or 12 copies of final printed labeling).

(iii) *Statement on proposed labeling.* A statement that the applicant's proposed labeling (including, if applicable, any Medication Guide required under part 208 of this chapter) is the same as the labeling of the reference listed drug except for differences annotated and explained under paragraph (a)(8)(iv) of this section.

(iv) *Comparison of approved and proposed labeling.* A side-by-side comparison of the applicant's proposed labeling (including, if applicable, any Medication Guide required under part 208 of this chapter) with the approved labeling for the reference listed drug with all differences annotated and explained. Labeling (including the container label, package insert, and, if applicable, Medication Guide) proposed for the drug product must be the same as the labeling approved for the reference listed drug, except for changes required because of differences approved under a petition filed under § 314.93 or because the drug product and the reference listed drug are produced or distributed by different manufacturers. Such differences between the applicant's proposed labeling and labeling approved for the reference listed drug may include differences in expiration date, formulation, bioavailability, or pharmacokinetics, labeling revisions made to comply with current FDA labeling guidelines or other guidance, or omission of an indication or other aspect of labeling protected by patent or accorded exclusivity under section 505(j)(4)(D) of the act.

* * * * *

PART 601—LICENSING

8. The authority citation for 21 CFR part 601 is revised to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 513–516, 518–520, 701, 704, 721, 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 374, 379e, 381); secs. 215, 301, 351, 352 of the Public Health Service Act (42 U.S.C. 216, 241, 262, 263); secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461).

9. Section 601.2 is amended in paragraph (a) by revising the first sentence to read as follows:

§ 601.2 Applications for establishment and product licenses; procedures for filing.

(a) *General.* To obtain a license for any establishment or product, the manufacturer shall make application to the Director, Center for Biologics Evaluation and Research, on forms prescribed for such purposes, and in the case of an application for a product license, shall submit data derived from nonclinical laboratory and clinical studies which demonstrate that the manufactured product meets prescribed standards of safety, purity, and potency; with respect to each nonclinical laboratory study, either a statement that the study was conducted in compliance with the requirements set forth in part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the

reason for the noncompliance; statements regarding each clinical investigation involving human subjects contained in the application, that it either was conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter or was not subject to such requirements in accordance with § 56.104 or § 56.105 of this chapter, and was conducted in compliance with requirements for informed consent set forth in part 50 of this chapter; a full description of manufacturing methods; data establishing stability of the product through the dating period; sample(s) representative of the product to be sold, bartered, or exchanged or offered, sent, carried, or brought for sale, barter, or exchange; summaries of results of tests performed on the lot(s) represented by the submitted sample(s); and specimens of the labels, enclosures, containers, and, if applicable, any Medication Guide required under part 208 of this chapter proposed to be used for the product. * * *

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Dated: July 17, 1995.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

Note: The following appendixes will not appear in the Code of Federal Regulations.

BILLING CODE 4160-01-P

APPENDIX A—A "shell" of the proposed uniform format

Appendix A

Medication Guide

Questions and Answers About

[Name of Drug]

(generic name = [name of generic drug product])

What is the most important information I should know about [name of drug]?

[Name of drug/phonetic spelling]

What is [name of drug]?

Who should not take [name of drug]?

PROTOTYPE

How should I take [name of drug]?

What should I avoid while taking [name of drug]?

What are the possible side effects of [name of drug]?

If you suspect that someone may have taken more than the prescribed dose of this medicine, contact your local poison control center or emergency room immediately. This medication was prescribed for your particular condition. Do not use it for another condition or give the drug to others.

This leaflet provides a summary of information about [name of drug]. Medicines are sometimes prescribed for uses other than those listed in a Medication Guide. If you have any questions or concerns, or want more information about [name of drug], contact your doctor or pharmacist. Your pharmacist also has a longer leaflet about [name of drug] that is written for health professionals that you can ask to read.

[name of company]

[address]

This Medication Guide has been approved by the U.S. Food and Drug Administration.

BILLING CODE 4160-01-C

Appendix B

APPENDIX B—Several sample Medication Guides using the proposed uniform format

Medication Guide

Questions and Answers About

Ceclor

(generic name = cefaclor for oral suspension)

What is the most important information I should know about Ceclor?

Ceclor (pronounced SEE-klor) is used to treat infections caused by certain bacteria. You should not take Ceclor if you are allergic to penicillin or other similar antibiotics. Allergic reactions to Ceclor, as with other drugs, can be fatal. If you experience difficulty breathing, swelling of the throat, rash, or severe diarrhea or abdominal pain, call your doctor immediately or seek medical help.

Take Ceclor for the full amount of time prescribed by your doctor, even if you feel better.

Shake your bottle well every time before taking Ceclor.

What is Ceclor?

Ceclor is used to treat infections caused by certain bacteria. These infections include middle ear, bladder, and skin infections, as well as strep throat, pneumonia and chronic bronchitis. Ceclor works by killing certain bacteria or preventing them from growing. It works only for certain bacteria and not for others. Your doctor may need to get results from laboratory tests or cultures to make sure you are taking the correct antibiotic. Ceclor will not work for colds, flu, or any viral infection. Ceclor is in a class of drugs known as cephalosporin antibiotics.

Who should not take Ceclor?

Do not take this drug if you are allergic to penicillin or any other cephalosporin-class antibiotic because it is likely that you may also be allergic to Ceclor.

Check with your doctor if you:

- have abdominal problems such as colitis
- are pregnant
- are breast-feeding
- are a diabetic and are checking your urine for sugar. (Ceclor can interfere with the urine test you may be using.)

How should I take Ceclor?

- Follow your doctor's advice about how to take Ceclor. Continue taking Ceclor even if you feel better. Be sure to take all of the medication for the length of time prescribed for you. If you stop taking your medication too soon, the bacteria can grow back and you may get sick again with the same infection.
- Shake your bottle well every time before taking this medicine.
- If you miss taking a dose of Ceclor, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and take your medicine as scheduled. Do not take double your prescribed dose

What are the possible side effects of Ceclor?

