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WHO: Sponsored by the Office of the Federal Register.

WHAT: Free public briefings (approximately 3 hours) to present:

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WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WASHINGTON, DC

[Two Sessions]

WHEN: February 6, 1996 at 9:00 am and February 21, 1996 at 9:00 am

WHERE: Office of the Federal Register Conference Room, 800 North Capitol Street, NW., Washington, DC (3 blocks north of Union Station Metro)

RESERVATIONS: 202–523–4538

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Additional information, including a list of public laws, telephone numbers, and finding aids, appears in the Reader Aids section at the end of this issue.

New Feature in the Reader Aids!

Beginning with the issue of December 4, 1995, a new listing will appear each day in the Reader Aids section of the **Federal Register** called "Reminders". The Reminders will have two sections: "Rules Going Into Effect Today" and "Comments Due Next Week". Rules Going Into Effect Today will remind readers about Rules documents published in the past which go into effect "today". Comments Due Next Week will remind readers about impending closing dates for comments on Proposed Rules documents published in past issues. Only those documents published in the Rules and Proposed Rules sections of the **Federal Register** will be eligible for inclusion in the Reminders.

The Reminders feature is intended as a reader aid only. Neither inclusion nor exclusion in the listing has any legal significance.

The Office of the Federal Register has been compiling data for the Reminders since the issue of November 1, 1995. No documents published prior to November 1, 1995 will be listed in Reminders.

Electronic Bulletin Board

Free **Electronic Bulletin Board** service for Public Law numbers, **Federal Register** finding aids, and a list of documents on public inspection is available on 202–275–1538 or 275–0920.

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Parts 53 and 54

[No. LS–94–009]

Standards for Grades of Slaughter Cattle and Standards for Grades of Carcass Beef

AGENCY: Agricultural Marketing Service (AMS), USDA.

ACTION: Final rule.

SUMMARY: This final rule revises the official U.S. standards for grades of carcass beef and the related standards for grades of slaughter cattle. The changes eliminate "B" maturity (approximately 30–42 months of age) carcasses with small or slight marbling degrees from the Choice and Select grades and include them in the Standard grade. This action is being taken because carcasses with these characteristics have been shown to be both quite variable and often unacceptable in palatability, which contributes significantly to inconsistent palatability of Choice and Select grade beef. The standards for grades of slaughter cattle, which are based on the beef carcass grades, are revised to parallel the changes in the beef carcass grade standards. This change should serve to strengthen the competitive position of beef products through increased quality and consistency, and thus be in the best interests of the beef industry. Also, it should provide the consumer with an improved product through greater consistency and predictability in the eating quality of Choice and Select grade beef. The changes should provide the industry with long-term benefits because pricing systems will be improved, quality inconsistencies will be reduced, demand for beef will be improved, and the market share beef commands should increase. These revisions are the same as those proposed in the January 19, 1995, Federal Register (60 FR 3982).

EFFECTIVE DATE: July 1, 1996.

FOR FURTHER INFORMATION CONTACT: Herbert C. Abraham, Chief, Livestock and Meat Standardization Branch, Livestock and Seed Division, Agricultural Marketing Service, U.S. Department of Agriculture, P.O. Box 96456, Washington, D.C. 20090–6456, 202/720–4486.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

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

Executive Order 12778

This rule has been reviewed under Executive Order 12778, Civil Justice Reform. This action is not intended to have retroactive effect. This rule would not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule. There are no administrative procedures which must be exhausted prior to any judicial challenge to the provisions of this rule.

Regulatory Flexibility Act

The Administrator, Agricultural Marketing Service (AMS), has certified that this action will not have a significant economic impact on a substantial number of small entities, as defined in the Regulatory Flexibility Act, P.L. 96–345 (5 U.S.C. 601). The use of the beef carcass and slaughter cattle grade standards is voluntary, and they are applied equally to all size entities covered by these regulations. Further, this action does not impose any new requirements or costs, it only modifies the grade requirements to reflect modern production practices. All entities can make needed management changes in response to market signals. The action is expected to benefit the industry by improving consumer satisfaction with beef products, and there should be a positive impact on overall industry returns.

Background

Federal beef grading is a voluntary fee for service program, provided under the Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1621 *et seq.*). A primary purpose of the grades is to divide the population of cattle and beef into uniform groups (of similar quality, yield, value, etc.), in order to facilitate marketing. Grades provide a simple, effective means of describing a product that is easily understood by both buyers and sellers. By identifying separate and distinct segments of a commodity, grades enable buyers to obtain that particular portion of the entire range of a commodity which meets their individual needs. At the same time, grades are important in transmitting information to cattle producers so that more informed production decisions can be made. For example, the market preference for a particular grade of beef can be communicated to cattle producers so they can adjust their production accordingly.

When beef is voluntarily graded, the official grade consists of a quality grade and/or a yield grade. The quality grades are intended to identify differences in the palatability (eating satisfaction) of cooked beef primarily through the combined characteristics of marbling and maturity. The principal official USDA quality grades for young (maturity groups A and B) cattle and carcasses are Prime, Choice, Select, and Standard.

In developing the grades, the Department has followed the philosophy that, to be effective, beef grades should sort the supply of beef carcasses into homogeneous groups having a sufficiently narrow range of grade-determining factors so that carcasses within a given grade are essentially interchangeable. Another major objective is to provide as uniform and consistent product as possible within a given grade.

National Cattlemen's Association Petition

In June 1994, the National Cattlemen's Association (NCA) petitioned USDA to modify the beef quality grade standards by removing B-maturity carcasses with small and slight marbling scores from the Choice and Select grades and include such carcasses in the Standard grade. This action was recommended by a NCA Carcass Quality Task Force which worked for approximately 1½ years to develop specific recommendations for the beef industry to win the "war on fat," while enhancing beef quality and consistency. The task force had broad representation

from the cattle production and feeding sectors, as well as packers, purveyors, and retailers. Several actions were recommended, but only this particular recommendation related directly to the beef grade standards.

The NCA petition stated the modern beef animal today is typically marketed at 12 to 15 months of age when fed as calves and 18 to 24 months of age when fed as yearlings. These modern animals are the result of progressive breeders and feeders who produce faster growing, more efficient cattle. If these animals receive proper care and nutrition, they should have no difficulty producing carcasses in the A-maturity group. Carcasses of B-maturity are typically from cattle which are 30 to 42 months of age when marketed.

Research conducted for the Department by Texas A&M University (Smith *et al.*, 1984, Journal of Food Quality), using trained taste panels, indicates that nearly 50 percent of the loin steaks from B-maturity carcasses with slight marbling, and over 30 percent of the loin steaks from B-maturity carcasses with small marbling, are less than satisfactory. These B-maturity carcasses significantly contribute to the variability of palatability within the Select and Choice grades and they do not epitomize the "modern beef carcass." Permitting B-maturity carcasses with a small and slight degree of marbling to be graded Choice and Select when they have been proven to be considerably more variable in palatability than A-maturity carcasses with slight and small marbling provides no incentives for the beef industry to decrease production and marketing of cattle which do not conform to consumer demand for quality and consistency.

Although these cattle make up only a small percentage of the U.S. fed beef supply, their variability in palatability can significantly affect overall consumer satisfaction with beef. According to a national beef quality audit conducted in 1991, B-maturity carcasses with slight and small marbling made up about 4.8 percent of the fed-beef supply. The beef industry processes approximately 26 million fed beef carcasses annually. The estimated 4.8 percent of fed-beef affected by the proposed grade change would represent approximately 1.3 million carcasses. It is estimated that 42 percent of these carcasses would have less than desirable palatability. This means over 500,000 carcasses with less than desirable palatability could be removed from the Choice and Select grades, which should have a very positive effect on consumer satisfaction with beef. The NCA believes producers can and will respond quickly to the market signals that these "older" cattle should be marketed at an age at which they can produce A-maturity carcasses and thus produce beef that is more acceptable to consumers. Such a shift in management could effectively eliminate most B-maturity carcasses from the beef supply without negatively affecting overall economic returns to the industry.

The proposed change was seen as having a positive effect on the marketing of Select grade beef. It would not only make the palatability more consistent, but it would also make the nutritional profile more consistent by removing from the Select grade, B-maturity carcasses which have higher amounts of fat due to the higher marbling level (small in B-maturity compared to slight in A-maturity) required for these carcasses to qualify for Select. This makes the Select grade more uniform in both fat content and consistency of palatability and enhance its acceptance by consumers who desire leaner beef. Since the U.S. Good name was changed to U.S. Select in 1987 (52 FR 35679), the percentage of Select graded beef has steadily increased, and in FY 93, 33.6 percent of graded steer and heifer beef was Select.

The NCA recommendation stated it was submitted to aid the beef industry in producing a higher quality, more consistent beef product under the Choice and Select grades. Eliminating B-maturity carcasses will allow market forces to further discourage the production of cattle which do not conform to consumers desire for tender, tasty beef products. The modern beef animal raised using modern breeding and feeding technology should have no trouble producing a carcass of A-maturity. The small proposed modification to the standards will strengthen consumer confidence in using grades to identify quality and consistency when purchasing beef.

Proposed Standards

The Department carefully evaluated the recommendation and concurred that the suggested changes should improve consumer satisfaction with the Choice and Select grades and thus strengthen the competitive position of beef in the marketplace while aiding the beef industry in its objective of providing more palatable, consistent beef to consumers.

Therefore, it was proposed that the beef carcass standards be revised to eliminate B-maturity (approximately 30–42 months of age) carcasses with small or slight marbling degrees from the Choice and Select grades and reduce their grade to Standard.

It was also proposed that the standards for grades of slaughter cattle, which are based on the beef carcass grade standards, be revised to reflect the changes proposed for the beef carcass grade standards. Grades of slaughter cattle are intended to be directly related to the grades of the carcasses they produce.

Comments

A 90-day comment period, which closed on April 19, 1995, was provided for submission of comments. The official number of comments submitted prior to the close of the comment period was 403. In addition, approximately 65 comments were received which were submitted after the close of the comment period. These 65 comments expressed essentially the same views as the 403 comments submitted in a timely manner. All submitted comments are part of the public record on the proposed change and are available for public review. The comments were divided into several groups (sectors) representing segments of the production and consumption chain with similar interests. The comments were also classified as being submitted by an individual or an organization. The distribution of comments by these categories is shown in Table 1.

The percentage support/opposition for the proposed change by source and classification (i.e., individual or organization) is shown in Table 2. Over 70 percent of the comments from both individuals and organizations supported the proposed change. The proposed change was strongly supported by the purveyor and processor, retail and restaurant, consumer, government, and academia sectors. Of the comments from these sectors, only two individual comments were opposed to the proposed changes. The strongest opposition to the proposed changes was from the cattle feeding, cattle marketing, and the packer sectors. All comments from packers, all but one comment from the cattle marketing sector, and a majority of cattle feeders were opposed to the proposed changes. While the majority of cattle feeding and marketing sector comments were opposed, if they are combined with the comments from the cattle production sector, a large majority of comments from both organizations (71.4%) and individuals (63.0%) representing cattle interests (production, feeding, and marketing) supported the proposed change.

Table 1—DISTRIBUTION OF COMMENTS

Source	Organizations [1]	Individuals [2]	Total
Cattle production	27	171	198
Cattle Feeding	4	96	100
Cattle Marketing	3	8	11
Packer	2	4	6
Purveyor and processor	2	17	19
Retail and Restaurant	1	6	7
Consumer	0	34	34
Government	0	5	5
Academia	0	15	15
Other	0	8	8
Total	39	364	403

[1] Includes comments of state, regional, and national organizations.
[2] Includes comments of individuals, comments with multiple signers, and businesses.

TABLE 2.—COMMENTS IN FAVOR OF OR OPPOSED TO ADOPTION OF USDA PROPOSED CHANGES.[1]

Source	Favor		Oppose		Total
	Number	Percent	Number	Percent	
Cattle Production:					
Individuals [2]	131	77.1	39	22.9	170
Organizations	25	92.6	2	7.4	27
Cattle Feeding:					
Individuals [2]	40	42.1	55	57.9	95
Organizations	0	0	4	100.0	4
Cattle Marketing:					
Individuals	1	12.5	7	87.5	8
Organizations	0	0	3	100.0	3
Packer:					
Individuals	0	0	4	100.0	4
Organizations	0	0	2	100.0	2
Purveyor and Processor:					
Individuals	16	94.1	1	5.9	17
Organizations	2	100.0	0	0	2
Retail and Restaurant:					
Individuals	6	100.0	0	0	6
Organizations	1	100.0	0	0	1
Consumer:					
Individuals [2]	32	97.0	1	3.0	33
Organizations	0	—	0	—	0
Government:					
Individuals	5	100.0	0	0	5
Organizations	0	—	0	—	0
Academia:					
Individuals [2]	14	100.0	0	0	14
Organizations	0	—	0	—	0
Other:					
Individuals	7	100.0	0	0	7
Organizations	0	—	0	—	0
Total	280	70.2	119	29.8	399
Individuals	252	70.0	108	30.0	360
Organizations	28	71.2	11	28.2	39

[1] Includes all written comments except 4 which were nonresponsive or noncommittal regarding the proposed changes.
[2] One comment from this source was nonresponsive or noncommittal regarding the proposed changes.

Comments in favor of the change strongly supported the removal of B-maturity carcasses with small and slight marbling from the Choice and Select grades. The proposed change was seen by many commenters as an opportunity to improve the overall quality of beef from these grades by removing a group of carcasses which only comprise a small percentage of the fed-beef supply, but contribute significantly to beef with less than desirable eating satisfaction for consumers. These commenters indicated that removal of a group of carcasses of which up to approximately 50 percent may produce an inconsistent, variable product which provides consumers with a less than desirable eating experience was a first step toward restoring consumer confidence and market share which has been eroding over the last several years. These comments expressed the view that any group of carcasses with this degree of variability should not be allowed in the Choice and Select grades if the industry is serious in its desire to be consumer driven.

Many supporters of the proposed change, including several from the academic sector, stated the scientific evidence strongly supports the proposed changes. These comments supported the conclusions of the NCA task force which concluded the scientific evidence supported the proposed changes. These studies indicated variability and inconsistency of palatability of beef with small and slight marbling in B-maturity was much greater than comparable levels of marbling in A-maturity, even though some data did not indicate significant differences in overall palatability. The high degree of inconsistency was cited by many

comments from the cattle production and feeding sectors as a situation which must be corrected. Consumption sectors (consumer, purveyor and processor, retail and restaurant) were also very concerned over product which failed to meet consumer desires. Supporters of the proposed changes postulated that few successful businesses would choose to do nothing if they found a product line with up to 50 percent customer dissatisfaction.

Many comments from cattle sectors and academia expressed the belief that a large majority of B-maturity carcasses are the result of management decisions that can be modified by the industry. Further, these comments stated that by sending a strong market signal that these cattle will not be included in the Choice and Select grades, management decisions can be made that will eliminate a large number of them from the fed-beef supply. Many supporters as well as opponents of the proposed changes indicated many B-maturity carcasses are from older "Mexican feeders" or first or second-calf heifers. Supporters strongly believed these management practices could be modified and were against allowing these types of cattle to be included in the same grades as properly managed, A-maturity cattle. Several cattle producers and/or feeders indicated they had taken advantage of the system that allowed these types of cattle to be included in the Choice and Select grades, but feel it is now time to take a positive step with long-term benefits in mind to improve the quality and consistency of beef.

Comments from cattle feeders, producers, and marketers which opposed the changes often stated the belief that there would be a significant negative economic impact. Estimates of over $100 million annually in lost revenue were predicted by some of these commenters. Similarly, comments from the packer sector indicated a projected reductions of $20 million to $78 million in revenue annually. These estimates were generally based solely on projected losses in value due to decreasing the grade of the affected B-maturity carcasses from Choice and Select to Standard. Some feeders and producers were concerned that the changes would simply be used by packers as an opportunity to further discount cattle, who would then pass the beef through the system as "no-roll" product that would not be discounted appropriately, thus providing an economic windfall for packers. These commenters also believed the beef targeted by the change would not be eliminated from the beef supply, but would simply be marketed in a different manner.

Several of the comments opposed to the changes expressed the concern that the changes "unfairly penalized" the approximately 50 percent of the affected B-maturity carcasses which are considered to produce "desirable" product. As discussed previously, supporters of the proposal believed any dissatisfaction level of this magnitude was extremely detrimental to consumer acceptance of beef. Several of the comments from cattle producers and feeders also expressed concern that the proposed changes would unfairly penalize operations that grazed older yearling cattle or fed "older Mexican" cattle or 1st or 2nd-calf heifers. These comments suggested that these cattle would be severely discounted in the market and would severely affect their production and marketing.

Some comments from the packing and cattle feeding sectors questioned the interpretation of the research considered in developing the proposal which indicated higher variability in palatability of B-maturity carcasses. A few of these comments indicated some studies showed beef of B-maturity to be similar to A-maturity beef in overall palatability. Two studies (National Consumer Retail Beef Study-1986 and Beef Customer Satisfaction-1994) were cited by a few commenters as showing consumers do not regard fed-beef as having palatability problems.

Evaluation of Comments

Supporters of the changes indicated the approximately 50 percent of B-maturity carcasses with less than desirable palatability have a significant negative impact on consumer satisfaction with beef. Many opponents of the changes did not disagree with the evidence of palatability problems in up to 50 percent of B-maturity carcasses. However, these commenters believed the remaining 50 percent of B-maturity carcasses would be "unfairly discounted" under the proposal. Even though it would be preferable to not exclude the approximately 50 percent of carcasses in B-maturity which have desirable eating satisfaction from the Choice and Select grades, no method for distinguishing these carcasses from those with undesirable eating satisfaction is currently available. Although these B-maturity carcasses with less than desirable palatability represent a relatively small portion of the fed-beef supply, AMS recognizes that the negative impact they can have on consumer satisfaction with Choice and Select beef supports their exclusion from these grades. AMS also has carefully reevaluated the supporting scientific evidence which compares the palatability of A and B-maturity beef and concludes there is strong evidence of greater variability of eating quality in B-maturity beef than in A-maturity beef. While some opponents of the proposed changes questioned some of the evidence, most of the comments (including several from opponents of the changes) supported the evidence. The two studies (National Consumer Retail Beef Study-1986 and Beef Customer Satisfaction-1994) cited by some opponents as evidence that the changes should not be made evaluated only A-maturity carcasses, B-maturity carcasses were not included in these studies. In addition to the scientific evidence, the very strong support for the proposed changes from the consumption sectors (purveyor, processor, retail, restaurant, and consumer) indicates that consumers desire a more consistent, less variable eating experience from beef products. The need for improved consumer satisfaction is evident, and this action should provide the industry with an opportunity to eliminate a source of beef from the Choice and Select grades that has been shown to be much more variable in palatability than A-maturity beef.

Commenters who both supported and opposed the proposed changes indicated several management practices which contribute to the production of B-maturity carcasses. These include feeding of "older Mexican" cattle and 1st and 2nd-calf heifers. While these types of cattle are not the only source of B-maturity carcasses, they potentially are a significant source. AMS believes these comments support the ability of the industry to identify many sources of B-maturity carcasses and either alter management practices to prevent their production as fed-beef or to merchandize them according to their value in the marketing system. Beef produced from such management systems cannot be properly marketed with beef produced from young, fed-cattle under 30 months of age because of the variability they introduce into the Choice and Select grades.

A few comments from "stocker" operators were concerned the changes would cause their cattle which are grazed up until about 20 months of age and leave the feedlot at about 23–24 months to be discounted because they would produce B-maturity carcasses. There is no evidence to indicate these cattle when properly managed and marketed would not produce A-maturity carcasses (approximately 30 months of age).

Supporters of the grade change generally indicated a belief that the proposed changes would have a beneficial long-term impact on the industry, but provided no monetary figures. Much of the opposition to the proposed changes was due to potential negative economic impact. Some opponents of the changes provided estimates of negative economic impact on the industry from $20 million to over $100 million annually. Because of the wide variation in the type and magnitude of the predicted impacts expressed by commenters, AMS concluded an independent economic study would better enable AMS to most effectively evaluate the proposed changes. AMS contracted with Dr. Wayne Purcell, Director, Research Institute on Livestock Pricing, Virginia Tech University, to conduct an independent economic analysis. Dr. Purcell is widely accepted by the industry as an authority on livestock marketing. His analysis has been made part of the public record on the proposed changes.

The economic impact study found if management strategies are not changed and the same number of B-maturity carcasses continue to be produced, a short-run negative impact on the industry of −$21 million could be projected. These immediate costs come from the reduced prices of B-maturity carcasses that are in the pipeline and from the price depressing influence of an increase in ungraded and processing beef as these carcasses are marketed. However, if management strategies are improved to eliminate even 25 percent of these B-maturity carcasses, a positive impact of $86 million would occur, and if 50 percent are eliminated due to management, a positive impact of $194 million would occur over an adjustment period of about 18 months. If credit is given to longer term benefits coming from improved demand as some of the quality inconsistency is eliminated, the benefits to the industry could easily exceed $1.0 billion across the next 10 years. This study concluded the benefits to the whole industry far outweigh short-run adjustments. Longer term, it concluded the entire industry would benefit because of improved pricing systems, reduction of quality inconsistencies, improved demand for beef, and a larger market share for beef.

AMS concludes that the industry can utilize improved management strategies to eliminate a portion of B-maturity carcasses from the fed-beef supply. AMS also concludes the economic impact study provides the most reliable indication of potential economic impacts from the changes. The projected negative impacts provided by some commentors generally only accounted for the decrease in value of the B-maturity carcasses which would not grade Choice or Select after the grade change. The commentors did not account for price-related benefits, improved consumer demand, or changes in the supply/demand price relationship for Choice and Select beef after removal of B-maturity carcasses. Many comments indicated producers and feeders have the ability to identify and manage differently cattle types which contribute significantly to production of B-maturity carcasses. What percentage of B-maturity carcasses will be eliminated and over what time period is difficult to predict. However, based on the comments and other information, it is reasonable to assume that improved management strategies will enable the industry to achieve a 25 percent reduction in the number of B-maturity carcasses in the first or second year of the change, if an adjustment period is provided prior to implementation of the change. A 25 percent reduction would enable the industry to realize the net benefits projected by the economic study of $86 million over the eighteen months following implementation of the change by removing an identifiable source of inconsistent quality from the Choice and Select grades and the fed-beef supply.

In consideration of the public comments submitted in response to the proposed rule of January 19, 1995 (60 FR 3982–3986), and all other available information, USDA adopts the proposed rule to revise the official U.S. standards for grades of carcass beef and the related standards for grades of slaughter cattle by eliminating "B" maturity (approximately 30–42 months of age) carcasses with small or slight marbling degrees from the Choice and Select grades and including them in the Standard grade. However, in order to allow the industry time to adjust its production and marketing practices and to market beef currently in the pipeline, implementation will be delayed until July 1, 1996.

List of Subjects

7 CFR Part 53

Cattle, Hogs, Livestock, Sheep.

7 CFR Part 54

Food grades and standards, Food labeling, Meat and meat products.

For the reasons set forth in the preamble, 7 CFR Part 53 and 7 CFR Part 54 are amended as follows:

PART 53—LIVESTOCK (GRADING, CERTIFICATION, AND STANDARDS)

1. The authority citation for Parts 53 and 54 continues to read as follows:

Authority: 7 U.S.C. 1621–1627.

2. In § 53.203, paragraph (b) (3) is revised to read as follows:

§ 53.203 Application of standards for grades of slaughter cattle.

* * * * *

(b) * * *

(3) The approximate maximum age limitation for the Prime, Choice, and Standard grades of steers, heifers, and cows is 42 months. The maximum age limitation for the Select grade for steers, heifers, and cows is approximately 30 months. The Commercial grade for steers, heifers, and cows includes only cattle over approximately 42 months. There are no age limitations for the Utility, Cutter, and Canner grades of steers, heifers, and cows. The maximum age limitation for all grades of bullocks is approximately 24 months.[1]

* * * * *

3. In § 53.204, paragraph (c) (1) is revised to read as follows:

§ 53.204 Specifications for official U.S. standards for grades of slaughter steers, heifers, and cows (quality).

* * * * *

(c) *Select.* (1) The Select grade is limited to steers, heifers, and cows with a maximum age limitation of approximately 30 months. Slaughter cattle possessing the minimum qualifications for Select have a thin fat covering which is largely restricted to the back and loin. The brisket, flanks, twist, and cod or udder are slightly full and the muscling is slightly firm.

* * * * *

PART 54—MEATS, PREPARED MEATS, AND MEAT PRODUCTS (GRADING, CERTIFICATION, AND STANDARDS)

4. Section 54.104 is revised by removing the word "Select" in paragraph (n), revising the third and fifth sentences in paragraph (o) and revising Figure 1 in paragraph (o) to read as follows:

§ 54.104 Application of standards for grades of carcass beef.

* * * * *

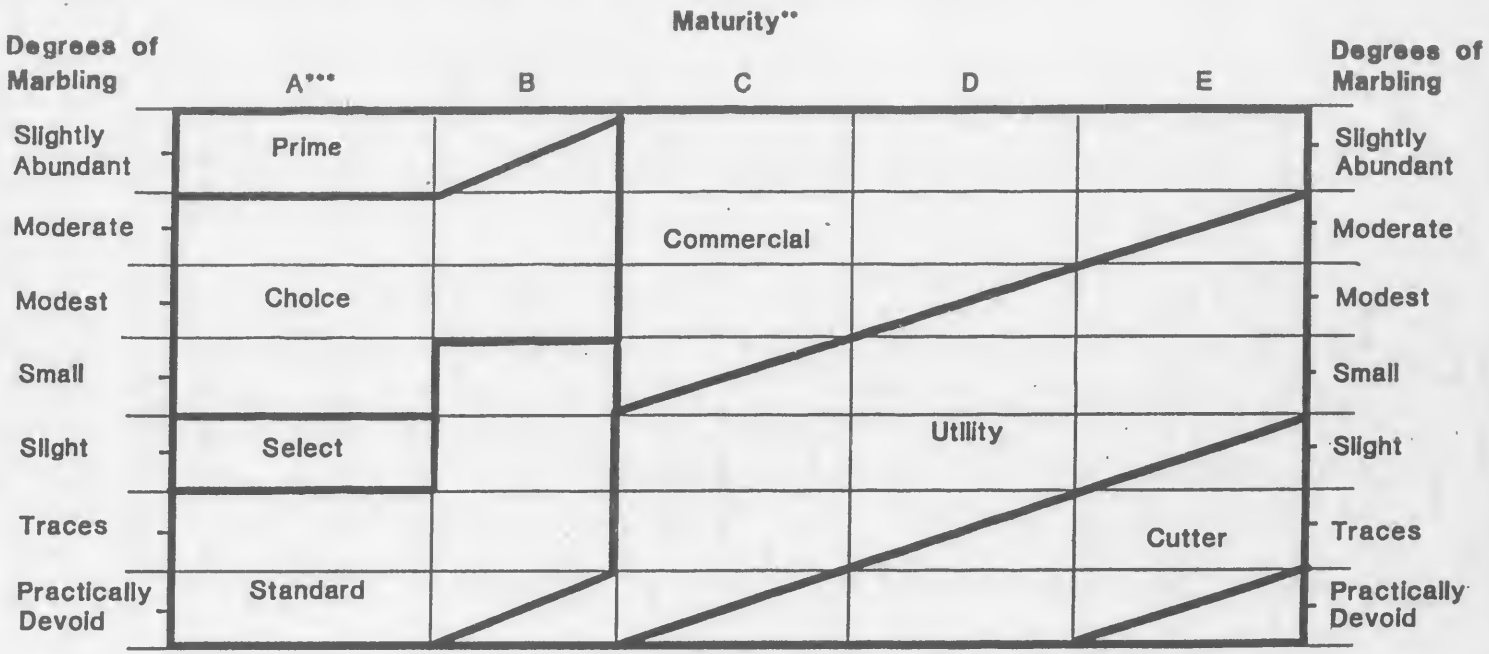
[1] Maximum maturity limits for bullock carcasses are the same as those described in the beef carcass grade standards for steers, heifers, and cows at about 30 months of age. However, bullocks develop carcass indicators of maturity at younger chronological ages than steers. Therefore, the approximate age at which bullocks develop carcass indicators of maximum maturity is shown herein as 24 months rather than 30 months.

(o) * * * The Prime, Choice, Select, and Standard grades are restricted to beef from young cattle; the Commercial grade is restricted to beef from cattle too mature for Prime, Choice, and Standard; and the Utility, Cutter, and Canner grades may include beef from animals of all ages. * * * Except for the youngest maturity group and the Choice grade in the second maturity group, within any specified grade, the requirements for marbling increase progressively with evidences of advancing maturity. * * *

BILLING CODE 3410-02-P

BILLING CODE 3410-02-C

Relationship Between Marbling, Maturity, and Carcass Quality Grade*



* Assumes that firmness of lean is comparably developed with the degree of marbling and that the carcass is not a "dark cutter."

** Maturity increases from left to right (A through E).

*** The A maturity portion of the Figure is the only portion applicable to bullock carcasses.

Figure 1

* * * * *

5. Section 54.106 is amended by revising the third sentence in paragraph (b) (3), revising paragraphs (c) (1) and (c) (2) and removing paragraph (c) (3) as follows:

§ 54.106 Specifications for official United States standards for grades of carcass beef (quality-steer, heifer, cow).

* * * * *

(b) * * *

(3) * * * In carcasses throughout the range of maturity included in this group, a minimum modest amount of marbling is required (see Figure 1) and the ribeye muscle is slightly firm.

(c) *Select* (1) For carcasses throughout the range of maturity permitted in the Select grade, the minimum degree of marbling required is a minimum slight amount (see Figure 1) and the ribeye may be moderately soft.

(2) Carcasses in the maturity group permitted range from the youngest that are eligible for the beef class to those at the juncture of the two youngest maturity groups, which have slightly red and slightly soft chine bones and cartilages on the ends of the thoracic vertebrae that have some evidence of ossification. In addition, the sacral vertebrae are completely fused and the cartilages on the ends of the lumbar vertebrae are nearly completely ossified. The rib bones are slightly wide and slightly flat and the ribeye muscle is slightly light red in color and is fine in texture.

* * * * *

Dated: January 25, 1996.

Kenneth C. Clayton,

Acting Administrator.

[FR Doc. 96–1816 Filed 1–26–96; 11:27 am]

BILLING CODE 3410–02–P

Foreign Agricultural Service

7 CFR Parts 1520, 2101, 2200, and 2507

Availability of Information to the Public and Removal of CFR Chapters

AGENCY: Foreign Agricultural Service.

ACTION: Final rule.

SUMMARY: This document revises regulations governing the availability of information to the public by the Foreign Agricultural Service (FAS) to reflect reorganizations of the Department of Agriculture since these regulations were first published. The Foreign Economic Development Service has been eliminated and both the Office of International Cooperation and Development and the Office of the General Sales Manager are part of FAS and will not have separate Freedom of Information Act responsibilities. Therefore, this regulation also removes 7 CFR parts 2101, 2200, and 2507 and their respective CFR chapters, relating to the availability of information by these offices. The regulation also makes other internal management changes to the regulations.

EFFECTIVE DATE: January 30, 1996.

FOR FURTHER INFORMATION CONTACT: Carolyn Harris, (202) 690–1851.

SUPPLEMENTARY INFORMATION: Pursuant to the reorganization of the Department of Agriculture under Public Law 103–354, the Secretary of Agriculture reassigned departmental functions relating to foreign agricultural programs to the Under Secretary of Agriculture for Farm and Foreign Agricultural Services. See 59 FR 66517, December 27, 1994. The Under Secretary delegated certain of those functions to the Administrator of the Foreign Agricultural Service. See 60 FR 56433, November 8, 1995. In this document, the Foreign Agricultural Service is amending regulations governing the availability of information to the public to reflect the reorganization of these functions.

This rule relates to internal agency management. Therefore, pursuant to 5 U.S.C. 553, notice of proposed rulemaking and opportunity for comment are not required, and this rule may be made effective less than 30 days after publication in the **Federal Register**. Further, since this rule relates to internal agency management, it is exempt from the provisions of Executive Order Nos. 12778 and 12866. This action is not a rule as defined by the Regulatory Flexibility Act, Pub. L. 96–354, and, thus, is exempt from the provisions of that Act.

List of Subjects in 7 CFR Parts 1520, 2101, 2200 and 2507

Freedom of information.

Accordingly, and under the authority of 5 U.S.C. 552, Title A of the Code of Federal Regulations is amended to read as follows:

CHAPTER XV

PART 1520—[AMENDED]

1. The authority citation for part 1520 continues to read as follows:

Authority: 5 U.S.C. 552.

2. Section 1520.3 is revised to read as follows:

§ 1520.3 Public inspection and copying.

5 U.S.C. 552(a)(2) requires that certain materials be made available for public inspection and copying. Members of the public may request access to such materials through the Information Division, FAS, Room 5074, South Building, Department of Agriculture, 14th Street and Independence Avenue, SW., Washington, DC 20250–1004. The office will be open from 8:30 a.m. to 5 p.m. Monday through Friday, except legal holidays.

3. Section 1520.4 is revised to read as follows:

§ 1520.4 Indexes.

5 U.S.C. 552(a)(2) required that each agency publish or otherwise make available a current index of all materials required to be made available for public inspection and copying. Copies of the FAS Index may be obtained free of charge by telephoning (202) 720–7115 or writing to the Freedom of Information Officer, Information Division, FAS, Ag Box 1004, Department of Agriculture, 14th Street and Independence Avenue SW., Washington, DC 20250–1004.

4. Section 1520.5 is revised to read as follows:

§ 1520.5 Request for records.

(a) Requests for records under 5 U.S.C. 552(a)(3) shall be made in accordance with 7 CFR 1.3(a) and addressed to the Freedom of Information Officer, Information Division, Foreign Agricultural Service, Ag Box 1004, Department of Agriculture, 14th Street and Independence Avenue, SW., Washington, DC 20250–1004.

(b) Processing of a request for information can be facilitated if "FOIA REQUEST" is placed in capital letters on the front of the envelope and at the top of the letter. Additional information may be obtained by telephoning the FAS Information Division on (202) 720–7115.

5. In section 1520.6, paragraph (a) is amended by removing "20250" and adding, in its place, "20250–1001", and paragraph (b) is amended by adding at the end thereof a new sentence to read as follows:

§ 1520.6 Appeals.

* * * * *

(b) * * * Additional information may be obtained by telephoning the FAS Information Division on (202) 720–7115.

CHAPTERS XXI, XXII, XXV—[REMOVED]

PARTS 2101, 2200, AND 2507—[REMOVED]

6. Parts 2101, 2200 and 2507 are removed and chapters XXI, XXII, and XXV are vacated.

Signed at Washington, DC on December 1, 1995.

August Schumacher, Jr.,

Administrator, Foreign Agricultural Service.

[FR Doc. 96–330 Filed 1–29–96; 8:45 am]

BILLING CODE 3410–10–M

Rural Housing Service

Rural Business-Cooperative Service

Rural Utilities Service

Farm Service Agency

7 CFR Chapter XVIII

Agency Name Change

AGENCIES: Rural Housing Service, Rural Business-Cooperative Service, Rural Utilities Service, and Farm Service Agency.

ACTION: Final rule.

SUMMARY: This document amends the regulations to change the names of the Rural Housing and Community Development Service to the Rural Housing Service and the Rural Business and Cooperative Development Service to the Rural Business-Cooperative Service as a result of the Department of Agriculture reorganization.

EFFECTIVE DATE: January 30, 1996.

FOR FURTHER INFORMATION CONTACT: Richard A. Gartman, Regulations and Paperwork Management Division, Rural Economic and Community Development, room 6348–S, Washington, DC 20250, telephone 202–720–9745.

SUPPLEMENTARY INFORMATION:

Background

The Secretary of Agriculture announced that the agency previously referred to as the Rural Housing and Community Development Service (RHCDS) is to be named the Rural Housing Service (RHS), and the agency previously referred to as the Rural Business and Cooperative Development Service (RBCDS) is to be named the Rural Business-Cooperative Service (RBS). On December 26, 1995, USDA published in the **Federal Register** (60 FR 66713) a final rule that contained redelegations of authority for the Department of Agriculture and changed the names of RHCDS to RHS and RBCDS to RBS. This rule includes amendments to 7 CFR chapter XVIII that are necessary to bring agency regulations into alignment with the departmental reorganization.

This action is not subject to the provisions of Executive Order 12866 since it involves only internal agency management. This action is not published for comment under the Administrative Procedure Act since it involves only internal agency management and publication for comment is unnecessary.

Accordingly, 7 CFR Chapter XVIII is amended as follows:

1. The heading of 7 CFR chapter XVIII is revised to read as follows:

CHAPTER XVIII—RURAL HOUSING SERVICE, RURAL BUSINESS-COOPERATIVE SERVICE, RURAL UTILITIES SERVICE, AND FARM SERVICE AGENCY, DEPARTMENT OF AGRICULTURE

2. In 7 CFR chapter XVIII, all references to "Rural Housing and Community Development Service" are revised to read "Rural Housing Service", all references to "Rural Business and Cooperative Development Service" are revised to read "Rural Business-Cooperative Service", all references to "RHCDS" are revised to read "RHS" and all references to "RBCDS" are revised to read "RBS".

Dated: January 23, 1996.

Arthur C. Campbell,

Acting Under Secretary, Rural Economic and Community Development.

[FR Doc. 96–1577 Filed 1–29–96; 8:45 am]

BILLING CODE 3410–07–U

FEDERAL RESERVE SYSTEM

12 CFR Part 211

[Regulation K; Docket No. R–0754]

Foreign Banking Organizations

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule.

SUMMARY: The Board is publishing amendments to Subpart B of Regulation K (Foreign Banking Organizations). The amendments permit the establishment of U.S. representative offices by certain foreign banks through prior notice procedures. These prior notice procedures are designed to permit foreign banks meeting certain requirements to establish representative offices without the need to file a formal application with the Board. A foreign bank that is subject to federal regulation under the Bank Holding Company Act (BHC Act), either directly or through the International Banking Act (IBA), and that the Board has previously determined is subject to comprehensive supervision or regulation on a consolidated basis by its home country supervisor, or which previously has been approved for a representative office by Board order, would be permitted to establish a full service representative office by prior notice. In addition, the amendments clarify that only those foreign banking organizations subject to the IBA and the BHC Act may establish under general consent procedures a representative office to engage in limited administrative functions in connection with their existing U.S. banking operations. Lastly, the Board has determined to review and act upon inquiries by "special purpose government banks" seeking exemptions from regulation under the Foreign Bank Supervision Enhancement Act (FBSEA) on the basis that they do not fall within the definition of "foreign bank" under Regulation K. Such inquiries would be handled on a case-by-case basis.

EFFECTIVE DATE: January 24, 1996.

FOR FURTHER INFORMATION CONTACT: Kathleen M. O'Day, Associate General Counsel (202/452–3786), Ann E. Misback, Managing Senior Counsel (202/452–6406), or Andres L. Navarrete, Attorney (202/452–2300), Legal Division; William A. Ryback, Associate Director (202/452–2722), Michael G. Martinson, Assistant Director (202/452–2798), or Betsy Cross, Manager (202/452–2574), Division of Banking Supervision and Regulation, Board of Governors of the Federal Reserve System. For the users of Telecommunication Device for the Deaf (TDD) only, please contact Dorothea Thompson (202/452–3544), Board of Governors of the Federal Reserve System, 20th and C Streets NW., Washington, DC 20551.

SUPPLEMENTARY INFORMATION: The FBSEA required for the first time that a foreign bank receive federal approval to establish a representative office. Prior to the FBSEA, federal regulation provided a limited definition of a representative office of a foreign bank and only required a foreign bank to register a representative office established in the United States with the Treasury Department. Federal law did not provide for the ongoing oversight or regulation of representative offices of foreign banks.

To fill these and other gaps in federal regulation of foreign banks, Congress adopted a broader definition of representative office in the FBSEA to ensure that all direct operations of a foreign bank are subject to federal regulation and supervision. The FBSEA expanded the definition of a representative office of a foreign bank in the IBA to include any place of business of a foreign bank that is not a branch, agency, or subsidiary.

The FBSEA also provided standards for establishing, examining, and regulating a representative office of a foreign bank. These standards are less rigorous than the standards governing the establishment, examination, and supervision of a branch or agency of a foreign bank. In evaluating an application to establish a representative office, the FBSEA only requires the Board to take into account the standards that are mandatory for the establishment of a branch or an agency. Thus, for example, the Board may permit a foreign bank to establish a representative office even though its home country supervision or financial condition might not support the establishment of a branch oran agency. Similarly, unlike the mandatory, annual examinations required for a branch or agency, the Board may examine a representative office as often as deemed appropriate.

The Board has implemented the FBSEA and the provisions governing a representative office of a foreign bank through two rulemakings. First, in an interim rule, the Board defined a representative office of a foreign bank as a limited purpose office that may only engage in representational and administrative functions on behalf of a foreign bank. The interim rule also stated that a representative office may not make any business decision on behalf of the foreign bank. 57 FR 12992 (April 15, 1992). In taking this approach, the Board adhered to the traditional view that a representative office may only engage in limited functions that facilitate the banking activities of a foreign bank, but may not engage in the activities themselves.

Both foreign banks and some state supervisors objected to this restrictive definition because, in some instances, it would have been more limiting than state laws on representative offices. In response to comments received and initial experience gained in implementing these and other portions of the FBSEA, the Board broadened these interim provisions in a second, final rulemaking. 58 FR 6348 (January 28, 1993). The Board determined that a representative office is permitted to perform any activity that is neither a banking activity nor an activity that is prohibited by state law, Board ruling, or Board order. The Board also introduced two sub-types of representative offices that perform activities that raise few regulatory and supervisory issues and therefore may be established under expedited procedures. Specifically, the Board granted its general consent to the establishment of a representative office that solely performs limited administrative functions for the foreign bank (a general consent office). The foreign bank must notify the Board of the establishment of a general consent office. The Board also provided a 45 day prior notice procedure for the establishment of a regional administrative office that coordinates operations in a particular geographic region.

In adopting the final rule, the Board recognized that further experience might warrant future revision of the provisions governing a representative office of a foreign bank. Therefore, the Board sought additional comment on these provisions and stated that it would revisit the regulations after gaining additional information on the matter.

The Board received public comments from the Conference of State Bank Supervisors, a trade association, and a foreign bank. These commenters supported the adoption of a broader definition of a representative office and a wider range of permissible activities provided in the final rule. Two commenters sought clarification and expansion of the activities deemed permissible for a representative office. The commenters also recommended measures to reduce and streamline the application procedures for establishing a representative office. Lastly, one commenter requested that representative offices be permitted to send unsolicited financial instruments through inter-office mail to a branch or bank subsidiary that is authorized to accept deposits. The Board is of the view that this activity may constitute deposit-taking, and is therefore inappropriate for a representative office to conduct.

Establishment of Representative Offices by Prior Notice

The Board has concluded that the prior notice procedures may be applied to the establishment of representative offices by foreign banks that are subject to the BHC Act, either directly or through section 8(a) of the IBA, where the Board has made a previous determination that the particular foreign bank is subject to comprehensive supervision on a consolidated basis by its home country supervisor, or previously has been approved for a representative office by Board order. This expanded authority is intended to reduce the burden associated with the filing of a formal representative office application by a foreign banking organization meeting these requirements.[1]

The Board has taken the position that a 45-day prior notice review period to establish such an office is sufficient where the Board has made a formal determination that the foreign bank is subject to CCS in the context of a previous application to establish a branch, agency, commercial lending company, or to acquire a bank, or previously has been approved for a representative office by Board order. The Board has found that the goal of reducing burden for foreign banking organizations, where possible and prudent, outweighs the limited additional supervisory benefits of requiring a formal application for a representative office under these circumstances.

In addition, the final rule clarifies that only foreign banks subject to the BHC Act, either directly or through section 8(a) of the IBA, may establish under the Board's general consent authority a representative office to engage in limited administrative or "back office" functions, and that such "back office" functions may only be performed in connection with the U.S. banking activities of the foreign bank. General consent representative offices were intended to facilitate the establishment of limited offices by foreign banks seeking administrative support for their existing U.S. banking operations, and not as stand-alone operations. In that regard, the activities must be clearly defined, performed in connection with the U.S. banking activities of the foreign bank, and must not involve contact or liaison with customers or potential customers beyond incidental contact relating to administrative matters (such as verification or correction of account information). "Back office" and other administrative functions linked to banking present the fewest supervisory and prudential concerns in the group of representative office activities that are linked to banking. These limited activities reflect a balancing of the Board's desire to reduce regulatory burden with its need to continue to monitor closely the direct operations of foreign banks.

By allowing a foreign bank meeting the criteria outlined above to utilize the Board's prior notice procedures or general consent authority to establish a representative office, the Board does not intend to permit a foreign bank to

[1] Applications by foreign banks that have received comprehensive consolidated supervision (CCS) determinations to establish branches, agencies and commercial lending companies will continue to be delegated to Reserve Banks. 12 CFR 265.11(d)(11).

expand broadly its U.S. banking and nonbanking activities. The proposed rule is designed merely to reduce the burden on those foreign banks seeking to provide additional support for their existing U.S. banking operations.

Special Purpose Government Banks

The FBSEA requires any foreign bank to obtain prior Board approval to establish a branch, agency, commercial lending company, or representative office. In issuing the final rule, the Board exempted the central bank of a foreign country that does not engage in commercial banking activities in the Untied States from the definition of "foreign bank" and therefore from regulation under the FBSEA. The Board has received several requests from government-owned entities that engage in banking that is not commercial in nature for similar exemptive treatment. A prototypical example of this type of entity is an export-import bank of a foreign country. These so-called "special purpose government banks" maintain offices in the United States that, without this exemption, are representative offices under the FBSEA.

The Board has found that the types of institutions seeking this exemptive relief vary considerably in their legal structure, governmental mandate, and actual operations. Creating a regulatory exemption akin to that provided for central banks in these circumstances would prove unworkable and imprecise. Furthermore, each of the requests for an exemption from regulation under the FBSEA is in fact a request for an interpretation that the entity in question is not a foreign bank within the meaning of the FBSEA and Regulation K. Accordingly, the Board has determined to review and act upon each of these interpretive requests on a case-by-case basis. Among the factors the Board will consider are whether the foreign organization is: (i) established and regulated pursuant to a distinct regulatory scheme that differs from that applied to traditional commercial banks; (ii) owned and capitalized substantially, if not exclusively, by its home government; (iii) subject to direct government control and examination; (iv) engaged exclusively in activities designed to serve specific government policy goals; and (v) prohibited from accepting deposits. This approach, in the Board's view, will provide the best mechanism for determining whether the relief requested is in fact warranted.

Regulatory Review

A full review of Regulation K, as required by the IBA, is underway and will proceed during the course of the next year. The subject of representative offices will be revisited at that time, and will provide additional opportunity for interested parties to express their concerns regarding these and other relevant issues.

Regulatory Flexibility Analysis

Pursuant to section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Board certifies that this final rule will not have a significant economic impact on a substantial number of small business entities that are subject to the regulation.

Pursuant to 5 U.S.C. § 553(d), this amendment to Regulation K will become effective immediately. This final grants an exemption for certain foreign banking organizations, and, therefore, the Board waives the 30-day general requirement for publication of a substantive rule.

Paperwork Reduction Act

In accordance with section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Ch. 35; 5 CFR 1320 Appendix A.1), the Board reviewed the proposed rule under the authority delegated to the Board by the Office of Management and Budget. No collections of information pursuant to the Paperwork Reduction Act are contained in the final rule.

List of Subjects in 12 CFR Part 211

Exports, Federal Reserve System, Foreign banking, Holding companies, Investments, Reporting and recordkeeping requirements.

For the reasons set out in the preamble, the Board of Governors amends 12 CFR Part 211 as set forth below:

PART 211—INTERNATIONAL BANKING OPERATIONS (REGULATION K)

1. The authority citation for 12 CFR part 211 continues to read as follows:

Authority: 12 U.S.C. 221 *et seq.*, 1818, 1841 *et seq.*, 3101 *et seq.*, 3901 *et seq*).

2. Section 211.24 is amended by:

a. Revising paragraphs (a)(2)(i) and (a)(2)(ii); and

b. Redesignating paragraph (d)(3) as paragraph (d)(4), and adding a new paragraph (d)(3).

The revisions and addition read as follows:

§ 211.24 Approval of offices of foreign banks; procedures for applications; standards for approval; representative office activities and standards for approval; preservation of existing authority.

(a) * * *

(2) * * *

(i) *Prior notice for certain representative offices.* After providing 45 days' prior written notice to the Board, a foreign bank that is subject to the BHC Act, either directly or through section 8(a) of the IBA (12 U.S.C. 3106(a)), may establish:

(A) A regional administrative office; or

(B) A representative office, but only if the Board has previously determined that the foreign bank proposing to establish a representative office is subject to comprehensive supervision or regulation on a consolidated basis by its home country supervisor, or previously has been approved for a representative office by Board order. The Board may waive the 45-day period if it finds that immediate action is required by the circumstances presented. The notice period shall commence at the time the notice is received by the appropriate Reserve Bank. The Board may suspend the period or require Board approval prior to the establishment of such an office if the notification raises significant policy, prudential or supervisory concerns.

(ii) *General consent for representative offices.* The Board grants its general consent for a foreign bank that is subject to section 8(a) of the IBA (12 U.S.C. 3106(a)), to establish a representative office that solely engages in limited administrative functions (such as separately maintaining back office support systems) that are clearly defined, are performed in connection with the United States banking activities of the foreign bank, and do not involve contact or liaison with customers or potential customers beyond incidental contact with existing customers relating to administrative matters (such as verification or correction of account information), provided that the foreign bank notifies the Board in writing within 30 days of the establishment of the representative office.

* * * * *

(d) * * *

(3) *Special purpose foreign government banks.* A foreign government-owned organization engaged in banking activities in its home country that are not commercial in nature may apply to the Board for a determination that the organization is not a *foreign bank* for purposes of this section. A written request setting forth the basis for such a determination may be submitted to the Reserve Bank of the District in which the foreign organization's representative office is located in the United States or to the Board in the case of a proposed establishment of a representative office.

The Board will review and act upon each such request on a case-by-case basis.

* * * * *

By order of the Board of Governors of the Federal Reserve System, January 24, 1996.

William W. Wiles,

Secretary of the Board.

[FR Doc. 96–1650 Filed 1–29–96; 8:45 a.m.]

BILLING CODE 6210–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 94–NM–178–AD; Amendment 39–9498; AD 95–13–11 R1]

Airworthiness Directives; McDonnell Douglas Model DC–10–10 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; correction.

SUMMARY: This amendment clarifies information in an existing airworthiness directive (AD), applicable to certain McDonnell Douglas Model DC–10–10 airplanes, that currently requires repetitive inspections to detect cracking of the upper caps in the front spar of the left and right wing, and repair, if necessary. The actions specified in that AD are intended to prevent progression of fatigue cracking, which could cause reduced structural integrity of the wing front spar and damage to adjacent structures. This amendment clarifies the requirements of the current AD by revising the area of inspection. This amendment is prompted by communications received from affected operators that the current requirements of the AD are unclear.

DATES: Effective August 7, 1995.

The incorporation by reference of certain publications listed in the regulations was approved previously by the Director of the Federal Register as of August 7, 1995 (60 FR 35326, July 7, 1995).

ADDRESSES: The service information referenced in this AD may be obtained from McDonnell Douglas Corporation, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Technical Publications Business Administration, Department C1–L51 (2–60). This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Los Angeles Aircraft Certification Office, Transport Airplane Directorate, 3960 Paramount Boulevard, Lakewood, California; or at the Office of the Federal Register, 800 North Capitol Street NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: John Cecil, Aerospace Engineer, Airframe Branch, ANM–120L, FAA, Transport Airplane Directorate, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California 90712; telephone (310) 627–5322; fax (310) 627–5210.

SUPPLEMENTARY INFORMATION: On June 22, 1995, the FAA issued AD 95–13–11, amendment 39–9291 (60 FR 35326, July 7, 1995), which is applicable to certain McDonnell Douglas Model DC–10–10 airplanes. That AD requires repetitive eddy current test high frequency (ETHF) surface inspections to detect fatigue cracking, and repair of the upper cap in the front spar of the wing if any cracking is found. That AD also requires additional repetitive inspections after any repair of the upper cap. Additionally, that AD stipulates that, if the preventive modification is installed on an airplane on which no cracks are found during the initial inspection, the repetitive inspections may be terminated. That action was prompted by reports of fatigue cracking in the upper cap of the front spar of the wing in the forward flange area. The actions required by that AD are intended to prevent progression of fatigue cracking, which could cause reduced structural integrity of the wing front spar and damage to adjacent structures.

Since the issuance of that AD, the FAA has received communications from affected operators that the area defined for the ETHF surface inspection is unclear. Specifically, these operators have indicated that the referenced McDonnell Douglas DC–10 Service Bulletin 57–129, dated August 12, 1994, recommends inspection of the upper cap of the front spar of the left and right wing "between" stations Xos 667.678 and Xos 789.645 in certain paragraphs but describes the inspection "at" stations Xos 667.678 and Xos 789.645 in the accomplishment instructions. AD 95–13–11 requires inspection "between" stations Xos 667.678 and Xos 789.645.

These operators have therefore, requested that the FAA clarify the AD to indicate exactly what area is required to be inspected.

In considering this request, and upon further review of the wording of the current AD, the FAA concurs that some clarification is necessary.

It was the FAA's intent that the requirements of AD 95–13–11 be parallel to those actions recommended by the manufacturer in the accomplishment instructions of its referenced service bulletin. The intended requirements of the AD were that affected operators would conduct the ETHF inspections to detect fatigue cracks at the areas where cracking had been reported, namely at stations Xos 667.678 and Xos 789.645. However, as AD 95–13–11 is currently worded, operators may incorrectly conduct ETHF inspections "between" these stations, rather than "at" those stations. Such misunderstanding could result in operators unnecessarily conducting ETHF inspections at other stations, which would be of no significant safety value and would entail incurring needless additional costs in labor and downtime.

Operators should note that the economic information supplied in the preamble of AD 95–13–11 remains unchanged since that information was based on the workhours required to perform the ETHF inspection at stations Xos 667.678 and Xos 789.645, in accordance with data supplied in McDonnell Douglas Service Bulletin 57–129, dated August 12, 1994.

Since it is obvious that the required ETHF inspection area is not totally clear in the way that AD 95–13–11 is currently worded, the FAA has determined that the wording of paragraph (a) of the AD must be revised to clarify the intent of the required actions. This action revises that paragraph to specify that the inspection area is at stations Xos 667.678 and Xos 789.645.

Action is taken herein to clarify these requirements of AD 95–13–11 and to correctly add the AD as an amendment to section 39.13 of the Federal Aviation Regulations (14 CFR 39.13).

The final rule is being reprinted in its entirety for the convenience of affected operators. The effective date remains August 7, 1995.

Since this action only clarifies a current requirement, it has no adverse economic impact and imposes no additional burden on any person. Therefore, notice and public procedures hereon are unnecessary.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Correction

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), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39–9291 (60 FR 35326, July 7, 1995), and by adding a new airworthiness directive (AD), amendment 39–9498, to read as follows:

95–13–11 R1 McDonnell Douglas: Amendment 39–9498. Docket 94–NM–178–AD. Revises AD 95–13–11, Amendment 39–9291.

Applicability: Model DC–10–10 airplanes, as listed in McDonnell Douglas DC–10 Service Bulletin 57–129, dated August 12, 1994; certificated in any category.

Note 1: This AD applies to each airplane 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 airplanes 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 (e) of this AD 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 airplane from the applicability of this AD.

Compliance: Required as indicated, unless accomplished previously.

To prevent reduced structural integrity of the wing front spar and damage to adjacent structures due to fatigue cracking in the upper cap of the front spar of the wing, accomplish the following:

(a) Prior to the accumulation of 10,000 total landings, or within 1,800 landings after the effective date of this AD, whichever occurs later, perform an initial eddy current test high frequency (ETHF) surface inspection to detect cracks in the upper cap of the front spar of the left and right wing at stations Xos 667.678 and Xos 789.645, in accordance with McDonnell Douglas DC–10 Service Bulletin 57–129, dated August 12, 1994. Repeat this inspection thereafter at the intervals specified in paragraph (b) or (c) of this AD, as applicable.

(b) For airplanes on which no crack is found: Repeat the inspection required by paragraph (a) of this AD thereafter at intervals not to exceed 10,000 landings, or accomplish the crack preventative modification in accordance with McDonnell Douglas DC–10 Service Bulletin 57–129, dated August 12, 1994. Accomplishment of that preventative modification constitutes terminating action for the requirements of this paragraph.

(c) For airplanes on which any crack is found that is identified as "Condition II" in McDonnell Douglas DC–10 Service Bulletin 57–129, dated August 12, 1994: Accomplish paragraphs (c)(1) and (c)(2) of this AD in accordance with that service bulletin.

(1) Prior to further flight, perform the permanent repair for cracks in accordance with the service bulletin; and

(2) Within 12,500 landings after the installation of the permanent repair specified in paragraph (c)(1) of this AD, perform an ETHF surface inspection for cracks, in accordance with the service bulletin. Repeat this inspection thereafter at intervals not to exceed 7,000 landings.

(d) For airplanes on which any crack is found that is identified as "Condition III" in McDonnell Douglas DC–10 Service Bulletin 57–129, dated August 12, 1994: Prior to further flight, repair the cracking in accordance with a method approved by the Manager, Los Angeles Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate.

(e) 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, Los Angeles ACO. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Los Angeles ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Los Angeles ACO.

(f) 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 airplane to a location where the requirements of this AD can be accomplished.

(g) The inspections, modification, and permanent repair shall be done in accordance with McDonnell Douglas DC–10 Service Bulletin 57–129, dated August 12, 1994. This incorporation by reference was approved previously by the Director of the Federal Register, in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 as of August 7, 1995 (60 FR 35326, July 7, 1995). Copies may be obtained from McDonnell Douglas Corporation, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Technical Publications Business Administration, Department C1–L51 (2–60). Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Transport Airplane Directorate, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(g) This amendment is effective on August 7, 1995.

Issued in Renton, Washington, on January 22, 1996.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 96–1569 Filed 1–29–96; 8:45 am]

BILLING CODE 4910–13–U

14 CFR Part 97

[Docket No. 28426; Amdt. No. 1703]

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 December 29, 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 continues 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 and 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 February 29, 1996*

Galliano, LA, South Lafourche, GPS RWY 18, Orig
Grand Rapids, MI, Kent County Intl, VOR OR GPS RWY 18, Amdt 6, CANCELLED
Grand Rapids, MI, Kent County Intl, VOR–OR GPS RWY 36, Amdt 11, CANCELLED
Grand Rapids, MI, Kent County Intl, VOR–A, Orig
Grand Rapids, MI, Kent County Intl, VOR–B, Orig
Grand Rapids, MI, Kent County Intl, NDB or GPS RWY 26L, Amdt 20
Grand Rapids, MI, Kent County Intl, ILS RWY 8R, Amdt 5
Grand Rapids, MI, Kent County Intl, ILS RWY 26L, Amdt 20
Grand Rapids, MI, Kent County Intl, RADAR–1, Amdt 10
Greenville, MI, Greenville Muni, VOR/DME OR GPS–A, Amdt 1
Hastings, MI, Hastings, VOR RWY 12, Orig
Hastings, MI, Hastings, VOR OR GPS–A, Orig, CANCELLED
Kalamazoo, MI, Kalamazoo/Battle Creek Intl, GPS RWY 5, Orig
Kalamazoo, MI, Kalamazoo/Battle Creek Intl, GPS RWY 23, Orig
Port Huron, MI, St. Clair County Intl, NDB or GPS RWY 4, Amdt 3
Port Huron, MI St. Clair County Intl, ILS RWY 4, Amdt 3
Rugby, ND, Rugby Muni, GPS RWY 30, Orig
Ashland, OH, Ashland County, VOR OR GPS–A, Amdt 7
Ashland, OH, Ashland County, NDB OR GPS RWY 18, Amdt 9
Huntingdon, TN, Carroll County, GPS RWY 19, Orig
Millington, TN, Charles W. Baker, VOR/DME RWY 18, Amdt 1
Millington, TN, Millington Muni, VOR/DME RWY 22, Amdt 1
Salt Lake City, UT, Salt Lake City Muni 2, GPS RWY 34, Orig
Burlington/Mount Vernon, Skagit Regional/Bay View, GPS RWY 10, Orig
Burlington/Mount Vernon, Skagit Regional/Bay View, GPS RWY 28, Orig
Cheyenne, WY, Cheyenne, GPS RWY 12, Orig

[FR Doc. 96–1625 Filed 1–29–96; 8:45 am]
BILLING CODE 4910–13–M

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14 CFR Part 97

[Docket No. 28442; Amdt. No. 1706]

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 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 matter 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 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 on each SIAP is contained in the appropriate FAA Form 8260 and the National Flight Data Center (FDC)/Permanent (P) Notices to Airmen (NOTAM) which are incorporated by reference in the amendment under 5 U.S.C. 552(a), 1 CFR part 51, and § 97.20 of the Federal Aviation Regulations (FAR). 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 of 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 of the Federal Aviation Regulations (14 CFR part 97) establishes, amends, suspends, or revokes SIAPs. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained in the content of the following FDC/P NOTAM for each SIAP. The SIAP information in some previously designated FDC/Temporary (FDC/T) NOTAMs is of such duration as to be permanent. With conversion to FCD/P NOTAMs, the respective FDC/T NOTAMs have been cancelled.

The FDC/P NOTAMs for 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 chart changes to SIAPs by FDC/P NOTAMs, the TERPS criteria were applied to only these specific conditions existing at the affected airports. All SIAP amendments in this rule 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 all these SIAP amendments requires making them effective in less than 30 days.

Further, the SIAPs contained in this amendment are based on the criteria contained in the TERPS. 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 these SIAPs effective in less than 30 days.

Conclusion

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 January 19, 1996.

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. 40103, 40113, 40120, 44701; 49 U.S.C. 106(g); 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 Upon Publication

FDC date	State	City	Airport	FDC No.	SIAP
01/05/96	ME	Eastport	Eastport Muni	6/0099	GPS RWY 15 ORIG...
01/02/96	KY	Louisville	Louisville Intl-Standiford Field	6/0017	ILS RWY 17 ORIG...
01/04/96	MO	St Louis	Lambert-St Louis Intl	6/0072	ILS RWY 30R, AMDT 6C...
01/04/96	TX	Mexia	Mexia-Linestone County	6/0073	GPS RWY 36, ORIG...
01/05/96	AR	Springdale	Springdale Muni	6/0098	VOR OR GPS RWY 18, AMDT 14A...
01/11/96	OK	Lawton	Lawton Muni	6/0289	RADAR 1, AMDT 3...
01/11/96	VT	Lyndonville	Caledonia County	6/0281	NDB RWY 2 AMDT 3...
01/16/95	CO	Gunnison	Gunnison County	6/0400	VOR OR GPS–A, AMDT 7A...
01/16/96	AR	Brinkley	Frank Federer Memorial	6/0391	NDB OR GPS–A, ORIG–A...
01/16/96	CO	Gunnison	Gunnison County	6/0399	ILS RWY 6 AMDT 3...
01/16/96	TX	Abilene	Abilene Regional	6/0394	ILS RWY 35R, AMDT 5...
01/16/96	TX	Abilene	Abilene Regional	6/0395	NDB OR GPS RWY 35R, AMDT 4...
01/17/96	AZ	Scottsdale	Scottsdale	6/0420	VOR OR GPS–A AMDT 2...
01/17/96	AZ	Scottsdale	Scottsdale	6/0421	VOR OR GPS–C ORIG...
12/29/95	MS	Jackson	Hawkins Field	5/6937	RNAV OR GPS RWY 16, AMDT 4...

[FR Doc. 96–1738 Filed 1–29–96; 8:45 am]
BILLING CODE 4910–13–M

14 CFR Part 97

[Docket No. 28441; Amdt. No. 1705]

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 19 January 1996.

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:

** * * February 1, 1996 * * **

Farmingdale, NY, Republic, NDB or GPS RWY 1, Amdt 13
Farmingdale, NY, Republic, ILS RWY 14, Amdt 6
Mesquite, TX, Phil L. Hudson Muni, LOC RWY 17, Amdt 3, CANCELLED
Mesquite, TX, Mesquite Metro, ILS RWY 17, Orig

** * * February 29, 1996 * * **

Gadsden, AL, Gadsden Muni, GPS RWY 24, Orig
Flagstaff, AZ, Flagstaff Pulliam, GPS RWY 21, Orig
Page, AZ, Page Muni, GPS RWY 15, Orig
Longmont, CO, Vance Brand, GPS RWY 29, Orig
Indianapolis, IN, Indianapolis Intl, VOR OR GPS RWY 14, Amdt 25
Indianapolis, IN, Indianapolis Intl, ILS RWY 14, Amdt 4
Indianapolis, IN, Indianapolis Intl, Radar-1, Amdt 31
Bowling Green, KY, Bowling Green-Warren County Regional, VOR OR GPS RWY 3, Amdt 14
Bowling Green, KY, Bowling Green-Warren County Regional, VOR/DME OR GPS RWY 21, Amdt 7
Bowling Green, KY, Bowling Green-Warren County Regional, NDB RWY 3, Orig
Bowling Green, KY, Bowling Green-Warren County Regional, ILS RWY 3, Orig
Farmington, MO, Farmington Regional, GPS RWY 2, Orig
Albemarle, NC, Stanly County, NDB OR GPS RWY 4, AMDT 3, CANCELLED
Albemarle, NC, Stanly County, NDB OR GPS RWY 22, Orig, CANCELLED
Albemarle, NC, Stanly County, LOC RWY 22, Orig
Albemarle, NC, Stanly County, NDB RWY 22, Orig
Winnemucca, NV, Winnemucca Muni, GPS RWY 14, Orig
Winnemucca, NV, Winnemucca Muni, GPS RWY 32, Orig
Britton, SD, Britton Muni, NDB OR GPS RWY 13, Amdt 3, CANCELLED
Britton, SD, Britton Muni, NDB OR GPS RWY 13, Orig
Renton, WA, Renton Muni, GPS RWY 15, Orig

** * * April 25, 1996 * * **

Boca Raton, FL, Boca Raton, GPS RWY 5, Orig
Harrisburg, IL, Harrisburg-Raleigh, GPS RWY 24, Orig
Clinton, IA, Clinton Muni, GPS RWY 14, Orig
Clinton, IA, Clinton Muni, GPS RWY 21, Orig
Clinton, IA, Clinton Muni, GPS RWY 32, Orig
Lafayette, LA, Lafayette Regional, GPS RWY 29, Orig
Tallulah/Vicksburg, LA, Vicksburg Tallulah Rgnl, GPS RWY 18, Orig
Greenville, MI, Greenville Muni, GPS RWY 27, Orig
Ludington, MI, Mason County, GPS RWY 25, Orig
Monett, MO, Monett Muni, GPS RWY 36, Orig

The FAA published an Amendment in Docket No. 28390, Amdt. No. 1695 to

Part 97 of the Federal Aviation Regulations (VOL 60 FR No. 239 Page 63905, dated Wednesday, December 13, 1995) under Section 97.25 effective February 29, 1996 which is hereby rescinded: Blacksburg, VA, Virginia Tech, LOC RWY 12, Amdt 4.

[FR Doc. 96–1739 Filed 1–29–96; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Parts 10, 113, 141, 144 and 181

[T.D. 96–14]

RIN 1515–AB87

North American Free Trade Agreement (NAFTA)—Implementation of Duty-Deferral Program Provisions

AGENCY: Customs Service, Treasury.

ACTION: Interim regulations; solicitation of comments.

SUMMARY: In response to comments received on the final rule implementing NAFTA, this document sets forth interim regulations establishing procedural and other requirements that apply to the collection, waiver and reduction of duties under the duty-deferral program provisions of the North American Free Trade Agreement. The document prescribes the documentary and other requirements that must be followed when merchandise is withdrawn from a U.S. duty-deferral program either for exportation to another NAFTA country or for entry into a duty-deferral program of another NAFTA country, the procedures that must be followed in filing a claim for a waiver or reduction of duties collected on such merchandise, and the procedures for finalization of duty collections and duty waiver or reduction claims.

DATES: Interim rule effective January 1, 1996; comments must be submitted by April 1, 1996.

ADDRESSES: Written comments (preferably in triplicate) may be addressed to the Regulations Branch, U.S. Customs Service, Franklin Court, 1301 Constitution Avenue, N.W., Washington, D.C. 20229. Comments submitted may be inspected at the Regulations Branch, Office of Regulations and Rulings, Franklin Court, 1099 14th Street, NW., Suite 4000, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Angela Downey, Office of Field Operations (202–927–1082).

SUPPLEMENTARY INFORMATION:

Background

On September 6, 1995, Customs published in the **Federal Register** (60 FR 46334) a document which adopted, as a final rule, interim regulations implementing the Customs-related provisions of the North American Free Trade Agreement (NAFTA) which was adopted by the United States with the enactment of the North American Free Trade Agreement Implementation Act (the "Act"), Public Law 103–182, 107 Stat. 2057. The majority of the NAFTA implementing regulations are set forth in Part 181 of the Customs Regulations (19 CFR Part 181) which includes, in Subpart E, regulations implementing the NAFTA drawback (including duty-deferral) provisions of Article 303 of the NAFTA and section 203 of the Act which apply to goods imported into the United States and then subsequently exported from the United States to Canada on or after January 1, 1996, or to Mexico on or after January 1, 2001.

Within Subpart E of Part 181, § 181.53 specifically addresses the provisions concerning the collection, and waiver or reduction, of duty on goods imported into the United States pursuant to a duty-deferral program (that is, imported into a manipulation warehouse, manufacturing warehouse, smelting or refining warehouse or foreign trade zone, or imported under a temporary importation bond) and subsequently exported, or used as a material in the production of another good that is exported, to Canada or Mexico. Paragraph (a)(1) defines the term "duty-deferral program" for purposes of the section. Paragraph (a)(2) provides that the exported good shall be treated as if it had been entered or withdrawn for consumption and thus subject to duty. Paragraph (a)(3) states that Customs shall waive or reduce, in accordance with paragraphs (b) through (f), the duties paid or owed under paragraph (a)(2) provided that evidence of exportation and satisfactory evidence of duties paid in Canada or Mexico are submitted within 60 calendar days of the date of exportation. Paragraphs (b) through (f) set forth the duty assessment and waiver or reduction rules with reference to each type of duty-deferral program, and each of these paragraphs provides that the duty shall be waived or reduced in an amount that does not exceed the lesser of the total amount of duty payable under the section or the total amount of customs duties paid to Canada or Mexico.

In the discussion of public comments submitted on the interim NAFTA implementing regulations, the September 6, 1995, final rule document noted that a number of commenters raised questions regarding the procedures, including documentary requirements, that would apply for purposes of the collection and waiver or reduction of duty under § 181.53. In responding to these comments, Customs agreed that the regulations should specifically address such procedural issues. Customs further stated that it would be preferable to address these issues in a separate **Federal Register** document, with a view to having appropriate regulations in place on January 1, 1996, when the Subpart E regulations go into effect (that is, with regard to goods exported to or entered into a duty-deferral program in Canada). The regulatory amendments set forth in this document are intended to accomplish that purpose.

Discussion of Amendments

Section 10.31

In § 10.31, which concerns temporary importations under bond, paragraph (h) is amended by adding at the end a new sentence regarding merchandise imported under subheading 9813.00.05, HTSUS, that is exported to Canada or Mexico, because the entry and bond requirements under amended § 181.53 may apply to such merchandise.

Section 113.62

In § 113.62, which sets forth the basic importation and entry bond conditions, paragraphs (a) and (b) are amended by the addition of references to the withdrawal of merchandise from a duty-deferral program either for exportation to Canada or Mexico or for entry into a duty-deferral program in Canada or Mexico because such transactions will involve the filing of an entry under amended § 181.53 as discussed below. Paragraph (a) concerns the agreement to pay duties, taxes and fees, and paragraph (b) concerns the agreement to make or complete entry.

Section 141.0a

The definition of "entry" in paragraph (a) and the definition of "entered for consumption" in paragraph (f) have been expanded by the addition of a sentence at the end referring to documentation required under amended § 181.53 as discussed below.

Section 141.68

A new paragraph (i) has been added to § 141.68 (time of entry) regarding merchandise covered by the entry procedures contained in amended § 181.53 as discussed below.

Section 144.38

In § 144.38, which concerns withdrawals for consumption, a new paragraph (b) has been added to cover withdrawals either for exportation to Canada or Mexico or for entry into a duty-deferral program in Canada or Mexico.

Section 181.53

Section 181.53 is retitled to reflect that the section also covers collection (rather than only waiver or reduction) of duty, and the section text is extensively revised in order to accommodate the necessary documentation and other procedural requirements regarding the collection and waiver or reduction of duty under the NAFTA duty-deferral provisions. In addition to editorial, nonsubstantive changes to enhance the clarity of the text, the revised text incorporates a number of organizational and substantive changes that are outlined below.

Paragraph (a)(1) is retitled as a definitions paragraph and a new definition of "date of exportation" has been added as subparagraph (i) thereof.

Paragraph (a)(2) still concerns the "treatment as entered or withdrawn for consumption" principle but is divided into the following subparagraphs:

1. Subparagraph (i) incorporates the provisions of former paragraph (a)(2) and also includes two new principles stating that the documentation required to be filed under the section shall constitute an entry or withdrawal for consumption for purposes of the Customs Regulations and that any assessment of duty under this section shall include the duties and fees referred to in §§ 181.42 (a)–(c) (that is, antidumping and countervailing duties, premiums on quota, tariff rate quota or tariff preference level goods, and fees under section 22 of the Agricultural Adjustment Act) and the fees provided for in § 24.23 (that is, fees for processing merchandise). Subparagraph (i) refers to goods withdrawn for exportation to Canada or Mexico (subparagraph (i)(A)) and goods withdrawn and entered into a duty-deferral program in Canada or Mexico (subparagraph (i)(B)) because Canada, Mexico and the United States (the three NAFTA Parties) agreed that goods withdrawn from a duty-deferral program in one NAFTA country and entered into a duty-deferral program in another NAFTA country shall be deemed not to have been exported (see section F, article X of the "Regulatory Standards for Implementation of the North American Free Trade Agreement" published in the **Federal Register** on September 6, 1995, at 60 FR 46464).

2. Subparagraph (ii) is new and provides for application of the bond provisions of § 142.4 to each withdrawal and exportation transaction under § 181.53.

3. Subparagraph (iii) is a new provision covering documentation filing and duty payment procedures. Subparagraph (A) thereunder specifies the persons who must file the documentation required under the section. Subparagraph (B) provides for the filing of a Customs Form 7501 within 10 working days of the date of exportation or within 10 working days after being entered into a duty-deferral program in Canada or Mexico. Subparagraph (C) concerns duty payment and requires that the duty be deposited with Customs at any time prior to, but no later than, 60 calendar days after the date of exportation of the good or 60 calendar days after the date the good is entered into a duty-deferral program in Canada or Mexico, and subparagraph (C) also provides for the calculation of interest from the applicable 60th calendar day.

Paragraph (a)(3) is retitled "waiver or reduction of duties" and is divided into the following subparagraphs:

1. Subparagraph (i) incorporates the provisions of former paragraph (a)(3) but also includes two new substantive provisions. The first of these new provisions consists of an exception clause at the beginning of the subparagraph regarding duties and fees referred to in §§ 181.42 (a)–(c) and fees provided for in § 24.23, because such duties and fees may not be waived or reduced under the NAFTA drawback (including duty-deferral) provisions. The second of these new substantive provisions requires the filing of a "claim" for waiver or reduction of duties and states that the claim shall be "based on" evidence of exportation to Canada or Mexico or of entry into a duty-deferral program in Canada or Mexico and satisfactory evidence of duties paid in Canada or Mexico. The "based on" provision replaces the former requirement of submission of such evidence, is modeled on the approach used for NAFTA preferential duty claims (see § 181.21(a) of the NAFTA regulations), and is intended to reduce the paperwork burden and to facilitate electronic filings.

2. Subparagraph (ii) is a new provision covering the procedures for filing claims and paying reduced duties. This subparagraph requires that the claim be filed on Customs Form 7501 which must include specified Canadian or Mexican import information and provides that any reduced duties must be deposited with Customs when a claim for reduced duties is filed.

3. Subparagraph (iii) is a new provision which provides for the filing of a drawback claim if goods entered into a Canadian or Mexican duty-deferral program are subsequently withdrawn from that duty-deferral program.

Paragraph (a)(4) is a new provision setting forth procedures regarding the liquidation of entries filed under § 181.53 both if no claim for waiver or reduction of duties is filed (subparagraph (i)) and if a claim is filed (subparagraph (ii)). This paragraph generally reflects existing statutory and regulatory standards regarding liquidations, including notices of liquidation, deemed liquidations, and the time for filing protests after liquidation. In addition, in cases in which a claim is filed, this paragraph provides for an automatic 3-year extension of liquidation, because Customs will require additional time to obtain any information from Canadian or Mexican Customs necessary to verify a claim (see § 181.50(b) which provides for a 3-year delay in liquidation of drawback claims).

Former paragraphs (b) through (f) are redesignated as subparagraphs (1) through (5) under a new paragraph (b) titled "assessment and waiver or reduction of duty". The introductory texts and/or examples in newly designated paragraphs (b) (1)–(5), each of which still deals with a separate type of duty-deferral program, have been modified as follows: (1) by replacing the references to evidence of exportation and payment of duty by references to the filing of a proper claim under paragraph (a)(3) of the section; (2) to refer, where appropriate, to the filing of Customs Form 7501; and (3) by revising the examples to more accurately reflect a NAFTA duty-deferral context. In addition, the example concerning manipulation in warehouse (former paragraph (b), now paragraph (b)(1)) has been removed because it no longer reflects current law as interpreted by the courts (see *Tropicana Products Inc.* v. *U.S.*, 789 F.Supp. 1154, 16 CIT 155 (1992)). Finally, an exception regarding a good imported from Canada or Mexico for repair or alteration has been added at the beginning of the text covering temporary importation under bond (former paragraph (f), now paragraph (b)(5)), in order to reflect the terms of article 307(2) of the NAFTA.

Paragraph (c) concerns recordkeeping and corresponds to former paragraph (g) but includes a new requirement that evidence of exportation or of entry into a Canadian or Mexican duty-deferral

program and payment of Canadian or Mexican duty be maintained by the person who files a claim for waiver or reduction of duty under the section.

Paragraph (d) corresponds to former paragraph (h) and differs from the former text in referring to a failure to file a proper claim (rather than to a failure to provide evidence of duties paid or owed to Canada or Mexico) and also in referring more specifically to the persons who are liable for the payment of full duties.

Finally, paragraph (e) corresponds to former paragraph (i) but has been modified to refer to reliquidation of the "entry filed under this section pursuant to 19 U.S.C. 1508(b)(2)(B)(iii) even after liquidation of the entry has become final" (see § 181.50(b)).

Comments

Before adopting these interim regulations as a final rule, consideration will be given to any written comments timely submitted to Customs. Comments submitted will be available for public inspection in accordance with the Freedom of Information Act (5 U.S.C. 552), § 1.4, Treasury Department Regulations (31 CFR 1.4), and § 103.11(b), Customs Regulations (19 CFR 103.11(b)), on regular business days between the hours of 9 a.m. and 4:30 p.m. at the Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service, Franklin Court, 1099 14th Street, NW., Suite 4000, Washington, DC.

Inapplicability of Notice and Delayed Effective Date Requirements

Pursuant to the provisions of 5 U.S.C. 553(a), public notice is inapplicable to these interim regulations because they are within the foreign affairs function of the United States. The United States is obligated under Chapter Three of the NAFTA to implement the NAFTA duty-deferral provisions with respect to exportation to Canada on January 1, 1996. Furthermore, for the same reason, it is determined that good cause exists under the provisions of 5 U.S.C. 553(d)(3) for dispensing with a delayed effective date.

Executive Order 12866

Because this document involves a foreign affairs function of the United States and implements an international agreement, it is not subject to the provisions of E.O. 12866.

Regulatory Flexibility Act

Because no notice of proposed rulemaking is required for interim regulations, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply.

Paperwork Reduction Act

These regulations are being issued without prior notice and public procedure pursuant to the Administrative Procedure Act (5 U.S.C. 553). For this reason, the collections of information contained in these regulations have been reviewed and, pending receipt and evaluation of public comments, approved by the Office of Management and Budget in accordance with the requirements of the Paperwork Reduction Act (44 U.S.C. 3507) under control number 1515–0208.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

The collection of information in these regulations is in § 181.53. This information is required in connection with the withdrawal of goods from U.S. duty deferral programs for export to Canada or Mexico and will be used by the U.S. Customs Service both to determine the amount of duty to be collected on the exported goods and to determine eligibility for a waiver or reduction of such duty. The likely respondents are business organizations including importers, exporters and manufacturers.

Estimated total annual reporting and/or recordkeeping burden: 405,070 hours.

Estimated average annual burden per respondent/recordkeeper: 227 hours.

Estimated number of respondents and/or recordkeepers: 1783.

Estimated annual frequency of responses: 1,069,800.

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Comments should be directed to the Office of Management and Budget, Attention: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503. A copy should also be sent to the Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service, 1301 Constitution Avenue, NW., Washington, DC 20229.

Drafting Information. The principal author of this document was Francis W. Foote, Office of Regulations and Rulings, U.S. Customs Service. However, personnel from other offices participated in its development.

List of Subjects

19 CFR Part 10

Alterations, Bonds, Customs duties and inspection, Exports, Imports, Preference programs, Repairs, Reporting and recordkeeping requirements, Trade agreements.

19 CFR Part 113

Air carriers, Bonds, Customs duties and inspection, Exports, Foreign commerce and trade statistics, Freight, Imports, Reporting and recordkeeping requirements, Vessels.

19 CFR Part 141

Bonds, Customs duties and inspection, Entry of merchandise, Invoices, Powers of attorney, Packaging, Release of merchandise, Reporting and recordkeeping requirements.

19 CFR Part 144

Bonds, Customs duties and inspection, Reporting and recordkeeping requirements, Warehouses.

19 CFR Part 181

Administrative practice and procedure, Canada, Customs duties and inspection, Exports, Imports, Mexico, Reporting and recordkeeping requirements, Trade agreements (North American Free-Trade Agreement).

Amendments to the Regulations

Accordingly, parts 10, 113, 141, 144 and 181, Customs Regulations (19 CFR parts 10, 113, 141, 144 and 181), are amended as set forth below.

PART 10—ARTICLES CONDITIONALLY FREE, SUBJECT TO A REDUCED RATE, ETC.

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

Authority: 19 U.S.C. 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States), 1321, 1481, 1484, 1498, 1508, 1623, 1624, 3314;

* * * * *

2. In § 10.31, paragraph (h) is amended by adding a new sentence at the end to read as follows:

§ 10.31 Entry; bond.