The most common side effects are mild upset stomach, diarrhea, and rash. Call your doctor if these side effects persist or are bothersome

Call your doctor immediately if the following side effects occur:

- Swelling of the throat or difficulty breathing
- Hives, itching, and rash
- Severe or bloody diarrhea
- Abdominal pain
- Tiredness or faintness (that lasts after taking this medication for 24 hours)
- Fever (that lasts after taking this medication for 24 hours)
- Joint aches or stiffness (that lasts after taking this medication for 24 hours)

How should I store Ceclor?

- Keep Ceclor in the refrigerator.
- Throw away any unused portion after the expiration date.

If you suspect that someone may have taken more than the prescribed dose of this medicine, contact your local poison control center or emergency room immediately. This medication was prescribed for your particular condition. Do not use it for another condition or give the drug to others.

This leaflet provides a summary of information about Ceclor. Medicines are sometimes prescribed for uses other than those listed in a Medication Guide. If you have any questions or concerns, or want more information about Ceclor, contact your doctor or pharmacist. Your pharmacist also has a longer leaflet about Ceclor that is written for health professionals that you can ask to read.

[name of company]
[revision date]

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Medication Guide

Questions and Answers About

Cardizem

(generic name = diltiazem tablets)

What is the most important information that I should know about Cardizem?

Cardizem (pronounced KAR-de-zem) is used to treat angina pectoris (chest pain).

- Cardizem may lower your blood pressure. If you get dizzy while using Cardizem, call your doctor.
- Cardizem can interact with certain medications. Check with your doctor if you are taking a beta-blocker, cimetidine, or digitalis.
- You should not use Cardizem if you have certain heart conditions.
- If you notice very slow heart rate, palpitations, or feel very weak, call your doctor.

What is Cardizem?

Cardizem is used to treat angina pectoris (chest pain caused by narrowing of an artery in the heart). Cardizem relaxes or dilates blood vessels in the body. This increases blood flow to the heart and helps reduce chest pain. Cardizem is in a class of drugs known as calcium channel blockers.

Who should not take Cardizem?

- **If you have heart problems:** Your doctor needs to know if you have low blood pressure, heart block, a pacemaker, heart failure, or any other heart problem. Some patients with these conditions should not take Cardizem.
- **If you have liver or kidney problems:** Your doctor needs to know if you have any liver or kidney problems. Your doctor may need to monitor the effect of Cardizem on your liver or kidneys and may need to adjust the dose that you take.
- **If you are pregnant:** The use of Cardizem in pregnant women has not been studied. Studies with animals suggest, however, that Cardizem may cause miscarriages or stillbirths. Therefore, you should only use Cardizem during pregnancy if you and your doctor believe the benefits of using it outweigh the risks.
- **If you are nursing:** Cardizem is passed on to the child through breast milk. If you must take Cardizem, use some other form of infant feeding.

How should I take Cardizem?

You should take this medicine before meals if possible. If you miss taking a dose of Cardizem, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and take your medicine as scheduled. Do not take double your prescribed dose.

What should I avoid while taking Cardizem?

Cardizem can interact with several other medications. Your doctor may need to change the dosage of Cardizem or your other medicines. Check with your doctor before taking the following medicines:

- beta-blocker drugs (used for high blood pressure and other heart conditions);
- cimetidine (used for ulcers); and
- digitalis (used for heart failure or other heart problems).

What are the possible side effects of Cardizem?

Minor common side effects of using Cardizem are edema (swelling of the legs), headache, dizziness, rash, and weakness.

A small number, (less than 1/2 percent), of patients taking Cardizem get heart palpitations, very slow heart rate or missed heart beats. If you notice a very slow heart beat, palpitations, or feel very weak, call your doctor.

Also, call your doctor if you have:

- Difficulty breathing (this may be a sign of heart failure)
- Dizziness (this may be a sign of low blood pressure).

If you suspect that someone may have taken more than the prescribed dose of this medicine, contact your local poison control center or emergency room immediately. This medication was prescribed for your particular condition. Do not use it for another condition or give the drug to others.

This leaflet provides a summary of information about Cardizem. Medicines are sometimes prescribed for uses other than those listed in a Medication Guide. If you have any questions or concerns, or want more information about Cardizem, contact your doctor or pharmacist. Your pharmacist also has a longer leaflet about Cardizem that is written for health professionals that you can ask to read.

[name of company]
[revision date]

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Medication Guide

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Questions and Answers About

Halcion

(generic name = triazolam tablets)

What is the most important information I should know about Halcion?

Halcion (pronounced HAL-see-on) is used to help you sleep.

- For many patients, Halcion should be used for a brief period (7 to 10 days). Halcion's effectiveness may decrease with longer use.
- Important risks of Halcion include: (1) memory problems, (2) withdrawal effects, (3) dependence, and (4) the possibility of serious mental and behavioral changes. The risk of these problems may increase with longer use.
- There are important cautions to consider while taking Halcion. Do not increase the dose or take other medicines without your doctor's advice. Avoid using alcohol. Avoid driving and other activities that require you to be alert until you know how this medication will affect you. Do not take Halcion if you are pregnant.

What is Halcion?

Halcion treats insomnia (difficulty in falling asleep, frequent awakenings during the night, or early morning awakening). Halcion is in a class of drugs called benzodiazepines.

Who should not take Halcion?

Halcion should not be used during pregnancy. Some sleeping pills have been linked to birth defects when taken during the early months of pregnancy. Sedation and withdrawal effects have been seen in newborn infants of mothers who had taken sleeping pills late in pregnancy.

How should I take Halcion?