* * * * *

(h) * * * However, a TIB importer may be required to file an entry for consumption and pay duties, or pay liquidated damages under its bond for a failure to do so, in the case of

merchandise imported under subheading 9813.00.05, HTSUS, and subsequently exported to Canada or Mexico (see § 181.53 of this chapter).

PART 113—CUSTOMS BONDS

1. The authority citation for part 113 continues to read in part as follows:

Authority: 19 U.S.C. 66, 1623, 1624.

* * * * *

2. In § 113.62, the introductory texts of paragraphs (a)(1) and (b) are revised to read as follows:

§ 113.62 Basic importation and entry bond conditions.

* * * * *

(a) *Agreement to Pay Duties, Taxes, and Charges.*

(1) If merchandise is imported and released from Customs custody or withdrawn from a Customs bonded warehouse into the commerce of, or for consumption in, the United States, or under § 181.53 of this chapter is withdrawn from a duty-deferral program for exportation to Canada or Mexico or for entry into a duty-deferral program in Canada or Mexico, the obligors (principal and surety, jointly and severally) agree to:

* * * * *

(b) *Agreement to Make or Complete Entry.* If all or part of imported merchandise is released before entry under the provisions of the special delivery permit procedures under 19 U.S.C. 1448(b), or released before the completion of the entry under 19 U.S.C. 1484(a), or withdrawn from a duty-deferral program for either exportation to Canada or Mexico or for entry into a duty-deferral program in Canada or Mexico before the filing of the documentation provided for in § 181.53(a)(2) of this chapter, the principal agrees to file within the time and in the manner prescribed by law and regulation, documentation to enable Customs to:

* * * * *

PART 141—ENTRY OF MERCHANDISE

1. The authority citation for part 141 continues to read in part as follows:

Authority: 19 U.S.C. 66, 1448, 1484, 1624.

* * * * *

Section 141.68 also issued under 19 U.S.C. 1315;

* * * * *

2. In § 141.0a, paragraphs (a) and (f) are amended by adding a sentence at the end to read as follows:

§ 141.0a Definitions.

* * * * *

(a) *Entry.* * * * "Entry" also means that documentation required by § 181.53 of this chapter to be filed with Customs to withdraw merchandise from a duty-deferral program in the United States for exportation to Canada or Mexico or for entry into a duty-deferral program in Canada or Mexico.

* * * * *

(f) *Entered for consumption.* * * * "Entered for consumption" also means the necessary documentation has been filed with Customs to withdraw merchandise from a duty-deferral program in the United States for exportation to Canada or Mexico or for entry into a duty-deferral program in Canada or Mexico (see § 181.53 of this chapter).

* * * * *

3. Section 141.68 is amended by adding a new paragraph (i) to read as follows:

§ 141.68 Time of entry.

* * * * *

(i) *Exportation to Canada or Mexico of goods imported into the United States under a duty-deferral program defined in § 181.53 of this chapter.* When merchandise in a U.S. duty-deferral program is withdrawn for exportation to Canada or Mexico or for entry into a duty-deferral program in Canada or Mexico, the date of entry is the date the entry is required to be filed under § 181.53(a)(2)(iii) of this chapter.

PART 144—WAREHOUSE AND REWAREHOUSE ENTRIES AND WITHDRAWALS

1. The authority citation for part 144 continues to read in part as follows:

Authority: 19 U.S.C. 66, 1484, 1557, 1559, 1624.

* * * * *

2. Section 144.38 is amended by adding a new paragraph (b) to read as follows:

§ 144.38 Withdrawal for consumption.

* * * * *

(b) *Withdrawal for exportation to Canada or Mexico.* A withdrawal for exportation to Canada or Mexico or for entry into a duty-deferral program in Canada or Mexico is considered a withdrawal for consumption pursuant to § 181.53 of this chapter.

* * * * *

PART 181—NORTH AMERICAN FREE TRADE AGREEMENT

1. The authority citation for part 181 continues to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States), 1624, 3314.

2. Section 181.53 is revised to read as follows:

§ 181.53 Collection and waiver or reduction of duty under duty-deferral programs.

(a) *General.*

(1) *Definitions.* The following definitions shall apply for purposes of this section:

(i) *Date of exportation.* "Date of exportation" means the date of importation into Canada or Mexico as reflected on the applicable Canadian or Mexican entry document (see § 181.47(c) (1) and (2)).

(ii) *Duty-deferral program.* A "duty-deferral program" means any measure which postpones duty payment upon arrival of a good in the United States until withdrawn or removed for exportation to Canada or Mexico or for entry into a Canadian or Mexican duty-deferral program. Such measures govern manipulation warehouses, manufacturing warehouses, smelting and refining warehouses, foreign trade zones, and those temporary importations under bond that are specified in paragraph (b)(5) of this section.

(2) *Treatment as entered or withdrawn for consumption.*

(i) *General.*

(A) Where a good is imported into the United States pursuant to a duty-deferral program and is subsequently withdrawn from the duty-deferral program for exportation to Canada or Mexico or is used as a material in the production of another good that is subsequently withdrawn from the duty-deferral program for exportation to Canada or Mexico, and provided that the good is a "good subject to NAFTA drawback" within the meaning of 19 U.S.C. 3333 and is not described in § 181.45 of this part, the documentation required to be filed under this section in connection with the exportation of the good shall, for purposes of this chapter, constitute an entry or withdrawal for consumption and the exported good shall be subject to duty which shall be assessed in accordance with paragraph (b) of this section.

(B) Where a good is imported into the United States pursuant to a duty-deferral program and is subsequently withdrawn from the duty-deferral program and entered into a duty-deferral program in Canada or Mexico or is used as a material in the production of another good that is subsequently withdrawn from the duty-deferral program and entered into a duty-

deferral program in Canada or Mexico, and provided that the good is a "good subject to NAFTA drawback" within the meaning of 19 U.S.C. 3333 and is not described in § 181.45, the documentation required to be filed under this section in connection with the withdrawal of the good from the U.S. duty-deferral program shall, for purposes of this chapter, constitute an entry or withdrawal for consumption and the withdrawn good shall be subject to duty which shall be assessed in accordance with paragraph (b) of this section.

(C) Any assessment of duty under this section shall include the duties and fees referred to in § 181.42 (a) through (c) and the fees provided for in § 24.23 of this chapter; these inclusions shall not be subject to refund, waiver, reduction or drawback.

(ii) *Bond requirements.* The provisions of § 142.4 of this chapter shall apply to each withdrawal and exportation transaction described in paragraph (a)(2)(i) of this section. However, in applying the provisions of § 142.4 of this chapter in the context of this section, any reference to release from Customs custody in § 142.4 of this chapter shall be taken to mean exportation to Canada or Mexico.

(iii) *Documentation filing and duty payment procedures.*

(A) *Persons required to file.* In the circumstances described in paragraph (a)(2)(i) of this section, the documentation described in paragraph (a)(2)(iii)(B) of this section must be filed by one of the following persons:

(*1*) In the case of a withdrawal of the goods from a warehouse, the person who has the right to withdraw the goods;

(*2*) In the case of a temporary importation under bond (TIB) specified in paragraph (b)(5) of this section, the TIB importer whether or not he sells the goods for export to Canada or Mexico unless § 10.31(h) of this chapter applies; or

(*3*) In the case of a withdrawal from a foreign trade zone, the person who has the right to make entry. However, if a zone operator is not the person with the right to make entry of the good, the zone operator shall be responsible for the payment of any duty due in the event the zone operator permits such other person to remove the goods from the zone and such other person fails to comply with §§ 146.67 and 146.68 of this chapter.

(B) *Documentation required to be filed and required filing date.* The person required to file shall file Customs Form 7501 no later than 10 working days after the date of exportation to Canada or Mexico or 10 working days after being entered into a duty-deferral program in Canada or Mexico. Except where the context otherwise requires and except as otherwise specifically provided in this paragraph, the procedures for completing and filing Customs Form 7501 in connection with the entry of merchandise under this chapter shall apply for purposes of this paragraph. For purposes of completing Customs Form 7501 under this paragraph, any reference on the form to the entry date shall be taken to refer to the date of exportation of the good or the date the goods are entered into a duty-deferral program in Canada or Mexico. The Customs Form 7501 required under this paragraph may be transmitted electronically.

(C) *Duty payment.* The duty estimated to be due under paragraph (b) of this section shall be deposited with Customs 60 calendar days after the date of exportation of the good. If a good is entered into a duty-deferral program in Canada or Mexico, the duty estimated to be due under paragraph (b) of this section, but without any waiver or reduction provided for in that paragraph, shall be deposited with Customs 60 calendar days after the date the good is entered into such duty-deferral program. Nothing shall preclude the deposit of such estimated duty at the time of filing the Customs Form 7501 under paragraph (a)(2)(iii)(B) of this section or at any other time within the 60-day period prescribed in this paragraph. However, any interest calculation shall run from the date the duties are required to be deposited.

(3) *Waiver or reduction of duties.*

(i) *General.* Except in the case of duties and fees referred to in §§ 181.42(a) through (c) and fees provided for in § 24.23 of this chapter, Customs shall waive or reduce the duties paid or owed under paragraph (a)(2) of this section by the person who is required to file the Customs Form 7501 (see paragraph (a)(2)(iii)(A) of this section) in accordance with paragraph (b) of this section, provided that a claim for waiver or reduction of the duties is filed with Customs within the appropriate 60-day time frame. The claim shall be based on evidence of exportation or entry into a Canadian or Mexican duty-deferral program and satisfactory evidence of duties paid in Canada or Mexico (see § 181.47(c)).

(ii) *Filing of claim and payment of reduced duties.* A claim for a waiver or reduction of duties under paragraph (a)(3)(i) of this section shall be made on Customs Form 7501 which shall set forth, in addition to the information required under paragraph (a)(2)(iii)(B) of this section, a description of the good exported to Canada or Mexico and the Canadian or Mexican import entry number, date of importation, tariff classification number, rate of duty and amount of duty paid. If a claim for reduction of duties is filed under this paragraph, the reduced duties shall be deposited with Customs when the claim is filed.

(iii) *Drawback on goods entered into a duty-deferral program in Canada or Mexico.* After goods in a duty-deferral program in the United States which have been sent from the United States and entered into a duty-deferral program in Canada or Mexico are then withdrawn from that Canadian or Mexican duty-deferral program either for entry into Canada or Mexico or for export to a non-NAFTA country, the person who filed the Customs Form 7501 (see paragraph (a)(2)(iii)(A) of this section) may file a claim for drawback if the goods are withdrawn within 5 years from the date of the original importation of the good into the United States. If the goods are entered for consumption in Canada or Mexico, drawback will be calculated in accordance with § 181.44 of this part.

(4) *Liquidation of entry.*

(i) *If no claim is filed.* If no claim for a waiver or reduction of duties is filed in accordance with paragraph (a)(3) of this section, Customs shall determine the final duties due under paragraph (a)(2)(i) of this section and shall post a bulletin notice of liquidation of the entry filed under this section in accordance with § 159.9 of this chapter. Where no claim was filed in accordance with this section and Customs fails to liquidate, or extend liquidation of, the entry filed under this section within 1 year from the date of the entry, upon the date of expiration of that 1-year period the entry shall be deemed liquidated by operation of law in the amount asserted by the exporter on the Customs Form 7501 filed under paragraph (a)(2)(iii)(A) of this section. A protest under section 514, Tariff Act of 1930, as amended (19 U.S.C. 1514), and part 174 of this chapter shall be filed within 90 days from the date of posting of the notice of liquidation under this section.

(ii) *If a claim is filed.* If a claim for a waiver or reduction of duties is filed in accordance with paragraph (a)(3) of this section, an extension of liquidation of the entry filed under this section shall take effect for a period not to exceed 3 years from the date the entry was filed. Before the close of the extension period, Customs shall liquidate the entry filed under this section and shall post a bulletin notice

of liquidation in accordance with § 159.9 of this chapter. If Customs fails to liquidate the entry filed under this section within 4 years from the date of the entry, upon the date of expiration of that 4-year period the entry shall be deemed liquidated by operation of law in the amount asserted by the exporter on the Customs Form 7501 filed under paragraph (a)(3)(ii) of this section. A protest under section 514, Tariff Act of 1930, as amended (19 U.S.C. 1514), and part 174 of this chapter shall be filed within 90 days from the date of posting of the notice of liquidation under this section.

(b) *Assessment and waiver or reduction of duty.*

(1) *Manipulation in warehouse.* Where a good subject to NAFTA drawback under this subpart is withdrawn from a bonded warehouse (19 U.S.C. 1562) after manipulation for exportation to Canada or Mexico or for entry into a duty-deferral program in Canada or Mexico, duty shall be assessed on the good in its condition and quantity, and at its weight, at the time of such withdrawal from the warehouse and with such additions to, or deductions from, the final appraised value as may be necessary by reason of its change in condition. Such duty shall be paid no later than 60 calendar days after the date of exportation or of entry into the duty-deferral program of Canada or Mexico, except that, upon filing of a proper claim under paragraph (a)(3) of this section, the duty shall be waived or reduced in an amount that does not exceed the lesser of the total amount of duty payable on the good under this section or the total amount of customs duties paid to Canada or Mexico.

(2) *Bonded manufacturing warehouse.* Where a good is manufactured in a bonded warehouse (19 U.S.C. 1311) with imported materials and is then withdrawn for exportation to Canada or Mexico or for entry into a duty-deferral program in Canada or Mexico, duty shall be assessed on the materials in their condition and quantity, and at their weight, at the time of their importation into the United States. Such duty shall be paid no later than 60 calendar days after either the date of exportation or of entry into a duty-deferral program of Canada or Mexico, except that, upon filing of a proper claim under paragraph (a)(3) of this section, the duty shall be waived or reduced in an amount that does not exceed the lesser of the total amount of duty payable on the materials under this section or the total amount of customs duties paid to Canada or Mexico.

Example. Company N imports tea into the United States and makes a Class 6 warehouse entry. Company N manufactures sweetened ice tea mix by combining the imported tea with refined cane sugar and other flavorings and packaging it in retail size canisters. Upon withdrawal of the ice tea mix from the warehouse for exportation to Canada, a Customs Form 7501 is filed showing $900 in estimated U.S. duties on the basis of the unmanufactured tea. Upon entry into Canada, the equivalent of US$800 is assessed on the exported ice tea mix. Company N submits to Customs a proper claim under paragraph (a)(3) of this section showing payment of the US$800 equivalent in duties to Canada. Company N will only be required to pay $100 in U.S. duties out of the $900 amount reflected on the Customs Form 7501.

(3) *Bonded smelting or refining warehouse.* For any qualifying imported metal-bearing materials (19 U.S.C. 1312), duty shall be assessed on the imported materials and the charges against the bond canceled no later than 60 calendar days after either the date of exportation of the treated materials to Canada or Mexico or the date of entry of the treated materials into a duty-deferral program of Canada or Mexico, either from the bonded smelting or refining warehouse or from such other customs bonded warehouse after the transfer of the same quantity of material from a bonded smelting or refining warehouse. However, upon filing of a proper claim under paragraph (a)(3) of this section, the duty on the imported materials shall be waived or reduced in an amount that does not exceed the lesser of the total amount of duty payable on the imported materials under this section or the total amount of customs duties paid to Canada or Mexico.

Example. Company Z imports 47 million pounds of electrolytic zinc which is entered into a bonded smelting and refining warehouse (Class 7) for processing. Thereafter, Company Z withdraws the merchandise for exportation to Canada and files a Customs Form 7501 showing $90,000 in estimated U.S. duty on the dutiable quantity of metal contained in the imported metal-bearing materials. Upon entry of the processed zinc into Canada, the equivalent of US$50,000 in duties are assessed. Within 60 days of exportation Company Z files a proper claim under paragraph (a)(3) of this section and Customs liquidates the entry with duty due in the amount of $40,000.

(4) *Foreign trade zone.* For a good that is manufactured or otherwise changed in condition in a foreign trade zone (19 U.S.C. 81c(a)) and then withdrawn from the zone for exportation to Canada or Mexico or for entry into a Canadian or Mexican duty-deferral program, the duty assessed, as calculated under paragraph (e)(1) or (e)(2) of this section, shall be paid no later than 60 calendar days after either the date of exportation of the good to Canada or Mexico or the date of entry of the good into a duty-deferral program of Canada or Mexico, except that, upon filing of a proper claim under paragraph (a)(3) of this section, the duty shall be waived or reduced in an amount that does not exceed the lesser of the total amount of duty payable on the good under this section or the total amount of customs duties paid to Canada or Mexico.

(i) *Nonprivileged foreign status.* In the case of a nonprivileged foreign status good, duty is assessed on the good in its condition and quantity, and at its weight, at the time of its exportation from the zone to Canada or Mexico or its entry into a duty-deferral program of Canada or Mexico.

Example. CMG imports $1,000,000 worth of auto parts from Korea and admits them into Foreign-Trade Subzone number 00, claiming nonprivileged foreign status. (If the auto parts had been regularly entered they would have been dutiable at 4 percent, or $40,000.) CMG manufactures subcompact automobiles. Automobiles are dutiable at 2.5 percent ($25,000) if entered for consumption in the United States. CMG withdraws the automobiles from the zone and exports them to Mexico. Upon entry of the automobiles in Mexico, CMG pays the equivalent of US$20,000 in duty. Before the expiration of 60 calendar days from the date of exportation, CMG files a proper claim under paragraph (a)(3) of this section and pays $5,000 in duty to Customs representing the difference between the $25,000 which would have been paid if the automobiles had been entered for consumption from the zone and the US$20,000 equivalent paid to Mexico.

(ii) *Privileged foreign status.* In the case of a privileged foreign status good, duty is assessed on the good in its condition and quantity, and at its weight, at the time privileged status is granted in the zone.

Example. O&G, Inc. admits Kuwaiti crude petroleum into its zone and requests, one month later, privileged foreign status on the crude before refining the crude into motor gasoline and kerosene. Upon withdrawal of the refined goods from the zone by O&G, Inc. for exportation to Canada, a Customs Form 7501 is filed showing $700 in estimated duties on the imported crude petroleum (rather than on the refined goods which would have been assessed $1,200). D&O is the consignee in Canada and pays the Canadian customs duty assessment of the equivalent of US$1,500 on the goods. O&G, Inc. is entitled to a waiver of the full $700 in duties upon filing of a proper claim under paragraph (a)(3) of this section.

(5) *Temporary importation under bond.* Except in the case of a good imported from Canada or Mexico for repair or alteration, where a good, regardless of its origin, was imported temporarily free of duty for repair,

alteration or processing (subheading 9813.00.05, Harmonized Tariff Schedule of the United States) and is subsequently exported to Canada or Mexico, duty shall be assessed on the good on the basis of its condition at the time of its importation into the United States. Such duty shall be paid no later than 60 calendar days after either the date of exportation or the date of entry into a duty-deferral program of Canada or Mexico, except that, upon filing of a proper claim under paragraph (a)(3) of this section, the duty shall be waived or reduced in an amount that does not exceed the lesser of the total amount of duty payable on the good under this section or the total amount of customs duties paid to Canada or Mexico.

Example. Company A imports glassware under subheading 9813.00.05, HTSUS. The glassware is from France and would be dutiable under a regular consumption entry at $6,000. Company A alters the glassware by etching hotel logos on the glassware. Two weeks later, Company A sells the glassware to Company B, a Mexican company, and ships the glassware to Mexico. Company B enters the glassware and is assessed duties in an amount equivalent to US$6,200 and claims NAFTA preferential tariff treatment. Company B provides a copy of the Mexican landing certificate to Company A showing that the US$6,200 equivalent in duties was assessed but not yet paid to Mexico. If Mexico ultimately denies Company B's NAFTA claim and the Mexican duty payment becomes final, Company A, upon submission to Customs of a proper claim under paragraph (a)(3) of this section, is entitled to a waiver of the full $6,000 in U.S. duty.

(c) *Recordkeeping requirements.* If a person intends to claim a waiver or reduction of duty on goods under this section, that person shall maintain records concerning the value of all involved goods or materials at the time of their importation into the United States and concerning the value of the goods at the time of their exportation to Canada or Mexico or entry into a duty-deferral program of Canada or Mexico, and if a person files a claim under this section for a waiver or reduction of duty on goods exported to Canada or Mexico or entered into a Canadian or Mexican duty-deferral program, that person shall maintain evidence of exportation or entry into a Canadian or Mexican duty-deferral program and satisfactory evidence of the amount of any customs duties paid to Canada or Mexico on the good (see § 181.47(c)). Failure to maintain adequate records will result in denial of the claim for waiver or reduction of duty.

(d) *Failure to file proper claim.* If the person identified in paragraph (a)(2)(iii)(A) of this section fails to file a proper claim within the 60-day period specified in this section, that person, or the FTZ operator pursuant to paragraph (a)(2)(iii)(A)(*3*) of this section, will be liable for payment of the full duties assessed under this section and without any waiver or reduction thereof.

(e) *Subsequent claims for preferential tariff treatment.* If a claim for a refund of duties is allowed by the Canadian or Mexican customs administration under Article 502(3) of the NAFTA or under any other circumstance after duties have been waived or reduced under this section, Customs may reliquidate the entry filed under this section pursuant to 19 U.S.C. 1508(b)(2)(B)(iii) even after liquidation of the entry has become final.

George J. Weise,

Commissioner of Customs.

Approved: January 24, 1996.

John P. Simpson,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 96–1677 Filed 1–29–96; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Oxytetracycline Hydrochloride Soluble Powder

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for the use of a generic oxytetracycline hydrochloride soluble powder administered orally in drinking water for either control or control and treatment of certain diseases of chickens, turkeys, swine, cattle, and sheep.

EFFECTIVE DATE: January 30, 1996.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Ter., P.O. Box 6457, St. Joseph, MO 64506–0457, filed ANADA 200–146 which provides for use of oxytetracycline hydrochloride soluble powder in the drinking water of chickens, turkeys, swine, cattle, and sheep. The medicated drinking water is used as follows: (1) Chickens for control of infectious synovitis caused by *Mycoplasma synoviae*, chronic respiratory disease and air sac infections caused by *Mycoplasma gallisepticum* and *Escherichia coli*, and fowl cholera caused by *Pasteurella multocida*; (2) turkeys for control of hexamitiasis caused by *Hexamita meleagridis*, infectious synovitis caused by *M. synoviae*, and complicating bacterial organisms associated with blue comb (transmissible enteritis; coronaviral enteritis); (3) swine for control and treatment of bacterial enteritis caused by *E. coli* and *Salmonella choleraesuis* and bacterial pneumonia caused by *P. multocida*; (4) breeding swine for control and treatment of leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by *Leptospira pomona*; (5) calves, beef cattle, and nonlactating dairy cattle for control and treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia (shipping fever complex) caused by *P. multocida*; and (6) sheep for control and treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia (shipping fever complex) caused by *P. multocida*.

ANADA 200–146 for Phoenix Scientific's oxytetracycline hydrochloride soluble powder is approved as a generic copy of Pfizer's Terramycin® Soluble Powder which is covered by NADA 8–622. The ANADA is approved as of December 7, 1995, and the regulations in 21 CFR 520.1660d are amended to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(i) 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.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 520.1660d is amended by adding new paragraphs (a)(7) and (b)(5) to read as follows:

§ 520.1660d Oxytetracycline hydrochloride soluble powder.

(a) * * *

(7) Each 18.14 grams of powder contains 1 gram of OTC HCl (pail: 2 lb).

(b) * * *

(5) No. 059130 for use of OTC HCl concentration in paragraph (a)(7) of this section in chickens, turkeys, swine, cattle, and sheep.

* * * * *

Dated: January 3, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–1741 Filed 1–29–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF STATE

22 CFR Part 31

[Public Notice 2298]

Repeal of Certain Tort and Property Damage Claims Regulations

AGENCY: Office of the Legal Adviser, Department of State.

ACTION: Direct final rule.

SUMMARY: The Department of State will repeal 22 CFR part 31, which contains regulations implementing the Federal Tort Claims Act (FTCA) with respect to the Department (subparts A and B), the State Department's independent authority to pay tort claims arising in foreign countries (subpart C), and certain claims against the International Boundary and Water Commission, United States and Mexico (IBWC) (subpart D).

DATES: This rule is effective May 13, 1996, unless significant adverse comments are received on or before March 8, 1996.

If significant adverse comments are received, the State Department will publish a document in the Federal Register before May 13, 1996 withdrawing this rule.

ADDRESSES: Interested persons are invited to submit comments to the Office of International Claims and Investment Disputes, Office of the Legal Adviser, Suite 203, South Building, 2430 E Street NW., Washington, DC 20037–2800.

FOR FURTHER INFORMATION CONTACT: Stephen D. McCreary, Attorney-Adviser, Office of International Claims and Investment Disputes, Office of the Legal Adviser, Suite 203, South Building, 2430 E Street NW., Washington, DC 20037–2800; telephone (202) 776–8440.

SUPPLEMENTARY INFORMATION: The State Department regulations implementing the Federal Tort Claims Act are a combination of substantive provisions largely drawn from the Department of Justice FTCA regulations in 28 CFR part 14, which apply to tort claims against all government agencies, and procedural provisions drawn from the State Department's internal Foreign Affairs Manual. The State Department FTCA regulations in subparts A and B of part 31 add little additional information, and are thus duplicative and unnecessary. Section 2672 of the FTCA (28 U.S.C. 2672) provides that claims are to be considered in accordance with regulations issued by the Attorney General. Section 14.11 of the Justice Department regulations authorize agencies to issue supplementary FTCA regulations, but do not require that they do so. The State Department has concluded that it need not maintain supplementary FTCA regulations.

Claims against the Department of State should continue to be submitted directly to the office, bureau, division, or Foreign Service establishment out of whose activities the claim arises, if known; or if not known, to the Assistant Legal Adviser for International Claims and Investment Disputes, L/CID, Department of State, Washington, DC 20520.

Subpart C of part 31 concerns the Department's independent authority to pay tort claims arising overseas, and has no counterpart in the Justice Department's FTCA regulations. However, subpart C is a single paragraph which provides little information beyond that already available in the statute (22 U.S.C. 2669(f)). Thus, the Department has concluded that subpart C may be deleted.

The regulations in subpart D of part 31 regarding claims against the International Boundary and Water Commission, United States and Mexico, have not been used in many years, and in any case essential repeat the provisions of the underlying statute. Repeal of these regulations has been coordinated with the Legal Adviser's Office of the IBWC, United States Section. The State Department and the IBWC, United States Section, have concluded that it is appropriate to delete subpart D.

Implemention of this rule as a direct final rule, with provision for postpromulgation comments, is based on the "good cause" exception to the Administrative Procedures Act found at 5 U.S.C. 553(b)(B). Repeal of these regulations is expected to be noncontroversial, and therefore unlikely to engender public comment. Thus, provision for prepromulgation notice and comment is considered unnecessary. Written comments are invited from the public on or before March 8, 1996. Unless the State Department receives on or before that date significant comments adverse to repeal of these regulations, and publishes a notice in the **Federal Register** before May 13, 1996, withdrawing this rule, this rule becomes effective on May 13, 1996.

Repeal of these regulations by this rule is not expected to have a significant impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. This rule does not impose a Federal regulatory mandate on state, local, or tribal government entities under the Unfunded Mandates Act (P.L. 104–4) because it repeals regulations which themselves created no such mandate. This rule has been reviewed as required by Executive Order 12778 and is in compliance therewith. This rule is exempt from review under Executive Order 12866, but has been reviewed to ensure consistency with its overall policies and purposes. This rule does not contain a new or amended information requirement subject to the Paperwork Reduction Act of 1980.

List of Subjects in 22 CFR Part 31

Claims.

PART 31—[REMOVED]

Accordingly, under the authority of 22 U.S.C. 2651a(4), 22 CFR part 31 is removed.

Dated: December 8, 1995.

Jamison Selby Borek,

Deputy Legal Adviser.

[FR Doc. 96–1531 Filed 1–29–96; 8:45 am]

BILLING CODE 4710–08–M

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 312, 317, 318, 320, 321, 323, 505, 701, and 806b

Privacy Program

AGENCY: Department of Defense.
ACTION: Final rule.

SUMMARY: The President signed Executive Order 12958 on April 17, 1995, replacing Executive Order 12356 effective October 14, 1995. Therefore, the Department of Defense is amending Privacy Act procedural and exemption rules where they cite the old Executive Order 12356, replacing it with Executive Order 12958.

EFFECTIVE DATE: October 14, 1995.

FOR FURTHER INFORMATION CONTACT: Ms. Jody Sinkler at (703) 607–2943 or DSN 327–2943.

SUPPLEMENTARY INFORMATION: Executive Order 12866. The Director, Administration and Management, Office of the Secretary of Defense has determined that this proposed Privacy Act rule for the Department of Defense does not constitute 'significant regulatory action'. Analysis of the rule indicates that it does not have an annual effect on the economy of $100 million or more; does not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; does not materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; does not raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866 (1993).

Regulatory Flexibility Act of 1980. The Director, Administration and Management, Office of the Secretary of Defense certifies that this Privacy Act rule for the Department of Defense does not have significant economic impact on a substantial number of small entities because it is concerned only with the administration of Privacy Act systems of records within the Department of Defense.

Paperwork Reduction Act. The Director, Administration and Management, Office of the Secretary of Defense certifies that this Privacy Act proposed rule for the Department of Defense imposes no information requirements beyond the Department of Defense and that the information collected within the Department of Defense is necessary and consistent with 5 U.S.C. 552a, known as the Privacy Act of 1974.

The President signed Executive Order 12958 on April 17, 1995, replacing Executive Order 12356 effective October 14, 1995. Therefore, the Office of the Inspector General is amending Privacy Act procedural and exemption rules where they cite the old Executive Order 12356, replacing it with Executive Order 12958.

List of Subjects in 32 CFR part 312, 317, 318, 320, 321, 323, 505, 701, and 806b

Privacy.

Accordingly, 32 CFR part 312 is amended as follows:

1. The authority citation for 32 CFR part 312, 317, 318, 320, 321, 323, 505, 701, and 806b continues to read as follows:

Authority: Pub. L. 93–579, 88 Stat 1896 (5 U.S.C.552a).

2. Section 312.12, paragraph (a), is amended by revising the first sentence to read as follows:

§ 312.12 Exemptions.

(a) Any record in a system of records maintained by the Office of the Inspector General which falls within the provisions of 5 U.S.C. 552a(k)(1) may be exempt from the following subsections of 5 U.S.C. 552a: (c)(3), (d), (e)(1), (e)(4)(G) through (I) and (f) to the extent that a record system contains any record properly classified under Executive Order 12958 and that the record is required to be kept classified in the interest of national defense or foreign policy.* * *

* * * * *

3. Section 317.133, paragraph (b), is amended by revising the first sentence to read as follows:

§ 317.133 DCAA exempt record systems.

* * * * *

(b) *Classified material.* The Director, DCAA has made a determination that all systems of records maintained by the agency shall be exempt from 5 U.S.C. 552a(d) of the Privacy Act pursuant to 5 U.S.C. 552a(k)(1) to the extent that the record system contains any information properly classified under Executive Order 12958 and required by the executive order to be withheld in the interest of national defense or foreign policy.* * *

* * * * *

4. Section 318.5, paragraph (a), is amended by revising the first sentence to read as follows:

§ 318.5 Exemptions.

(a) *Exemption for classified material.* All systems of records maintained by the Defense Nuclear Agency shall be exempt under section (k)(1) of 5 U.S.C. 552a, to the extent that the systems contain any information properly classified under E.O. 12958 and that is required by that E.O. to be kept secret in the interest of national defense or foreign policy.* * *

* * * * *

5. Section 320.11, is amended by revising the first sentence to read as follows:

§ 320.11 Specific exemptions.

All systems of records maintained by the Defense Mapping Agency and its components shall be exempt from the requirements of 5 U.S.C. 552a(d) pursuant to 5 U.S.C. 552a(k)(1) to the extent that the system contains any information properly classified under Executive Order 12958 and that is required by Executive Order to be kept secret in the interest of national defense or foreign policy.* * *

6. Section 321.14, paragraph (b), first sentence is revised to read as follows:

§ 321.14 Exemptions.

* * * * *

(b) All systems of records maintained by DIS shall be exempt from the requirements of 5 U.S.C. 552a(d) pursuant to 5 U.S.C. 552a(k)(1) to the extent that the system contains any information properly classified under Executive Order 12958 and which is required by the Executive Order to be withheld in the interest of national defense of foreign policy.* * *

* * * * *

7. Appendix H to part 323, introductory text, first sentence is revised to read as follows:

Appendix H to Part 323–DLA Exemption Rules

Exempt Records Systems. All systems of records maintained by the Defense Logistics Agency will be exempt from the requirements of 5 U.S.C. 552a(d) pursuant to 5 U.S.C. 552a(k)(1) to the extent that the system contains any information properly classified under Executive Order 12958 and which is required by the Executive Order to be kept secret in the interest of national defense or foreign policy.* * *

* * * * *

8. Section 505.5 is amended in paragraphs (e)k.(4), (e)m.(4), (e)n.(4), (e)o.(4), and (e)p.(4) by revising '12356' to read '12958' and by revising paragraph (c)(1) to read as follows:

§ 505.5 Exemptions.

* * * * *

(c) *Specific exemptions.*

(1) *Classified information in every Army system of records.* This exemption is not limited to the systems listed in paragraph (d) of this section. Before denying as individual access to classified information, the Access and Amendment Refusal Authority must make sure that it was properly classified under the standards of Executive Orders 11652, 12065, or 12958 and that it must remain so in the interest of national defense of foreign policy. (5 U.S.C. 552a(k)(1)).

* * * * *

9. Part 701 is amended by revising '12356' to read '12958' in the following sections:

a. Section 701.113 paragraphs (d) and (g)(1).

b. Section 701.117.

c. Section 701.118, paragraphs (a) *Reasons:*, (m) *Reasons:*, (p) *Reasons:*.

d. Section 701.119, paragraph (b) *Reasons:*.

10. Appendix C to Part 806b, paragraph (b)(1)(i), is amended by revising '12356' to read '12958'.

Dated: December 4, 1995.

L. M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense

[FR Doc. 96–1614 Filed 1–29–96; 8:45 am]

BILLING CODE 5000–04–F

DEPARTMENT OF THE INTERIOR

National Park Service

36 CFR Part 1

RIN 1024–AC06

Penalty Provisions

AGENCY: National Park Service, Interior.

ACTION: Final rule.

SUMMARY: The National Park Service (NPS) is amending the existing penalty provisions for convictions of violating NPS regulations to conform with the Criminal Fine Improvements Act of 1987 (Pub. L. 100–185; 18 U.S.C. 3571). This Act changed the maximum fine levels for all petty offenses, including those of a regulatory nature, to $5,000 for individuals and $10,000 for organizations.

EFFECTIVE DATE: This rule is effective January 30, 1996.

ADDRESSES: Comments should be addressed to Dennis Burnett, National Park Service, Ranger Activities Division, P.O. Box 37127, Washington, DC 20013–7127.

FOR FURTHER INFORMATION CONTACT: Dennis Burnett, Ranger Activities Division, at the above address. Phone: 202–208–4874.

SUPPLEMENTARY INFORMATION:

Background

The current NPS penalty provisions are found in 36 CFR 1.3. Under these provisions, four levels of penalties are delineated under different penalty authorities. First, in § 1.3(a), a person convicted of violating applicable NPS regulations in 36 CFR Chapter 1 "shall be punished by a fine not exceeding $500 or by imprisonment not exceeding 6 months, or both", as authorized by 16 U.S.C. 3. Second, § 1.3(b) applies to certain military parks, battlefield sites, national monuments, or other memorials originally under the jurisdiction of the Secretary of the Army. In these areas the fine and penalty are currently set, pursuant to the Act of March 2, 1933 (47 Stat. 1420), at "not more than $100, or by imprisonment for not more than 3 months, or by both" for persons who "knowingly and willfully" violate applicable regulations. Third, at § 1.3(c), persons convicted of violating applicable regulations in park areas established by the Act of August 21, 1935 (79 Stat. 971) "shall be punished by a fine of not more than $500". Last, at § 1.3(d), a person convicted of violating 36 CFR 2.23 relating to recreation fees, pursuant to Pub. L. No. 92–347 (86 Stat. 459) "shall be punished by a fine of not more than $100".

This rule will revise the penalty language at 36 CFR 1.3 (a), (b), (c) and (d) to reflect the revised statutory fine provisions of the Criminal Fine Improvements Act of 1987 (18 U.S.C. 3571).

Fines: On January 1, 1985, the Criminal Fine Enforcement Act of 1984 (Pub. L. No. 98–596) became effective, in which the definition of "petty offense" was changed to include an offense in which the maximum fine level was $5,000 for an individual and $10,000 for an organization. However, this Act did not change the actual fine levels themselves for petty offenses. This was accomplished by the Criminal Fine Improvements Act of 1987 (Pub. L. No. 100–185). This latter Act specifically established the maximum fine levels for petty offenses to be $5,000 for individuals and $10,000 for organizations (18 U.S.C. 3571). Petty offenses were also defined to mean any Class B or C misdemeanor, or an infraction, as defined in 18 U.S.C. 3559.

Additionally, Chapter 227 of Title 18, which became effective on November 1, 1987, states:

> Except as otherwise specifically provided, a defendant who has been found guilty of an offense described in *any Federal statute*, other than an Act of Congress applicable exclusively in the District of Columbia or the Uniform Code of Military Justice, shall be sentenced in accordance with the provisions of this chapter. (18 U.S.C. 3551(a); emphasis added).

Therefore, this rule will reflect the change in law, making the fine levels as stated in 18 U.S.C. 3571 apply to NPS regulations.

Applicability: Section 3 of the Act of August 25, 1916 (NPS Organic Act), as amended by § 5 of the Act of June 2, 1920 (41 Stat. 732), provides the Secretary of the Interior with the authority to "make and publish such rules and regulations as he may deem necessary or proper for the use and management of the parks, monuments, and reservations under the jurisdiction of the National Park Service, and any violation of any of the rules and regulations authorized by this section and sections 1, 2, and 4 of this title shall be punished by a fine of not more than $500 or imprisonment for not exceeding six months, or both, and be adjudged to pay all cost of the proceedings." (16 U.S.C. 3).

The NPS is adopting this final rule pursuant to the "agency procedure" exception of the Administrative Procedures Act (5 U.S.C. 553(b)(A)) from general notice and comment rulemaking. The NPS believes that this exception from rulemaking procedures is warranted because it is merely conforming the penalty language found at 36 CFR 1.3 (a), (b), (c) and (d) to reflect the revised statutory fine provisions of the Criminal Fine Improvements Act of 1987 (18 U.S.C. 3571). The NPS finds that notice and comment are unnecessary and contrary to the public interest for this final rule.

The NPS has also determined, in accordance with the Administrative Procedures Act (5 U.S.C. 553(d)(3)), that the publishing of this final rule 30 days prior to the rule becoming effective would be counterproductive and unnecessary for the reasons discussed above. A 30-day delay would be contrary to the public interest and the interest of the agency. Therefore, under the "good cause" exception of the Administrative Procedure Act (5 U.S.C. 553(b)(3)), it has been determined that this rulemaking is excepted from the 30-day delay in the effective date and shall therefore become effective on the date published in the **Federal Register.**

Public Participation

It is the policy of the Department of the Interior, whenever practicable, to

afford the public an opportunity to participate in the rulemaking process. Accordingly, interested persons may submit written comments regarding this final rule to the address noted at the beginning of this rulemaking.

Drafting Information

The primary authors of this regulation are Tony Sisto, Superintendent, Fort Vancouver NHS; Dennis Burnett, Washington Office of Ranger Activities, NPS; and Michael Tiernan, Division of Conservation and Wildlife, Office of the Solicitor, Department of the Interior, Washington, D.C.

Paperwork Reduction Act

This rulemaking does not contain collections of information requiring approval by the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

Compliance With Other Laws

This rule was not subject to Office of Management and Budget review under Executive Order 12866. The Department of the Interior determined that this document will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 USC 601 *et seq.*). The economic effects of this rulemaking are local in nature and negligible in scope.

The NPS has determined that this proposed rulemaking will not have a significant effect on the quality of the human environment, health and safety because it is not expected to:

(a) increase public use to the extent of compromising the nature and character of the area or causing physical damage to it;

(b) Introduce incompatible uses which compromise the nature and character of the area or causing physical damage to it;

(c) Conflict with adjacent ownerships or land uses; or

(d) Cause a nuisance to adjacent owners or occupants.

Based on this determination, this regulation is categorically excluded from the procedural requirements of the National Environmental Policy Act (NEPA) by Departmental guidelines in 516 DM 6 (49 FR 21438). As such, neither an Environmental Assessment (EA) nor an Environmental Impact Statement (EIS) has been prepared.

List of Subjects in 36 CFR Part 1

National parks, Penalties, Reporting and recordkeeping requirements.

In consideration of the foregoing, 36 CFR Chapter I is amended as follows:

PART 1—GENERAL PROVISIONS

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

Authority: 16 U.S.C. 1, 3, 460 1–6a(e), 469(k); D.C. Code 8–137, 40–721 (1981).

2. Section 1.3 is revised to read as follows:

§ 1.3 Penalties

(a) A person convicted of violating a provision of the regulations contained in Parts 1 through 7, 12 and 13 of this chapter, within a park area not covered in paragraphs (b) or (c) of this section, shall be punished by a fine as provided by law, or by imprisonment not exceeding 6 months, or both, and shall be adjudged to pay all costs of the proceedings.