- You should take Halcion only when 7 to 8 hours of sleep is possible.
- Take the dose your doctor prescribes. Do not increase the dose without consulting your doctor.
- Insomnia is often a short-term problem. It can be treated by a brief course of Halcion (7 to 10 days). When used for longer periods, Halcion's effectiveness may decrease and the risk of side effects may increase. You must discuss with your doctor the risks and benefits of continuing to use Halcion for more than a week.

What should I avoid while taking Halcion?

- Do not drink alcohol while taking Halcion.
- Halcion can make you sleepy, drowsy, dizzy, lightheaded, and less physically coordinated. Be careful doing anything hazardous that requires you to be mentally alert. Do not drive a car or operate any dangerous machinery until you know how the drug affects you.
- Check with your doctor before taking any other medicines. Be especially careful about any medicines that can make you drowsy.

What are the possible side effects of Halcion?

Next-Day Drowsiness: All sleeping pills can make you drowsy the next day. Although Halcion may cause less next-day drowsiness than some other sleeping pills, you should take the lowest effective dose possible. Do not take Halcion when you need to be alert but cannot get 7 to 8 hours of sleep (for example, on a short airplane flight).

Memory Problems: All sleeping pills can cause memory loss (amnesia) for several hours after taking the drug. This is not generally a problem because people usually are asleep during this period. Halcion may be more likely than some other sleeping pills to cause memory loss. If you will need to be awakened within several hours after falling asleep, you should not take Halcion.

Withdrawal: All sleeping pills may have withdrawal effects when they are stopped. Halcion may be more likely than some other sleeping pills to have such problems. When Halcion is stopped, you may temporarily have worse insomnia than when you started. Another withdrawal effect includes unpleasant feelings. Less common withdrawal effects include abdominal and muscle cramps, vomiting, sweating, tremors (shakes), and rarely, convulsions. Withdrawal effects are more common and more severe after longer use.

Halcion may cause withdrawal effects between doses. You may have more problems sleeping (rebound insomnia) the third of the night or you may be nervous during the day.

Dependence: If Halcion is used for more than a few weeks, you may become "dependent" upon the drug. You may feel increased urgency to continue to take it or to increase the dose.

Mental and Behavior Changes: Changes in thinking and behavior have been reported by people taking Halcion and other sleeping pills. As with alcohol intoxication, sometimes people taking Halcion become more uninhibited, outgoing, or aggressive. More unusual changes include confusion, strange behavior, agitation, hallucinations, worsening of depression, and suicidal thinking. It is not known if these more unusual changes are caused by the drug, by some underlying illness, or have another cause. It is important to discuss any such changes in thinking or behavior with your doctor.

If you suspect that someone may have taken more than the prescribed dose of this medicine, contact your local poison control center or emergency room immediately. This medication was prescribed for your particular condition. Do not use it for another condition or give the drug to others.

This leaflet provides a summary of information about Halcion. Medicines are sometimes prescribed for uses that are not listed in a Medication Guide. If you have any questions or concerns, or want more information about Halcion, contact your doctor or pharmacist. Your pharmacist also has a longer leaflet about Halcion that is written for health professionals that you can ask to read.

(name of company)
(revision date)

This Medication Guide has been approved by the U.S. Food and Drug Administration.

BILLING CODE 4160–01–C

Medication Guide

Questions and Answers About

Diltiazem tablets

What is the most important information that I should know about Diltiazem?

Diltiazem (pronounced Dill-tie-a-zehm) is used to treat angina pectoris (chest pain).

- Diltiazem may lower your blood pressure. If you get dizzy while using Diltiazem, call your doctor.
- Diltiazem can interact with certain medications. Check with your doctor if you are taking a beta-blocker, cimetidine, or digitalis.
- You should not use Diltiazem if you have certain heart conditions.
- If you notice very slow heart rate, palpitations, or feel very weak, call your doctor.

What is Diltiazem?

Diltiazem is used to treat angina pectoris (chest pain caused by narrowing of an artery in the heart). Diltiazem relaxes or dilates blood vessels in the body. This increases blood flow to the heart and helps relieve chest pain. Diltiazem is in a class of drugs known as calcium channel blockers.

Who should not take Diltiazem?

- If you have heart problems: Your doctor needs to know if you have low blood pressure, heart block, a pacemaker, heart failure, or any other heart problem. Some patients with these conditions should not take Diltiazem.
- If you have liver or kidney problems: Your doctor needs to know if you have any liver or kidney problems. Your doctor may need to monitor the effect of Diltiazem on your liver or kidneys and may need to adjust the dose that you take.
- If you are pregnant: The use of Diltiazem in pregnant women has not been studied. Studies with animals suggest, however, that Diltiazem may cause miscarriages or stillbirths. Therefore, you should only use Diltiazem during pregnancy if you and your doctor believe the benefits of using it outweigh the risks.
- If you are nursing: Diltiazem is passed on to the child through breast milk. If you must take Diltiazem, use some other form of infant feeding.

How should I take Diltiazem?

You should take this medicine before meals if possible. If you miss taking a dose of Diltiazem, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and take your medicine as scheduled. Do not take double your prescribed dose.

What should I avoid while taking Diltiazem?

Diltiazem can interact with several other medications. Your doctor may need to change the dosage of Diltiazem or your other medicines. Check with your doctor before taking the following medicines:

- beta-blocker drugs (used for high blood pressure and other heart conditions);
- cimetidine (used for ulcers); and
- digitalis (used for heart failure or other heart problems).

What are the possible side effects of Diltiazem?

The most common side effects of using Diltiazem are edema (swelling of the [illegible] headache, dizziness, rash, and weakness.

Very small number, (less than 1/2 percent), of patients taking Diltiazem get heart palpitations, very slow heart rate or missed heart beats. If you notice a very slow heart beat, palpitations, or feel very weak, call your doctor.

Also, call your doctor if you have:

- Difficulty breathing (this may be a sign of heart failure)
- Dizziness (this may be a sign of low blood pressure).