(b) A person who knowingly and willfully violates any provision of the regulations contained in parts 1 through 5, 7 and 12 of this chapter, within any national military park, battlefield site, national monument, or miscellaneous memorial transferred to the jurisdiction of the Secretary of the Interior from that of the Secretary of War by Executive Order No. 6166, June 10, 1933, and enumerated in Executive Order No. 6228, July 28, 1933, shall be punished by a fine as provided by law, or by imprisonment for not more than 3 months, or by both.

Note: These park areas are enumerated in a note under 5 U.S.C. 901.

(c) A person convicted of violating any provision of the regulations contained in parts 1 through 7 of this chapter, within a park area established pursuant to the Act of August 21, 1935, 49 Stat. 666, shall be punished by a fine as provided by law and shall be adjudged to pay all costs of the proceedings. 16 U.S.C. 462.

(d) Notwithstanding the provisions of paragraphs (a), (b) and (c) of this section, a person convicted of violating § 2.23 of this chapter shall be punished by a fine as provided by law. 16 U.S.C. 460.

Dated: October 20, 1995.

George T. Frampton, Jr.,

Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 96–1748 Filed 1–29–96; 8:45 am]

BILLING CODE 4310–70–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[FRL–5321–4]

Approval and Promulgation of Implementation Plans and Designation of Areas for Air Quality Planning Purposes; State of Massachusetts; Change in National Policy Regarding Applicability of Conformity Requirements to Redesignation Requests

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: On December 12, 1994, the Massachusetts Department of Environmental Protection (MA DEP) submitted a request to redesignate the Boston metropolitan area, including the communities of Boston, Cambridge, Chelsea, Everett, Malden, Medford, Quincy, Revere, and Somerville, from nonattainment to attainment for carbon monoxide (CO). Under the Clean Air Act as amended in 1990 (CAA), designations can be revised if sufficient data is available to warrant such revisions. In this action, EPA is approving the Massachusetts request because it meets the redesignation requirements set forth in the CAA.

In addition, EPA is approving two related State Implementation Plan (SIP) submissions by Massachusetts DEP. On November 15, 1993, Massachusetts DEP submitted a final 1990 base year emission inventory for CO emissions, which includes emissions data for all sources of CO in Massachusetts' CO nonattainment areas, as well as CO emissions for the entire state. On October 29, 1993, Massachusetts DEP submitted an oxygenated gasoline program for the Boston consolidated metropolitan statistical area (CMSA). In this action, EPA is approving the CO emissions inventory and oxygenated fuels SIP submissions.

DATES: This final rule will be effective April 1, 1996 unless critical or adverse comments are received by February 29, 1996. If the effective date is delayed, timely notice will be published in the **Federal Register.**

ADDRESSES: Written comments should be sent to Susan Studlien, Acting Director of the Air, Pesticides and Toxics Management Division, at the EPA Regional Office listed below. Copies of the redesignation request and the State of Massachusetts' submittal are available for public review during normal business hours at the addresses listed below.

Air and Radiation Docket and Information Center, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, and; Environmental Protection Agency, One Congress Street, Boston, MA 02203.

FOR FURTHER INFORMATION CONTACT: Wing Chau of the EPA Region I Air, Pesticides and Toxics Management Division at (617) 565–3570.

SUPPLEMENTARY INFORMATION:

I. Background

In a March 15, 1991 letter to the EPA Region I Administrator, the Governor of Massachusetts recommended the Boston metropolitan area, which covers the nine surrounding cities (the "Boston area"), be designated as nonattainment for CO as required by section 107(d)(1)(A) of the 1990 Clean Air Act Amendments (CAA) (Public Law 101–549, 104 Stat. 2399, codified at 42 U.S.C. 7401–7671q). The area was designated nonattainment and classified as "moderate" under the provisions outlined in sections 186 and 187 of the CAA. (See 56 FR 56694 (Nov. 6, 1991) and 57 FR 56762 (Nov. 30, 1992), codified at 40 CFR part 81, § 81.322.) Because the area had a design value of 9.8 ppm (based on 1986 data), the area was considered moderate. The CAA established an attainment date of December 31, 1995, for all moderate CO areas. The Boston area has ambient monitoring data showing attainment of the CO NAAQS, since 1988. Therefore, in an effort to comply with the CAA and to ensure continued attainment of the NAAQS, on December 12, 1994 the State of Massachusetts submitted a CO redesignation request and a maintenance plan for the Boston area. Massachusetts submitted evidence that public hearings were held on September 29, 1994 in Springfield and on September 30, 1994 in Boston.

II. Evaluation Criteria

Section 107(d)(3)(E) of the 1990 Clean Air Act Amendments provides five specific requirements that an area must meet in order to be redesignated from nonattainment to attainment.

1. The area must have attained the applicable NAAQS;
2. The area must have a fully approved SIP under section 110(k) of CAA;
3. The air quality improvement must be permanent and enforceable;
4. The area must have a fully approved maintenance plan pursuant to section 175A of the CAA;
5. The area must meet all applicable requirements under section 110 and Part D of the CAA.

III. Review of State Submittal

On January 17, 1995, EPA-New England determined that the information received from the MA DEP constituted a complete redesignation request under the general completeness criteria of 40 CFR part 51, appendix V, §§ 2.1 and 2.2.

The Massachusetts redesignation request for the Boston area meets the five requirements of section 107(d)(3)(E), noted above. The following is a brief description of how the State has fulfilled each of these requirements.

1. Attainment of the CO NAAQS

Massachusetts has quality-assured CO ambient air monitoring data showing that the Boston area has met the CO NAAQS. The Massachusetts request is based on an analysis of quality-assured CO air monitoring data which is relevant to the maintenance plan and to the redesignation request. To attain the CO NAAQS, an area must have complete quality-assured data showing no more than one exceedance of the standard per year over at least two consecutive years. The ambient air CO monitoring data for calendar year 1988 through calendar year 1993, relied upon by Massachusetts in its redesignation request, shows no violations of the CO NAAQS in the Boston area. The most recent ambient CO data shows no exceedances in the calendar years 1994 and 1995. Because the area has complete quality assured data showing no more than one exceedance of the standard per year over at least two consecutive years (1991 and 1992), the area has met the first statutory criterion of attainment of the CO NAAQS (40 CFR 50.9 and appendix C). Massachusetts has committed to continue monitoring in this area in accordance with 40 CFR part 58.

2. Fully Approved SIP Under Section 110(k) of the CAA

Massachusetts's CO SIP is fully approved by EPA as meeting all the requirements of Section 110(a)(2)(I) of the Act, including the requirements of Part D (relating to nonattainment), which were due prior to the date of Massachusetts' redesignation request. Massachusetts' 1982 CO SIP was fully approved by EPA in 1983 as meeting the CO SIP requirements in effect under the CAA at that time. The 1990 CAAA required that nonattainment areas achieve specific new requirements depending on the severity of the nonattainment classification. Requirements for the Boston area include the preparation of a 1990 emission inventory with periodic updates, adoption of an oxygenated fuels program, the development of contingency measures, and development of conformity procedures. Each of these requirements added by the 1990 Amendments to the CAA are discussed in greater detail below.

Consistent with the October 14, 1994 EPA guidance from Mary D. Nichols entitled "Part D New Source Review (Part D NSR) Requirements for Areas Requesting Redesignation to Attainment," EPA is not requiring full approval of a Part D NSR program by Massachusetts as a prerequisite to redesignation to attainment. Under this guidance, nonattainment areas may be redesignated to attainment notwithstanding the lack of a fully-approved Part D NSR program, so long as the program is not relied upon for maintenance. Massachusetts has not relied on a NSR program for CO sources to maintain attainment. Although EPA is not treating a Part D NSR program as a prerequisite for redesignation, it should be noted that EPA is in the process of taking final action on the State's revised NSR regulation, which includes requirements for CO nonattainment areas. Because the Boston area is being redesignated to attainment by this action, Massachusetts' Prevention of Significant Deterioration (PSD) requirements will be applicable to new or modified sources in the Boston area.

A. Emission Inventory

Massachusetts submitted its base year inventory to EPA on November 15, 1993, which included estimates for CO at the statewide, county and CO nonattainment city/town levels, as required under Section 187(a)(1) of the CAA. EPA is approving the CO portion of the Massachusetts Base Year emission inventory with this redesignation request.

Section 172(c)(3) of the CAA requires that nonattainment plan provisions include a comprehensive, accurate, and current inventory of actual emissions from all sources of relevant pollutants in the nonattainment area. Massachusetts included the requisite inventory in the CO SIP. The base year for the inventory was 1990, using a three month CO season of November 1990 through January 1991. Stationary point sources, stationary area sources, on-road mobile sources, and nonroad mobile sources of CO were included in the inventory. Stationary sources with emissions of greater than 100 tons per year were also included in the inventory.

The following list presents a summary of the CO peak season daily emissions estimates in tons per winter day by

source category: Point Sources, 32.77 tons per day; Area Sources, 711.95 tons per day; Mobile On-Road Sources, 3,387.69 tons per day; Mobile Nonroad Sources, 109.36 tons per day; Total Sources, 4,241.77 tons per day. Available guidance for preparing emission inventories is provided in the General Preamble (57 FR 13498, April 16, 1992).

Section 110(k) of the CAA sets out provisions governing the EPA's review of base year emission inventory submittals in order to determine approval or disapproval under section 187(a)(1). The EPA is granting approval of the Massachusetts 1990 base year CO emissions inventory submitted on November 15, 1993, based on the EPA's technical review of the CO inventory. For further details, the reader is referred to the Technical Support Document, which is available for review at the addresses provided above.

B. Oxygenated Gasoline

Motor vehicles are significant contributors of CO emissions. An important measure toward reducing these emissions is the use of cleaner-burning oxygenated gasoline. Extra oxygen, contained within the oxygenate in the fuel, enhances fuel combustion and helps to offset fuel-rich operating conditions, particularly during vehicle starting, which are more prevalent in the winter.

Section 211(m) of the CAA requires that CO nonattainment areas, with a design value of 9.5 parts per million based on data for the 2-year period of 1988 and 1989, submit a SIP revision for an oxygenated fuel program for such area. The oxygenated fuel requirement must apply to all fuel refiners or marketers who sell or dispense gasoline in the Metropolitan Statistical area (MSA) or Consolidated Statistical Area (CMSA) in which the nonattainment area is located. The Boston area has a design value above 9.5 parts per million based on 1986 and 1987 data (1988 and 1989 data was not used due to insufficient data at one of the CO monitors) and consequently were subject to the requirement to adopt an oxygenated fuel program. Massachusetts submitted an oxygenated fuel SIP revision for the Boston CO nonattainment area to EPA on October 29, 1993. As noted in Massachusetts' redesignation request, the State intends to relegate the oxygenated fuel program to contingency status upon EPA's approval of Massachusetts' redesignation request. As part of this action, EPA is approving Massachusetts' oxygenated fuel program for the Boston CO area.

The oxygenated gasoline program is one in which all oxygenated gasoline must contain a minimum oxygen content of 2.7 percent by weight of oxygen. Under section 211(m)(4) of the CAA, EPA also issued requirements for the labeling of gasoline pumps used to dispense oxygenated gasoline, as well as guidelines on the establishment of an appropriate control period. These labeling requirements and control period guidelines may be found in 57 FR 47849, dated October 20, 1992. Massachusetts' oxygenated gasoline regulation requires the minimum 2.7 percent oxygen content in the Boston CMSA. The regulation also contains the necessary labeling regulations, enforcement procedures, and oxygenate test methods. For a more detailed description of the manner in which Massachusetts' oxygenated fuels program meets the requirements of Section 211(m) of the CAA, the reader is referred to the Technical Support Document, which is available for review at the addresses provided above.

As mentioned above, Massachusetts has chosen to convert its oxygenated fuels requirement in the Boston CMSA to a contingency measure in its maintenance plan upon redesignation. Because Massachusetts attained the CO standard based on data before the oxygenated fuel program was implemented in the Boston CMSA, oxygenated gasoline was not necessary to reach attainment. In its demonstration of maintenance, described below, the State has shown that oxygenated gasoline in the Boston CMSA is not necessary for continued maintenance of the CO NAAQS. Consequently, by this action, EPA is both approving Massachusetts' oxygenated fuels regulation and simultaneously approving its use as a contingency measure for the Boston area.

C. Conformity

Under section 176(c) of the CAA, states were required to submit revisions to their SIPs that include criteria and procedures to ensure that Federal actions conform to the air quality planning goals in the applicable SIPs. The requirement to determine conformity applies to transportation plans, programs and projects developed, funded or approved under Title 23 U.S.C. or the Federal Transit Act ("transportation conformity"), as well as all other Federal actions ("general conformity"). Congress provided for the State revisions to be submitted one year after the date of promulgation of final EPA conformity regulations.

EPA promulgated final transportation conformity regulations on November 24, 1993 (58 FR 62188) and final general conformity regulations on November 30, 1993 (58 FR 63214). These conformity rules require that the States adopt both transportation and general conformity provisions in the SIP for areas designated nonattainment or subject to a maintenance plan approved under CAA section 175A. Pursuant to § 51.396 of the transportation conformity rule, the State of Massachusetts was required to submit a SIP revision containing transportation conformity criteria and procedures consistent with those established in the Federal rule by November 25, 1994. Similarly, pursuant to § 51.851 of the general conformity rule, Massachusetts was required to submit a SIP revision containing general conformity criteria and procedures consistent with those established in the Federal rule by December 1, 1994. Massachusetts submitted its transportation conformity SIP revision to EPA on December 30, 1994. This SIP was determined to be administratively and technically complete on March 16, 1995; however, this SIP has not been fully approved by EPA. Massachusetts has not submitted its general conformity SIP revision.

Although this redesignation request was submitted to EPA after the due dates for the SIP revisions for transportation conformity [58 FR 62188] and general conformity [58 FR 63214] rules , EPA believes it is reasonable to interpret the conformity requirements as not being applicable requirements for purposes of evaluating the redesignation request under section 107(d). The rationale for this is based on a combination of two factors. First, the requirement to submit SIP revisions to comply with the conformity provisions of the Act continues to apply to areas after redesignation to attainment. Therefore, the State remains obligated to adopt the transportation and general conformity rules even after redesignation and would risk sanctions for failure to do so. While redesignation of an area to attainment enables the area to avoid further compliance with most requirements of section 110 and part D, since those requirements are linked to the nonattainment status of an area, the conformity requirements apply to both nonattainment and maintenance areas. Second, EPA's federal conformity rules require the performance of conformity analyses in the absence of state-adopted rules. Therefore, a delay in adopting State rules does not relieve an area from the obligation to implement conformity requirements.

Because areas are subject to the conformity requirements regardless of whether they are redesignated to attainment and must implement conformity under Federal rules if State rules are not yet adopted, EPA believes it is reasonable to view these requirements as not being applicable requirements for purposes of evaluating a redesignation request.

Therefore, with this notice, EPA is modifying its national policy regarding the interpretation of the provisions of section 107(d)(3)(E) concerning the applicable requirements for purposes of reviewing a carbon monoxide redesignation request.

Under this new policy, for the reasons just discussed, EPA believes that the CO redesignation request for the Boston area may be approved notwithstanding the lack of submitted and approved state transportation and general conformity rules.

3. Improvement in Air Quality Due to Permanent and Enforceable Measures

EPA approved Massachusetts' CO SIP under the 1977 CAA. Emission reductions achieved through the implementation of control measures contained in that SIP are enforceable. These measures were: transportation plan reviews, a basic Inspection and Maintenance Program, right turn on red, and the Federal Motor Vehicle Control Program. As discussed above, the State initially attained the NAAQS in 1988 with monitored attainment through the 1994–1995 CO season. This indicates that the improvements are due to the permanent and enforceable measures contained in the 1982 CO SIP.

The State of Massachusetts has demonstrated that actual enforceable emission reductions are responsible for the air quality improvement and that the CO emissions in the base year are not artificially low due to local economic downturn. EPA finds that the combination of certain existing EPA-approved SIP and federal measures contribute to the permanence and enforceability of reduction in ambient CO levels that have allowed the area to attain the NAAQS.

4. Fully Approved Maintenance Plan Under Section 175A

Section 175A of the CAA sets forth the elements of a maintenance plan for areas seeking redesignation from nonattainment to attainment.

The plan must demonstrate continued attainment of the applicable NAAQS for at least ten years after the Administrator approves a redesignation to attainment. Eight years after the redesignation, the state must submit a revised maintenance plan which demonstrates attainment for the ten years following the initial ten-year period. To provide for the possibility of future NAAQS violations, the maintenance plan must contain contingency measures, with a schedule for implementation adequate to assure prompt correction of any air quality problems. In this notice, EPA is approving the State of Massachusetts' maintenance plan for the Boston area because EPA finds that Massachusetts' submittal meets the requirements of section 175A.

A. Attainment Emission Inventory

As previously noted, on November 15, 1993, the State of Massachusetts submitted a comprehensive inventory of CO emissions for the Boston area. The inventory includes emissions from area, stationary, and mobile sources using 1990 as the base year for calculations.

The State submittal contains the detailed inventory data and summaries by county and source category. The comprehensive base year emissions inventory was submitted in the National Emission Data System format. This inventory was prepared in accordance with EPA guidance.

Although the 1990 inventory can be considered representative of attainment conditions because the NAAQS was not violated during 1990, Massachusetts established CO emissions for the attainment year, 1993, as well as four forecast years out to the year 2010 (1995, 2000, 2005, and 2010) in their redesignation request. These estimates were derived from the State's 1990 emissions inventory. The future emission estimates are based on assumptions about economic and vehicle miles travelled growth. These assumptions are documented in the Massachusetts Growth Factors report dated November 1993.

1990 CO Base Year Emissions Inventory Boston Nonattainment Area (Tons per Day)

Year	Area	Nonroad	Mobile	Point	Total
1990	126.76	59.04	343.41	7.62	536.83

Boston Nonattainment Area CO Emissions Inventory Summary (Tons per Day)

Year	Area	Nonroad	Mobile	Point	Total
1990	126.76	59.04	343.41	7.62	536.83
1993	128.32	59.823	305.43	7.96	501.53
1995	129.35	60.344	280.10	8.19	477.98
2000	131.20	62.995	147.56	8.87	350.625
2005	134.39	64.961	125.93	9.69	334.97
2010	137.93	66.695	121.75	10.05	336.425

B. Demonstration of Maintenance-Projected Inventories

Total CO emissions were projected from 1990 base year out to 2010. These projected inventories were prepared in accordance with EPA guidance. Massachusetts will not implement the Oxygenated Fuel program in the Boston CMSA unless a violation is measured. The projections show that calculated CO emissions, assuming no oxygenated fuels program, are not expected to exceed the level of the base year inventory during this time period. Therefore, it is anticipated that the Boston area will maintain the CO standard without the program, and the oxygenated fuel program would not need to be implemented following redesignation, except as a contingency measure.

C. Verification of Continued Attainment

Continued attainment of the CO NAAQS in the Boston area depends, in part, on the State's efforts toward tracking indicators of continued attainment during the maintenance period. The State has also committed to

submit periodic inventories of CO emissions every three years.

D. Contingency Plan

The level of CO emissions in the Boston area will largely determine its ability to stay in compliance with the CO NAAQS in the future. Despite the State's best efforts to demonstrate continued compliance with the NAAQS, the ambient air pollutant concentrations may exceed or violate the NAAQS. Section 175A(d) of the CAA requires that the contingency provisions include a requirement that the State implement all measures contained in the SIP prior to redesignation. Therefore, Massachusetts has provided contingency measures with a schedule for implementation in the event of a future CO air quality problem. The plan contains triggering mechanisms to determine when contingency measures are needed.

Massachusetts has developed a contingency plan which contains a mix of contingency measures that will address site specific CO problems and regional CO emissions. The first set of contingency measures deals with localized CO problems, which is either an engineering fix or traffic flow improvement at any site which triggers the need for the contingency measure. The second set of contingency measures deals with regional CO emissions, which include the implementation of an oxygenated fuels program throughout the Boston CMSA, implementation of an enhanced inspection and maintenance program and implementation of travel demand measures.

In order to be an adequate maintenance plan, the plan should include at least one contingency measure that will go into effect with a triggering event. Massachusetts is relying largely on a contingency measure that is expected to be implemented regardless of any triggering event, namely, enhanced Inspection and Maintenance (I/M). Massachusetts is implementing I/M to meet other requirements of the CAA and it has the additional benefit of reducing CO emissions. Massachusetts has two measures that will not go into effect unless a triggering event occurs, namely oxygenated fuels and traffic flow improvements.

E. Subsequent Maintenance Plan Revisions

In accordance with section 175A(b) of the CAA, the State has agreed to submit a revised maintenance SIP eight years after the area is redesignated to attainment. Such revised SIP will provide for maintenance for an additional ten years.

5. Meeting Applicable Requirements of Section 110 and Part D

In Section III.2. above, EPA sets forth the basis for its conclusion that Massachusetts has a fully approved SIP which meets the applicable requirements of Section 110 and Part D of the CAA.

Final Action

EPA is approving the Boston CO maintenance plan because it meets the requirements set forth in section 175A of the CAA. In addition, the Agency is approving the request and redesignating the Boston CO area to attainment, because the State has demonstrated compliance with the requirements of section 107(d)(3)(E) for redesignation. EPA is also approving Massachusetts' 1990 base year CO emissions inventory and the State's oxygenated gasoline program for the Boston CMSA. The EPA is publishing this action without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in a separate document in this **Federal Register** publication, the EPA is proposing to approve the SIP revision should adverse or critical comments be filed. This action will be effective April 1, 1996 unless, by February 29, 1996 adverse or critical comments are received. If the EPA receives such comments, this action will be withdrawn before the effective date by publishing a subsequent document that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule based on this action serving as a proposed rule. The EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time. If no such comments are received, the public is advised that this action will be effective April 1, 1996.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any SIP. Each request for revision to the SIP shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

The CO SIP is designed to satisfy the requirements of part D of the CAA and to provide for attainment and maintenance of the CO NAAQS. This final redesignation should not be interpreted as authorizing the State to delete, alter, or rescind any of the CO emission limitations and restrictions contained in the approved CO SIP. Changes to CO SIP regulations rendering them less stringent than those contained in the EPA approved plan cannot be made unless a revised plan for attainment and maintenance is submitted to and approved by EPA. Unauthorized relaxations, deletions, and changes could result in both a finding of non-implementation (section 179(a) of the CAA) and in a SIP deficiency call made pursuant to sections 110(a)(2)(H) and 110(k)(2) of the CAA.

Under the Regulatory Flexibility Act, 5 U.S.C. 600 et seq., EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000. SIP approvals under section 110 and subchapter I, part D of the CAA do not create any new requirements, but simply approve requirements that the State is already imposing. Therefore, because the federal SIP approval does not impose any new requirements, it does not have any economic impact on any small entities. Redesignation of an area to attainment under section 107(d)(3)(E) of the CAA does not impose any new requirements on small entities.

Redesignation is an action that affects the status of a geographical area and does not impose any regulatory requirements on sources. Accordingly, I certify that the approval of the redesignation request will not have an impact on any small entities.

Unfunded Mandates

Under Sections 202, 203, and 205 of the Unfunded Mandates Reform Act of 1995 ("Unfunded Mandates Act"), signed into law on March 25, 1995, EPA must undertake various actions in association with proposed or final rules that include a Federal mandate that may result in estimated costs of $100 million or more to the private sector, or to State, local, or tribal governments in the aggregate.

Through submission of this state implementation plan or plan revision, the State and any affected local or tribal governments have elected to adopt the program provided for under section 175A and section 187(a)(1) of the Clean Air Act. The rules and commitments approved in this action may bind State, local and tribal governments to perform certain actions and also may ultimately

lead to the private sector being required to certain duties. To the extent that the imposition of any mandate upon the State, local or tribal governments either as the owner or operator of a source or as mandate upon the private sector, EPA's action will impose no new requirements under State law; such sources are already subject to these requirements under State law. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, results from this action. EPA has also determined that this final action does not include a mandate that may result in estimated costs of $100 million or more to State, local, or tribal governments in the aggregate or to the private sector.

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Ozone.

40 CFR Part 81

Air pollution control, National parks, and Wilderness areas.

Dated: September 29, 1995.

John P. DeVillars,

Regional Administrator.

Chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42.U.S.C. 7401–7671q.

Subpart W—Massachusetts

2. Section 52.1120 is amended by adding paragraph (c)(107) to read as follows:

§ 52.1120 Identification of plan.

* * * * *

(c) * * *

(107) Massachusetts submitted the Oxygenated Gasoline Program on October 29, 1993. This submittal satisfies the requirements of section 211(m) of the Clean Air Act, as amended.

(i) Incorporation by reference.

(A) Letter dated October 29, 1993 which included the oxygenated gasoline program, amendments to the Massachusetts Air Pollution Control Regulations, 310 CMR 7.00, with an effective date of March 1, 1994, requesting that the submittal be approved and adopted as part of Massachusetts' SIP.

(ii) Additional materials.

(A) The Technical Support Document for the Redesignation of the Boston Area as Attainment for Carbon Monoxide submitted on December 12, 1994.

3. Section 52.1132 is added to read as follows:

§ 52.1132 Control strategy: Carbon Monoxide.

(a) Approval-On November 13, 1992, the Massachusetts Department of Environmental Protection submitted a revision to the carbon monoxide State Implementation Plan for the 1990 base year emission inventory. The inventory was submitted by the State of Massachusetts to satisfy Federal requirements under section 182(a)(1) of the Clean Air Act as amended in 1990, as a revision to the carbon monoxide State Implementation Plan.

(i) Approval—On December 12, 1994, the Massachusetts Department of Environmental Protection submitted a request to redesignate the Boston Area carbon monoxide nonattainment area to attainment for carbon monoxide. As part of the redesignation request, the State submitted a maintenance plan as required by 175A of the Clean Air Act, as amended in 1990. Elements of the section 175A maintenance plan include a base year (1993 attainment year) emission inventory for carbon monoxide, a demonstration of maintenance of the carbon monoxide NAAQS with projected emission inventories to the year 2010 for carbon monoxide, a plan to verify continued attainment, a contingency plan, and an obligation to submit a subsequent maintenance plan revision in 8 years as required by the Clean Air Act. If the area records a violation of the carbon monoxide NAAQS (which must be confirmed by the State), Massachusetts will implement one or more appropriate contingency measure(s) which are contained in the contingency plan. The menu of contingency measures includes an enhanced motor vehicle inspection and maintenance program and implementation of the oxygenated fuels program. The redesignation request and maintenance plan meet the redesignation requirements in sections 107(d)(3)(E) and 175A of the Act as amended in 1990, respectively. The redesignation meets the Federal requirements of section 182(a)(1) of the Clean Air Act as a revision to the Massachusetts Carbon Monoxide State Implementation Plan for the above mentioned area.

PART 81—[AMENDED]

Subpart C—Section 107 Attainment Status Designations

1. The authority citation for part 81 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

2. In § 81.322, the table for "Massachusetts-Carbon Monoxide" is revised to read as follows:

§ 81.322 Massachusetts.

* * * * *

MASSACHUSETTS-CARBON MONOXIDE

Designated area	Designation		Classification	
	Date [1]	Type	Date [1]	Type
Boston area:				
Middlesex County (part) Cities of: Cambridge, Everett, Malden, Medford, and Somerville.	April 1, 1996	Attainment.		
Norfolk County (part) Quincy City	April 1, 1996	Attainment.		
Suffolk County (part) Cities of: Boston, Chelsea, and Revere.	April 1, 1996	Attainment.		
Lowell area:				
Middlesex County (part) Lowell City		Nonattainment		Not classified.
Springfield area:				
Hampden County (part) Springfield City		Nonattainment		Not classified.
Waltham area:				
Middlesex County (part) Waltham City		Nonattainment		Not classified.
Worcester area:				
Worcester County (part) City of Worcester		Nonattainment		Not classified.

MASSACHUSETTS-CARBON MONOXIDE—Continued

Designated area	Designation		Classification	
	Date [1]	Type	Date [1]	Type
AQCR 042 Hartford-New Haven-Springfield		Unclassifiable/Attainment.		
Franklin County:				
Hampden County (part):				
Cities of: Chicopee, Holyoke, and Westfield. Townships of: Agawam, Blandford, Brimfield, Chester, East Longmeadow, Granville, Hampden, Holland, Longmeadow, Ludlow, Monson, Montgomery, Palmer, Russell, Southwick, Tolland, Wales, West Springfield, and Wilbraham.				
Hampshire County (part):				
City of Northampton. Townships of: Amherst, Belchertown, Chesterfield, Cummington, Eastampton, Goshen, Granby, Hadley, Hatfield, Huntington, Middlefield, Pelham, Southampton, South Hadley, Ware, Westhampton, Williamsburg, and Worthington.				
AQCR 117 Berkshire Intrastate Berkshire County		Unclassifiable/Attainment.		
AQCR 118 Central Massachusetts Intrastate		Unclassifiable/Attainment.		
Middlesex County (part):				
Townships of: Ashby, Shirley, and Townsend				
Worcester County (part):				
Cities of: Leominster, Fitchburg, and Gardner. Townships of: Ashburnham, Athol, Auburn, Barre, Berlin, Blackstone, Boylston, Brookfield, Charlton, Clinton, Douglas, Dudley, East Holden, Hopedale, Hubbardstown, Lancaster, Leicester, Lunenburg, Mendon, Millbury, Millville, New Braintree, Northborough, Northbridge, North Brookfield, Oakham, Oxford, Paxton, Petersham, Phillipston, Princeton, Royalston, Rutland, Shewsbury, Southbridge, Spencer, Sterling, Sutton, Templeton, Upton, Uxbridge, Warren, Webster, Westborough, West Boylston, West Brookfield, Westminster, and Winchendon				
AQCR 119 Metropolitan Boston Intrastate		Unclassifiable/Attainment.		

MASSACHUSETTS-CARBON MONOXIDE—Continued

Designated area	Designation		Classification	
	Date [1]	Type	Date [1]	Type
Essex County (part):				
Cities of: Beverly, Gloucester, Lynn, Peabody, and Salem. Townships of: Danvers, Essex, Ipswitch, Lynnfield, Manchester, Marblehead, Middletown, Nahant, Rockport, Saugus, Swampscott, Topsfield, and Wenham.	.....	.....	.....	
Middlesex County (part):				
Cities of: Marlborough, Melrose, Newton, and Woburn. Townships of: Acton, Arlington, Ashland, Bedford, Belmont, Boxborough, Burlington, Concord, Framingham, Holliston, Hopkinton, Hudson, Lexington, Lincoln, Maynard, Natick, North Reading, Reading, Sherborn, Stoneham, Stow, Sudbury, Wakefield, Watertown, Wayland, Wilmington, and Winchester.				
Norfolk County (part):				
Townships of: Avon, Braintree, Brookline, Canton, Cohasset, Dedham, Dover, Holbrook, Medfield, Millis, Milton, Needham, Norfolk, Norwood, Randolph, Sharon, Stoughton, Walpole, Wellesley, Westwood, and Weymouth.	.....	.....	.....	
Plymouth County:				
City of Brockton. Townships of: Abington, Bridgewater, Duxbury, East Bridgewater, Hanover, Hanson, Hingham, and Hull..				
AQCR 120 Metropolitan Providence Interstate	.....	Unclassifiable/Attainment.	.....	
Barnstable County (part):				
Townships of: Barnstable, Bourne, Brewster, Chatham, Dennis, Eastham, Falmouth, Harwich, Mashpee, Orleans, Provincetown, Sandwich, Truro, Wellfleet, and Yarmouth.				
Bristol County (part)				
Cities of: Attleboro, Fall River, New Bedford, and Taunton. Townships of: Acushnet, Berkley, Dartmouth, Dighton, Fairhaven, Freetown, Mansfield, North Attleborough, Norton, Raynham, Rehoboth, Seekonk, Somerset, Swansea, and Westport.	.....	.....	.....	
Dukes County (part):				
Townships of: Chilmark, Edgartown, Gay Head, Gosnold, Oak Bluffs, Tisbury, and West Tisbury.	.....	.....	.....	
Norfolk County (part):				
Townships of: Bellingham, Foxborough, Franklin, and Wrenton.	.....	.....	.....	
Plymouth County (part):				
Townships of: Carver, Halifax, Kingston, Lakeville, Marion, Mattapoisett, Middleborough, Plymouth, Plympton, Rochester, and Warham.				
Worcester County (part) Milford Township.				
AQCR 121 Merrimack Valley-S New Hampshire	.....	Unclassifiable/Attainment.	.....	

MASSACHUSETTS-CARBON MONOXIDE—Continued

Designated area	Designation		Classification	
	Date[1]	Type	Date[1]	Type
Essex County (part): Townships of: Andover, Amesbury, Boxford, Georgetown, Groveland, Haverhill, Lawerence, Merrimac, Methuen, Newbury, Newburyport, North Andover, Rowley, Salisbury, and West Newbury. Middlesex County (part): Townships of: Ayer, Billerica, Carlisle, Chelmsford, Dracut, Dunstable, Groton, Littleton, Pepperell,Tewksbury, Tyngsborough, and Westford.				

[1] This date is November 15, 1990, unless otherwise noted.

[FR Doc. 96–1589 Filed 1–29–96; 8:45 am]
BILLING CODE 6560–60–P

40 CFR Parts 52 and 81

[SIPTRAX No. PA075–4001; PA075–4002; PA024–4005; FRL–5329–1]

Approval and Promulgation of Implementation Plans; Designation of Areas for Air Quality Planning Purposes; Redesignation of the Philadelphia County Carbon Monoxide Area to Attainment and Approval of the Area's Maintenance Plan and the Philadelphia County 1990 Base Year Carbon Monoxide Emission Inventory; Commonwealth of Pennsylvania

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving a maintenance plan and a request to redesignate part of Philadelphia County from nonattainment to attainment for carbon monoxide (CO) and is also approving the 1990 base year CO emissions inventory for Philadelphia County. The maintenance plan, redesignation request and 1990 base year CO emissions inventory were submitted by the Commonwealth of Pennsylvania. Under the 1990 amendments of the Clean Air Act (CAA) designations can be revised if sufficient data is available to warrant such revisions. In this action, EPA is approving the Pennsylvania request because it meets the maintenance plan and redesignation requirements set forth in the CAA. This action is being taken under section 110 of the CAA.

EFFECTIVE DATE: This action will become effective on March 15, 1996 unless, within 30 days of publication, adverse or critical comments are received. If the effective date is delayed, timely notice will be published in the **Federal Register.**

ADDRESSES: Comments may be mailed to Marcia L. Spink, Associate Director, Air Programs, Mailcode 3AT00, U.S. Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, Pennsylvania 19107. Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air, Radiation, and Toxics Division, U.S. Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, Pennsylvania 19107; Pennsylvania Department of Environmental Protection, Bureau of Air Quality, P.O. Box 8468, 400 Market Street, Harrisburg, Pennsylvania 17105 and Philadelphia Department of Public Health, Air Management Services, 321 University Avenue, Philadelphia, Pennsylvania 19104.

FOR FURTHER INFORMATION CONTACT: Kelly L. Bunker, (215) 597–4554.

SUPPLEMENTARY INFORMATION: On September 8, 1995 the Commonwealth of Pennsylvania submitted a request for parallel processing of a redesignation request and maintenance plan for the Philadelphia portion of the Philadelphia-Camden County CO nonattainment area and supplemented the request on October 30, 1995, in order to formalize the submittal as an official revision to its State Implementation Plan (SIP). The SIP revision consists of a maintenance plan and a request to redesignate part of Philadelphia County from nonattainment to attainment for carbon monoxide and the 1990 base year CO emissions inventory for Philadelphia County.

I. Background

Part of Philadelphia County in Pennsylvania, specifically the high traffic areas within the Central Business District and certain other high traffic density areas of the City of Philadelphia, was a pre-1990 CO nonattainment area and continued to be designated as nonattainment for CO by operation of law as per section 107 (d)(1)(C)(i) of the Clean Air Act Amendments of 1990. The National Ambient Air Quality Standard (NAAQS) for CO is 9.5 parts per million (ppm). Philadelphia County is part of the Philadelphia-Camden County CO nonattainment area. CO nonattainment areas can be classified as moderate or serious, based on their design values. Since the Philadelphia CO nonattainment area had a design value of 11.6 ppm (based on 1988 and 1989 data), the area was classified as moderate. The CAA established an attainment date of December 31, 1995, for all moderate CO areas. Philadelphia County has ambient air quality monitoring data showing attainment of the CO NAAQS from 1990 through 1994. No exceedances or violations of the CO NAAQS have been monitored in Philadelphia County to date during calendar year 1995. Therefore, in an effort to comply with the CAA and to ensure continued attainment of the NAAQS, on September 8, 1995 and October 30, 1995 the Commonwealth of Pennsylvania submitted a CO redesignation request and a maintenance plan for Philadelphia County. Pennsylvania submitted evidence that a public hearing was held on October 16, 1995 in Philadelphia.

II. Evaluation Criteria

Section 107(d)(3)(E) of the 1990 Clean Air Act Amendments provides five specific requirements that an area must meet in order to be redesignated from nonattainment to attainment.

1. The area must have attained the applicable NAAQS;

2. The area must have a fully approved SIP under section 110(k) of CAA;

3. The air quality improvement must be permanent and enforceable;

4. The area must have a fully approved maintenance plan pursuant to section 175A of the CAA;

5. The area must meet all applicable requirements under section 110 and Part D of the CAA;

III. Review of State Submittal

On October 31, 1995, EPA determined that the information received from the Commonwealth of Pennsylvania constituted a complete redesignation request under the general completeness criteria of 40 CFR part 51, appendix V, §§ 2.1 and 2.2.

The Pennsylvania redesignation request for part of Philadelphia County meets the five requirements of section 107(d)(3)(E), noted above. The following is a brief description of how the Commonwealth has fulfilled each of these requirements.

1. Attainment of the CO NAAQS

Pennsylvania has quality-assured CO ambient air monitoring data showing that Philadelphia County has met the CO NAAQS. The Pennsylvania request is based on an analysis of quality-assured CO air monitoring data which is relevant to the maintenance plan and to the redesignation request. To attain the CO NAAQS, an area must have complete quality-assured data showing no more than one exceedance of the standard per year over at least two consecutive years. The ambient air CO monitoring data for calendar year 1990 through calendar year 1994, relied upon by Pennsylvania in its redesignation request, shows no violations of the CO NAAQS in Philadelphia County. The most recent ambient CO data shows one exceedance in the calendar years 1993 and 1994. In addition, the most recent ambient CO data for calendar year 1995 shows no exceedances of the NAAQS to date in Philadelphia County. Because the area has complete quality assured data showing no more than one exceedance of the standard per year over at least two consecutive years (1993 and 1994), the area has met the first statutory criterion of attainment of the CO NAAQS (40 CFR 50.8 and appendix C). Pennsylvania has committed to continue monitoring in this area in accordance with 40 CFR part 58.

Furthermore, air quality data for the New Jersey portion of the Philadelphia-Camden County CO nonattainment area shows that the remainder of the nonattainment area has met the CO NAAQS since 1990. Therefore, air quality in the entire area has been meeting the CO standards since 1990.

2. Fully Approved SIP Under Section 110(k) of the CAA

Pennsylvania's CO SIP is fully approved by EPA as meeting all the requirements of Section 110(a)(2)(I) of the Act, including the requirements of Part D (relating to nonattainment), which were due prior to the date of Pennsylvania's redesignation request. All portions of Pennsylvania's CO SIP, except for the motor vehicle inspection and maintenance (I/M) portion, were fully approved by EPA on February 26, 1985, at 40 CFR § 52.2020(c)(63), (50 FR 7772). The I/M portion of the CO SIP was approved by EPA on April 8, 1987 at 40 CFR § 52.2020(c)(66), (52 FR 11259). The 1990 CAA required that nonattainment areas achieve specific new requirements depending on the severity of the nonattainment classification. Requirements for the Philadelphia area include the preparation of a 1990 emission inventory with periodic updates, adoption of an oxygenated fuels program, the development of contingency measures, and development of conformity procedures. Each of these requirements added by the 1990 Amendments to the CAA are discussed in greater detail below.

Consistent with the October 14, 1994 EPA guidance from Mary D. Nichols entitled "Part D New Source Review (Part D NSR) Requirements for Areas Requesting Redesignation to Attainment," EPA is not requiring full approval of a Part D NSR program by Pennsylvania as a prerequisite to redesignation to attainment. Under this guidance, nonattainment areas may be redesignated to attainment notwithstanding the lack of a fully-approved Part D NSR program, so long as the program is not relied upon for maintenance. Pennsylvania has not relied on a NSR program for CO sources to maintain attainment. Although EPA is not treating a Part D NSR program as a prerequisite for redesignation, it should be noted that EPA is in the process of taking final action on the State's revised NSR regulation, which includes requirements for CO nonattainment areas. Because part of Philadelphia County is being redesignated to attainment by this action, Pennsylvania's Prevention of Significant Deterioration (PSD) requirements will be applicable to new or modified sources in Philadelphia County. Pennsylvania has been delegated PSD authority (see CFR § 52.2058 Pennsylvania and 49 FR 33128, August 21, 1984).

A. Emission Inventory

Pennsylvania submitted its 1990 base year emissions inventory as part of the maintenance plan which was submitted on September 8, 1995 and October 30, 1995. The inventory estimated CO emissions for Philadelphia County, as required under Section 187(a)(1) of the CAA.

This inventory was used as the basis for calculations to demonstrate maintenance. Pennsylvania's submittal contains the detailed inventory data and summaries by source category. The inventory was prepared in accordance with EPA guidance. A summary of the base year and projected maintenance year inventories are shown in the following table in this section.

Section 172(c)(3) of the CAA requires that nonattainment plan provisions include a comprehensive, accurate, and current inventory of actual emissions from all sources of relevant pollutants in the nonattainment area. Pennsylvania included the requisite inventory in the redesignation request and maintenance plan SIP revision. The base year for the inventory was 1990, using a three month CO season of December 1990 through February 1991. Stationary sources, area sources, on-road mobile sources, and non-road mobile sources of CO were included in the inventory. The following table, Table 1, presents a summary of the base year (1990), attainment year (1992) and projected year (2007) CO peak season daily emissions estimates in tons per winter day (tpd) by source category:

TABLE 1.—CO PEAK SEASON DAILY EMISSIONS

	1990 Base year emissions (tons per day)	1992 Attainment year emissions (tons per day)	2007 Projected year emissions (tons per day)
On-road Mobile	608.99	561.25	334.33
Non-road Mobile	9.62	9.69	10.11
Area	13.77	13.80	13.98
Stationary	20.98	22.07	31.11
Total	653.36	606.81	389.53

Available guidance for preparing emission inventories is provided in the General Preamble (57 FR 13498, April 16, 1992).

Section 110(k) of the CAA sets out provisions governing the EPA's review of base year emission inventory submittals in order to determine approval or disapproval under section 187(a)(1). The EPA is granting approval

of the Philadelphia County 1990 base year CO emissions inventories as found in the Pennsylvania CO Redesignation Request, based on the EPA's technical review of the CO inventory. For further details on the emission inventory, the reader is referred to the Technical Support Document, which is available for review at the addresses provided above.

B. Oxygenated Gasoline

Section 211(m) of the CAA requires that each State in which there is located a CO nonattainment area with a design value of 9.5 ppm or above based on data for the 2-year period of 1988 and 1989 shall submit a SIP revision which requires the implementation of an oxygenated gasoline program in the Consolidated Metropolitan Statistical Area (CMSA) in which the nonattainment area is located. The Philadelphia-Camden County CO nonattainment area has a design value above 11.6 ppm based on 1988 and 1989 data and consequently was subject to the requirement to adopt an oxygenated fuel program. Pennsylvania submitted an oxygenated gasoline SIP revision for the Pennsylvania portion of the Philadelphia CMSA to EPA on November 12, 1992. EPA approved the SIP revision on July 21, 1994 at 40 CFR § 52.2020(c)(88), (59 FR 37162). As noted in the Pennsylvania redesignation request, the State intends to relegate the oxygenated fuel program to contingency status upon EPA's approval of Pennsylvania's redesignation request. On August 19, 1995 Pennsylvania modified their oxygenated gasoline regulations to allow for the discontinuance of the program if EPA approves a redesignation request and maintenance plan which does not require the implementation of an oxygenated gasoline program. The modified Pennsylvania oxygenated gasoline regulation also states that if an area is redesignated to attainment and then violates the CO standard that the program must be reinstated at the beginning of the next oxygenated gasoline control period. In its demonstration of maintenance, described below, the Commonwealth has shown that oxygenated gasoline in the Pennsylvania portion of the Philadelphia CMSA is not necessary for continued maintenance of the CO NAAQS. Consequently, by this action, EPA is approving Pennsylvania's use of oxygenated gasoline as a contingency measure for the Philadelphia area.[1]

[1] Cecil County, Maryland is part of the Philadelphia CMSA and had implemented the oxygenated gasoline program. This action will also serve to remove the oxygenated fuel requirement from Cecil County, Maryland.

C. Conformity

Under section 176(c) of the CAA, states were required to submit revisions to their SIPs that include criteria and procedures to ensure that Federal actions conform to the air quality planning goals in the applicable SIPs. The requirement to determine conformity applies to transportation plans, programs and projects developed, funded or approved under Title 23 U.S.C. or the Federal Transit Act ("transportation conformity"), as well as all other Federal actions ("general conformity"). Congress provided for the State revisions to be submitted one year after the date of promulgation of final EPA conformity regulations. EPA promulgated final transportation conformity regulations on November 24, 1993 (58 FR 62188) and final general conformity regulations on November 30, 1993 (58 FR 63214). These conformity rules require that the States adopt both transportation and general conformity provisions in the SIP for areas designated nonattainment or subject to a maintenance plan approved under CAA section 175A. Pursuant to § 51.396 of the transportation conformity rule and § 51.851 of the general conformity rule, the Commonwealth of Pennsylvania was required to submit a SIP revision containing transportation conformity criteria and procedures consistent with those established in the Federal rule by November 25, 1994. Similarly, Pennsylvania was required to submit a SIP revision containing general conformity criteria and procedures consistent with those established in the Federal rule by December 1, 1994. Pennsylvania submitted its transportation conformity SIP revision to EPA on November 21, 1994. This SIP was determined to be administratively and technically complete on February 21, 1995. Pennsylvania has not submitted its general conformity SIP revision.

Although this redesignation request was submitted to EPA after the due dates for the SIP revisions for transportation conformity and general conformity rules, EPA believes it is reasonable to interpret the conformity requirements as not being applicable requirements for purposes of evaluating the redesignation request under section 107(d). The rationale for this is based on a combination of two factors. First, the requirement to submit SIP revisions to comply with the conformity provisions of the Act continues to apply to areas after redesignation to attainment. Therefore, the State remains obligated to adopt the transportation and general conformity rules even after redesignation and would risk sanctions for failure to do so. While redesignation of an area to attainment enables the area to avoid further compliance with most requirements of section 110 and part D, since those requirements are linked to the nonattainment status of an area, the conformity requirements apply to both nonattainment and maintenance areas. Second, EPA's federal conformity rules require the performance of conformity analyses in the absence of state-adopted rules. Therefore, a delay in adopting State rules does not relieve an area from the obligation to implement conformity requirements.

Because areas are subject to the conformity requirements regardless of whether they are redesignated to attainment and must implement conformity under Federal rules if State rules are not yet adopted, EPA believes it is reasonable to view these requirements as not being applicable requirements for purposes of evaluating a redesignation request.

For the reasons just discussed, EPA believes that the CO redesignation request for Philadelphia County may be approved notwithstanding the lack of a general conformity submittal and an approved state transportation conformity rule.

3. Improvement in Air Quality Due to Permanent and Enforceable Measures

EPA approved Pennsylvania's CO SIP under the 1977 CAA. Emission reductions achieved through the implementation of control measures contained in that SIP are enforceable. Pennsylvania cites the Federal Motor Vehicle Control Program (FMVCP) and the basic Inspection and Maintenance Program as the major sources of reduction that led to attainment of the CO standard. As discussed above, the State initially attained the NAAQS in 1990 with monitored attainment through 1994. This indicates that the improvements are due to the permanent and enforceable measures contained in the 1982 CO SIP.

The Commonwealth of Pennsylvania has demonstrated that actual enforceable emission reductions are responsible for the air quality improvement and that the CO emissions in the base year are not artificially low due to local economic downturn. EPA finds that the combination of certain existing EPA-approved SIP and federal measures contribute to the permanence and enforceability of reduction in ambient CO levels that have allowed the area to attain the NAAQS.

4. Fully Approved Maintenance Plan Under Section 175A

Section 175A of the CAA sets forth the elements of a maintenance plan for areas seeking redesignation from nonattainment to attainment.

The plan must demonstrate continued attainment of the applicable NAAQS for at least ten years after the Administrator approves a redesignation to attainment. Eight years after the redesignation, the state must submit a revised maintenance plan which demonstrates attainment for the ten years following the initial ten-year period. To provide for the possibility of future NAAQS violations, the maintenance plan must contain contingency measures, with a schedule for implementation adequate to assure prompt correction of any air quality problems. In this notice, EPA is approving the Commonwealth of Pennsylvania's maintenance plan for the Philadelphia area because EPA finds that Pennsylvania's submittal meets the requirements of section 175A.

A. Attainment Emission Inventory

As previously noted, Pennsylvania submitted its 1990 base year emissions inventory for Philadelphia County as part of the maintenance plan which was submitted on September 8, 1995 and October 30, 1995. The inventory includes emissions from stationary, area, and mobile sources using 1990 as the base year for calculations.

The State submittal contains the detailed inventory data and summaries by source category. The comprehensive base year emissions inventory was submitted in the National Emission Data System format. This inventory was prepared in accordance with EPA guidance.

The 1992 emission inventory was selected as representative of Philadelphia County emissions during the period showing attainment. Pennsylvania established the 1992 inventory as the attainment inventory and forecasted future emissions out to the year 2007 in its maintenance plan. The future emission estimates were all calculated by applying appropriate growth factors to the 1990 base year inventory, consistent with EPA guidance.

B. Demonstration of Maintenance-Projected Inventories

Total CO emissions were projected from 1990 base year out to 2007. These projected inventories were prepared in accordance with EPA guidance. Pennsylvania will not implement the oxygenated gasoline program in the Pennsylvania portion of the Philadelphia CMSA unless a violation of the standard triggers the implementation of the program. The projections show that calculated CO emissions, assuming no oxygenated fuels program, are not expected to exceed the level of the base year inventory during this time period. Therefore, it is anticipated that the Philadelphia area will maintain the CO standard without the program, and the oxygenated gasoline program would not need to be implemented following redesignation, except as a contingency measure.

C. Verification of Continued Attainment

Continued attainment of the CO NAAQS in Philadelphia County depends, in part, on the Commonwealth's efforts toward tracking indicators of continued attainment during the maintenance period. The Commonwealth commits to revise the emission inventory every three years beginning in 1993, until at least 2007. If future emission levels exceed those in the 1992 attainment inventory, the Commonwealth commits to investigate the reasons and take appropriate action.

D. Contingency Plan

The level of CO emissions in Philadelphia County will largely determine its ability to stay in compliance with the CO NAAQS in the future. Despite the Commonwealth's best efforts to demonstrate continued compliance with the NAAQS, the ambient air pollutant concentrations may exceed or violate the NAAQS. Section 175(A)(d) of the CAA requires that the contingency provisions include a requirement that the State implement all measures contained in the SIP prior to redesignation. Therefore, Pennsylvania has provided contingency measures with a schedule for implementation in the event of a future CO air quality problem. The plan contains triggering mechanism (a violation of the CO standard) to determine when contingency measures are needed.

On August 19, 1995 Pennsylvania modified their oxygenated gasoline regulations to allow for the discontinuance of the program if EPA approves a redesignation request and maintenance plan which does not require the implementation of an oxygenated gasoline program. The modified Pennsylvania oxygenated gasoline regulation states that if an area is redesignated to attainment and then violates the CO standard that the program must be reinstated at the beginning of the next oxygenated gasoline control period.

E. Subsequent Maintenance Plan Revisions

In accordance with section 175A(b) of the CAA, the Commonwealth has agreed to submit a revised maintenance SIP eight years after the area is redesignated to attainment. Such a revised SIP will provide for maintenance for an additional ten years.

5. Meeting Applicable Requirements of Section 110 and Part D

In Section III.2. above, EPA sets forth the basis for its conclusion that Pennsylvania has a fully approved SIP which meets the applicable requirements of Section 110 and Part D of the CAA.

EPA is approving this SIP revision without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in a separate document in this **Federal Register** publication, EPA is proposing to approve the SIP revision should adverse or critical comments be filed. This action will be effective March 15, 1996 unless, within 30 days of publication, adverse or critical comments are received.

If EPA receives such comments, this action will be withdrawn before the effective date by publishing a subsequent notice that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule based on this action serving as a proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time. If no such comments are received, the public is advised that this action will be effective on March 15, 1996.

Final Action

EPA is approving the Philadelphia County CO maintenance plan because it meets the requirements set forth in section 175A of the CAA. In addition, the Agency is approving the request and redesignating the Philadelphia County CO area to attainment, because the Commonwealth has demonstrated compliance with the requirements of section 107(d)(3)(E) for redesignation. EPA is also approving Pennsylvania's 1990 base year CO emissions inventory for Philadelphia County, as found in the Commonwealth's redesignation request and maintenance plan. The EPA is publishing this action without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in a separate document in this

Federal Register publication, the EPA is proposing to approve the SIP revision should adverse or critical comments be filed. This action will be effective March 15, 1996 unless, by February 29, 1996 adverse or critical comments are received. If the EPA receives such comments, this action will be withdrawn before the effective date by publishing a subsequent document that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule based on this action serving as a proposed rule. The EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time. If no such comments are received, the public is advised that this action will be effective March 15, 1996.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any state implementation plan. Each request for revision to the state implementation plan shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

Under the Regulatory Flexibility Act, 5 U.S.C. 600 *et seq.*, EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

Under Section 202 of the Unfunded Mandates Reform Act of 1995 ("Unfunded Mandates Act"), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate; or to the private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action proposed/promulgated does not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new Federal requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

The CO SIP is designed to satisfy the requirements of part D of the CAA and to provide for attainment and maintenance of the CO NAAQS. This final redesignation should not be interpreted as authorizing the State to delete, alter, or rescind any of the CO emission limitations and restrictions contained in the approved CO SIP. Changes to CO SIP regulations rendering them less stringent than those contained in the EPA approved plan cannot be made unless a revised plan for attainment and maintenance is submitted to and approved by EPA. Unauthorized relaxations, deletions, and changes could result in both a finding of non-implementation (section 179(a) of the CAA) and in a SIP deficiency call made pursuant to sections 110(a)(2)(H) and 110(k)(2) of the CAA.

SIP approvals under section 110 and subchapter I, part D of the CAA do not create any new requirements, but simply approve requirements that the State is already imposing. Therefore, because the federal SIP approval does not impose any new requirements, it does not have any economic impact on any small entities. Redesignation of an area to attainment under section 107(d)(3)(E) of the CAA does not impose any new requirements on small entities. Redesignation is an action that affects the status of a geographical area and does not impose any regulatory requirements on sources. Accordingly, I certify that the approval of the redesignation of an area to attainment under section 107(d)(3)(E) of the CAA will not affect a substantial number of small entities.

This action has been classified as a Table 3 action for signature by the Regional Administrator under the procedures published in the Federal Register on January 19, 1989 (54 FR 2214–2225), as revised by a July 10, 1995 memorandum from Mary Nichols, Assistant Administrator for Air and Radiation. The Office of Management and Budget (OMB) has exempted this regulatory action from E.O. 12866 review.

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by April 1, 1996. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action on the Philadelphia CO redesignation request, maintenance plan and the 1990 base year CO emission inventory may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements.

40 CFR Part 81

Air pollution control.

Dated: October 31, 1995.

Stanley Laskowski,

Acting Regional Administrator, Region III.

For the reasons set forth in the preamble 40 CFR part 52, subpart NN of chapter I, title 40 is amended as follows:

PART 52—[AMENDED]

1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

Subpart NN—Pennsylvania

2. Section 52.2020 is amended by adding paragraph (c)(105) to read as follows:

§ 52.2020 Identification of plan.

* * * * *

(c) * * *

(105) The carbon monoxide redesignation and maintenance plan for part of Philadelphia County submitted by the Pennsylvania Department of Environmental Protection on September 8, 1995 and October 30, 1995, as part of the Pennsylvania SIP. The 1990 base year CO emission inventory and projections are included in the maintenance plan.

(i) Incorporation by reference.

(A) Letters of September 8, 1995 and October 30, 1995 from the Pennsylvania Department of Environmental Protection requesting the redesignation and submitting the maintenance plan.

(B) Maintenance Plan for the Philadelphia Carbon Monoxide Nonattainment Area adopted on October 16, 1995.

(ii) Additional Material.

(A) Remainder of September 8, 1995 and October 30, 1995 State submittal.

3. Section 52.2036 is added to read as follows:

§ 52.2036 1990 Base Year Carbon Monoxide Emission Inventory for Philadelphia County.

EPA approves as a revision to the Pennsylvania State Implementation Plan the 1990 base year carbon monoxide emission inventory for Philadelphia County, submitted by the Secretary, Pennsylvania Department of Environmental Protection, on September 8, 1995 and October 30, 1995. This submittal consists of the 1990 base year stationary, area, non-road mobile and on-road mobile emission inventories in Philadelphia County for the pollutant carbon monoxide (CO).

PART 81—[AMENDED]

Subpart C—Section 107 Attainment Status Designations

1. The authority citation for part 81 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

2. In § 81.339, the table for "Pennsylvania-Carbon Monoxide" is amended by revising the entry for the Philadelphia-Camden County area to read as follows:

§ 81.339 Pennsylvania.

* * * * *

PENNSYLVANIA—CARBON MONOXIDE

Designated Area	Designation		Classification	
	Date [1]	Type	Date [1]	Type
	.....	Nonattainment	.....	Not Classified.
* * *	*	*	*	*
Philadelphia-Camden County Area				
Philadelphia County (part)				
City of Philadelphia-high traffic areas within the Central Business District and certain other high traffic density areas.	March 15, 1996	Attainment	.....	
* * *	*	*	*	*

[1] This date is November 15, 1990, unless otherwise noted.

[FR Doc. 96–1104 Filed 1–29–96; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Parts 52 and 81

[FRL–5324–9; MD–45–3003, MD–45–3004; MD–45–3007; VA–53–5001, VA–53–5002; VA–34–5003, VA–34–5004; DC–30–2001; DC–30–2002, DC–10–2003]

Approval and Promulgation of Implementation Plans; Designation of Areas for Air Quality Planning Purposes; Redesignation of the Metropolitan Washington Carbon Monoxide Area to Attainment and Approval of the Area's Maintenance Plan and Emission Inventory; Commonwealth of Virginia, District of Columbia and the State of Maryland

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving a maintenance plan and a request to redesignate the Metropolitan Washington area; including the Counties of Alexandria and Arlington, Virginia; Prince Georges and Montgomery Counties in Maryland, and the District of Columbia (the "Washington Carbon Monoxide (CO) nonattainment area") from nonattainment to attainment for CO. The maintenance plan and redesignation requests were submitted by the Commonwealth of Virginia and the State of Maryland and the District of Columbia. Under the 1990 amendments of the Clean Air Act (CAA) designations can be revised if sufficient data is available to warrant such revisions. In this action, EPA is approving Virginia, Maryland and the District of Columbia requests because it meets the maintenance plan and redesignation requirements set forth in the CAA. This action is being taken under section 110 of the CAA.

DATES: This action will become effective on March 15, 1996 unless, by February 29, 1996 adverse or critical comments are received. If the effective date is delayed, timely notice will be published in the **Federal Register.**

ADDRESSES: Comments may be mailed to Marcia L. Spink, Associate Director, Air Programs, Mailcode 3AT00, U.S. Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, Pennsylvania 19107. Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air, Radiation, and Toxics Division, U.S. Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, Pennsylvania 19107; the Air and Radiation Docket and Information Center, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; District of Columbia Department of Consumer and Regulatory Affairs, 2100 Martin Luther King Ave, S.E., Washington, DC 20020; Maryland Department of the Environment, 2500 Broening Highway, Baltimore, Maryland 21224; Virginia Department of Environmental Quality, 629 East Main Street, Richmond, Virginia 23219.

FOR FURTHER INFORMATION CONTACT: Kelly A. Sheckler, (215) 597–6863.

SUPPLEMENTARY INFORMATION: On October 4, 1995 the Commonwealth of Virginia, and on October 12, 1995 the State of Maryland and the District of Columbia submitted formal revisions to their State Implementation Plans (SIP). The SIP revisions consists of a request to redesignate the Virginia, Maryland and District of Columbia portions of the Metropolitan Washington area from nonattainment to attainment for carbon monoxide and a maintenance plan.

I. Background

The Metropolitan Washington area, was a pre-1990 CO nonattainment area and continued to be designated as nonattainment for CO by operation of law as per section 107(d)(1)(C)(i) of the Clean Air Act Amendments of 1990. The National Ambient Air Quality Standard (NAAQS) for CO is 9.5 parts per million (ppm). CO nonattainment areas can be classified as moderate or serious, based on their design values. Since the Washington CO nonattainment area had a design value of 11.6 ppm (based on 1988 and 1989 data), the area was classified as moderate. The CAA established an attainment date of December 31, 1995, for all moderate CO areas. The Metropolitan Washington area has ambient air quality monitoring data showing attainment of the CO NAAQS from 1989 through 1993. Therefore, in an effort to comply with the CAA and to ensure continued attainment of the NAAQS, on October 4, 1995 the Commonwealth of Virginia submitted a CO redesignation request and a maintenance plan for the Virginia portion of the Metropolitan Washington area. The State of Maryland submitted on October 12, 1995 a CO redesignation request and maintenance plan for the Maryland portion of the Metropolitan Washington area and on October 12, 1995 the District of Columbia submitted a CO redesignation request and maintenance plan. Virginia, Maryland and the District of Columbia submitted evidence that public hearings were held on September 6, 1995 in Virginia, September 15, 1995 in Maryland and September 18, 1995 in the District of Columbia.

II. Evaluation Criteria

Section 107(d)(3)(E) of the 1990 Clean Air Act Amendments provides five specific requirements that an area must meet in order to be redesignated from nonattainment to attainment.

1. The area must have attained the applicable NAAQS;
2. The area must have a fully approved SIP under section 110(k) of CAA;
3. The air quality improvement must be permanent and enforceable;
4. The area must have a fully approved maintenance plan pursuant to section 175A of the CAA;
5. The area must meet all applicable requirements under section 110 and Part D of the CAA;

III. Review of State Submittal

On October 12, 1995, EPA determined that the information received from the Commonwealth of Virginia, the State of Maryland and the District of Columbia constituted a complete redesignation request under the general completeness criteria of 40 CFR part 51, appendix V, §§ 2.1 and 2.2.

The Virginia, Maryland and District of Columbia redesignation requests for the Metropolitan Washington area meets the five requirements of section 107(d)(3)(E), noted above. The following is a brief description of how the State has fulfilled each of these requirements.

1. Attainment of the CO NAAQS

Virginia, Maryland and the District of Columbia have quality-assured CO ambient air monitoring data showing that the Metropolitan Washington area has met the CO NAAQS. The Virginia, Maryland and District of Columbia requests are based on an analysis of quality-assured CO air monitoring data which is relevant to the maintenance plan and to the redesignation request. To attain the CO NAAQS, an area must have complete quality-assured data showing no more than one exceedance of the standard per year over at least two consecutive years. The ambient air CO monitoring data for calendar year 1988 through calendar year 1995, relied upon by Virginia, Maryland and the District of Columbia in their redesignation requests, shows no violations of the CO NAAQS in the Metropolitan Washington area. Because the area has complete quality assured data showing no more than one exceedance of the standard per year over at least two consecutive years (1994 and 1995), the area has met the first statutory criterion of attainment of the CO NAAQS (40 CFR 50.8 and appendix C). Virginia, Maryland and the District of Columbia have committed to continue monitoring in this area in accordance with 40 CFR part 58.

2. Fully Approved SIP Under Section 110(k) of the CAA

Virginia's, Maryland's and the District of Columbia's CO SIPs are fully approved by EPA as meeting all the requirements of Section 110(a)(2)(I) of the Act, including the requirements of Part D (relating to nonattainment), which were due prior to the date of Virginia's, Maryland's and the District of Columbia's redesignation requests. Maryland's CO SIP was fully approved by EPA on September 19, 1994, at 40 CFR § 52.1070(c)(71), (49 FR 36645). Virginia's CO SIP was approved by EPA on January 25, 1984 at 40 CFR § 52.2420(c)(78), (49 FR 3083). The District's CO SIP approved by EPA on October 3, 1984 at 40 CFR § 52.47(c)(28), (49 FR 39059). The 1990 CAAA required that nonattainment areas achieve specific new requirements depending on the severity of the nonattainment classification. Requirements for the Metropolitan Washington area include the preparation of a 1990 emission inventory with periodic updates, adoption of an oxygenated fuels program, the development of contingency measures, and development of conformity procedures. Each of these requirements added by the 1990 Amendments to the CAA are discussed in greater detail below.

Consistent with the October 14, 1994 EPA guidance from Mary D. Nichols entitled "Part D New Source Review (Part D NSR) Requirements for Areas Requesting Redesignation to Attainment," EPA is not requiring full approval of a Part D NSR program by Virginia, Maryland and the District of Columbia as a prerequisite to redesignation to attainment. Under this guidance, nonattainment areas may be redesignated to attainment notwithstanding the lack of a fully-approved Part D NSR program, so long as the program is not relied upon for maintenance. Because the Metropolitan Washington area is being redesignated to attainment by this action, Virginia's, Maryland's and the District of Columbia's Prevention of Significant Deterioration (PSD) requirements will be applicable to new or modified sources in the Metropolitan Washington area. All three States have been delegated PSD authority (See § 52.499 District of Columbia, 43 FR 26410, June 19, 1978, as amended 45 FR 52741, August 7, 1980; § 52.1116 Maryland, 45 FR 52741, August 7, 1980, as amended 47 FR 7835, February 23, 1982; § 52.2448 Virginia 39 FR 7284, February 25, 1974.)

A. Emission Inventory

On March 1994 Maryland submitted a 1990 CO base year inventory to EPA for review and approval. On November 1, 1993 and April 3, 1995, Virginia submitted a 1990 CO base year emissions inventory to EPA for review and approval. On January 13, 1994 the District of Columbia submitted a 1990 CO base year emissions inventory to EPA for review and approval. This inventory was used as the basis for calculations to demonstrate maintenance. Virginia's, Maryland's and the District of Columbia's submittal contains the detailed inventory data and summaries by source category. Each of the State's submittals also contains information related to how it comported with EPA's guidance, and which model and emission factors were used (note, the MOBILE 5a model was used), how

vehicle miles travelled (VMT) data was generated, and other technical information verifying the emission inventory. A summary of the base year and projected maintenance year inventories are shown in the following table in this section.

Section 172(c)(3) of the CAA requires that nonattainment plan provisions include a comprehensive, accurate, and current inventory of actual emissions from all sources of relevant pollutants in the nonattainment area. Maryland, Virginia and the District of Columbia included the requisite inventory in the CO SIP. The base year for the inventory was 1990, using a three month CO season of November 1990 through January 1991.

Stationary point sources, stationary area sources, on-road mobile sources, and nonroad mobile sources of CO were included in the inventory. Stationary sources with emissions of greater than 100 tons per year were also included in the inventory.

The following list presents a summary of the CO peak season daily emissions estimates in tons per winter day by source category:

WINTERTIME CO EMISSIONS

[Tons per day]

State	Mobile sources	Area sources	Point (stationary) sources
Virginia	288.55	9.89	.92
Maryland	1161.34	71.36	4.61
District of Columbia ..	410.30	18.08	3.32

Available guidance for preparing emission inventories is provided in the General Preamble (57 FR 13498, April 16, 1992).

Section 110(k) of the CAA sets out provisions governing the EPA's review of base year emission inventory submittals in order to determine approval or disapproval under section 187(a)(1). The EPA is granting approval of the Virginia, Maryland and District of Columbia 1990 base year CO emissions inventories submitted on November 11, 1994 and April 3, 1995, March 21, 1994 and January 13, 1994 respectively, based on the EPA's technical review of the CO inventory. For further details, the reader is referred to the Technical Support Document, which is available for review at the addresses provided above.

B. Oxygenated Gasoline

Section 211(m) of the CAA requires that each State in which there is located a CO nonattainment area with a design value of 9.5 ppm or above based on data for the 2-year period of 1988 and 1989 shall submit a SIP revision which requires the implementation of an oxygenated gasoline program in the Consolidated Metropolitan Statistical Area (CMSA) in which the nonattainment area is located. The Metropolitan Washington area has a design value above 9.6 ppm based on 1988 and 1989 data and consequently was subject to the requirement to adopt an oxygenated fuel program. Virginia, Maryland and the District of Columbia submitted oxygenated gasoline SIP revisions for the Metropolitan Washington CMSA to EPA on November 8, 1993, November 13, 1992 and October 22, 1993, respectively. EPA approved the SIP revisions for Virginia and Maryland on April 15, 1994 and June 6, 1994 respectively. As noted in the Virginia, Maryland and District of Columbia redesignation requests, the States intend to relegate the oxygenated fuel program to contingency status upon EPA's approval of their redesignation requests. By September 1, 1997 Virginia commits to adopt and submit to EPA an oxygenated fuel regulation that will be effective at the beginning of the next control period upon a monitored violation of the CO NAAQS (two or more exceedances of the CO NAAQS in a single calendar year). By January 1996, Maryland commits to adopt and submit to EPA an oxygenated fuel regulation that will be effective at the beginning of the next control period upon a monitored violation of the CO NAAQS (two or more exceedances of the CO NAAQS in a single calendar year). EPA took a limited approval/limited disapproval action of the District of Columbia's oxygenated fuels SIP. The District's regulations at 20 District of Columbia Municipal Regulations Chapter 1, Section 199—definitions was deficient in that it lacks the following: A definition for the terms "carriers; a sampling procedure; and procedures for the calculation of oxygenated content in the gasoline sampled. With approval of the redesignation request the oxygenated fuels program will only be relied upon as a contingency measure. For purposes of section 175A, a state is not required to have fully adopted contingency measures that will take effect without further action by the State in order for the maintenance plan to be approved. However, as stated above, the contingency plan is considered an enforceable part of the SIP and should ensure that the contingency measures are adopted expediently once they are triggered. The plan needs to identify the measure to be adopted and a schedule and procedure for adoption and implementation. For these reasons, the District can correct the deficiency subject to the approval of the District's oxygenated fuels SIP at 40 CFR part 52, § 52.472, (published at 60 FR 5134 on January 26, 1995) when it submits the revised regulation as a contingency measure. EPA's January 26, 1995 limited approval/limited disapproval of the District's oxygenated fuels SIP also initiated an 18-month sanctions clock under section 179 of the Act. By this action to move the oxygenated fuels program into the contingency measure portion of the maintenance plan, the sanction clock is no longer applicable. By December 1995, the District of Columbia commits to adopt and submit to EPA an oxygenated fuel regulation that will be effective at the beginning of the next control period upon a monitored violation of the CO NAAQS (two or more exceedances of the CO NAAQS in a single calendar year), and correct the deficiencies previously identified by EPA in the January 26, 1995 rulemaking.

In its demonstration of maintenance, described below, the States have shown that oxygenated gasoline in the Metropolitan Washington CMSA is not necessary for continued maintenance of the CO NAAQS. Consequently, by this action, EPA is approving Virginia, Maryland and the District of Columbia's use of oxygenated gasoline as a contingency measure for the Metropolitan Washington area.

C. Conformity

Under section 176(c) of the CAA, states were required to submit revisions to their SIPs that include criteria and procedures to ensure that Federal actions conform to the air quality planning goals in the applicable SIPs. The requirement to determine conformity applies to transportation plans, programs and projects developed, funded or approved under Title 23 U.S.C. or the Federal Transit Act ("transportation conformity"), as well as all other Federal actions ("general conformity"). Congress provided for the State revisions to be submitted one year after the date of promulgation of final EPA conformity regulations. EPA promulgated final transportation conformity regulations on November 24, 1993 (58 FR 62188) and final general conformity regulations on November 30, 1993 (58 FR 63214). These conformity rules require that the States adopt both transportation and general conformity provisions in the SIP for areas designated nonattainment or subject to a maintenance plan approved under CAA section 175A. Pursuant to § 51.396 of the transportation conformity rule

and § 51.851 of the general conformity rule, the Commonwealth of Virginia, State of Maryland and the District of Columbia were required to submit a SIP revision containing transportation conformity criteria and procedures consistent with those established in the Federal rule by November 25, 1994. Similarly, Virginia, Maryland and the District of Columbia were required to submit a SIP revision containing general conformity criteria and procedures consistent with those established in the Federal rule by December 1, 1994. Maryland, Virginia and the District of Columbia submitted transportation conformity SIP revisions to EPA on May 15, 1995; May 16, 1995; and, May 15, 1995, respectively. Furthermore, Virginia, Maryland and the District of Columbia have all submitted on May 15, 1995 SIP revisions for general conformity. Although this redesignation request was submitted to EPA after the due dates for the SIP revisions for transportation conformity [58 FR 62188] and general conformity [58 FR 63214] rules, EPA believes it is reasonable to interpret the conformity requirements as not being applicable requirements for purposes of evaluating the redesignation request under section 1079d). The rationale for this is based on a combination of two factors. First, the requirement to submit SIP revisions to comply with the conformity provisions of the Act continues to apply to areas after redesignation to attainment. Therefore, the State remains obligated to adopt the transportation and general conformity rules even after redesignation and would risk sanctions for failure to do so. While redesignation of an area to attainment enables the area to avoid further compliance with most requirements of section 110 and Part D, since those requirements are linked to the nonattainment status of an area, the conformity requirements apply to both nonattainment and maintenance areas. Second, EPA's federal conformity rules require the performance of conformity analyses in the absence of state-adopted rules. Therefore, a delay in adopting State rules does not relieve an area from the obligation to implement conformity requirements.

Because areas are subject to the conformity requirements regardless of whether they are redesignated to attainment and must implement conformity under Federal rules if State rules are not yet adopted, EPA believes it is reasonable to view these requirements as not being applicable requirements for purposes of evaluating a redesignation request.

Under this policy, EPA believes that the CO redesignation request for the Washington area may be approved notwithstanding the lack of approved state transportation and general conformity rules.

3. Improvement in Air Quality Due to Permanent and Enforceable Measures

EPA approved Virginia's, Maryland's and the District of Columbia's CO SIPs under the 1977 CAA. Emission reductions achieved through the implementation of control measures contained in that SIP are enforceable. These measures were: The Federal Motor Vehicle Control Program, the basic automobile inspection and maintenance program (I/M), Federal Reformulated Gasoline Program, Tier I controls on new vehicles, Low Emission Vehicles (LEV) (in Maryland and Washington, DC only), State II Vapor Recovery, Evaporative Emissions Control Program, and On-Board Diagnostics Controls.

As discussed above, the State initially attained the NAAQS in 1988 with monitored attainment through 1993. This indicates that the improvements are due to the permanent and enforceable measures contained in the 1982 CO SIP. With the exception of the LEV program and on-board diagnostics controls, all these measures are permanent and enforceable because they are either an existing program in the State and part of the federally approved SIP (e.g., basic I/M, stage II vapor recovery) or are a federally implemented program (e.g., reformulated gasoline, FMVCP, or Tier I controls on new vehicles).

The Commonwealth of Virginia and the State of Maryland and the District of Columbia have demonstrated that actual enforceable emission reductions are responsible for the air quality improvement and that the CO emissions in the base year are not artificially low due to local economic downturn. EPA finds that the combination of certain existing EPA-approved SIP and federal measures contribute to the permanence and enforceability of reduction in ambient CO levels that have allowed the area to attain the NAAQS.

4. Fully Approved Maintenance Plan Under Section 175A

Section 175A of the CAA sets forth the elements of a maintenance plan for areas seeking redesignation from nonattainment to attainment.

The plan must demonstrate continued attainment of the applicable NAAQS for at least ten years after the Administrator approves a redesignation to attainment. Eight years after the redesignation, the state must submit a revised maintenance plan which demonstrates attainment for the ten years following the initial ten-year period. To provide for the possibility of future NAAQS violations, the maintenance plan must contain contingency measures, with a schedule for implementation adequate to assure prompt correction of any air quality problems. In this notice, EPA is approving the State of Virginia's, Maryland's and the District of Columbia's maintenance plans for the Metropolitan Washington area because EPA finds that Virginia's, Maryland's, and District of Columbia's submittal meets the requirements of section 175A.

A. Attainment Emission Inventory

As previously noted, on March 1994, November 11 and 30, 1992 and January 7, 1993, Maryland, Virginia and the District of Columbia respectively submitted a 1990 base year emissions inventory to EPA for review and approval. The inventory includes emissions from area, stationary, and mobile sources using 1990 as the base year for calculations.

The State submittal contains the detailed inventory data and summaries by county and source category. The comprehensive base year emissions inventory was submitted in the National Emission Data System format. This inventory was prepared in accordance with EPA guidance.

Although the 1990 inventory can be considered representative of attainment conditions because the NAAQS was not violated during 1990, Virginia, Maryland and the District of Columbia established CO emissions for the attainment year, as well as two forecast years out to the year 2010 (2007 and 2010) in their redesignation request. These estimates were derived from the State's 1990 emissions inventory. The state projected emissions for the end of the maintenance period using appropriate growth factors, consistent with EPA guidance. To project future emissions from mobile sources, MOBILE5a was used to assess the benefits gained from federally mandated control measures. The control programs assumed are listed in Section III. Stationary source emissions were projected using the 1990 base year inventory and multiplying with EGAS factors. The area source future emissions were projected using the 1990 base year inventory and multiplying the inventory with household, population, and employment growth factors from the national Capital Region Transportation Planning Board (TPB) Round 5.1 forecasting system.

B. Demonstration of Maintenance-Projected Inventories

Total CO emissions were projected from 1990 base year to 2010. These projected inventories were prepared in accordance with EPA guidance. Virginia, Maryland and the District of Columbia will not implement the Oxygenated Fuel program in the Metropolitan Washington CMSA unless a violation is measured. The projections show that calculated CO emissions, assuming no oxygenated fuels program, are not expected to exceed the level of the base year inventory during this time period. Therefore, it is anticipated that the Metropolitan Washington area will maintain the CO standard without the program, and the oxygenated fuel program would not need to be implemented following redesignation, except as a contingency measure.

C. Verification of Continued Attainment

Continued attainment of the CO NAAQS in the Metropolitan Washington area depends, in part, on the State's efforts toward tracking indicators of continued attainment during the maintenance period. In addition, comprehensive reviews will be conducted periodically of the factors used to develop the attainment inventories and those used to project CO emissions levels for 1995 and 2007. If any of the localities find significant differences between actual and projected growth, updated emission inventories will be developed to compare with the projections.

D. Contingency Plan

The level of CO emissions in the Metropolitan Washington area will largely determine its ability to stay in compliance with the CO NAAQS in the future. Despite the State's best efforts to demonstrate continued compliance with the NAAQS, the ambient air pollutant concentrations may exceed or violate the NAAQS. Section 175(A)(d) of the CAA requires that the contingency provisions include a requirement that the State implement all measures contained in the SIP prior to redesignation. Therefore, Virginia, Maryland and the District of Columbia have provided contingency measures with a schedule for implementation in the event of a future CO air quality problem. The plan contains triggering mechanisms to determine when contingency measures are needed.

The Virginia, Maryland and District of Columbia contingency plan triggers will be a violation of the CO NAAQS. By September 1, 1997 Virginia commits to adopt and submit to EPA an oxygenated fuel regulations that will be effective at the beginning of the next control period upon a monitored violation of the CO NAAQS (two or more exceedances of the CO NAAQS in a single calendar year). By January 1996, Maryland commits to adopt and submit to EPA a oxygenated fuel regulations that will be effective at the beginning of the next control period upon a monitored violation of the CO NAAQS (two or more exceedances of the CO NAAQS in a single calendar year). By December 1995, the District of Columbia commits to adopt and submit to EPA a oxygenated fuel regulations that will be effective at the beginning of the next control period upon a monitored violation of the CO NAAQS (two or more exceedances of the CO NAAQS in a single calendar year). EPA finds that the contingency measure provided in the Virginia, Maryland and the District of Columbia submittals meet the requirements of section 175A(d) of the CAA.

E. Subsequent Maintenance Plan Revisions

In accordance with section 175A(b) of the CAA, the State has agreed to submit a revised maintenance SIP eight years after the area is redesignated to attainment. Such revised SIP will provide for maintenance for an additional ten years.

5. Meeting Applicable Requirements of Section 110 and Part D

In Section III.2. above, EPA sets forth the basis for its conclusion that Virginia, Maryland and the District of Columbia have a fully approved SIP which meets the applicable requirements of Section 110 and Part D of the CAA.

EPA is approving this SIP revision without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in a separate document in this **Federal Register** publication, EPA is proposing to approve the SIP revision should adverse or critical comments be filed. This action will be effective March 15, 1996 unless, within 30 days of publication, adverse or critical comments are received.

If EPA receives such comments, this action will be withdrawn before the effective date by publishing a subsequent notice that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule based on this action serving as a proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time. If no such comments are received, the public is advised that this action will be effective on March 15, 1996.

Final Action

EPA is approving the Metropolitan Washington area CO maintenance plan because it meets the requirements set forth in section 175A of the CAA. In addition, the Agency is approving the request and redesignating the Metropolitan Washington CO area to attainment, because the State has demonstrated compliance with the requirements of section 107(d)(3)(E) for redesignation. EPA is also approving Virginia's, Maryland's and the District of Columbia's 1990 base year CO emissions inventory for the Metropolitan Washington CMSA. The EPA is publishing this action without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in a separate document in this **Federal Register** publication, the EPA is proposing to approve the SIP revision should adverse or critical comments be filed. This action will be effective March 15, 1996 unless, by February 29, 1996 adverse or critical comments are received. If the EPA receives such comments, this action will be withdrawn before the effective date by publishing a subsequent document that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule based on this action serving as a proposed rule. The EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time. If no such comments are received, the public is advised that this action will be effective March 15, 1996.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any state implementation plan. Each request for revision to the state implementation plan shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

Under the Regulatory Flexibility Act, 5 U.S.C. 600 *et seq.*, EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit

enterprises, and government entities with jurisdiction over populations of less than 50,000.

Under Section 202 of the Unfunded Mandates Reform Act of 1995 ("Unfunded Mandates Act"), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate; or to the private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action proposed/promulgated does not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new Federal requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

Redesignation of an area to attainment under section 107(d)(3)(E) of the CAA does not impose any new requirements on small entities. Redesignation is an action that affects the status of a geographical area and does not impose any regulatory requirements on sources. The Administrator certifies that the approval of the redesignation request will not affect a substantial number of small entities.