If you suspect that someone may have taken more than the prescribed dose of this medicine, contact your local poison control center or emergency room immediately. This medication was prescribed for your particular condition. Do not use it for another condition or give the drug to others.

This leaflet provides a summary of information about Diltiazem. Medicines are sometimes prescribed for uses other than those listed in a Medication Guide. If you have any questions or concerns, or want more information about Diltiazem, contact your doctor or pharmacist. Your pharmacist also has a longer leaflet about Diltiazem that is written for health professionals that you can ask to read.

(name of company)
(revision date)

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Medication Guide

Ceclor

(generic name = cefaclor for oral suspension)

Summary

Ceclor (pronounced SEE-Klor) is used to treat infections caused by certain bacteria. You should not take Ceclor if you are allergic to penicillin or other similar antibiotics. Allergic reactions to Ceclor, as with other drugs, can be fatal. If you experience difficulty breathing, swelling of the throat, rash, or severe diarrhea or abdominal pain, call your doctor immediately or seek medical help.

Take Ceclor for the full amount of time prescribed by your doctor, even if you feel better.

Shake your bottle well every time before taking Ceclor.

Uses

Ceclor is used to treat infections caused by certain bacteria. These infections include middle ear, bladder, and skin infections, as well as strep throat, pneumonia and chronic bronchitis. Ceclor works by killing certain bacteria or preventing them from growing. It works only for certain bacteria and not for others. Your doctor may need to get results from laboratory tests or cultures to make sure you are taking the correct antibiotic. Ceclor will not work for colds, flu, or any viral infection. Ceclor is in a class of drugs known as cephalosporin antibiotics.

General Cautions

- Do not take this drug if you are allergic to penicillin or any other cephalosporin-class antibiotic because it is likely that you may also be allergic to Ceclor.

Check with your doctor if you:

- have abdominal disease, such as colitis
- are pregnant
- are breast-feeding
- are a diabetic and are checking your urine for sugar. (Ceclor can interfere with the urine test you may be using.)

Proper Use

- Follow your doctor's advice about how to take Ceclor. Continue taking Ceclor even if you feel better. Be sure to take all of the medication for the length of time prescribed for you. If you stop taking your medication too soon, the bacteria can grow back and you may get sick again with the same infection.
- Shake your bottle well every time before taking this medicine.
- If you miss taking a dose of Ceclor, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and take your medicine as scheduled. Do not take double your prescribed dose.

Possible Side Effects

The most common side effects are mild upset stomach, diarrhea, and rash. Call your doctor if these side effects persist or are bothersome.

Call your doctor immediately if the following side effects occur:

- Swelling of the throat or difficulty breathing
- Hives, itching, and rash
- Severe or bloody diarrhea
- Abdominal pain
- Tiredness or faintness (that lasts after taking this medication for 24 hours)
- Fever (that lasts after taking this medication for 24 hours)
- Joint aches or stiffness (that lasts after taking this medication for 24 hours)

Storage

- Keep Ceclor in the refrigerator.
- Throw away any unused portion after the expiration date.

Each teaspoon (5ml) of Ceclor for Oral Suspension contains either 125, 250, or 375 mg of cefaclor monohydrate and is pink in color.

If you suspect that someone may have taken more than the prescribed dose of this medicine, contact your local poison control center or emergency room immediately. This medication was prescribed for your particular condition. Do not use it for another condition or give the drug to others.

This leaflet provides a summary of information about Ceclor. Medicines are sometimes prescribed for uses other than those listed in a Medication Guide. If you have any questions or concerns, or want more information about Ceclor, contact your doctor or pharmacist. Your pharmacist also has a longer leaflet about Ceclor that is written for health professionals that you can ask to read.

[name of company]
[revision date]

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Medication Guide

Cardizem

(generic name = diltiazem tablets)

Summary

Cardizem (pronounced KAR-de-zem) is used to treat angina pectoris (chest pain).

- Cardizem may lower your blood pressure. If you get dizzy while using Cardizem, call your doctor.
- Cardizem can interact with certain medications. Check with your doctor if you are taking a beta-blocker, cimetidine, or digitalis.
- You should not use Cardizem if you have certain heart conditions.
- If you notice very slow heart rate, palpitations, or feel very weak, call your doctor.

Uses

Cardizem is used to treat angina pectoris (chest pain caused by narrowing of an artery in the heart). Cardizem relaxes or dilates blood vessels in the body. This increases blood flow to the heart and helps reduce chest pain. Cardizem is in a class of drugs known as calcium channel blockers.

Cautions

- **Heart Problems:** Your doctor needs to know if you have low blood pressure, heart block, a pacemaker, heart failure, or any other heart problem. Some patients with these conditions should not take Cardizem.
- **Liver or Kidney Problems:** Your doctor needs to know if you have any liver or kidney problems. Your doctor may need to monitor the effect of Cardizem on your liver or kidneys and may need to adjust the dose that you take.
- **Pregnancy:** The use of Cardizem in pregnant women has not been studied. Studies in animals suggest, however, that Cardizem may cause miscarriages or stillbirths. Therefore, you should only use Cardizem during pregnancy if you and your doctor believe the benefits of using it outweigh the risks.
- **Nursing Mothers:** Cardizem is passed on to the child through breast milk. If you must take Cardizem, use some other form of infant feeding.

Cardizem can interact with several other medications. Your doctor may need to change the dosage of Cardizem or your other medicines. **Check with your doctor before taking the following medicines:**

- beta-blocker drugs (used for high blood pressure and other heart conditions);
- cimetidine (used for ulcers); and
- digitalis (used for heart failure or other heart problems).

Proper Use

You should take this medicine before meals if possible. If you miss taking a dose of Cardizem, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and take your medicine as scheduled. Do not double your prescribed dose.

Possible Side Effects

The most common side effects of [illegible] are edema (swelling of the legs), headache, dizziness, rash, and weakness.