The CO SIP is designed to satisfy the requirements of part D of the CAA and to provide for attainment and maintenance of the CO NAAQS. This final redesignation should not be interpreted as authorizing the State to delete, alter, or rescind any of the CO emission limitations and restrictions contained in the approved CO SIP. Changes to CO SIP regulations rendering them less stringent than those contained in the EPA approved plan cannot be made unless a revised plan for attainment and maintenance is submitted to and approved by EPA. Unauthorized relaxations, deletions, and changes could result in both a finding of non-implementation (section 179(a) of the CAA) and in a SIP deficiency call made pursuant to sections 110(a)(2)(H) and 110(k)(2) of the CAA.

SIP approvals under section 110 and subchapter I, part D of the CAA do not create any new requirements, but simply approve requirements that the State is already imposing. Therefore, because the federal SIP approval does not impose any new requirements, it does not have any economic impact on any small entities. Redesignation of an area to attainment under section 107(d)(3)(E) of the CAA does not impose any new requirements on small entities.

This action has been classified as a Table 3 action for signature by the Regional Administrator under the procedures published in the **Federal Register** on January 19, 1989 (54 FR 2214–2225), as revised by a July 10, 1995 memorandum from Mary Nichols, Assistant Administrator for Air and Radiation. The Office of Management and Budget (OMB) has exempted this regulatory action from E.O. 12866 review.

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by April 1, 1996. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements.

40 CFR Part 81

Air pollution control.

Dated: October 23, 1995.

Stanley Laskowski,

Acting Regional Administrator, Region III.

Chapter I, title 40 is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

Subpart J—District of Columbia

2. Section 52.470 is amended by adding paragraph (c)(36) to read as follows:

§ 52.470 Identification of plan.

* * * * *

(c) * * *

(36) The carbon monoxide redesignation and maintenance plan for the District of Columbia submitted by the District of Columbia Department of Consumer and Regulatory Affairs on October 12, 1995, as part of the District of Columbia SIP. The emission inventory projections are included in the maintenance plan.

(i) Incorporation by reference.

(A) Letter of October 12, 1995 from the District of Columbia Department of Consumer and Regulatory Affairs requesting the redesignation and submitting the maintenance plan.

(B) Maintenance Plan for the Metropolitan Washington Carbon Monoxide Nonattainment Area adopted on September 20, 1995.

(ii) Additional material.

(A) Remainder of October 12, 1995 State submittal.

§ 52.472 [Amended]

2a. Section 52.472 is amended by removing and reserving paragraph (e).

3. Section 52.474 is added to read as follows:

§ 52.474 1990 Base Year Emission Inventory for Carbon Monoxide

EPA approves as a revision to the District of Columbia Implementation Plan the 1990 base year emission inventory for the Washington Metropolitan Statistical Area, submitted by Director, District of Columbia Consumer and Regulatory Affairs, on January 13, 1994 and October 12, 1995. This submittal consist of the 1990 base year stationary, area and off-road mobile and on-road mobile emission inventories in the Washington Statistical Area for the pollutant, carbon monoxide (CO).

Subpart V—Maryland

4. Section 52.1070 is amended by adding paragraph(c)(118) to read as follows:

§ 52.1070 Identification of plan.

* * * * *

(c) * * *

(118) The carbon monoxide redesignation and maintenance plan for the Counties of Montgomery and Prince George, Maryland submitted by the Maryland Department of the Environment on October 12, 1995, as

part of the Maryland SIP. The emission inventory projections are included in the maintenance plan.

(i) Incorporation by reference.

(A) Letter of October 12, 1995 from the Maryland Department of the Environment requesting the redesignation and submitting the maintenance plan.

(B) Maintenance Plan for the Maryland portion of the Metropolitan Washington Carbon Monoxide Nonattainment Area adopted on September 20, 1995.

(ii) Additional material.

(A) Remainder of October 12, 1995 State submittal.

5. Section 52.1075 is amended by redesignating existing text as paragraph (a) and adding paragraph (b) to read as follows:

§ 52.1075 1990 Base Year Emission inventory for Carbon Monoxide

* * * * *

(b) EPA approves as a revision to the Maryland Implementation Plan the 1990 base year emission inventory for the Washington Metropolitan Statistical Area, submitted by Secretary, Maryland Department of the Environment, on March 21, 1994 and October 12, 1995. This submittal consist of the 1990 base year stationary, area and off-road mobile and on-road mobile emission inventories in the Washington Statistical Area for the pollutant, carbon monoxide (CO).

Subpart VV—Virginia

6. Section 52.2420 is amended by adding paragraphs (c)(107) to read as follows:

§ 52.2420 Identification of plan.

* * * * *

(c) * * *

(107) The carbon monoxide redesignation and maintenance plan for the Counties of Arlington and Alexandria, Virginia submitted by the Virginia Department of Environmental Quality on October 4, 1995, as part of the Virginia SIP. The emission inventory projections are included in the maintenance plan.

(i) Incorporation by reference.

(A) Letter of October 4, 1995 from the Virginia Department of Environmental Quality requesting the redesignation and submitting the maintenance plan.

(B) Maintenance Plan for the Virginia portion of the Metropolitan Washington Carbon Monoxide Nonattainment Area adopted on September 20, 1995.

(ii) Additional material.

(A) Remainder of October 4, 1995 State submittal.

7. Section 52.2425 is added to read as follows:

§ 52.2425 1990 Base Year Emission inventory for Carbon Monoxide.

EPA approves as a revision to the Virginia Implementation Plan the 1990 base year emission inventory for the Washington Metropolitan Statistical Area, submitted by Director, Virginia Department of Environmental Quality, on November 1, 1993, April 3, 1995 and October 12, 1995. This submittal consist of the 1990 base year stationary, area and off-road mobile and on-road mobile emission inventories in the Washington Statistical Area for the pollutant, carbon monoxide (CO).

PART 81—[AMENDED]

8. The authority citation for part 81 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

Subpart C—Section 107 Attainment Status Designations

9. In § 81.309, the table for "District of Columbia-Carbon Monoxide" is amended by revising the entry for the "Washington Area Entire Washington Area" to read as follows:

§ 81.309 District of Columbia.

* * * * *

DISTRICT OF COLUMBIA-CARBON MONOXIDE

Designated area	Designation		Classification	
	Date[1]	Type	Date[1]	Type
Washington Area:				
Washington Entire Area.		Attainment		

[1] This date is November 15, 1990, unless otherwise noted.

* * * * *

10. In § 81.321, the table for "Maryland-Carbon Monoxide" is amended by revising the entry for "Montgomery County" and for "Prince George's County" to read as follows:

§ 81.321 Maryland.

* * * * *

MARYLAND-CARBON MONOXIDE

Designated area	Designation		Classification	
	Date[1]	Type	Date[1]	Type
*	*	*	*	*
Washington Area:				
Montgomery County (part) Election Districts 4, 7, 13		Attainment		
Prince George's County (part) Election Districts 2, 6, 12, 16, 17, 18		Attainment		
*	*	*	*	*

[1] This date is November 15, 1990, unless otherwise noted.

* * * * *

11. In § 81.347, the table for "Virginia-Carbon Monoxide" is amended by revising the entry for "Alexandria" and for "Arlington County" to read as follows:

§ 81.347 Virginia.

* * * * *

VIRGINIA-CARBON MONOXIDE

Designated area	Designation		Classification	
	Date [1]	Type	Date [1]	Type
Washington area:				
Alexandria		Attainment		
Arlington County		Attainment		
* * * * * * *				

[1] This date is November 15, 1990, unless otherwise noted.

* * * * *

[FR Doc. 96–1592 Filed 1–29–96; 8:45 am]
BILLING CODE 6560–50–P

40 CFR Part 70

[KS001; AD–FRL–5407–8]

Clean Air Act (CAA) Final Full Approval of Operating Permits Programs; State of Kansas, and Delegation of 112(l) Authority

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final full approval.

SUMMARY: The EPA is fully approving the operating permits program submitted by the state of Kansas for the purpose of complying with Federal requirements for an approvable state program to issue operating permits to all major stationary sources and certain other sources. EPA is also approving, under section 112(l), the state program for accepting delegation of section 112 standards to enforce air toxics regulations.

EFFECTIVE DATE: February 29, 1996.

ADDRESSES: Copies of the state's submittal and other supporting information used in developing the final full approval are available for inspection during normal business hours at the following location: EPA Region VII, 726 Minnesota Avenue, Kansas City, Kansas 66101.

FOR FURTHER INFORMATION CONTACT: Wayne A. Kaiser at (913) 551–7603.

SUPPLEMENTARY INFORMATION:

I. Background and Purpose

Title V of the 1990 Clean Air Act Amendments (sections 501–507 of the Clean Air Act ("the Act")), and implementing regulations at 40 Code of Federal Regulations (CFR) Part 70, require that states develop and submit operating permits programs to EPA by November 15, 1993, and that EPA act to approve or disapprove each program within one year after receiving the submittal. The EPA's program review occurs pursuant to section 502 of the Act and the Part 70 regulations, which together outline criteria for approval or disapproval.

On July 3, 1995, EPA proposed full approval of the operating permits program for Kansas (60 FR 34493). No public comments were received. In this notice, EPA is taking final action to promulgate full approval of the operating permits program for the state of Kansas, including delegation of 112(l) authority.

II. Final Action and Implications

A. Fulfillment of EPA Requested Modifications

The July 3, 1995, **Federal Register** notice proposing approval of the Kansas program discussed three areas of the Kansas program which required additional action prior to qualifying for full approval. The state needed to: (1) modify certain regulations to ensure that they were consistent with Part 70, (2) submit an Implementation Agreement (I.A.) which describes certain provisions for state implementation of the Part 70 program, and (3) submit an insignificant activities list. The July 3, 1995, **Federal Register** notice and the Technical Support Document for the notice describe in detail the changes in the program required for full approval. The reader should refer to those documents for a complete description of the changes required by Kansas.

The state of Kansas has satisfied the requirements for full program approval as described in the notice proposing approval. The required revisions were made to rules K.A.R. 28–19–7, K.A.R. 28–19–511, K.A.R. 28–19–512, and K.A.R. 28–19–518. The rule revisions were adopted by the Secretary of the Kansas Department of Health and Environment (KDHE) on November 14, 1995, and were effective December 8, 1995. The state also submitted an I.A. which satisfactorily addresses the deficiencies described in the notice which were to be addressed in the I.A. The state also submitted an adequate insignificant activities list.

The I.A. includes a commitment that the permitting agency will not exercise its authority under state law to grant a variance from the duty to comply with a federally enforceable Part 70 permit, except where such relief is granted through procedures allowed by Part 70. Therefore, the state variance provision is not part of the Kansas Title V program.

B. Final Action

The EPA is promulgating full approval of the operating permits program submitted to EPA by the state of Kansas on December 12, 1994, with supplemental submissions on April 7 and 17, 1995; November 14, 1995; and December 13, 1995. Among other things, the state of Kansas has demonstrated its program meets the minimum elements of a state operating permits program as specified in 40 CFR Part 70.

1. Regulations. This approval includes the following regulations adopted by the KDHE as they relate to the Kansas Class I operating permit program: K.A.R. 28–19–7, General provisions, definitions; K.A.R. 28–19–202, Annual emissions fee; K.A.R. 28–19–204, General provisions, permit issuance and modification, public participation; K.A.R. 28–19–400 through –404, General permits; K.A.R. 28–19–500 through –502, Operating permits; and K.A.R. 28–19–510 through –518, Class I operating permits.

2. Jurisdiction. The scope of the Part 70 program approved in this notice applies to all Part 70 sources (as defined in the approved program), within the state of Kansas, except any sources of air pollution over which an Indian Tribe has jurisdiction. See 59 FR 55813, 55815–18 (November 9, 1994). The term "Indian Tribe" is defined under the Act as "any Indian Tribe, Band, Nation, or other organized group or community, including any Alaska Native village, which is Federally recognized as eligible for the special programs and services provided by the United States to Indians, because of their status as Indians." See section 302(r) of the CAA;

59 FR 43956, 43962 (August 25, 1994); 58 FR 54364 (October 21, 1993).

3. CAA section 112(l). Requirements for approval, specified in 40 CFR 70.4(b), encompass section 112(l)(5) requirements for approval of a program for delegation of section 112 standards as promulgated by EPA as they apply to Part 70 sources. Section 112(l)(5) requires that the state's program contain adequate authorities, adequate resources for implementation, and an expeditious compliance schedule, which are also requirements under Part 70. Therefore, the EPA is also approving under section 112(l)(5) and 40 CFR 63.91 the state's program for receiving delegation of section 112 standards for both Part 70 and non-Part 70 sources that are unchanged from Federal standards as promulgated.

4. CAA section 112(g). The EPA issued an interpretive notice on February 14, 1995 (60 FR 8333), which outlines EPA's revised interpretation of 112(g) applicability. The notice postpones the effective date of 112(g) until after EPA has promulgated a rule addressing that provision. The notice sets forth in detail the rationale for the revised interpretation.

The section 112(g) interpretive notice explains that EPA is still considering whether the effective date of section 112(g) should be delayed beyond the date of promulgation of the Federal rule so as to allow states time to adopt rules implementing the Federal rule, and that EPA will provide for any such additional delay in the final section 112(g) rulemaking. Unless and until EPA provides for such an additional postponement of section 112(g), Kansas must have a Federally enforceable mechanism for implementing section 112(g) during the period between promulgation of the Federal section 112(g) rule and adoption of implementing Federal regulations.

The EPA is aware that Kansas lacks a program designed specifically to implement section 112(g). However, Kansas does have a preconstruction review program that can serve as an adequate implementation vehicle during the transition period, because it would allow Kansas to select control measures that would meet Maximum Available Control Technology, as defined in section 112, and incorporate these measures into a Federally enforceable preconstruction permit.

EPA is approving Kansas' preconstruction permitting program under the authority of Title V and Part 70, solely for the purpose of implementing section 112(g) to the extent necessary, during the transition period between 112(g) promulgation and adoption of a state rule implementing EPA's section 112(g) regulations. Although section 112(l) generally provides authority for approval of state air programs to implement section 112(g), Title V and section 112(g) provide for this limited approval because of the direct linkage between the implementation of section 112(g) and Title V.

The scope of this approval is narrowly limited to section 112(g), and does not confer or imply approval for purposes of any other provision under the Act (e.g., section 110). This approval will be without effect, if EPA decides in the final section 112(g) rule that sources are not subject to the requirements of the rule until state regulations are adopted. The duration of this approval is limited to 18 months following promulgation by EPA of the 112(g) rule to provide adequate time for the state to adopt regulations consistent with the Federal requirements.

III. Administrative Requirements

A. Docket

Copies of the state submittal and other information relied upon for the final full approval are contained in a docket maintained at the EPA Regional Office. The docket is an organized and complete file of all the information submitted to, or otherwise considered by, EPA in the development of this final full approval. The docket is available for public inspection at the location listed under the **ADDRESSES** section of this document.

B. Executive Order 12866

The Office of Management and Budget has exempted this action from Executive Order 12866 review.

C. Regulatory Flexibility Act

The EPA's actions under section 502 of the Act do not create any new requirements, but simply address operating permits programs submitted to satisfy the requirements of 40 CFR Part 70. Because this action does not impose any new requirements, it does not have a significant impact on a substantial number of small entities.

D. Unfunded Mandates

Under sections 202, 203, and 205 of the Unfunded Mandates Reform Act of 1995 ("Unfunded Mandates Act"), signed into law on March 22, 1995, EPA must undertake various actions in association with proposed or final rules that include a Federal mandate that may result in estimated costs of $100 million or more to the private sector, or to state, local, or tribal governments in the aggregate.

Through submission of these operating permit programs, the state of Kansas has elected to adopt the program provided for under Title V of the CAA. These rules bind the state to perform certain actions and also require the private sector to perform certain duties.

To the extent that the rules being proposed for approval by this action will impose new requirements, sources are already subject to these regulations under state law. EPA has determined that this proposed action does not include a mandate that may result in estimated costs of $100 million or more to state, local, or tribal governments in the aggregate or to the private sector.

List of Subjects in 40 CFR Part 70

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Operating permits, Reporting record keeping requirements.

Dated: December 18, 1995.

Dennis Grams,

Regional Administrator.

Part 70, title 40 of the Code of Federal Regulations is amended as follows:

PART 70—[AMENDED]

1. The authority citation for part 70 continues to read as follows:

Authority: 42 U.S.C. 7401—7671q.

2. Appendix A to part 70 is amended by adding the entry for Kansas to read as follows:

Appendix A to Part 70—Approval Status of State and Local Operating Permits Programs

* * * * *

Kansas

(a) The Kansas Department of Health and Environment program submitted on December 12, 1994; April 7 and 17, 1995; November 14, 1995; and December 13, 1995. Full approval effective on February 29, 1996.

(b) [Reserved.]

* * * * *

[FR Doc. 96–1722 Filed 1–29–96; 8:45 am]

BILLING CODE 6560–50–P

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40 CFR Part 81

[Region II Docket No.147; NJ24–1–7249a, FRL–5404–8]

Air Quality Designations: Deletion of TSP Designations From New Jersey, New York, Puerto Rico and Virgin Islands

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is removing all total suspended particulate (TSP) area designations in New Jersey, New York, Puerto Rico and the Virgin Islands because they are no longer relevant. EPA promulgated revised prevention of significant deterioration (PSD) increments for particulate matter so that the PSD increments are now measured in terms of particulate matter with an aerodynamic diameter less than 10 microns (PM_{10}) instead of TSP. Section 107(d)(4)(B) of the Clean Air Act (Act) authorizes EPA to eliminate all area TSP designations once the PSD increments for PM_{10} are promulgated.

DATES: This rule is effective on April 1, 1996 unless adverse or critical comments are received by February 29, 1996. If the effective date is delayed, timely notice will be published in the **Federal Register**.

ADDRESSES: All comments should be addressed to: William S. Baker, Chief, Air Programs Branch, Environmental Protection Agency, Region II Office, 290 Broadway, New York, New York 10007–1866.

Copies of the documents relevant to this action are available for inspection during normal business hours at the following address: Environmental Protection Agency, Region II Office, Air Programs Branch, 290 Broadway, 20th Floor, New York, New York 10007–1866.

FOR FURTHER INFORMATION CONTACT: Kirk J. Wieber, Air Programs Branch, Environmental Protection Agency, 290 Broadway, 20th Floor, New York, New York 10007–1866, (212) 637–4249.

SUPPLEMENTARY INFORMATION:

Background

In 1971, EPA promulgated primary and secondary National Ambient Air Quality Standards (NAAQS) for particulate matter to be measured as TSP. Based upon better health effects information, on July 1, 1987 (52 FR 242634), EPA replaced the TSP NAAQS for particulate matter with a PM_{10} standard. On the same date, EPA promulgated final regulations under 40 CFR part 51 for state implementation of the revised NAAQS (52 FR 24672). In the preamble to that action, EPA announced that, because of the importance of the section 107 area designations to the applicability of the PSD increments for TSP, it would retain the TSP designations beyond the date on which EPA approves a state's revised PM_{10} State Implementation Plan (SIP). This would protect the applicability of the PSD increments for TSP until a PSD increment for PM_{10} could be established.

The 1990 Amendments to the Act contained several pertinent provisions relating to or affecting the TSP area designations. Under section 107(d)(4)(B) of the amended Act, Congress established by operation of law the first nonattainment area designations for PM_{10}, and mandated that areas not initially defined as nonattainment are considered to be unclassifiable.

Moreover, section 107(d)(4)(B) provided that any designation for particulate matter (measured in terms of TSP) that the Administrator promulgated prior to the date of enactment of the 1990 Amendments shall remain in effect for purposes of implementing the maximum allowable concentrations of particulate matter (measured in terms of TSP) PSD increments until the Administrator determines that such designation is no longer necessary for that purpose.

On June 3, 1993 (58 FR 31622), under the authority of section 166(f) of the Act, EPA published the final rulemaking replacing the PSD increments for TSP with equivalent PSD increments for PM_{10}, which became effective on June 3, 1994. As announced in the June 3, 1993 **Federal Register** notice, EPA intends to eliminate the TSP area designations from states and territories where the Federal PSD program is in effect. EPA has the legal responsibility for implementing the PSD program in New Jersey, New York, Puerto Rico, and the Virgin Islands pursuant to 40 CFR 52.1603, 52.1689, 52.2729, 52.2779, respectively. However, EPA has delegated the day-to-day PSD program administration to the states of New Jersey and New York. The delegation agreement provides for automatic adoption of the PSD increments for PM_{10} once the increments became effective.

Conclusion

In accordance with the information provided above, the states affected by today's rule do not have PSD regulations which have been approved by the EPA under the applicable implementation plan. Instead, the PSD regulations contained in 40 CFR 52.21 (the Federal PSD program) govern the review and approval of permits to construct and operate major stationary sources in these areas. Pursuant to section 166(b) of the Act, the new PSD increments for PM_{10} became effective on June 3, 1994—one year after promulgation. Accordingly, EPA is today deleting from the list of area designations in 40 CFR part 81, all of the designations for TSP in New Jersey, New York, Puerto Rico, and the Virgin Islands. Area designations which indicate the attainment status of each affected area with respect to the PM_{10} NAAQS already exist (56 FR 56694, November 1991), and the TSP area designations are no longer needed.

Nothing in this rule should be construed as permitting or allowing or establishing a precedent for any future request for revision to any applicable implementation plan. Each request for revision to any SIP shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

EPA is publishing this rule without prior proposal because EPA views this as a noncontroversial amendment and anticipates no adverse comments. However, in a separate document in this **Federal Register** publication, the EPA is proposing to approve the SIP revision should adverse or critical comments be filed. Thus, this direct final action will be effective April 1, 1996 unless, by February 29, 1996, adverse or critical comments are received.

If the EPA receives such comments, this rule will be withdrawn before the effective date by publishing a subsequent notice that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule based on this action serving as a proposed rule. The EPA will not institute a second comment period on this action. Any parties interested in commenting on this rule should do so at this time. If no adverse comments are received, the public is advised that this rule will be effective April 1, 1996. (See 47 FR 27073 and 59 FR 24059).

Under the Regulatory Flexibility Act, 5 U.S.C. 600 et seq., EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000. The deletion of TSP tables in part 81 does not create any new requirements.

Under section 202 of the Unfunded Mandates Reform Act of 1995 ("Unfunded Mandates Act"), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to state, local, or tribal governments in the

aggregate; or to the private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the deletion of no longer applicable TSP tables does not include a Federal mandate that may result in estimated costs of $100 million or more to either state, local, or tribal governments in the aggregate, or to the private sector.

The Office of Management and Budget has exempted this action from review under Executive Order 12866.

Under section 307(b)(l) of the Act, petitions for judicial review of this rule must be filed in the United States Court of Appeals for the appropriate circuit within 60 days from date of publication. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed and shall not postpone the effectiveness of such rule or action. This rule may not be challenged later in proceedings to enforce its requirements. (See 307(b)(2).)

List of Subjects in 40 CFR Part 81

Environmental protection, Air pollution control, Particulate matter.

Dated: December 18, 1995.

Jeanne M. Fox,

Regional Administrator.

Part 81, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 81—[AMENDED]

1. The authority citation for part 81 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

§ 81.331 New Jersey

2. In § 81.331 the table entitled "New Jersey—TSP" is removed.

§ 81.333 New York

3. In § 81.333 the table entitled "New York—TSP" is removed.

§ 81.355 Puerto Rico

4. In § 81.355 the table entitled "Puerto Rico—TSP" is removed.

§ 81.356 Virgin Islands

5. In § 81.356 the table entitled "Virgin Islands—TSP" is removed.

[FR Doc. 96–1588 Filed 1–29–96; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 228

[FRL–5346–2]

Ocean Dumping; Final Site Designation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA designates an Ocean Dredged Material Disposal Site (ODMDS) in the Atlantic Ocean offshore Miami, Florida, as an EPA-approved ocean dumping site for the disposal of suitable dredged material. This action is necessary to provide an acceptable ocean disposal site for consideration as an option for dredged material disposal projects in the greater Miami, Florida vicinity. This site designation is for an indefinite period of time, but the site is subject to continuing monitoring to insure that unacceptable adverse environmental impacts do not occur.

EFFECTIVE DATE: February 29, 1996.

ADDRESSES: The supporting document for this designation is the Final Environmental Impact Statement (EIS) for Designation of an Ocean Dredged Material Disposal Site offshore Miami, Florida, August 1995, which is available for public inspection at the following locations:

A. EPA/Region 4, Coastal Programs Section, 345 Courtland Street, NE., Atlanta, Georgia 30365

B. Department of the Army, Jacksonville District Corps of Engineers, Planning Division, 400 West Bay Street, Jacksonville, FL 32232–0019.

FOR FURTHER INFORMATION CONTACT: Christopher J. McArthur, 404/347–1740 ext. 4289.

SUPPLEMENTARY INFORMATION:

A. Background

Section 102(c) of the Marine Protection, Research, and Sanctuaries Act (MPRSA) of 1972, as amended, 33 U.S.C. 1401 *et seq.*, gives the Administrator of EPA the authority to designate sites where ocean disposal may be permitted. On October 1, 1986, the Administrator delegated the authority to designate ocean disposal sites to the Regional Administrator of the Region in which the sites are located. This designation of a site offshore Miami, Florida, which is within Region 4, is being made pursuant to that authority.

The EPA Ocean Dumping Regulations promulgated under MPRSA (40 CFR ch. I, subchapter H, § 228.4) state that ocean dumping sites will be designated by promulgation in this part 228. A list of "Approved Interim and Final Ocean Dumping Sites" was published on January 11, 1977 (42 FR 2461 (January 11, 1977)). The list established the existing Miami ("Miami Beach") site as an interim site. The site is now listed in 40 CFR 228.14(h)(6).

B. EIS Development

Section 102(2)(C) of the National Environmental Policy Act (NEPA) of 1969, as amended, 42 U.S.C. 4321 *et seq.*, requires that federal agencies prepare an Environmental Impact Statement (EIS) on proposals for legislation and other major federal actions significantly affecting the quality of the human environment. The object of NEPA is to build into the Agency decision making process careful consideration of all environmental aspects of proposed actions. While NEPA does not apply to EPA activities of this type, EPA has voluntarily committed to prepare EISs in connection with ocean disposal site designations such as this (see 39 FR 16186 (May 7, 1974).

EPA Region 4, in cooperation with the Jacksonville District of the U.S. Army Corps of Engineers (COE), has prepared a Final EIS entitled, "Final Environmental Impact Statement for Designation of An Ocean Dredged Material Disposal Site Located Offshore Miami, Florida." On September 1, 1995, the Notice of Availability (NOA) of the FEIS for public review and comment was published in the **Federal Register** (60 FR 45717 (September 1, 1995)). Anyone desiring a copy of the EIS may obtain one from the address given above. The public comment period on the Final EIS was to have closed on October 2, 1995. However, the closing date was extended until October 17, 1995 due to a request by the State of Florida.

One comment letter was received in support of the Final EIS and no letters were received critical of the Final EIS. The letter of support endorsed the Site Management and Monitoring Plan (SMMP) and the SMMP team.

The EIS has served as a Biological Assessment for purposes of Section 7 of the Endangered Species Act coordination. By itself, site designation of the Miami ODMDS will not adversely impact any threatened or endangered species under the purview of the National Marine Fisheries Service

(NMFS) and the U.S. Fish and Wildlife Service (FWS). Use of the ODMDS is not expected to adversely impact any threatened or endangered species. Pursuant to Section 7 of the Endangered Species Act, the National Marine Fisheries Service (NMFS) has been asked by EPA to concur with EPA's conclusion that this site designation will not affect the endangered species under their jurisdictions. The National Marine Fisheries Service determined that populations of endangered/threatened species under their purview would not be adversely affected by the designation and use of the proposed ODMDS. This consultation process has been fully documented in the Final EIS.

EPA has evaluated the site designation for consistency with the State of Florida's (the State) approved coastal management program. EPA determined that the designation of the site is consistent to the maximum extent practicable with the State coastal management program, and submitted this determination to the State for review in accordance with EPA policy. The State has concurred with this determination. In addition, as part of the NEPA process, EPA has consulted with the State regarding the effects of the dumping at the proposed site on the State coastal zone. There were three main concerns raised by the State during consultation: (1) placement of beach quality sand in the ODMDS; (2) potential for movement of silt and clay sized particles out of the disposal area and onto environmentally sensitive hardbottoms and coral reefs to the west during the occurrence of Gulf Stream frontal eddies; and (3) disposal of contaminated sediments from locations such as the Miami River. Concerns raised by the State of Florida, regarding use of suitable material for beach nourishment, were addressed in the Final EIS. EPA concurs with the State of Florida regarding the use of suitable material for beach nourishment, in circumstances where this use is practical. To address the concern regarding movement of material, a real-time monitoring system has been instituted by the Army Corps of Engineers to identify the occurrence of Gulf Stream frontal eddies. During the occurrence of such eddies, disposal at the ODMDS will discontinue. Details of the monitoring plan and protocol has been included in the Site Management and Monitoring Plan as part of the Final EIS. With regard to contaminated materials, before any material can be placed within an ODMDS, it must be evaluated and shown to be acceptable for ocean disposal in accordance with ocean dumping regulations (40 CFR 227.13). Certain portions of the sediments proposed to be dredged from the Miami River have been found to be unacceptable for ocean disposal.

In a letter dated September 13, 1990, the Florida Department of State agreed that the designation will have no effect on any archaeological or historic sites or properties listed, or eligible for listing, in the *National Register of Historic Places* in accordance with the National Preservation Act of 1966 (Pub. L. 89–6654), as amended.

The action discussed in the EIS is the permanent designation for continuing use of the existing interim ocean disposal site near Miami, Florida. The purpose of the action is to provide an environmentally acceptable option for the ocean disposal of dredged material. The need for the permanent designation of the Miami ODMDS is based on a demonstrated COE need for ocean disposal of maintenance dredged material from the Federal navigation projects in the greater Miami area. However, every disposal activity by the COE is evaluated on a case-by-case basis to determine the need for ocean disposal for that particular case. The need for ocean disposal for other projects, and the suitability of the material for ocean disposal, will be determined on a case-by-case basis as part of the COE's process of issuing permits for ocean disposal for private/federal actions and a public review process for their own actions.

For the Miami ODMDS, the COE and EPA would evaluate all federal dredged material disposal projects pursuant to the EPA criteria given in the Ocean Dumping Regulations (40 CFR parts 220–229) and the COE regulations (33 CFR 209.120 and 335–338). The COE also issues Marine Protection, Research, and Sanctuaries Act (MPRSA) permits to private applicants for the transport of dredged material intended for disposal after compliance with regulations is determined. EPA has the right to disapprove any ocean disposal project if, in its judgment, all provisions of MPRSA and the associated implementing regulations have not been met.

The EIS discusses the need for this site designation and examines ocean disposal site alternatives to the final action. Non-ocean disposal options have been examined in the previously published Feasibility Report and EIS for the Miami Harbor Channel Project. Alternatives to ocean disposal may include upland disposal within the port area, disposal in Biscayne Bay, and beach disposal. Upland disposal in the intensively developed Port of Miami-Biscayne Bay area has not been found feasible. The Port of Miami itself is built partially on fill in Biscayne Bay. Undeveloped areas within cost-effective haul distances are environmentally valuable in their own right.

Almost all inshore waters of the Biscayne Bay area are part of the Biscayne Bay Aquatic Preserve. The waters of the southern portion of Biscayne Bay, now included in the Aquatic Preserve, are to be incorporated, along with some offshore waters, into the Biscayne National Park in the near future. The Florida Department of Environmental Regulation (DER) has afforded the waters of these areas special protection as Outstanding Florida Waters. This effectively removes virtually all of the Biscayne Bay area from consideration for disposal of dredged material.

Dredged sand might be placed on beaches in the Miami Beach area. Suitable rock might be placed in nearshore waters. These options may be feasible where a substantial quantity of the desired type of material is separable from silt or other undesirable material. Such usage will be considered on a case by case basis.

The COE has been authorized to deepen Miami Harbor. For that project, environmental and economic analyses were performed and an EIS was prepared. The COE examined and documented the feasibility of each of the above-described disposal options and found none to be feasible.

The following ocean disposal alternatives were evaluated in the EIS:

1. Alternative Sites on the Continental Shelf

In the Miami nearshore area, hardgrounds supporting coral and algal communities are concentrated on the continental shelf. Disposal operations on the shelf could adversely impact this reef habitat. Because the shelf is narrow, about 3.3 nmi (6 km) off Government Cut, the transport of dredged materials for disposal beyond the shelf is both practical and economically feasible. Therefore, alternative sites on the continental shelf are not desirable.

2. Designated Interim Site (Candidate Site)

The preferred alternative considered in this document is the final designation of an ODMDS. This site is an area of approximately one square nautical mile with the following corner coordinates: 25°45′30″ N, 80°03′54″ W; 25°45′30″ N, 80°02′50″ W; 25°44′30″ N, 80°02′50″ W; 25°44′30″ N, 80°03′54″ W. The site is centered at: 25°45′00″ N and 80°03′22″ W. This site is considered suitable in

terms of practicality and economic feasibility. Sections 228.5 and 228.6 of EPA's Ocean Dumping Regulations and Criteria 40 CFR establish criteria for the evaluation of ocean disposal sites.

3. Alternative Sites Beyond the Continental Shelf

The candidate site is beyond the continental shelf. The western edge of the Gulf Stream meanders about one mile east of the candidate site. Dumping in the Gulf Stream was considered, but the enormous task and expense of monitoring disposal under such conditions caused sufficient concern to eliminate that option. Therefore, additional sites beyond the continental shelf and beyond the candidate site are not desirable.

4. No Action

Under the "no action" alternative, the interim site would not receive final designation. The Water Resources Act of 1992, title V, section 506(a) prohibits the continued use of ocean dump sites which have not been designated by EPA as section 102 dump sites after January 1, 1997. If EPA fails to designate the Miami ODMDS by that date, the continued foreseeable need to have an appropriate site for disposal of suitable sediments from dredging projects in the Miami area would place pressure on the Corps and EPA to approve on a project-by-project basis the use of temporary ocean dumping locations pursuant to either Clean Water Act section 404 or MPRSA section 103.

The EIS presents the information needed to evaluate the suitability of ocean disposal areas for final designation use and is based on one of a series of disposal site environmental studies. The environmental studies and final designation are being conducted in accordance with the requirements of MPRSA, the Ocean Dumping Regulations, and other applicable Federal environmental legislation.

This final rulemaking notice fills the same role as the Record of Decision required under regulations promulgated by the Council on Environmental Quality for agencies subject to NEPA.

C. Site Designation

On October 27, 1994, EPA proposed designation of this site for the continueing disposal of dredged materials from the greater Miami, Florida vicinity. The public comment period on this proposed action closed on December 12, 1994. EPA received 1 letter regarding the proposed rule. The letter—s comments are listed and addressed below.

1. Dredged Material Evaluation

The commentor was concerned as to whether EPA will evaluate the contents of the dredged material for toxins and make them public.

Response. The suitability of dredged material for ocean disposal must be verified by the COE and agreed to by EPA prior to disposal. Verification will be valid for 3 years from the time last verified with the option of a 2-year extension. Verification will involve: (1) A case-specific evaluation against the exclusion criteria (40 CFR 227.13(b)), (2) A determination of the necessity for bioassay (toxicity and bioaccumulation) testing for non-excluded material based on the potential for contamination of the sediment since last tested, and (3) Carrying out the testing and determining that the non-excluded, tested material is suitable for ocean disposal.

Documentation of verification will be completed prior to use of the site. Documentation for material suitability for dredging events proposed for ocean disposal more than 5 years since last verified will be a new 103 evaluation and public notice. Documentation for material suitability for dredging events proposed for ocean disposal less than 5 years but more than 3 years since last verified will be an exchange of letters between the COE and EPA.

Should EPA conclude that reasonable potential exists for contamination to have occurred, acceptable testing will be completed prior to use of the site. Testing procedures to be used will be those delineated in the 1991 EPA/COE Dredged Material Testing Manual and 1992 Regional Implementation Manual. Only material determined to be suitable through the verification process by the COE and EPA will be placed at the designated ocean disposal site.

Verification documentation will be provided to the public in one of two ways. For federal dredged material disposal projects, verification documentation will be provided to the public by the COE through the NEPA process, either in the form of an EIS or an Environmental Assessment. The COE also issues MPRSA permits to private applicants for the transport of dredged material intended for disposal. In this case verification documentation will be made available to the public by the COE through the Public Notice process.

2. Sources of Dredged Material

The commentor was concerned as to what regions the greater Miami, Florida vicinity include and whether or not other sources besides the Miami Harbor Channel Project may use the site.

Response. The primary need for designation of the Miami ODMDS was for disposal of dredged material from the Miami Harbor Channel and the Federal Miami Harbor Deepening Project.

However, other projects such as the maintenance dredging of that portion of the Atlantic Intracoastal Waterway (AIWW) in the vicinity of Miami Harbor and locally constructed channels within an economic haul distance of the Miami ODMDS can use the site provided the material is suitable for ocean disposal. Restrictions of use of the site to specific projects has not been deemed necessary at this time. If in the future, it is determined that use of the site should be restricted to a specific project, appropriate changes will be made to the Site Management and Monitoring Plan.

3. Period of Use

The commentor was concerned as to why a closing date of the site had not been determined.

Response. The period of use of the Miami ODMDS has been designated as continueing. Because the site is located in deep water, no restrictions are presently placed on disposal volumes. Future disposal of unrestricted volumes is dependent upon results from future monitoring surveys. If future surveys indicate that capacity of the site is being reached or unacceptable adverse environmental impacts are occurring, then either the ODMDS Management and Monitoring Plan will be modified or use of the site will be modified or discontinued.

4. Long-term Movement of Dredged Material

The commentor was concerned about movement of disposed dredged material moving to more environmentally sensitive areas in the event of an extreme storm event.

Response. Long-term modeling efforts were conducted to determine whether a disposal mound is stable over long periods of time. A 24-hour sustained storm surge simulation showed that essentially no material would be transported as a result of the surge. A second study investigated the potential for moving material other than uniformly graded, non-cohesive sediments by calculating shear stress values on the mound and in the surrounding area. Under normal environmental conditions, shear stress values at the ODMDS are low, and little movement is anticipated for either cohesive or non-cohesive material. During storm events, the shear stress values increase by an order of magnitude. However, the shear stress on the dredged material disposal mound increases by less than 2 dynes/cm^2

above the shear stress of the surrounding area. When subjected to storms, material is anticipated to move from the mound for short periods of time but large dispersion of the mound is not predicted. For the proposed Miami ODMDS, simulations show that local velocity fields are simply not adequate to move material in 600 feet or more of water. Both the short-term disposal and long-term erosion simulations of sediment transport as a function of local velocity fields indicate little possibility of affecting reefs as a direct result of use of the disposal site.

In addition, should the results of the monitoring surveys indicate that continuing use of the site would lead to unacceptable impacts, then either the ODMDS Management and Monitoring Plan will be modified to alleviate the impacts, or the location or use of the ODMDS would be modified.

5. Availability of Monitoring Results

The commentor asked if the monitoring results of the site will be made public.

Response. Monitoring results will be available to the public upon request. As discussed in the Final EIS, monitoring data will be provided to the ODMDS Site Management and Monitoring team members for review. Data will be provided to other interested parties requesting such data to the extent possible.

The site is located east of Miami, Florida, the western boundary being 3.6 nautical miles (nmi) offshore. The ODMDS occupies an area of about 1 square nautical mile (nmi^2), in the configuration of an approximate 1 nmi by 1 nmi square. Water depths within the area range from 130 to 240 meters (427 to 785 feet). The coordinates of the Miami site for designation are as follows:

25°45′30″ N	80°03′54″ W;
25°45′30″ N	80°02′50″ W;
25°44′30″ N	80°03′54″ W; and
25°44′30″ N	80°02′50″ W.

Center coordinates are 25°45′00″ N and 80°03′22″ W.

If at any time disposal operations at the site cause unacceptable adverse impacts, further use of the site will be restricted or terminated.

D. Regulatory Requirements

Pursuant to the Ocean Dumping Regulations, 40 CFR § 228.5, five general criteria are used in the selection and approval for continuing use of ocean disposal sites. Sites are selected so as to minimize interference with other marine activities, to prevent any temporary perturbations associated with the disposal from causing impacts outside the disposal site, and to permit effective monitoring to detect any adverse impacts at an early stage. Where feasible, locations off the Continental Shelf and other sites that have been historically used are to be chosen. The site conforms to the five general criteria.

In addition to these general criteria in §§ 228.5, 228.6 lists the 11 specific criteria used in evaluating a proposed disposal site to assure that the general criteria are met. Application of these 11 criteria constitutes an environmental assessment of the impact of disposal at the site. The characteristics of the proposed site are reviewed below in terms of these 11 criteria (the EIS may be consulted for additional information).

1. Geographical Position, Depth of Water, Bottom Topography, and Distance From Coast (40 CFR 228.6(a)(1))

The boundary and center coordinates of the site are given above. The western boundary of the site is located about 3.6 nmi offshore of Miami, Florida. The site is an approximate 1 nmi by 1 nmi square configuration. Water depth in the area ranges from 427 to 785 feet.

2. Location in Relation to Breeding, Spawning, Nursery, Feeding, or Passage Areas of Living Resources in Adult or Juvenile Phases (40 CFR 228.6(a)(2))

Many of the area's species spend their adult lives in the offshore region, but are estuary-dependent because their juvenile stages use a low salinity estuarine nursery region. Specific migration routes are not known in the Miami area. The site is not known to include any major breeding or spawning area, except for sea turtles which use the entire beach area of eastern Florida as nesting habitat. Due to the motility of finfish, it is unlikely that disposal activities will have any significant impact on any of the species found in the area.

3. Location in Relation to Beaches and Other Amenity Areas (40 CFR 228.6(a)(3))

The western edge of the candidate site is located 3.6 nautical miles from the coast. Shore-related amenities include Virginia Key, the Biscayne Bay Aquatic Preserve, Biscayne National Park, and the Bill Baggs Cape Florida State Recreational Area. Currents in the vicinity trend alongshore in a general north-south orientation. It is not expected that detectable quantities of dredged material will be transported onto beaches. Considering the distance that the disposal site is offshore of beach areas, dredged material disposal at the site is not expected to have an effect on the recreational uses of these beaches. Modelling performed by the COE indicates that disposed material will not impact these areas.

4. Types and Quantities of Wastes Proposed To Be Disposed of, and Proposed Methods of Release, Including Methods of Packing the Waste, if any (40 CFR 228(a)(4))

It is anticipated that the candidate site will be used primarily for disposal of maintenance material from the Port of Miami. Maintenance dredging has only occurred four times since 1957. Another use of the site would be the Miami Harbor Deepening Project. Estimated volume for this project is expected to be 6 million cubic yards. For each future dredging project, each disposal plan must be evaluated on a case-by-case basis to ensure that ocean disposal is the best alternative and that the material meets the Ocean Dumping Criteria in 40 CFR part 227.

5. Feasibility of Surveillance and Monitoring (40 CFR 228.6(a)(5))

Due to the proximity of the site to shore, surveillance will not be difficult. Survey vessels, dredges or aircraft overflights are feasible surveillance methods. However, the depths at this site make conventional ODMDS monitoring techniques difficult to utilize. An interagency Site Management and Monitoring Team was established to assist EPA in the development and implementation of a Site Monitoring Plan (SMMP) for the Miami ODMDS. The SMMP has been developed and was included as an appendix in the Final EIS. This SMMP establishes a sequence of monitoring surveys to be undertaken to determine any impacts resulting from disposal activities. The SMMP may be modified for cause by the responsible agencies.

6. Dispersal, Horizontal Transport and Vertical Mixing Characteristics of the Area Including Prevailing Current Direction and Velocity, if any (40 CFR 228.6(a)(6))

Prevailing currents parallel the coast and are generally oriented along a north-south axis. Northerly flow predominates. Mean surface currents range from 62 to 95 cm/sec with maximum velocities of about 150 cm/sec. Current speeds are lower and current reversals more common in near-bottom waters. Mean velocities of 3.5 cm/sec and maximum velocities of 27 cm/sec have been reported for near-bottom waters in the area. A pycnocline occurs in site waters throughout the

year at reported depths ranging from about 60 feet in the summer to 325 feet in the winter. A dredged material dispersion study conducted by the COE for both the short- and long-term fate of material disposed at the site indicates little possibility of disposed material affecting near-shore reefs. Measures as discussed in the Site Management and Monitoring Plan will be instituted during disposal operations to minimize the possibility of material being transported to the near-shore reefs.

7. Existence and Effects of Current and Previous Discharges and Dumping in the Area (Including Cumulative Effects) (40 CFR 228.6(a)(7))

The ODMDS was used for the first time in April 1990. Only 225,000 cubic yards of maintenance material was disposed in the ODMDS. In conjunction with this use of the site, the Corps of Engineers in cooperation with the National Oceanic and Atmospheric Administration (NOAA) monitored the physical processes and the dispersive characteristics of the dredged material plume. Monitoring results indicated that the material discharged, except for a low concentration residual remaining within the water column, reached the bottom within the designated site boundaries. During the monitoring, the resulting plumes were observed to be transported in a north to northeast direction. The full monitoring report has been included as part of the Final EIS. Effects monitoring is discussed in the Site Management and Monitoring Plan as part of the Final EIS.

No other discharges or dumping occurs in the site. The Miami-Dade Central publicly owned treatment plant outfall discharges approximately 1.2 nmiles west of the site. The effects from this discharge are local and predominately in a north-south direction due to prevailing currents and should not have any effect within the site.

8. Interference With Shipping, Fishing, Recreation, Mineral Extraction, Desalination, Fish and Shellfish Culture, Areas of Special Scientific Importance and Other Legitimate Uses of the Ocean (40 CFR 228.6(a)(8))

While shipping is heavy at the Port of Miami, the infrequent use of this site should not significantly disrupt either commercial shipping or recreational boating. Commercial and recreational fishing activities are concentrated in inshore and nearshore waters. No mineral extraction, desalination, or mariculture activities occur in the immediate area. Scientific resources present throughout this area are not geographically limited to the Miami ODMDS or nearby waters.

9. The Existing Water Quality and Ecology of the Site as Determined by Available Data or by Trend Assessment or Baseline Surveys (40 CFR 228.6(a)(9))

Water quality at the ODMDS is variable and is influenced by discharges from inshore systems, frequent oceanic intrusions, and periodic upwelling. The disposal site lies on the continental slope in an area traversed by the western edge of the Florida Current. The location of the western edge of the current determines to a large extent whether waters at the site are predominantly coastal or oceanic. Frequent intrusions or eddies of the Florida Current transport oceanic waters over the continental slope in the ODMDS vicinity. Periodic upwelling/downwelling events associated with wind stress also influence waters in the area.

No critical habitat or unique ecological communities have been identified at the candidate site. Buffer zone protection has been applied to any existing fish havens, artificial reef communities, turtle nesting areas, and onshore amenities in the general region of the site.

10. Potentiality for the Development or Recruitment of Nuisance Species in the Disposal Site (40 CFR 228.6(a)(10))

The disposal of dredged materials should not attract or promote the development of nuisance species. No nuisance species have been reported to occur at previously utilized disposal sites in the vicinity.

11. Existence at or in Close Proximity to the Site of any Significant Natural or Cultural Features of Historical Importance (40 CFR 228.6(a)(11))

No known natural or cultural features of historical importance occur at or in close proximity to the site. No such features were noted in a video survey of the disposal area.

E. Site Management

Site management of the Miami ODMDS is the responsibility of EPA as well as the COE. The COE issues permits to private applicants for ocean disposal; however, EPA/Region 4 assumes overall responsibility for site management.

The Site Management and Monitoring Plan (SMMP) for the Miami ODMDS was developed as a part of the process of completing the EIS. The plan was developed with the assistance of an interagency Site Management and Monitoring team. The Team will also provide assistance during the implementation of the plan. This plan provides procedures for both site management and for the monitoring of effects of disposal activities. This SMMP is intended to be flexible and may be modified by the responsible agencies for cause.

F. Final Action

The EIS concludes that the site may appropriately be designated for use. The site is compatible with the 11 specific and 5 general criteria used for site evaluation.

The designation of the Miami site as an EPA-approved ODMDS is being published as Final Rulemaking. Overall management of this site is the responsibility of the Regional Administrator of EPA/Region 4.

It should be emphasized that, if an ODMDS is designated, such a site designation does not constitute EPA's approval of actual disposal of material at sea. Before ocean disposal of dredged material at the site may commence, the COE must evaluate a permit application according to EPA's Ocean Dumping Criteria. EPA has the right to disapprove the actual disposal if it determines that environmental concerns under MPRSA have not been met.

The Miami ODMDS is not restricted to disposal use by federal projects; private applicants may also dispose suitable dredged material at the ODMDS once relevant regulations have been satisfied. This site is restricted, however, to suitable dredged material from the greater Miami, Florida vicinity.

G. Regulatory Assessments

Under the Regulatory Flexibility Act, EPA is required to perform a Regulatory Flexibility Analysis for all rules that may have a significant impact on a substantial number of small entities. EPA has determined that this action will not have a significant impact on small entities since the designation will only have the effect of providing a disposal option for dredged material. Consequently, this Rule does not necessitate preparation of a Regulatory Flexibility Analysis.

Under Executive Order 12291, EPA must judge whether a regulation is "major" and therefore subject to the requirement of a Regulatory Impact Analysis. This action will not result in an annual effect on the economy of $100 million or more or cause any of the other effects which would result in its being classified by the Executive Order as a "major" rule. Consequently, this Rule does not necessitate preparation of a Regulatory Impact Analysis.

This Final Rule does not contain any information collection requirements subject to Office Management and Budget review under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*

List of Subjects in 40 CFR Part 228

Water Pollution Control.

Dated: November 2, 1995.

Patrick M. Tobin,

Acting Regional Administrator.

In consideration of the foregoing, 40 CFR Chap. I, Subchapter H is amended as set forth below.

PART 228—[AMENDED]

1. The authority citation for part 228 continues to read as follows:

Authority: 33 U.S.C. Sections 1412 and 1418.

2. Section 228.14 is amended by removing paragraph (h)(6).

3. Section 228.15 is amended by adding paragraph (h)(19) to read as follows:

§ 228.15 Dumping sites designated on a final basis

* * * * *

(h) * * *

(19) Miami, Florida; Ocean Dredged Material Disposal Site.

(i) Location:

25°45′30″ N	80°03′54″ W;
25°45′30″ N	80°02′50″ W;
25°44′30″ N	80°03′54″ W;
25°44′30″ N	80°02′50″ W.

Center coordinates are 25°45′00″ N and 80°03′22″ W.

(ii) Size: Approximately 1 square nautical mile.

(iii) Depth: Ranges from 130 to 240 meters.

(iv) Primary use: Dredged material.

(v) Period of use: Continuing use.

(vi) Restriction: Disposal shall be limited to suitable dredged material from the greater Miami, Florida vicinity. Disposal shall comply with conditions set forth in the most recent approved Site Management and Monitoring Plan.

* * * * *

[FR Doc. 96–1709 Filed 1–29–96; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 575

[Docket No. 92–65; Notice 3]

RIN 2127–AE61

Consumer Information Regulations; Vehicle Stopping Distance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Response to petition for reconsideration.

SUMMARY: In response to a petition for reconsideration submitted by Advocates for Highway and Auto Safety, this document reaffirms NHTSA's decision to rescind the requirement that motor vehicle manufacturers provide consumers with information about vehicle stopping distance. The agency is taking this action because the information provided pursuant to that requirement did not permit consumers to distinguish between many of the new vehicles and was not used by consumers in their vehicle purchasing decisions. Further, upgrading the requirement would be unduly burdensome on manufacturers and could actually be counterproductive since it might mislead consumers about the ability of their vehicles to stop under varied circumstances.

FOR FURTHER INFORMATION CONTACT:

For non-legal issues: Ms. Henrietta Spinner, NPS–21, Office of Market Incentives, National Highway Traffic Safety Administration, 400 Seventh Street SW., Washington, DC 20590 (202–366–4802).

For legal issues: Mr. Marvin L. Shaw, NCC–20, Rulemaking Division, Office of Chief Counsel, National Highway Traffic Safety Administration, 400 Seventh Street SW., Washington, DC 20590 (202–366–2992).

SUPPLEMENTARY INFORMATION:

I. June 1995 Final Rule

On June 26, 1995, the National Highway Traffic Safety Administration (NHTSA) published a final rule that rescinded the stopping distance information requirements in § 575.101 of Title 49 of the Code of Federal Regulations (60 FR 32918). The agency explained that it reached this decision after concluding that the stopping distance requirement was not resulting in the provision of meaningful information to consumers about the differences between vehicle models in stopping distance and that an upgraded requirement to mandate model specific stopping distance information would have been costly and might not have provided significant safety benefits. The agency stated that mandating model specific stopping distance information might not reveal sufficiently large differences between vehicles in stopping distance to affect vehicle purchasing decisions. Further, such information might mislead some vehicle owners about their vehicle's braking ability under varied circumstances. The stopping distance measurements reflect the ability of a vehicle to stop only under optimum conditions of vehicle loading, tire-to-road peak friction coefficient, environment, and driver braking skills.

In considering whether to rescind § 575.101, NHTSA analyzed several alternatives to rescission, including the alternative of requiring manufacturers to provide model-specific stopping information. NHTSA concluded that generating such stopping distance information would be unduly burdensome for manufacturers to obtain, based on its assessment of the costs of such a program and the small safety benefits, if any, that might result.

NHTSA also explained its decision not to adopt more stringent requirements for stopping distance information because it did not appear that consumers would use the information in making their vehicle purchasing decisions. The agency stated that consumers typically consider and value such attributes as reliability, styling, price, reputation, roominess, and safety. While stopping distance relates to safety, NHTSA believed that the upgraded information would not impact purchasing decisions because precise stopping distance information would not yield differences sufficiently large to make stopping distance a factor in consumers' selections among similar vehicle models.

NHTSA stated that it remained committed to ensuring that consumers received appropriate safety information and noted that the agency is working with the National Academy of Sciences (NAS) to review and possibly expand the agency's consumer information efforts. According to the House Appropriations Committee report addressing the NAS study:

> The study should focus on the validity of current programs, public and private, in providing accurate information to consumers on the real-world safety of vehicles, the possibility of improving the system in a cost effective and realistic manner, and the best

methods of providing useful information to consumers.

This study is expected to be completed by the statutory due date of March 31, 1996, for the submission of a final report on the NAS findings to the House and Senate Appropriations Committees. NHTSA stated that it will review the NAS study for insights into whether there is an effective means to provide consumers with information about vehicle stopping ability. NHTSA nevertheless concluded that since commenters agreed that the previously required information is not meaningful or helpful to consumers, no purpose is served by retaining section 575.101.

II. Petition for Reconsideration

On July 25, 1995, Advocates for Highway and Auto Safety (Advocates) petitioned NHTSA to reconsider its decision to rescind the vehicle stopping distance consumer information regulation. Advocates stated that NHTSA's decision to rescind this regulation is "ill-timed and inappropriate." That organization requested the agency to reconsider its decision to rescind the regulation, given the previously mentioned NAS study of consumer information programs. It stated that the agency should not have rescinded this regulation until after the NAS study is completed.

III. NHTSA's Decision

After reviewing Advocates' petition, NHTSA continues to believe that its decision to rescind the vehicle stopping distance consumer information requirement was appropriate. The information provided pursuant to that requirement did not permit consumers to distinguish among many of the new vehicles and was not used by consumers in their vehicle purchasing decisions.

The agency disagrees with the petitioner that it should have waited to rescind the stopping distance requirements until completion of the NAS study on consumer information. That study will not address the rescinded requirements and thus will not yield any information or conclusions bearing on the merits of the agency's rescission decision. Further, the agency believes that no useful purpose would be served by reinstating the requirement until the NAS study is completed and the agency has a chance to analyze the findings and recommendations.

If the NAS study suggests an approach that would make the stopping distance information meaningful and helpful to consumers at reasonable cost, the agency would propose adopting such an approach. However, NHTSA notes that it is unlikely that the NAS study will emphasize vehicle stopping distance as a significant consumer information concern. Standard Numbers 105 and 135 regulate the stopping performance of light vehicles, thereby ensuring that these vehicles have safe braking performance. Further, NHTSA continues to believe that, in making their purchasing decisions, consumers will typically not be concerned with stopping performance.

Based on the above considerations, NHTSA again concludes that the previously required stopping distance information is not useful. The agency therefore has decided to reaffirm its decision to rescind its requirement for that information.

Authority: 49 U.S.C. 322, 30111, 30115, 30117, and 30166; delegation of authority at 49 CFR 1.50.

Issued on: January 24, 1996.

Ricardo Martinez,

Administrator.

[FR Doc. 96–1653 Filed 1–29–96; 8:45 am]

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Proposed Rules

Federal Register
Vol. 61, No. 20
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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.

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 170 and 171

RIN 3150–AF39

Revision of Fee Schedules; 100% Fee Recovery, FY 1996

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend the licensing, inspection, and annual fees charged to its applicants and licensees. The proposed amendments are necessary to implement the Omnibus Budget Reconciliation Act of 1990 (OBRA–90), which mandates that the NRC recover approximately 100 percent of its budget authority in Fiscal Year (FY) 1996 less amounts appropriated from the Nuclear Waste Fund (NWF). The amount to be recovered for FY 1996 is approximately $462.3 million.

DATES: The comment period expires February 29, 1996. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure only that comments received on or before this date will be considered. Because OBRA–90 requires that NRC collect the FY 1996 fees by September 30, 1996, requests for extensions of the comment period will not be granted.

ADDRESSES: Mail written comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Docketing and Service Branch. Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 am and 4:15 pm Federal workdays. (Telephone 301–415–1678). Copies of comments received may be examined at the NRC Public Document Room at 2120 L Street NW. (Lower Level), Washington, DC 20555–0001. For information on submitting comments electronically, see the discussion under Electronic Access in the Supplementary Information Section.

The agency workpapers that support these proposed changes to 10 CFR parts 170 and 171 may be examined at the NRC Public Document Room at 2120 L Street NW. (Lower Level), Washington, DC 20555–0001.

FOR FURTHER INFORMATION CONTACT: C. James Holloway, Jr., Office of the Controller, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Telephone 301–415–6213.

SUPPLEMENTARY INFORMATION:

I. Background

Pub. L. 101–508, the Omnibus Budget Reconciliation Act of 1990 (OBRA–90), enacted November 5, 1990, requires that the NRC recover approximately 100 percent of its budget authority, less the amount appropriated from the Department of Energy (DOE) administered NWF, for FYs 1991 through 1995 by assessing fees. OBRA–90 was amended in 1993 to extend the NRC's 100 percent fee recovery requirement through FY 1998.

The NRC assesses two types of fees to recover its budget authority. First, license and inspection fees, established in 10 CFR part 170 under the authority of the Independent Offices Appropriation Act (IOAA), 31 U.S.C. 9701, recover the NRC's costs of providing individually identifiable services to specific applicants and licensees. Examples of the services provided by the NRC for which these fees are assessed are the review of applications for the issuance of new licenses, approvals or renewals, and amendments to licenses or approvals. Second, annual fees, established in 10 CFR part 171 under the authority of OBRA–90, recover generic and other regulatory costs not recovered through 10 CFR part 170 fees.

On June 20, 1995 (60 FR 32218), the NRC published its final rule establishing the licensing, inspection, and annual fees necessary for the NRC to recover approximately 100 percent of its budget authority for FY 1995, less the appropriation received from the Nuclear Waste Fund.

The NRC stated in the FY 1995 final rule that in an effort to stabilize annual fees, beginning in FY 1996 the NRC would adjust the annual fees by the percentage change (plus or minus) in NRC's total budget authority unless there was a substantial change in the total NRC budget authority or the magnitude of the budget allocated to a specific class of licensees, in which case the annual fee base would be recalculated (60 FR 32225, June 20, 1995). The NRC also stated that the percentage change would be adjusted based on changes in the 10 CFR part 170 fees and other receipts as well as on the number of licensees paying fees.

II. Proposed Action

The NRC is proposing to amend its licensing, inspection, and annual fees to recover approximately 100 percent of its FY 1996 budget authority, including the budget authority for its Office of the Inspector General, less the appropriations received from the NWF. For FY 1996, the NRC's budget authority is $473.3 million, of which approximately $11.0 million has been appropriated from the NWF. Therefore, OBRA–90 requires that the NRC collect approximately $462.3 million in FY 1996 through 10 CFR part 170 licensing and inspection fees and 10 CFR part 171 annual fees. This amount to be recovered for FY 1996 is about $41.3 million less than the total amount to be recovered for FY 1995 and $50.7 million less when compared to the amount to be recovered for FY 1994. The NRC estimates that approximately $120.3 million will be recovered in FY 1996 from fees assessed under 10 CFR part 170 and other offsetting receipts. The remaining $342 million will be recovered through the 10 CFR part 171 annual fees established for FY 1996.

As a result of the reduced amount to be recovered for FY 1996 and the proposed changes outlined in this section, the FY 1996 annual fees for all licensees have been reduced by about 6 percent compared to the annual fees assessed for FY 1995. The following examples illustrate changes in annual fees.

	FY 1995 annual fee	FY 1996 annual fee
Class of licensees:		
Power Reactors	$2,936,000	$2,747,000
Nonpower Reactors	56,500	52,900
High Enriched Uranium Fuel Facility	2,569,000	2,404,000
Low Enriched Uranium Fuel Facility	1,261,000	1,180,000
UF_6 Conversion Facility	639,200	598,100
Uranium Mills	60,900	57,000
Typical materials licensees:		
Radiographers	13,900	13,000
Well Loggers	8,100	7,500
Gauge Users	1,700	1,600
Broad Scope Medical	23,200	21,700

The NRC is also proposing to continue its streamlining of the fee structure and process for materials licenses which began in FY 1995 and make other changes as discussed in Sections A and B. Among the changes would be a change in the billing date for the annual fees imposed on many materials licensees.

As in FYs 1991–1995, the fees will become effective 30 days after publication of the final rule in the **Federal Register**. The NRC would send a bill for the amount of the annual fee upon publication of the FY 1996 final rule to the licensee or certificate, registration or approval holder not subject to quarterly billing (those licensees who pay annual fees of less than $100,000) and whose anniversary date (the first day of the month in which the original license was issued) is before the effective date of the final FY 1996 rule. For these licensees, payment would be due on the effective date of the FY 1996 rule. Those materials licensees whose license anniversary date during FY 1996 falls after the effective date of the final FY 1996 rule would be billed during the anniversary month of the license and payment would be due 30 days after the initial invoice is issued.

If the NRC decides not to pursue some or all of these changes, based on the public comments, the respective current fee policies would continue in effect for FY 1996. Comments are also requested on whether the NRC should continue current fee policies in lieu of the changes in this proposed rule.

A. Amendments to 10 CFR Part 170: Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services

The NRC proposes four amendments to 10 CFR part 170. First, the NRC proposes that the two professional hourly rates established in FY 1995 in § 170.20 be revised based on the FY 1996 budget. These proposed rates would be based on the FY 1996 direct FTEs and that portion of the FY 1996 budget that either does not constitute direct program support (contractual services costs) or is not recovered through the appropriation from the NWF. These rates are used to determine the part 170 fees. The NRC is proposing to establish a rate of $128 per hour ($223,314 per direct FTE) for the reactor program. This rate is applicable to all activities whose fees are based on full cost under § 170.21 of the fee regulations. A second rate of $120 per hour ($209,057 per direct FTE) is proposed for the nuclear materials and nuclear waste program. This rate is applicable to all materials activities whose fees are based on full cost under § 170.31 of the fee regulations.

The two rates continue to be based on cost center concepts adopted in FY 1995 (60 FR 32225, June 20, 1995) and used for NRC budgeting purposes. In implementing cost center concepts, all budgeted resources are assigned to cost centers to the extent they can be separately distinguished. These costs include all salaries and benefits, contract support, and travel that support each cost center activity.

Second, the NRC proposes that the current part 170 licensing and inspection fees in §§ 170.21 and 170.31 for applicants and licensees be adjusted to reflect the changes in the revised hourly rates.

Third, to continue FY 1995 initiatives for streamlining its fee program and improving the predictability of fees, the NRC is proposing to eliminate certain materials "flat" renewal fees in § 170.31 and to amend § 170.12 accordingly. This proposed action is also consistent with NRC's recent Business Process Reengineering initiative to extend the duration of certain materials licenses. The NRC published a proposed rule in the **Federal Register** for comment on September 8, 1995 (60 FR 46784) explaining this initiative. In the September 8, 1995, proposed rule, certain materials licenses would be extended for five years beyond their expiration date. Additionally, comments were requested on the general topic of the appropriate duration of licenses. A final rule was published in the **Federal Register** on January 16, 1996 (61 FR 1109).

The proposed elimination of 10 CFR part 170 materials "flat" renewal fees continues to recognize that the NRC's "regulatory service" provided to licensees, as referred to in OBRA–90, is comprised of the total regulatory activities that the NRC determines are needed to regulate a class of licensees. These regulatory activities include not only renewals but also inspections, research, rulemaking, orders, enforcement actions, responses to allegations, incident investigations, and other activities necessary to regulate classes of licensees. This proposed action does not result in any net fee increases for affected licensees and would provide those licensees with greater fee predictability, a frequent licensee request in comments on past fee rules. The materials annual fees, which include the cost for any renewals, would become effective for FY 1996. Materials licensees who paid a "flat" 10 CFR part 170 renewal fee for renewal applications filed in FY 1996 would receive a refund for those payments, as appropriate.

Fourth, the language in § 170.31, Category 15, relating to export and import licenses, would be amended to clarify that export and import of materials includes the export and import of radioactive waste. The NRC amended 10 CFR part 110 effective August 21, 1995 (60 FR 37556, July 21, 1995), to require specific licenses for the export or import of radioactive waste.

In summary, the NRC is proposing to (1) Revise the two 10 CFR part 170 hourly rates; (2) revise the licensing fees assessed under 10 CFR part 170 to reflect the cost to the agency of providing the service; (3) eliminate the materials "flat" renewal fees in § 170.31 and amend § 170.12 accordingly; and (4) amend Category 15 in § 170.31 to make

clear that fees would be assessed for licenses authorizing the export or import of radioactive waste.

B. Amendments to 10 CFR Part 171: Annual Fees for Reactor Operating Licenses, and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by NRC

The NRC proposes three amendments to 10 CFR part 171. First, the NRC proposes to amend §§ 171.15 and 171.16 to revise the annual fees for FY 1996 to recover approximately 100 percent of the FY 1996 budget authority, less fees collected under 10 CFR part 170 and funds appropriated from the NWF.

In the FY 1995 final rule, the NRC stated that it would stabilize annual fees as follows. Beginning in FY 1996, the NRC would adjust the annual fees only by the percentage change (plus or minus) in NRC's total budget authority unless there was a substantial change in the total NRC budget authority or the magnitude of the budget allocated to a specific class of licensees. If either case occurred, the annual fee base would be recalculated (60 FR 32225, June 20, 1995). The NRC also indicated that the percentage change would be adjusted based on changes in the 10 CFR part 170 fees and other receipts as well as on the number of licensees paying the fees. The NRC does not believe the changes to the FY 1996 budget compared to the FY 1995 budget warrant establishing new baseline fees for FY 1996. Therefore, the NRC is proposing that the FY 1996 annual fees for all licensees be reduced by 6.4 percent. The 6.4 percent reduction is based on the changes in the budget to be recovered from fees, the amount of the budget recovered for 10 CFR part 170 fees and other offsetting receipts, and changes in the number of licensees paying annual fees. Table I shows the total budget and fee amounts for FY 1995 and FY 1996.

TABLE I.—CALCULATION OF THE PERCENTAGE CHANGE TO THE FY 1995 ANNUAL FEES

[Dollars in millions]

	FY95	FY96
Total budget	$525.6	$473.3
Less NWF	−22.0	−11.0
Total fee base	503.6	462.3
Less part 170 fees and other receipts	141.1	120.3
Total annual fee amount	362.5	342.0

As shown in Table I, the total amount to be recovered from annual fees in FY 1996 is $20.5M ($342.0–$362.5) or 5.7 percent less than the amount that was to be recovered from annual fees in FY 1995. This difference is the net change resulting from a reduction in the budget and a reduction in the expected collection from 10 CFR part 170 fees and other offsetting receipts. The NRC notes that the reduction in 10 CFR part 170 fees for FY 1996 results primarily from the fact that NRC had a one-time collection of five quarters of 10 CFR part 170 fees in FY 1995 as a result of changes in our billing practices which permits us to bill for services shortly after they are rendered.

In addition to changes in the budget and 10 CFR part 170 fees and other receipts, the number of licensees to pay fees in FY 1996 changed compared to FY 1995. Also, the amount of the small entity surcharge (difference between annual fee and small entity fee) decreased as the annual fees decreased. The changes in the number of licensees in the various classes plus the reduction in the small entity surcharge result in an additional decrease in the annual fee per licensee of 0.7 percent. Thus the total change in the annual fees for FY 1996 compared to FY 1995 is a decrease of 6.4 percent (5.7 percent plus 0.7 percent).

Second, Footnote 1 of 10 CFR 171.16(d) would be amended to provide for a waiver of annual fees for FY 1996 for those materials licensees, and holders of certificates, registrations, and approvals who either filed for termination of their licenses or approvals or filed for possession only/storage licenses before October 1, 1995, and permanently ceased licensed activities entirely by September 30, 1995. All other licensees and approval holders who held a license or approval on October 1, 1995, are subject to FY 1996 annual fees. This change is being made in recognition of the fact that since the final FY 1995 rule was published in June 1995, some licensees have filed requests for termination of their licenses or certificates with the NRC. Other licensees have either called or written to the NRC since the FY 1995 final rule became effective requesting further clarification and information concerning the annual fees assessed. The NRC is responding to these requests as quickly as possible. However, the NRC was unable to respond and take action on all such requests before the end of the fiscal year on September 30, 1995. Similar situations existed after the FY 1991–1994 rules were published, and in those cases, the NRC provided an exemption from the requirement that the annual fee is waived only when a license is terminated before October 1 of each fiscal year.

Third, beginning in FY 1996, the NRC proposes to assess § 171.16(d) annual fees, for those materials licenses whose annual fees are less than $100,000, based on the anniversary of the date the license was originally issued. Accordingly, a new section would be added to § 171.19. For example, if the original license was issued on June 17, then the anniversary date of that materials license, for annual fee purposes, would be June 1 and the licensee would be billed in June of each year for the annual fees in effect on the anniversary date (the first day of the month that the original license was issued) of the license. For FY 1996, those affected materials licenses with a license anniversary date between October 1, 1995, and the effective date of the final FY 1996 fee rule would be billed upon publication of the final rule in the **Federal Register** and annually thereafter during the anniversary month of the license. Those affected materials licenses whose license anniversary date is on or after the effective date of the final FY 1996 fee rule would be billed during the anniversary month of the license and annually thereafter based on the annual fee in effect at the time of billing. The specific license categories of materials licensees affected by this proposed change are listed in § 171.19(d) of this proposed rule.

Billing certain materials licensees on the anniversary date of the license would allow the NRC to make the billing process more efficient by distributing the billing and collection of annual fee invoices over the entire year. The current practice is to bill over 6,000 materials licenses simultaneously during the fiscal year. Section 171.19 would also be amended to credit quarterly partial annual fee payments for FY 1996 already made by certain licensees in FY 1996 either toward their total annual fee to be assessed, or to make refunds, if necessary. Materials licensees who paid a "flat" 10 CFR part 170 renewal fee for renewal applications filed in FY 1996 would receive a refund for those payments, as appropriate.

The proposed amendments to 10 CFR part 171 do not change the underlying basis for 10 CFR part 171; that is, charging a class of licensees for NRC costs attributable to that class of licensees. The proposed changes are consistent with the NRC's FY 1995 final rule indicating that, for the period FY 1996–1999, the annual fees would be adjusted by the percentage change (plus or minus) to the NRC's budget authority adjusted for NRC offsetting receipts and

the number of licensees paying annual fees.

III. Section-by-Section Analysis

The following analysis of those sections that would be amended by this proposed rule provides additional explanatory information. All references are to Title 10, Chapter I, U.S. Code of Federal Regulations.

Part 170

Section 170.12 Payment of fees

This section would be amended to conform to the streamlining changes being proposed by the NRC. Section 170.12(a), which describes application fees, would be amended to recognize that the NRC would not issue a new license or amendment prior to receipt of the prescribed fee. Section 170.12(d), which describes renewal fees, would be amended to recognize that materials "flat" renewal fees would be eliminated. Section 170.12(g), which discusses inspection fees, would be amended to recognize that materials "flat" inspection fees were eliminated in the FY 1995 final rule (60 FR 32218, June 20, 1995).

Section 170.20 Average cost per professional staff hour

This section would be amended to establish two professional staff-hour rates based on FY 1996 budgeted costs—one for the reactor program and one for the nuclear material and nuclear waste program. Accordingly, the NRC reactor direct staff-hour rate for FY 1996 for all activities whose fees are based on full cost under § 170.21 would be $128 per hour, or $223,314 per direct FTE. The NRC nuclear material and nuclear waste direct staff-hour rate for all materials activities whose fees are based on full cost under § 170.31 would be $120 per hour, or $209,057 per direct FTE. The rates are based on the FY 1996 direct FTEs and NRC budgeted costs that are not recovered through the appropriation from the NWF. The NRC has continued the use of cost center concepts established in FY 1995 in allocating certain costs to the reactor and materials programs in order to more closely align budgeted costs with specific classes of licensees. The method used to determine the two professional hourly rates is as follows:

1. Direct program FTE levels are identified for both the reactor program and the nuclear material and waste program.

2. Direct contract support, which is the use of contract or other services in support of the line organization's direct program, is excluded from the calculation of the hourly rate because the costs for direct contract support are charged directly through the various categories of fees.

3. All other direct program costs (i.e., Salaries and Benefits, Travel) represent "in-house" costs and are to be allocated by dividing them uniformly by the total number of direct FTEs for the program. In addition, salaries and benefits plus contracts for general and administrative support are allocated to each program based on that program's salaries and benefits. This method results in the following costs, to be included in the hourly rates.

TABLE II.—FY 1996 BUDGET AUTHORITY TO BE INCLUDED IN HOURLY RATES

[Dollars in millions]

	Reactor program	Materials program
Salary and benefits:		
Program	$149.6	$46.3
Allocated agency management and support	40.9	12.7
Subtotal	190.5	59.0
General and administrative support (G&A):		
Program travel and other support	11.7	3.2
Allocated agency management and support	69.5	21.5
Subtotal	81.2	24.7
Less offsetting receipts	.1	
Total budget included in hourly rate	271.6	83.7
Program direct FTEs	1,216.2	400.5
Rate per direct FTE	223,314	209,057
Professional hourly rate	128	120

Dividing the $271.6 million budget for the reactor program by the number of reactor program direct FTEs (1216.2) results in a rate for the reactor program of $223,314 per FTE for FY 1996. Dividing the $83.7 million budget for the nuclear materials and nuclear waste program by the number of program direct FTEs (400.5) results in a rate of $209,057 per FTE for FY 1996. The Direct FTE Hourly Rate for the reactor program is $128 per hour (rounded to the nearest whole dollar). This rate is calculated by dividing the cost per direct FTE ($223,314) by the number of productive hours in one year (1744 hours) as indicated in OMB Circular A–76, "Performance of Commercial Activities." The Direct FTE Hourly Rate for the materials program is $120 per hour (rounded to the nearest whole dollar). This rate is calculated by dividing the cost per direct FTE ($209,057) by the number of productive hours in one year (1744 hours). The method used to calculate the FY 1996 hourly rate is the same as the method used in the FY 1995 rule. The FY 1996 rate is slightly higher than the FY 1995 rate due in part to the increase is the Federal pay raise given to all Federal employees in January 1995.

Section 170.21 Schedule of Fees for Production and Utilization Facilities, Review of Standard Reference Design Approvals, Special Projects, Inspections and Import and Export Licenses

The NRC is proposing to revise the licensing and inspection fees in this section, which are based on full-cost recovery, to reflect FY 1996 budgeted costs and to recover costs incurred by the NRC in providing licensing and inspection services to identifiable recipients. The fees assessed for services provided under the schedule are based on the professional hourly rate, as shown in § 170.20, for the reactor

program and any direct program support (contractual services) costs expended by the NRC. Any professional hours expended on or after the effective date of the final rule will be assessed at the FY 1996 hourly rate for the reactor program, as shown in § 170.20. Although the average amounts of time needed to review import and export licensing applications have not changed, the fees in § 170.21, facility Category K, have increased from FY 1995 as a result of the increase in the hourly rate.

For those applications currently on file and pending completion, footnote 2 of § 170.21 would be revised to provide that professional hours expended up to the effective date of the final rule will be assessed at the professional rates in effect at the time the service was rendered. For topical report applications currently on file that are still pending completion of the review, and for which review costs have reached the applicable fee ceiling established by the July 2, 1990 rule, the costs incurred after any applicable ceiling was reached through August 8, 1991, will not be billed to the applicant. Any professional hours expended for the review of topical report applications, amendments, revisions, or supplements to a topical report on or after August 9, 1991, are assessed at the applicable rate established by § 170.20.

Section 170.31 Schedule of Fees for Materials Licenses and Other Regulatory Services, Including Inspections and Import and Export Licenses

The licensing and inspection fees in this section, which are based on full-cost recovery, would be modified to recover the FY 1996 costs incurred by the NRC in providing licensing and inspection services to identifiable recipients. The fees assessed for services provided under the schedule would be based on both the professional hourly rate as shown in § 170.20 for the materials program and any direct program support (contractual services) costs expended by the NRC. Licensing fees based on the average time to review an application ("flat" fees) would be adjusted to reflect the increase in the professional hourly rate from $116 per hour in FY 1995 to $120 per hour in FY 1996. The "flat" renewal fees for certain materials licenses in § 170.31 would be eliminated and combined with the materials annual fees in § 171.16(d).

The amounts of the licensing "flat" fees were rounded off so that the amounts would be de minimis and the resulting flat fee would be convenient to the user. Fees that are greater than $1,000 are rounded to the nearest $100. Fees under $1,000 are rounded to the nearest $10.

Fee Category 15, covering the fees for export and import licenses, would be amended to include clarifying language that export and import of materials includes the export and import of radioactive waste. The NRC amended 10 CFR part 110 on July 21, 1995 (60 FR 37556), to require specific licenses for the export and import of radioactive waste. The final rule became effective August 21, 1995.

The proposed licensing "flat" fees are applicable to fee categories 1.C and 1.D; 2.B and 2.C; 3.A through 3.P; 4.B through 9.D, 10.B, 15.A through 15.E and 16. Applications filed on or after the effective date of the final rule would be subject to the revised fees in this proposed rule. Although the average amounts of time needed to review licensing applications have not changed, the "flat" fees in § 170.31 have increased from FY 1995 as a result of the increase in the hourly rate.

For those licensing, inspection, and review fees that are based on full-cost recovery (cost for professional staff hours plus any contractual services), the materials program hourly rate of $120, as shown in § 170.20, would apply to those professional staff hours expended on or after the effective date of the final rule.

Part 171

Section 171.15 Annual Fee: Reactor Operating Licenses

The annual fees in this section would be revised as described below. Paragraph (d) would be removed and reserved and paragraphs (a), (b), (c), and (e) would be revised to comply with the requirement of OBRA–90 that the NRC recover approximately 100 percent of its budget for FY 1996.

Paragraph (b) would be revised in its entirety to establish the FY 1996 annual fee for operating power reactors and to change fiscal year references from FY 1995 to FY 1996. The fees would be established by reducing FY 1995 annual fees (prior to rounding) by 6.4 percent. The activities comprising the base FY 1995 annual fee and the FY 1995 additional charge (surcharge) are listed in paragraphs (b) and (c) and continue to be shown for convenience purposes. Paragraphs (c)(1) would be revised in its entirety and (c)(2) would be removed and reserved.

With respect to Big Rock Point, a smaller, older reactor, the NRC proposes to grant a partial exemption from the FY 1996 annual fees similar to FY 1995 based on a request filed with the NRC in accordance with § 171.11.

Each operating power reactor, except Big Rock Point, would pay an annual fee of $2,747,000 in FY 1996.

Paragraph (d) would be removed and reserved.

Paragraph (e) would be revised to show the amount of the FY 1996 annual fee for nonpower (test and research) reactors. In FY 1996, the fee is 6.4 percent below the FY 1995 level. The Energy Policy Act of 1992 established an exemption for certain Federally-owned research reactors that are used primarily for educational training and academic research purposes, where the design of the reactor satisfies certain technical specifications set forth in the legislation. Consistent with this legislative requirement, the NRC granted an exemption from annual fees for FY 1992 and FY 1993 to the Veterans Administration Medical Center in Omaha, Nebraska, the U.S. Geological Survey for its reactor in Denver, Colorado, and the Armed Forces Radiobiological Institute in Bethesda, Maryland, for its research reactor. This exemption was initially codified in the July 20, 1993 (58 FR 38695) final fee rule at § 171.11(a) and more recently in the March 17, 1994 (59 FR 12543) final rule at § 171.11(a)(2). The NRC amended § 171.11(a)(2) on July 20, 1994 (59 FR 36895) to exempt from annual fees the research reactor owned by the Rhode Island Atomic Energy Commission. The NRC will continue to grant exemptions from the annual fee to Federally-owned and State-owned research and test reactors that meet the exemption criteria specified in § 171.11.

Section 171.16 Annual fees: Materials Licensees, Holders of Certificates of Compliance, Holders of Sealed Source and Device Registrations, Holders of Quality Assurance Program Approvals, and Government agencies licensed by the NRC

Section 171.16(c) covers the fees assessed for those licensees that can qualify as small entities under NRC size standards. The NRC will continue to assess two fees for licensees that qualify as small entities under the NRC's size standards. In general, licensees with gross annual receipts of $350,000 to $5 million pay a maximum fee of $1,800. A second or lower-tier small entity fee of $400 is in place for small entities with gross annual receipts of less than $350,000 and small governmental jurisdictions with a population of less than 20,000. No change in the amount of the small entity fees is being proposed because the small entity fees are not based on the budget but are established at a level to reduce the impact of fees on small entities. The

small entity fees are shown in the proposed rule for convenience.

Section 171.16(d) would be revised to establish the FY 1996 annual fees for materials licensees, including Government agencies, licensed by the NRC. These fees were determined by reducing the FY 1995 annual fees (prior to rounding) by 6.4 percent.

For the first time, the NRC is proposing to combine the "flat" material renewal fees in 10 CFR part 170 with the annual fees in 10 CFR part 171. As described in the **Federal Register** on September 8, 1995 (60 FR 46784), recent NRC internal reviews and regulatory impact surveys of material licensees have highlighted areas in which the current materials licensing process can be improved. The NRC has completed the preliminary phases of its Business Process Reengineering (BPR) initiative to redesign the process of licensing medical, academic, and industrial users of byproduct materials as well as with regard to some small scope users of source and special nuclear materials. The NRC has extended, by rulemaking, certain specific material licenses by five years from the current expiration dates of those licenses. Resources that would have otherwise been used to renew these licenses would be devoted to the BPR project. The NRC is also examining whether to permanently change the license duration for materials licenses. The NRC estimates that approximately 80 percent of its approximately 6,500 materials licenses would be extended by the final rulemaking. Consistent with this change in license renewals, the NRC is proposing, for fee purposes, to combine the materials "flat" renewal fees in 10 CFR part 170 with the annual fees in 10 CFR part 171.