A small number, (less than 1/2 percent), of patients taking Cardizem get heart palpitations, very slow heart rate or missed heart beats. If you notice a very slow heart beat, palpitations, or feel very weak, call your doctor.

Also, call your doctor if you have:

- Difficulty breathing (this may be a sign of heart failure)
- Dizziness (this may be a sign of low blood pressure).

Each 30mg tablet is green and round, engraved with MARION on one side an 1771 on the other. Each 60mg tablet is yellow and round, engraved with MARION on one side and 1772 on the other. Each 90mg tablet is green and oblong, engraved with CARDIZEM on one side and 90mg on the other. Each 120mg tablet is yellow and oblong, engraved with CARDIZEM on one side and 120mg on the other.

If you suspect that someone may have taken more than the prescribed dose of this medicine, contact your local poison control center or emergency room immediately. This medication was prescribed for your particular condition. Do not use it for another condition or give the drug to others.

This leaflet provides a summary of information about Cardizem. Medicines are sometimes prescribed for uses other than those listed in a Medication Guide. If you have any questions or concerns, or want more information about Cardizem, contact your doctor or pharmacist. Your pharmacist also has a longer leaflet about Cardizem that is written for health professionals that you can ask to read.

[name of company]
[revision date]

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Medication Guide

6

Halcion

(generic name = triazolam tablets)

Summary

Halcion (pronounced HAL-see-on) is used to help you sleep.

- For many patients, Halcion should be used for a brief period (7 to 10 days). Halcion's effectiveness may decrease with longer use.
- Important risks of Halcion include: (1) memory problems, (2) withdrawal effects, (3) dependence, and (4) the possibility of serious mental and behavioral changes. The risk of these problems may increase with longer use.
- There are important cautions to consider while taking Halcion. Do not increase the dose or take other medicines without your doctor's advice. Avoid using alcohol. Avoid driving and other activities that require you to be alert until you know how this medication will affect you. Do not take Halcion if you are pregnant.

Uses

Halcion treats insomnia (difficulty in falling asleep, frequent awakening during the night, or early morning awakening). Halcion is in a class of drugs called benzodiazepines.

General Cautions

- Halcion should not be used during pregnancy. Some sleeping pills have been linked to birth defects when taken during the early months of pregnancy. Sedation and withdrawal effects have been seen in newborn infants of mothers who had taken sleeping pills late in pregnancy.
- Do not drink alcohol while taking Halcion.
- Halcion can make you sleepy, drowsy, dizzy, lightheaded, and less physically coordinated. Be careful doing anything hazardous that requires you to be mentally alert. Do not drive a car or operate any dangerous machinery until you know how the drug affects you.
- Check with your doctor before taking any other medicines. Be especially careful about any medicines that can make you drowsy.

Proper Use

You should take Halcion only when 7 to 8 hours of sleep is possible. Take the dose your doctor prescribes. Do not increase the dose without consulting your doctor. Insomnia is often a short-term problem. It can be treated by a brief course of Halcion (7 to 10 days). When used for longer periods, Halcion's effectiveness may decrease and the risk of side effects may increase. You must discuss with your doctor the risks and benefits of continuing to use Halcion for more than a week.

Possible Side Effects

Next-Day Drowsiness: All sleeping pills can make you drowsy the next day. Although Halcion may cause less next-day drowsiness than some other sleeping pills, you should take the lowest effective dose possible. Do not take Halcion when you need to be alert but cannot get 7 to 8 hours of sleep (for example, on a short airplane flight).

Memory Problems: All sleeping pills can cause memory loss (amnesia) for several hours after taking the drug. This is not generally a problem because people are usually asleep during this period. Halcion may be more likely than some other sleeping pills to cause memory loss. If you will need to be awakened within several hours after falling asleep, you should not take Halcion.

Withdrawal: All sleeping pills may have withdrawal effects when they are stopped. Halcion may be more likely than some other sleeping pills to have such problems. When Halcion is stopped, you may temporarily have worse insomnia than when you started taking it. This withdrawal effect may be accompanied by unpleasant feelings. Less common withdrawal effects include abdominal and muscle cramps, vomiting, sweating, tremors (shakes), and rarely, convulsions. Withdrawal effects are more common and more severe after longer use.

Halcion may cause withdrawal effects between doses. You may have more problems sleeping during the last third of the night or you may be nervous during the day.

Dependence: If Halcion is used for more than a few weeks, you may become "dependent" upon the drug. You may feel increased urgency to continue to take it or to increase the dose.

Mental and Behavior Changes: Changes in thinking and behavior have been reported by people taking Halcion and other sleeping pills. As with alcohol intoxication, sometimes people become more uninhibited, outgoing, or aggressive. More unusual changes include confusion, strange behavior, agitation, hallucinations, worsening of depression, and suicidal thinking. It is not known if these more unusual changes are caused by the drug, by some underlying illness, or have another cause. It is important to discuss any such changes in thinking or behavior with your doctor.

Each 0.125 mg tablet is white and round, engraved with HALCION .125 on one side and UP on the other. Each 0.25 mg tablet is green and round, with HALCION .25 on one side and UP on the other.

If you suspect that someone may have taken more than the prescribed dose of this medicine, contact your local poison control center or emergency room immediately. This medication was prescribed for your particular condition. Do not use it for another condition or give the drug to others.

This leaflet provides a summary of information about Halcion. Medicines are sometimes prescribed for uses other than those listed in a Medication Guide. If you have any questions or concerns, or want more information about Halcion, contact your doctor or pharmacist. Your pharmacist also has a longer leaflet about Halcion that is written for health professionals that you can ask to read.

[name of company]
[revision date]

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Medication Guide

Diltiazem tablets

Summary

Diltiazem (pronounced Dill-tie-a-zehm) is used to treat angina pectoris (chest pain).

- Diltiazem may lower your blood pressure. If you get dizzy while using Diltiazem, call your doctor.
- Diltiazem can interact with certain medications. Check with your doctor if you are taking a beta-blocker, cimetidine, or digitalis.
- You should not use Diltiazem if you have certain heart conditions.
- If you notice very slow heart rate, palpitations, or feel very weak, call your doctor.

Uses

Diltiazem is used to treat angina pectoris (chest pain caused by narrowing of an artery in the heart). Diltiazem relaxes or dilates blood vessels in the body. This increases blood flow to the heart and helps reduce chest pain. Diltiazem is in a class of drugs known as calcium channel blockers.

Cautions

- **Heart Problems:** Your doctor needs to know if you have low blood pressure, heart block, a pacemaker, heart failure, or any other heart problem. Some patients with these conditions should not take Diltiazem.
- **Liver or Kidney Problems:** Your doctor needs to know if you have any liver or kidney problems. Your doctor may need to monitor the effect of Diltiazem on your liver or kidneys and may need to adjust the dose that you take.
- **Pregnancy:** The use of Diltiazem in pregnant women has not been studied. Studies with animals suggest, however, that Diltiazem may cause birth defects or stillbirths. Therefore, you should only use Diltiazem during pregnancy if you and your doctor believe the benefits of using it outweigh the risks.
- **Nursing Mothers:** Diltiazem is passed on to the child through breast milk. If you must take Diltiazem, use some other form of infant feeding.

Diltiazem can interact with several other medications. Your doctor may need to change the dosage of Diltiazem or your other medicines. **Check with your doctor before taking the following medicines:**

- beta-blocker drugs (used for high blood pressure and other heart conditions);
- cimetidine (used for ulcers); and
- digitalis (used for heart failure or other heart problems).

Proper Use

You should take this medicine before meals if possible. If you miss taking a dose of Diltiazem, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and take your medicine as scheduled. Do not double your prescribed dose.

Possible Side Effects

The most common side effects of using Diltiazem are edema (swelling of the legs), headache, dizziness, rash, and weakness.

A small number, (less than 1/2 [illegible] patients taking Diltiazem) [illegible] heart palpitations, very slow heart rate or missed heart beats. If you notice a very slow heart beat, palpitations, or feel very weak, call your doctor.

Also, call your doctor if you have:

- Difficulty breathing (this may be a sign of heart failure)
- Dizziness (this may be a sign of low blood pressure).

Each 30mg tablet is green and round, engraved with COPLEY 631. Each 60mg tablet is yellow and round, engraved with COPLEY 662. Each 90mg tablet is green and oblong, engraved with COPLEY 691. Each 120mg tablet is yellow and oblong, engraved with COPLEY 720.

If you suspect that someone may have taken more than the prescribed dose of this medicine, contact your local poison control center or emergency room immediately. This medication was prescribed for your particular condition. Do not use it for another condition or give the drug to others.

This leaflet provides a summary of information about Diltiazem. Medicines are sometimes prescribed for uses other than those listed in a Medication Guide. If you have any questions or concerns, or want more information about Diltiazem, contact your doctor or pharmacist. Your pharmacist also has a longer leaflet about Diltiazem that is written for health professionals that you can ask to read.

[name of company]
[revision date]

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Medication Guide

Ceclor

(generic name = cefaclor for oral suspension)

What is the most important information I should know about Ceclor?

Ceclor (pronounced SEE-klor) is used to treat infections caused by certain bacteria. You should not take Ceclor if you are allergic to penicillin or other similar antibiotics. Allergic reactions to Ceclor, as with other drugs, can be fatal. If you experience difficulty breathing, swelling of the throat, rash, or severe diarrhea or abdominal pain, call your doctor immediately or seek medical help

- Take Ceclor for the full amount of time prescribed by your doctor, even if you feel better.

Shake your bottle well every time before taking Ceclor.

Ceclor is used to treat infections caused by certain bacteria. These infections include middle ear, bladder, and skin infections, as well as strep throat, pneumonia and chronic bronchitis. Ceclor works by killing certain bacteria or preventing them from growing. It works only for certain bacteria and not for others. Your doctor may need to get results from laboratory tests or cultures to make sure you are taking the correct antibiotic. Ceclor will not work for colds, flu, or any viral infection. Ceclor is in a class of drugs known as cephalosporin antibiotics.

Before Taking Your Medicine

Check with your doctor if you:

have abdominal problems such as colitis

are pregnant

are nursing

are a diabetic and checking your urine for sugar: Ceclor can interfere with the urine test you may be using to test for sugar.

are taking other medications: Do not take this drug if you are allergic to penicillin or any other cephalosporin-class antibiotic because it is likely that you may also be allergic to Ceclor.

While You Are Taking Your Medicine

Continue taking Ceclor even if you feel better. Be sure to take all of the medication for the length of time prescribed for you. If you stop taking your medication too soon, the bacteria can grow back and you may get sick again with the same infection. If you miss taking a dose of Ceclor, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and take your medicine as scheduled. Do not take double your prescribed dose.

The most common side effects are mild upset stomach, diarrhea, and rash. Call your doctor if these side effects persist or are bothersome.

Call your doctor if the following side effects occur:

- Swelling of the throat or difficulty breathing
- Hives, itching, and rash
- Severe or bloody diarrhea
- Abdominal pain
- Tiredness or faintness (that lasts after taking this medication
- Fever (that lasts after taking this medication for 24 hours)
- Joint aches or stiffness (that lasts after taking this medication for 24 hours)

Shake your bottle well every time before taking this medicine.

Keep Ceclor in the refrigerator. Throw away any unused portion after the expiration date.

Each teaspoon (5ml) of Ceclor for Oral Suspension contains either 125, 250, or 375 mg of cefaclor monohydrate and is pink in color.

If you suspect that someone may have taken more than the prescribed dose of this medicine, contact your local poison control center or emergency room immediately. This medication was prescribed for your particular condition. Do not use it for another condition or give the drug to others.

This leaflet provides a summary of information about Ceclor. Medicines are sometimes prescribed for uses other than those listed in a Medication Guide. If you have any questions or concerns, or want more information about Ceclor, contact your doctor or pharmacist. Your pharmacist also has a longer leaflet about Ceclor that is written for health professionals that you can ask to read.

[name of company]
[revision date]

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Medication Guide

Cardizem

(generic name = diltiazem tablets)

What is the most important information that I should know about Cardizem?

Cardizem (pronounced KAR-de-zem) is used to treat angina pectoris (chest pain).

- Cardizem may lower your blood pressure. If you get dizzy while using Cardizem, call your doctor.
- Cardizem can interact with certain medications. Check with your doctor if you are taking a beta-blocker, cimetidine, or digitalis.
- You should not use Cardizem if you have certain heart conditions.
- If you notice very slow heart rate, palpitations, or feel very weak, call your doctor.

Cardizem is used to treat angina pectoris (chest pain caused by narrowing of an artery in the heart). Cardizem relaxes or dilates blood vessels in the body. This increases blood flow to the heart and helps reduce chest pain. Cardizem is in a class of drugs known as calcium channel blockers.

Before Taking Your Medicine

If you have heart problems: Your doctor needs to know if you have low blood pressure, heart block, a pacemaker, heart failure, or any other heart problem. Some patients with these conditions should not take Cardizem.

If you have liver or kidney problems: Your doctor needs to know if you have any liver or kidney problems. Your doctor may need to monitor the effect of Cardizem on your liver or kidneys and may need to adjust the dose that you take.

If you are pregnant: The use of Cardizem in pregnant women has not been studied. Studies with animals suggest, however, that Cardizem may cause miscarriages or stillbirths. Therefore, you should only use Cardizem during pregnancy if you and your doctor believe the benefits of using it outweigh the risks.

If you are nursing: Cardizem is passed on to the child through breast milk. If you must take Cardizem, use some other form of infant feeding.

If you are taking other medications: Cardizem can interact with other medications. Your doctor may need to change the dosage of Cardizem or your other medicines. Check with your doctor before taking the following medicines:

- beta-blocker drugs (used for high blood pressure and other heart conditions);
- cimetidine (used for ulcers); and
- digitalis (used for heart failure or other heart problems)

While You Are Taking Your Medicine

You should take this medicine before meals if possible. If you miss taking a dose of Cardizem, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and take your medicine as scheduled. Do not take double your prescribed dose.

Call your doctor if the following side effects occur:

The most common side effects of using Cardizem are edema (swelling of the legs), headache, dizziness, rash, and weakness.

A small number, (less than 1/2 percent), of patients taking Cardizem get heart palpitations, very slow heart rate or missed heart beats. If you notice a very slow heart beat, palpitations, or feel very weak, call your doctor.

Call your doctor if you have:

- Difficulty breathing (this may be a sign of heart failure)
- Dizziness (this may be a sign of low blood pressure).

Each 30mg tablet is green and round, engraved with MARION on one side and 1771 on the other. Each 60mg tablet is yellow and round, engraved with MARION on one side and 1772 on the other. Each 90mg tablet is green and oblong, engraved with CARDIZEM on one side and 90mg on the other. Each 120mg tablet is yellow and oblong, engraved with CARDIZEM on one side and 120mg on the other.

If you suspect that someone may have taken more than the prescribed dose of this medicine, contact your local poison control center or emergency room immediately. This medication was prescribed for your particular condition. Do not use it for another condition or give the drug to others.

This leaflet provides a summary of information about Cardizem. Medicines are sometimes prescribed for uses other than those listed in a Medication Guide. If you have any questions or concerns, or want more information about Cardizem, contact your doctor or pharmacist. Your pharmacist also has a longer leaflet about Cardizem that is written for health professionals that you can ask to read.

[name of company]
[revision date]

This Medication Guide has been approved by the U.S. Food and Drug Administration.

PROTOTYPE

Medication Guide

Halcion

(generic name = triazolam tablets)

What is the most important information I should know about Halcion?

Halcion (pronounced HAL-see-on) is used to help you sleep.

- For many patients, Halcion should be used for a brief period (7 to 10 days). Halcion's effectiveness may decrease with longer use.
- Important risks of Halcion include: (1) memory problems, (2) withdrawal effects, (3) dependence, and (4) the possibility of serious mental and behavioral changes. The risk of these problems may increase with longer use.
- There are important cautions to consider while taking Halcion. Do not increase the dose or take other medicines without your doctor's advice. Avoid using alcohol. Avoid driving or other activities that require you to be alert until you know how this medication will affect you. Do not take Halcion if you are pregnant.

Halcion treats insomnia (difficulty in falling asleep, frequent awakening during the night, or early morning awakening). Halcion is in a class of drugs called [illegible] sedatives.

Before Taking Your Medicine

If you are pregnant: Halcion should not be used during pregnancy. Some sleeping pills have been linked to birth defects when taken during the early months of pregnancy. Sedation and withdrawal effects have been seen in newborn infants of mothers who had taken sleeping pills late in pregnancy.

While You Are Taking Your Medicine

- You should take Halcion only when 7 to 8 hours of sleep is possible.
- Take the dose your doctor prescribes. Do not increase the dose without consulting your doctor.
- Insomnia is often a short-term problem. It can be treated by a brief course of Halcion (7 to 10 days). When used for longer periods, Halcion's effectiveness may decrease and the risk of side effects may increase. You must discuss with your doctor the risks and benefits of continuing to use Halcion for more than a week.
- Do not drink alcohol while taking Halcion.
- Halcion can make you sleepy, drowsy, dizzy, lightheaded, and less physically coordinated. Be careful doing anything hazardous that requires you to be mentally alert. Do not drive a car or operate any dangerous machinery until you know how the drug affects you.
- Check with your doctor before taking any other medicines. Be especially careful about any medicines that can make you drowsy.

Call your doctor if the following side effects occur:

Next-Day Drowsiness: All sleeping pills can make you drowsy the next day. Although Halcion may cause less next-day drowsiness than some other sleeping pills, you should take the lowest effective dose possible. Do not take Halcion when you need to be alert but cannot get 7 to 8 hours of sleep (for example, on a short airplane flight).

Memory Problems: All sleeping pills can cause memory loss (amnesia) for several hours after taking the drug. This is not generally a problem because people usually are asleep during this period. Halcion may be more likely than some other sleeping pills to cause memory loss. If you will need to be awakened within several hours after falling asleep, you should not take Halcion.

Withdrawal: All sleeping pills may have withdrawal effects when they are stopped. Halcion may be more likely than some other sleeping pills to have such problems. When Halcion is stopped, you may temporarily have worse insomnia than when you started. Another withdrawal effect includes unpleasant feelings. Less common withdrawal effects include abdominal and muscle cramps, vomiting, sweating, tremors (shakes), and rarely, convulsions. Withdrawal effects are more common and more severe after longer use.

Halcion may cause withdrawal effects between doses. You may have more problems sleeping during the last third of the night or you may be nervous during the day.

Dependence: If Halcion is used for more than a few weeks, you may become [illegible] upon the drug. You may feel increased urgency to continue to take it [illegible] the dose.

[illegible] Behavior Changes: Changes in thinking and behavior have been reported by people taking Halcion and other sleeping pills. As with alcohol intoxication, sometimes people taking Halcion become more uninhibited, outgoing, or aggressive. More unusual changes include confusion, strange behavior, agitation, hallucinations, worsening of depression, and suicidal thinking. It is not known if these more unusual changes are caused by the drug, by some underlying illness, or have another cause. It is important to discuss any such changes in thinking or behavior with your doctor.

Each 0.125 mg tablet is white and round engraved with HALCION .125 on one side and 10 on the other. Each 0.25 mg tablet is green and round with HALCION .25 on one side and 17 on the other.

If you suspect that someone may have taken more than the prescribed dose of this medicine, contact your local poison control center or emergency room immediately. This medication was prescribed for your particular condition. Do not use it for another condition or give the drug to others.

This leaflet provides a summary of information about Halcion. Medicines are sometimes prescribed for uses not listed in a Medication Guide. If you have any questions or concerns, or want more information about Halcion, contact your doctor or pharmacist. Your pharmacist also has a longer leaflet about Halcion that is written for health professionals that you can read.

[name of company]
[revision date]

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Medication Guide

Diltiazem tablets

What is the most important information that I should know about Diltiazem?

Diltiazem (pronounced DIL-tie-a-zehm) is used to treat angina pectoris (chest pain).

- Diltiazem may lower your blood pressure. If you get dizzy while using Diltiazem, call your doctor.
- Diltiazem can interact with certain medications. Check with your doctor if you are taking a beta-blocker, cimetidine, or digitalis.
- You should not use Diltiazem if you have certain heart conditions.
- If you notice very slow heart rate, palpitations, or feel very weak, call your doctor.

Diltiazem is used to treat angina pectoris (chest pain caused by narrowing of an artery in the heart). Diltiazem relaxes or dilates blood vessels in the body. This increases blood flow to the heart and helps relieve angina. Diltiazem is in a class of drugs known as calcium channel blockers.

Before Taking Your Medicine

If you have heart problems: Your doctor needs to know if you have low blood pressure, heart block, a pacemaker, heart failure, or any other heart problem. Some patients with these conditions should not take Diltiazem.

If you have liver or kidney problems: Your doctor needs to know if you have any liver or kidney problems. Your doctor may need to monitor the effect of Diltiazem on your liver or kidneys and may need to adjust the dose that you take.

If you are pregnant: The use of Diltiazem in pregnant women has not been studied. Studies with animals suggest, however, that Diltiazem may cause miscarriages or stillbirths. Therefore, you should only use Diltiazem during pregnancy if you and your doctor believe the benefits of using it outweigh the risks.

If you are nursing: Diltiazem is passed on to the child through breast milk. If you must take Diltiazem, use some other form of infant feeding.

If you are taking other medications: Diltiazem can interact with other medications. Your doctor may need to change the dosage of Diltiazem or your other medicines. Check with your doctor before taking the following medicines:

- beta-blocker drugs (used for high blood pressure and other heart conditions);
- cimetidine (used for ulcers); and
- digitalis (used for heart failure or other heart problems)

While You Are Taking Your Medicine

You should take this medicine before meals if possible. If you miss taking a dose of Diltiazem, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and take your medicine as scheduled. Do not take double your prescribed dose.

Call your doctor if the following side effects occur:

The most common side effects of using Diltiazem are edema (swelling of the legs), headache, dizziness, rash, and weakness.

A small number, (less than 1/2 percent), of patients taking Diltiazem get heart palpitations, very slow heart rate or missed heart beats. If you notice very slow heart beat, palpitations, or feel very weak, call your doctor.

Other side effects: Insomnia, nervousness, trembling (this may be a sign of heart failure)
- Dizziness (this may be a sign of low blood pressure).

Each 30mg tablet is green and round, engraved with COPLEY 631. Each 60mg tablet is yellow and round, engraved with COPLEY 662. Each 90mg tablet is green and oblong, engraved with COPLEY 691. Each 120mg tablet is yellow and oblong, engraved with COPLEY 720.

If you suspect that someone may have taken more than the prescribed dose of this medicine, contact your local poison control center or emergency room immediately. This medication was prescribed for your particular condition. Do not use it for another condition or give the drug to others.

This leaflet provides a summary of information about Diltiazem. Medicines are sometimes prescribed for uses other than those listed in a Medication Guide. If you have any questions or concerns, or want more information about Diltiazem, contact your doctor or pharmacist. Your pharmacist also has a longer leaflet about Diltiazem that is written for health professionals that you can ask to read.

[illegible]

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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