This action also recognizes that the NRC's "regulatory service" provided to licensees, as referred to in OBRA–90, is comprised of the total regulatory activities that the NRC determines are needed to regulate a class of licensees. These regulatory activities include not only "flat" fee inspections but also research, rulemaking, orders, enforcement actions, responses to allegations, incident investigations, and other activities necessary to regulate classes of licensees. In addition to being consistent with the regulatory service concept of OBRA–90, the NRC believes that materials licensees' "flat" renewal fees can be combined with their annual fees without creating any significant questions of fairness. This is because the concept of the annual fee, including the renewal fee, has, in effect, already been implemented for most materials licensees. First, materials licensees currently pay a "flat fee" per renewal based on the average cost of a renewal for their fee category, and second, the renewal term of five years is identical for most materials licensees. Thus, licensees in the same materials license fee category already pay essentially the same average annual cost for renewals. Further, the average cost will decrease to a relatively small amount as a result of the five-year extension and potential change in license duration. Therefore, combining renewal and annual fees results in essentially the same average cost per license over time. This approach would provide materials licensees with simpler and more predictable NRC fee charges as there would be no additional fees paid for periodic renewals. Because certain materials FY 1996 annual fees would include renewals, those materials licensees who paid a "flat" 10 CFR Part 170 renewal fee for renewal applications filed in FY 1996 will be issued a refund, as appropriate.

Beginning in FY 1996, the NRC is also proposing that annual fees for most materials licenses be billed on the anniversary date of the license (licensees whose annual fees are $100,000 or more would continue to be assessed quarterly). The annual fee assessed would be the fee in effect on the license anniversary date. The proposal would apply to those materials licenses in the following fee categories: 1.C. and 1.D.; 2.A.(2) through 2.C.; 3.A. through 3.P.; 4.A. through 9.D., and 10.B. Billing most materials licenses on the anniversary date of the license would allow the NRC to improve the efficiency of its billing process; under this proposal an average of approximately 500 annual fee invoices would be sent to materials licensees each month. The current practice of billing over 6,000 materials licensees simultaneously each fiscal year would be eliminated. For annual fee purposes, the anniversary date of the materials license is considered to be the first day of the month in which the original materials license was issued. For example, if the original materials license was issued on June 17 then, for annual fee purposes, the anniversary date of the materials license would be June 1 and the licensee would be billed in June of each year for the annual fee in effect on June 1. The proposed change to the billing system would mean that during the transition period of FY 1996 affected materials licensees with an anniversary date falling between October 1, 1995, and the effective date of the FY 1996 fee rule would receive a bill payable on the effective date of the FY 1996 final rule. Affected materials licensees with license anniversary dates falling on or after the effective date of the FY 1996 final rule would be billed during their anniversary month of their license. Under this proposal, some materials licensees would unavoidably receive two annual fee bills during the 12 month transition period. For example, a materials licensee who paid its FY 1996 annual fee bill in April 1996, the planned effective date of the FY 1996 fee rule, would receive a bill six months later in October 1996 (FY 1997) if October is the anniversary month of that materials license. In this example, the licensee would pay the same annual fee in FY 1997 (October) as he paid in FY 1996 (April). Materials licensees would continue to pay fees at the FY 1996 rate in FY 1997 until such time as the FY 1997 final fee rule becomes effective. Each bill would be for a different fiscal year, therefore, no double billing would occur.

The NRC believes that the efficiencies gained by billing certain materials annual fees throughout the year as well as having materials licensees know exactly when they will be billed each year for the annual fee outweigh the inconveniences that may be caused during the transition period. New licenses issued during FY 1996 would receive a prorated annual fee in accordance with the current proration provision of § 171.17. For example, those new materials licenses issued during the period October 1 through March 31 of the FY would be assessed one-half the annual fee for FY 1996. New materials licenses issued on or after April 1, 1996, will not be assessed an annual fee for FY 1996.

Thereafter, the full annual fee is due and payable each subsequent fiscal year on the anniversary date of the license. Beginning with the effective date of the FY 1996 final rule, affected licensees would be billed and would pay the annual fee in effect on the anniversary date of the license. Affected licensees who are not sure of the anniversary date of their materials license should check the original issue date of the license.

A materials licensee may pay a reduced annual fee if the licensee qualifies as a small entity under the NRC's size standards and certifies that it is a small entity using NRC Form 526.

The amount or range of the FY 1996 annual fees for all materials licensees is summarized as follows:

MATERIALS LICENSES ANNUAL FEE RANGES

Category of license	Annual fees
Part 70—High enriched fuel facility.	$2,404,000.
Part 70—Low enriched fuel facility.	$1,180,000.
Part 40—UF_6 conversion facility.	$598,100.
Part 40—Uranium recovery facilities.	$20,600 to $57,000.
Part 30—Byproduct Material Licenses.	$450 to $21,700.[1]
Part 71—Transportation of Radioactive Material.	$950 to $72,800.
Part 72—Independent Storage of Spent Nuclear Fuel.	$261,100.

[1] Excludes the annual fee for a few military "master" materials licenses of broad-scope issued to Government agencies, which is $388,600.

Section 171.16(e) would be revised in its entirety to indicate the activities that were a part of the additional charge (surcharge) included in the FY 1995 annual fees. These activities are listed and would continue to be shown for convenience.

Footnote 1 of 10 CFR 171.16(d) would be amended to provide a waiver of the annual fees for materials licensees, and holders of certificates, registrations, and approvals, who either filed for termination of their licenses or approvals or filed for possession only/storage only licenses before October 1, 1995, and permanently ceased licensed activities entirely by September 30, 1995. All other licensees and approval holders who held a license or approval on October 1, 1995, are subject to the FY 1996 annual fees.

Section 171.19 Payment.

Paragraph (b) would be revised to give credit for partial payments made by certain licensees in FY 1996 toward their FY 1996 annual fees. The NRC anticipates that the first, second, and third quarterly payments for FY 1996 will have been made by operating power reactor licensees and some large materials licensees before the final rule is effective. Therefore, the NRC will credit payments received for those quarterly annual fee assessments toward the total annual fee to be assessed. The NRC will adjust the fourth quarterly bill to recover the full amount of the revised annual fee or to make refunds, as necessary. The NRC also expects that certain materials licensees will have paid renewal fees for renewal applications that were filed in FY 1996, whereas this proposed rule includes the renewals in the annual fee. The NRC will refund these renewal fee payments, as appropriate. Payment of the annual fee is due on the date of the invoice and interest accrues from the invoice date. However, interest will be waived if payment is received within 30 days from the invoice date.

Paragraph (c) would be revised to update fiscal year references and to delete the references concerning payment requirements for those licensees whose annual fees are less than $100,000.

A new paragraph (d) would be added to cover those licensees whose fees are less than $100,000 and who would be billed on the anniversary date of their license beginning in FY 1996.

During the past five years many licensees have indicated that, although they held a valid NRC license authorizing the possession and use of special nuclear, source, or byproduct material, they were either not using the material to conduct operations or had disposed of the material and no longer needed the license. In response, the NRC has consistently stated that annual fees are assessed based on whether a licensee holds a valid NRC license that authorizes possession and use of radioactive material. Whether or not a licensee is actually conducting operations using the material is a matter of licensee discretion. The NRC cannot control whether a licensee elects to possess and use radioactive material once it receives a license from the NRC. Therefore, the NRC reemphasizes that the annual fee will be assessed based on whether a licensee holds a valid NRC license that authorizes possession and use of radioactive material. To remove any uncertainty, the NRC issued minor clarifying amendments to 10 CFR 171.16, footnotes 1 and 7 on July 20, 1993 (58 FR 38700).

The NRC reinstated the exemption from 10 CFR part 171 annual fees for nonprofit educational institutions on April 18, 1994 (59 FR 12539, March 17, 1994). In that final rule, the NRC indicated that although nonprofit research institutions were not exempt from annual fees, such institutions were free to file an exemption request based on the "public good" concept if they felt they could qualify. Several nonprofit research institutions have since filed and been granted an exemption from the annual fees on that basis. In addition, some Federal agencies who hold materials licenses have filed for exemption from annual fees based on the public good concept as well. The requests from Federal agencies to receive public good exemptions have been denied by the NRC. The NRC did not intend to extend public good exemptions to Federal agencies. Therefore, the NRC does not intend to grant public good exemptions to Federal agencies.

IV. Electronic Access

Comments on the proposed rule may be submitted through the Internet by addressing electronic mail to INTERNET:SECY@NRC.GOV. Comments may also be submitted electronically, in either ASCII text or WordPerfect format (version 5.1 or later), by calling the NRC Electronic Rulemaking Bulletin Board (BBS) on FEDWORLD.

The BBS is an electronic information system operated by the National Technical Information Service of the Department of Commerce. The purpose of this BBS is to facilitate public participation in the NRC regulatory process, particularly rulemakings. This proposed rulemaking is available for review and comment on the BBS. The BBS may be accessed using a personal computer, a modem, and one of the commonly available communications software packages, or directly via the Internet.

The NRC rulemaking bulletin board (rulemaking subsystem) on FEDWORLD can be accessed directly by using a personal computer and modem, and dialing the toll free number 1–800–303–9672. Communication software parameters should be set as follows: parity to none, data bits to 8, and stop bits to 1 (N,8,1). Using ANSI or VT–100 terminal emulation, the NRC rulemaking subsystem can then be accessed by selecting the "Rules Menu" option from the "NRC Main Menu." For further information about options available for NRC at FEDWORLD consult the "Help/Information Center" from the "NRC Main Menu." Users will find the "FEDWORLD Online User's Guides" particularly helpful.

The NRC subsystem on FEDWORLD also can be accessed by a direct dial phone number for the main FEDWORLD BBS at 703–321–3339, or by using Telnet via Internet: fedworld.gov. Using the 703 number to contact FEDWORLD, the NRC subsystem will be accessed from the main FEDWORLD menu by selecting the "Regulatory, Government Administration and State Systems," then selecting "Regulatory Information Mall." At that point, a menu will be displayed that has the option "U.S. Nuclear Regulatory Commission" that will take you to the NRC Online main menu. The NRC Online area also can be accessed directly by typing "/go nrc" at a FEDWORLD command line. If you access NRC from FEDWORLD's main menu, you may return to FEDWORLD

by selecting the "Return to FEDWORLD" option from the NRC Online Main Menu. However, if you access NRC at FEDWORLD by using NRC's toll-free number, you will have full access to all NRC systems, but you will not have access to the main FEDWORLD system.

If you contact FEDWORLD using Telnet, you will see the NRC area and menus, including the "Rules Menu." Although you will be able to download documents and leave messages, you will not be able to write comments or upload files. If you contact FEDWORLD using File Transfer Program (FTP), all files can be accessed and downloaded, but uploads are not allowed, and all you will see is a list of files without descriptions (normal Gopher look). An index file listing all files within a subdirectory, with descriptions, is available. There is a 15-minute time limit for FTP access.

Although FEDWORLD can be accessed through the World Wide Web as well, like FTP, that mode only provides access for downloading files and does not display the NRC "Rules Menu."

For more information on NRC bulletin boards call Mr. Arthur Davis, Systems Integration and Development Branch, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone 301–415–5780; e-mail AXD3@nrc.gov.

V. Environmental Impact: Categorical Exclusion

The NRC has determined that this proposed rule is the type of action described in categorical exclusion 10 CFR 51.22(c)(1). Therefore, neither an environmental impact statement nor an environmental impact assessment has been prepared for the proposed regulation. By its very nature, this regulatory action does not affect the environment, and therefore, no environmental justice issues are raised. (A discussion of environmental justice can be found in Executive Order No. 12898—Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, dated February 11, 1994.)

VI. Paperwork Reduction Act Statement

This proposed rule contains no information collection requirements and, therefore, is not subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

VII. Regulatory Analysis

With respect to 10 CFR part 170, this proposed rule was developed pursuant to Title V of the Independent Offices Appropriation Act of 1952 (IOAA) (31 U.S.C. 9701) and the Commission's fee guidelines. When developing these guidelines the Commission took into account guidance provided by the U.S. Supreme Court on March 4, 1974, in its decision of *National Cable Television Association, Inc.* v. *United States,* 415 U.S. 36 (1974) and *Federal Power Commission* v. *New England Power Company,* 415 U.S. 345 (1974). In these decisions, the Court held that the IOAA authorizes an agency to charge fees for special benefits rendered to identifiable persons measured by the "value to the recipient" of the agency service. The meaning of the IOAA was further clarified on December 16, 1976, by four decisions of the U.S. Court of Appeals for the District of Columbia: *National Cable Television Association* v. *Federal Communications Commission,* 554 F.2d 1094 (D.C. Cir. 1976); *National Association of Broadcasters* v. *Federal Communications Commission,* 554 F.2d 1118 (D.C. Cir. 1976); *Electronic Industries Association* v. *Federal Communications Commission,* 554 F.2d 1109 (D.C. Cir. 1976) and *Capital Cities Communication, Inc.* v. *Federal Communications Commission,* 554 F.2d 1135 (D.C. Cir. 1976). These decisions of the Courts enabled the Commission to develop fee guidelines that are still used for cost recovery and fee development purposes.

The Commission's fee guidelines were upheld on August 24, 1979, by the U.S. Court of Appeals for the Fifth Circuit in *Mississippi Power and Light Co.* v. *U.S. Nuclear Regulatory Commission,* 601 F.2d 223 (5th Cir. 1979), *cert. denied,* 444 U.S. 1102 (1980). The Court held that—

(1) The NRC had the authority to recover the full cost of providing services to identifiable beneficiaries;

(2) The NRC could properly assess a fee for the costs of providing routine inspections necessary to ensure a licensee's compliance with the Atomic Energy Act and with applicable regulations;

(3) The NRC could charge for costs incurred in conducting environmental reviews required by NEPA;

(4) The NRC properly included the costs of uncontested hearings and of administrative and technical support services in the fee schedule;

(5) The NRC could assess a fee for renewing a license to operate a low-level radioactive waste burial site; and

(6) The NRC's fees were not arbitrary or capricious.

With respect to 10 CFR part 171, on November 5, 1990, the Congress passed Pub. L. 101–508, the Omnibus Budget Reconciliation Act of 1990 (OBRA–90) which required that for FYs 1991 through 1995, approximately 100 percent of the NRC budget authority be recovered through the assessment of fees. OBRA–90 was amended in 1993 to extend the 100 percent fee recovery requirement for NRC through FY 1998. To accomplish this statutory requirement, the NRC, in accordance with § 171.13, is publishing the proposed amount of the FY 1996 annual fees for operating reactor licensees, fuel cycle licensees, materials licensees, and holders of Certificates of Compliance, registrations of sealed source and devices and QA program approvals, and Government agencies. OBRA–90 and the Conference Committee Report specifically state that—

(1) The annual fees be based on the Commission's FY 1996 budget of $473.3 million less the amounts collected from Part 170 fees and the funds directly appropriated from the NWF to cover the NRC's high level waste program;

(2) The annual fees shall, to the maximum extent practicable, have a reasonable relationship to the cost of regulatory services provided by the Commission; and

(3) The annual fees be assessed to those licensees the Commission, in its discretion, determines can fairly, equitably, and practicably contribute to their payment.

10 CFR part 171, which established annual fees for operating power reactors effective October 20, 1986 (51 FR 33224; September 18, 1986), was challenged and upheld in its entirety in *Florida Power and Light Company* v. *United States,* 846 F.2d 765 (D.C. Cir. 1988), *cert. denied,* 490 U.S. 1045 (1989).

10 CFR parts 170 and 171, which established fees based on the FY 1989 budget, were also legally challenged. As a result of the Supreme Court decision in *Skinner* v. *Mid-American Pipeline Co.,* 109 S. Ct. 1726 (1989), and the denial of certiorari in *Florida Power and Light,* all of the lawsuits were withdrawn.

The NRC's FY 1991 annual fee rule was largely upheld by the D.C. Circuit Court of Appeals in *Allied Signal* v. *NRC,* 988 F.2d 146 (D.C. Cir. 1993).

VIII. Regulatory Flexibility Analysis

The NRC is required by the Omnibus Budget Reconciliation Act of 1990 to recover approximately 100 percent of its budget authority through the assessment of user fees. OBRA–90 further requires that the NRC establish a schedule of charges that fairly and equitably allocates the aggregate amount of these charges among licensees.

This proposed rule establishes the schedules of fees that are necessary to implement the Congressional mandate for FY 1996. The proposed rule results in a decrease in the annual fees charged to all licensees, and holders of certificates, registrations, and approvals. The Regulatory Flexibility Analysis, prepared in accordance with 5 U.S.C. 604, is included as Appendix A to this proposed rule.

IX. Backfit Analysis

The NRC has determined that the backfit rule, 10 CFR 50.109, does not apply to this proposed rule and that a backfit analysis is not required for this proposed rule. The backfit analysis is not required because these proposed amendments do not require the modification of or additions to systems, structures, components, or the design of a facility or the design approval or manufacturing license for a facility or the procedures or organization required to design, construct or operate a facility.

List of Subjects

10 CFR Part 170

Byproduct material, Import and export licenses, Intergovernmental relations, Non-payment penalties, Nuclear materials, Nuclear power plants and reactors, Source material, Special nuclear material.

10 CFR Part 171

Annual charges, Byproduct material, Holders of certificates, registrations, approvals, Intergovernmental relations, Non-payment penalties, Nuclear materials, Nuclear power plants and reactors, Source material, Special nuclear material.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, and 5 U.S.C. 553, the NRC is proposing to adopt the following amendments to 10 CFR parts 170 and 171.

PART 170—FEES FOR FACILITIES, MATERIALS, IMPORT AND EXPORT LICENSES, AND OTHER REGULATORY SERVICES UNDER THE ATOMIC ENERGY ACT OF 1954, AS AMENDED

1. The authority citation for part 170 continues to read as follows:

Authority: 31 U.S.C. 9701, 96 Stat. 1051; sec. 301, Pub. L. 92–314, 86 Stat. 222 (42 U.S.C. 2201w); sec. 201, Pub. L. 93–4381, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 205, Pub. L. 101–576, 104 Stat. 2842, (31 U.S.C. 901).

2. In § 170.12, paragraph (d)(1) is removed and reserved and paragraphs (a) and (g) are revised to read as follows:

§ 170.12 Payment of fees.

(a) *Application fees.* Each application for which a fee is prescribed shall be accompanied by a remittance in the full amount of the fee. The NRC will not issue a new license or amendment prior to the receipt of the prescribed fee. All application fees will be charged irrespective of the Commission's disposition of the application or a withdrawal of the application.

* * * * *

(d) * * *

(1) [Reserved].

* * * * *

(g) *Inspection fees.* Fees for all inspections subject to full cost recovery will be assessed on a per inspection basis for completed inspections and are payable, on a quarterly basis, upon notification by the Commission. Inspection costs include preparation time, time on site, and documentation time and any associated contractual service costs, but exclude the time involved in the processing and issuance of a notice of violation or civil penalty.

* * * * *

3. Section 170.20 is revised to read as follows:

§ 170.20 Average cost per professional staff-hour.

Fees for permits, licenses, amendments, renewals, special projects, Part 55 requalification and replacement examinations and tests, other required reviews, approvals, and inspections under §§ 170.21 and 170.31 that are based upon the full costs for the review or inspection will be calculated using the following applicable professional staff-hour rates:

Reactor Program (§ 170.21 Activities) .....$128 per hour

Nuclear Materials and Nuclear Waste Program (§ 170.31 Activities).....$120 per hour

4. In § 170.21, the introductory text, Category K, and footnotes 1 and 2 to the table are revised to read as follows:

§ 170.21 Schedule of fees for production and utilization facilities, review of standard referenced design approvals, special projects, inspections and import and export licenses.

Applicants for construction permits, manufacturing licenses, operating licenses, import and export licenses, approvals of facility standard reference designs, requalification and replacement examinations for reactor operators, and special projects and holders of construction permits, licenses, and other approvals shall pay fees for the following categories of services.

SCHEDULE OF FACILITY FEES

[See footnotes at end of table]

Facility Categories and Type of Fees	Fees[1 2]
* * * * * * *	
K. Import and export licenses:	
Licenses for the import and export only of production and utilization facilities or the export only of components for production and utilization facilities issued pursuant to 10 CFR Part 110.	
1. Application for import or export of reactors and other facilities and exports of components which must be reviewed by the Commissioners and the Executive Branch, for example, actions under 10 CFR 110.40(b).	
Application—new license	$7,800
Amendment	7,800
2. Application for export of reactor and other components requiring Executive Branch review only, for example, those actions under 10 CFR 110.41(a) (1)–(8).	
Application—new license	4,800
Amendment	4,800
3. Application for export of components requiring foreign government assurances only.	
Application—new license	3,000
Amendment	3,000

SCHEDULE OF FACILITY FEES—Continued

[See footnotes at end of table]

Facility Categories and Type of Fees	Fees [1] [2]
4. Application for export of facility components and equipment not requiring Commissioner review, Executive Branch review, or foreign government assurances.	
Application—new license	1,200
Amendment	1,200
5. Minor amendment of any export or import license to extend the expiration date, change domestic information, or make other revisions which do not require analysis or review. Ame	
Amendment	120

[1] Fees will not be charged for orders issued by the Commission pursuant to § 2.202 of this chapter or for amendments resulting specifically from the requirements of these types of Commission orders. Fees will be charged for approvals issued under a specific exemption provision of the Commission's regulations under Title 10 of the Code of Federal Regulations (e.g., §§ 50.12, 73.5) and any other sections now or hereafter in effect regardless of whether the approval is in the form of a license amendment, letter of approval, safety evaluation report, or other form. Fees for licenses in this schedule that are initially issued for less than full power are based on review through the issuance of a full power license (generally full power is considered 100 percent of the facility's full rated power). Thus, if a licensee received a low power license or a temporary license for less than full power and subsequently receives full power authority (by way of license amendment or otherwise), the total costs for the license will be determined through that period when authority is granted for full power operation. If a situation arises in which the Commission determines that full operating power for a particular facility should be less than 100 percent of full rated power, the total costs for the license will be at that determined lower operating power level and not at the 100 percent capacity.

[2] Full cost fees will be determined based on the professional staff time and appropriate contractual support services expended. For applications currently on file and for which fees are determined based on the full cost expended for the review, the professional staff hours expended for the review of the application up to the effective date of the final rule will be determined at the professional rates in effect at the time the service was provided. For those applications currently on file for which review costs have reached an applicable fee ceiling established by the June 20, 1984, and July 2, 1990, rules but are still pending completion of the review, the cost incurred after any applicable ceiling was reached through January 29, 1989, will not be billed to the applicant. Any professional staff-hours expended above those ceilings on or after January 30, 1989, will be assessed at the applicable rates established by § 170.20, as appropriate, except for topical reports whose costs exceed $50,000. Costs which exceed $50,000 for any topical report, amendment, revision or supplement to a topical report completed or under review from January 30, 1989, through August 8, 1991, will not be billed to the applicant. Any professional hours expended on or after August 9, 1991, will be assessed at the applicable rate established in § 170.20. In no event will the total review costs be less than twice the hourly rate shown in § 170.20.

* * * * * * *

5. Section 170.31 is revised to read as follows:

§ 170.31 Schedule of fees for materials licenses and other regulatory services, including inspections, and import and export licenses.

Applicants for materials licenses, import and export licenses, and other regulatory services and holders of materials licenses, or import and export licenses shall pay fees for the following categories of services. This schedule includes fees for health and safety and safeguards inspections where applicable.

SCHEDULE OF MATERIALS FEES

[See footnotes at end of table]

Category of materials licenses and type of fees [1]	Fee [2], [3]
1. Special nuclear material:	
A. Licenses for possession and use of 200 grams or more of plutonium in unsealed form or 350 grams or more of contained U–235 in unsealed form or 200 grams or more of U–233 in unsealed form. This includes applications to terminate licenses as well as licenses authorizing possession only:	
License, Renewal, Amendment	Full Cost
Inspections	Full Cost
B. Licenses for receipt and storage of spent fuel at an independent spent fuel storage installation (ISFSI):	
License, Renewal, Amendment	Full Cost
Inspections	Full Cost
C. Licenses for possession and use of special nuclear material in sealed sources contained in devices used in industrial measuring systems, including x-ray fluorescence analyzers: [4]	
Application—New license	550
Amendment	300
D. All other special nuclear material licenses, except licenses authorizing special nuclear material in unsealed form in combination that would constitute a critical quantity, as defined in § 150.11 of this chapter, for which the licensee shall pay the same fees as those for Category 1A: [4]	
Application—New license	600
Amendment	290
E. Licenses for construction and operation of a uranium enrichment facility.	
Application	125,000
License, Renewal, Amendment	Full Cost
Inspections	Full Cost
2. Source material:	
A. (1) Licenses for possession and use of source material in recovery operations such as milling, in-situ leaching, heap-leaching, refining uranium mill concentrates to uranium hexafluoride, ore buying stations, ion exchange facilities and in processing of ores containing source material for extraction of metals other than uranium or thorium, including licenses authorizing the possession of byproduct waste material (tailings) from source material recovery operations, as well as licenses authorizing the possession and maintenance of a facility in a standby mode:	
License, Renewal, Amendment	Full Cost
Inspections	Full Cost

SCHEDULE OF MATERIALS FEES—Continued

[See footnotes at end of table]

Category of materials licenses and type of fees [1]	Fee [2], [3]
(2) Licenses that authorize the receipt of byproduct material, as defined in Section 11e(2) of the Atomic Energy Act, from other persons for possession and disposal except those licenses subject to fees in Category 2.A.(1):	
License, renewal, amendment	Full Cost
Inspections	Full Cost
(3) Licenses that authorize the receipt of byproduct material, as defined in Section 11e(2) of the Atomic Energy Act, from other persons for possession and disposal incidental to the disposal of the uranium waste tailings generated by the licensee's milling operations, except those licenses subject to the fees in Category 2.A.(1):	
License, renewal, amendment	Full Cost
Inspections	Full Cost
B. Licenses which authorize the possession, use and/or installation of source material for shielding:	
Application—New license	160
Amendment	240
C. All other source material licenses:	
Application—New license	2,800
Amendment	420
3. Byproduct material:	
A. Licenses of broad scope for possession and use of byproduct material issued pursuant to parts 30 and 33 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution:	
Application—New license	3,000
Amendment	550
B. Other licenses for possession and use of byproduct material issued pursuant to part 30 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution:	
Application—New license	1,200
Amendment	580
C. Licenses issued pursuant to §§ 32.72, 32.73, and/or 32.74 of this chapter authorizing the processing or manufacturing and distribution or redistribution of radiopharmaceuticals, generators, reagent kits and/or sources and devices containing byproduct material:	
Application—New license	4,100
Amendment	520
D. Licenses and approvals issued pursuant to §§ 32.72, 32.73, and/or 32.74 of this chapter authorizing distribution or redistribution of radiopharmaceuticals, generators, reagent kits and/or sources or devices not involving processing of byproduct material:	
Application—New license	1,500
Amendment	430
E. Licenses for possession and use of byproduct material in sealed sources for irradiation of materials in which the source is not removed from its shield (self-shielded units):	
Application—New license	$1,200
Amendment	360
F. Licenses for possession and use of less than 10,000 curies of byproduct material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes. This category also includes underwater irradiators for irradiation of materials where the source is not exposed for irradiation purposes.	
Application—New license	1,500
Amendment	370
G. Licenses for possession and use of 10,000 curies or more of byproduct material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes. This category also includes underwater irradiators for irradiation of materials where the source is not exposed for irradiation purposes.	
Application—New license	6,000
Amendment	780
H. Licenses issued pursuant to subpart A of part 32 of this chapter to distribute items containing byproduct material that require device review to persons exempt from the licensing requirements of part 30 of this chapter, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of part 30 of this chapter:	
Application—New license	2,400
Amendment	1,000
I. Licenses issued pursuant to subpart A of part 32 of this chapter to distribute items containing byproduct material or quantities of byproduct material that do not require device evaluation to persons exempt from the licensing requirements of part 30 of this chapter, except for specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of part 30 of this chapter:	
Application—New license	4,400
Amendment	860
J. Licenses issued pursuant to subpart B of part 32 of this chapter to distribute items containing byproduct material that require sealed source and/or device review to persons generally licensed under part 31 of this chapter, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under part 31 of this chapter:	
Application—New license	1,600
Amendment	290
K. Licenses issued pursuant to subpart B of part 32 of this chapter to distribute items containing byproduct material or quantities of byproduct material that do not require sealed source and/or device review to persons generally licensed under part 31 of this chapter, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under part 31 of this chapter:	
Application—New license	1,300

SCHEDULE OF MATERIALS FEES—Continued

[See footnotes at end of table]

Category of materials licenses and type of fees [1]	Fee [2, 3]
Amendment	310
L. Licenses of broad scope for possession and use of byproduct material issued pursuant to parts 30 and 33 of this chapter for research and development that do not authorize commercial distribution:	
Application—New license	4,300
Amendment	660
M. Other licenses for possession and use of byproduct material issued pursuant to part 30 of this chapter for research and development that do not authorize commercial distribution:	
Application—New license	1,500
Amendment	610
N. Licenses that authorize services for other licensees, except:	
(1) Licenses that authorize only calibration and/or leak testing services are subject to the fees specified in fee Category 3P; and	
(2) Licenses that authorize waste disposal services are subject to the fees specified in fee Categories 4A, 4B, and 4C:	
Application—New license	1,900
Amendment	590
O. Licenses for possession and use of byproduct material issued pursuant to part 34 of this chapter for industrial radiography operations:	
Application—New license	3,900
Amendment	720
P. All other specific byproduct material licenses, except those in Categories 4A through 9D:	
Application—New license	550
Amendment	300
4. Waste disposal and processing:	
A. Licenses specifically authorizing the receipt of waste byproduct material, source material, or special nuclear material from other persons for the purpose of contingency storage or commercial land disposal by the licensee; or licenses authorizing contingency storage of low-level radioactive waste at the site of nuclear power reactors; or licenses for receipt of waste from other persons for incineration or other treatment, packaging of resulting waste and residues, and transfer of packages to another person authorized to receive or dispose of waste material:	
License, renewal, amendment	Full Cost
Inspections	Full Cost
B. Licenses specifically authorizing the receipt of waste byproduct material, source material, or special nuclear material from other persons for the purpose of packaging or repackaging the material. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material:	
Application—New license	3,400
Amendment	410
C. Licenses specifically authorizing the receipt of prepackaged waste byproduct material, source material, or special nuclear material from other persons. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material:	
Application—New license	1,700
Amendment	290
5. Well logging:	
A. Licenses for possession and use of byproduct material, source material, and/or special nuclear material for well logging, well surveys, and tracer studies other than field flooding tracer studies:	
Application—New license	3,200
Amendment	640
B. Licenses for possession and use of byproduct material for field flooding tracer studies:	
License, renewal, amendment	Full Cost
6. Nuclear laundries:	
A. Licenses for commercial collection and laundry of items contaminated with byproduct material, source material, or special nuclear material:	
Application—New license	5,100
Amendment	790
7. Human use of byproduct, source, or special nuclear material:	
A. Licenses issued pursuant to parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices:	
Application—New license	2,800
Amendment	470
B. Licenses of broad scope issued to medical institutions or two or more physicians pursuant to parts 30, 33, 35, 40, and 70 of this chapter authorizing research and development, including human use of byproduct material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices:	
Application—New license	3,000
Amendment	580
C. Other licenses issued pursuant to parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, and/or special nuclear material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices:	
Application—New license	1,400
Amendment	440
8. Civil defense:	
A. Licenses for possession and use of byproduct material, source material, or special nuclear material for civil defense activities:	
Application—New license	760

SCHEDULE OF MATERIALS FEES—Continued

[See footnotes at end of table]

Category of materials licenses and type of fees [1]	Fee [2, 3]
Amendment	350
9. Device, product, or sealed source safety evaluation:	
A. Safety evaluation of devices or products containing byproduct material, source material, or special nuclear material, except reactor fuel devices, for commercial distribution:	
Application—each device	3,400
Amendment—each device	1,200
B. Safety evaluation of devices or products containing byproduct material, source material, or special nuclear material manufactured in accordance with the unique specifications of, and for use by, a single applicant, except reactor fuel devices:	
Application—each device	1,700
Amendment—each device	600
C. Safety evaluation of sealed sources containing byproduct material, source material, or special nuclear material, except reactor fuel, for commercial distribution:	
Application—each source	720
Amendment—each source	240
D. Safety evaluation of sealed sources containing byproduct material, source material, or special nuclear material, manufactured in accordance with the unique specifications of, and for use by, a single applicant, except reactor fuel:	
Application—each source	360
Amendment—each source	120
10. Transportation of radioactive material:	
A. Evaluation of casks, packages, and shipping containers:	
Approval, Renewal, Amendment	Full Cost
Inspections	Full Cost
B. Evaluation of 10 CFR part 71 quality assurance programs:	
Application—Approval	340
Amendment	250
Inspections	Full Cost
11. Review of standardized spent fuel facilities:	
Approval, Renewal, Amendment	Full Cost
Inspections	Full Cost
12. Special projects: [5]	
Approvals and preapplication licensing activities	Full Cost
Inspections	Full Cost
13. A. Spent fuel storage cask Certificate of Compliance:	
Approvals	Full Cost
Amendments, revisions, and supplements	Full Cost
Reapproval	Full Cost
B. Inspections related to spent fuel storage cask	
Certificate of Compliance	Full Cost
C. Inspections related to storage of spent fuel under	
§ 72.210 of this chapter	Full Cost
14. Byproduct, source, or special nuclear material licenses and other approvals authorizing decommissioning, decontamination, reclamation, or site restoration activities pursuant to 10 CFR parts 30, 40, 70, and 72 of this chapter:	
Approval, Renewal, Amendment	Full Cost
Inspections	Full Cost
15. Import and Export licenses:	
Licenses issued pursuant to 10 CFR part 110 of this chapter for the import and export only of special nuclear material, source material, tritium and other byproduct material, heavy water, or nuclear grade graphite:	
A. Application for export or import of HEU and other materials, including radioactive waste, which must be reviewed by the Commissioners and the Executive Branch, for example, those actions under 10 CFR 110.40(b). This category includes application for export or import of radioactive wastes in multiple forms from multiple generators or brokers in the exporting country and/or going to multiple treatment, storage or disposal facilities in one or more receiving countries:	
Application-new license	7,800
Amendment	7,800
B. Application for export or import of special nuclear material, source material, tritium and other byproduct material, heavy water, or nuclear grade graphite, including radioactive waste, requiring Executive Branch review but not Commissioner review. This category includes application for the export or import of radioactive waste involving a single form of waste from a single class of generator in the exporting country to a single treatment, storage and/or disposal facility in the receiving country:	
Application-new license	4,800
Amendment	4,800
C. Application for export of routine reloads of low enriched uranium reactor fuel and exports of source material requiring only foreign government assurances under the Atomic Energy Act:	
Application-new license	3,000
Amendment	3,000

SCHEDULE OF MATERIALS FEES—Continued

[See footnotes at end of table]

Category of materials licenses and type of fees [1]	Fee [2], [3]
D. Application for export or import of other materials, including radioactive waste, not requiring Commissioner review, Executive Branch review, or foreign government assurances under the Atomic Energy Act. This category includes application for export or import of radioactive waste where the NRC has previously authorized the export or import of the same form of waste to or from the same or similar parties, requiring only confirmation from the receiving facility and licensing authorities that the shipments may proceed according to previously agreed understandings and procedures:	
Application-new license	1,200
Amendment	1,200
E. Minor amendment of any export or import license to extend the expiration date, change domestic information, or make other revisions which do not require analysis, review, or consultations with other agencies or foreign governments:	
Amendment	120
16. Reciprocity:	
Agreement State licensees who conduct activities in a non-Agreement State under the reciprocity provisions of 10 CFR 150.20:	
Application (initial filing of Form 241)	1,100
Revisions	200

[1] *Types of fees*—Separate charges, as shown in the schedule, will be assessed for preapplication consultations and reviews and applications for new licenses and approvals, issuance of new licenses and approvals, amendments and certain renewals to existing licenses and approvals, safety evaluations of sealed sources and devices, and certain inspections. The following guidelines apply to these charges:

(a) *Application fees.* Applications for new materials licenses and approvals; applications to reinstate expired, terminated or inactive licenses and approvals except those subject to fees assessed at full costs, and applications filed by Agreement State licensees to register under the general license provisions of 10 CFR 150.20, must be accompanied by the prescribed application fee for each category, except that:

(1) Applications for licenses covering more than one fee category of special nuclear material or source material must be accompanied by the prescribed application fee for the highest fee category; and

(2) Applications for licenses under Category 1E must be accompanied by the prescribed application fee of $125,000.

(b) *License/approval/review fees.* Fees for applications for new licenses and approvals and for preapplication consultations and reviews subject to full cost fees (fee Categories 1A, 1B, 1E, 2A, 4A, 5B, 10A, 11, 12, 13A, and 14) are due upon notification by the Commission in accordance with § 170.12(b), (e), and (f).

(c) *Renewal/reapproval fees.* Applications subject to full cost fees (fee Categories 1A, 1B, 1E, 2A, 4A, 5B, 10A, 11, 13A, and 14) are due upon notification by the Commission in accordance with § 170.12(d).

(d) *Amendment/Revision Fees.*

(1) Applications for amendments to licenses and approvals and revisions to reciprocity initial applications, except those subject to fees assessed at full costs, must be accompanied by the prescribed amendment/revision fee for each license/revision affected. An application for an amendment to a license or approval classified in more than one fee category must be accompanied by the prescribed amendment fee for the category affected by the amendment unless the amendment is applicable to two or more fee categories in which case the amendment fee for the highest fee category would apply. For those licenses and approvals subject to full costs (fee Categories 1A, 1B, 1E, 2A, 4A, 5B, 10A, 11, 12, 13A, and 14), amendment fees are due upon notification by the Commission in accordance with § 170.12(c).

(2) An application for amendment to a materials license or approval that would place the license or approval in a higher fee category or add a new fee category must be accompanied by the prescribed application fee for the new category.

(3) An application for amendment to a license or approval that would reduce the scope of a licensee's program to a lower fee category must be accompanied by the prescribed amendment fee for the lower fee category.

(4) Applications to terminate licenses authorizing small materials programs, when no dismantling or decontamination procedure is required, are not subject to fees.

(e) *Inspection fees.* Inspections resulting from investigations conducted by the Office of Investigations and nonroutine inspections that result from third-party allegations are not subject to fees. The fees assessed at full cost will be determined based on the professional staff time required to conduct the inspection multiplied by the rate established under § 170.20 plus any applicable contractual support services costs incurred. Inspection fees are due upon notification by the Commission in accordance with § 170.12(g).

[2] Fees will not be charged for orders issued by the Commission pursuant to 10 CFR 2.202 or for amendments resulting specifically from the requirements of these types of Commission orders. However, fees will be charged for approvals issued under a specific exemption provision of the Commission's regulations under Title 10 of the Code of Federal Regulations (e.g., 10 CFR 30.11, 40.14, 70.14, 73.5, and any other sections now or hereafter in effect) regardless of whether the approval is in the form of a license amendment, letter of approval, safety evaluation report, or other form. In addition to the fee shown, an applicant may be assessed an additional fee for sealed source and device evaluations as shown in Categories 9A through 9D.

[3] Full cost fees will be determined based on the professional staff time and appropriate contractual support services expended. For those applications currently on file and for which fees are determined based on the full cost expended for the review, the professional staff hours expended for the review of the application up to the effective date of the final rule will be determined at the professional rates in effect at the time the service was provided. For applications currently on file for which review costs have reached an applicable fee ceiling established by the June 20, 1984, and July 2, 1990, rules, but are still pending completion of the review, the cost incurred after any applicable ceiling was reached through January 29, 1989, will not be billed to the applicant. Any professional staff-hours expended above those ceilings on or after January 30, 1989, will be assessed at the applicable rates established by § 170.20, as appropriate, except for topical reports whose costs exceed $50,000. Costs which exceed $50,000 for each topical report, amendment, revision, or supplement to a topical report completed or under review from January 30, 1989, through August 8, 1991, will not be billed to the applicant. Any professional hours expended on or after August 9, 1991, will be assessed at the applicable rate established in § 170.20. The minimum total review cost is twice the hourly rate shown in § 170.20.

[4] Licensees paying fees under Categories 1A, 1B, and 1E are not subject to fees under Categories 1C and 1D for sealed sources authorized in the same license except in those instances in which an application deals only with the sealed sources authorized by the license. Applicants for new licenses that cover both byproduct material and special nuclear material in sealed sources for use in gauging devices will pay the appropriate application fee for fee Category 1C only.

[5] Fees will not be assessed for requests/reports submitted to the NRC:

(a) In response to a Generic Letter or NRC Bulletin that does not result in an amendment to the license, does not result in the review of an alternate method or reanalysis to meet the requirements of the Generic Letter, or does not involve an unreviewed safety issue;

(b) In response to an NRC request (at the Associate Office Director level or above) to resolve an identified safety or environmental issue, or to assist NRC in developing a rule, regulatory guide, policy statement, generic letter, or bulletin; or

(c) As a means of exchanging information between industry organizations and the NRC for the purpose of supporting generic regulatory improvements or efforts.

PART 171—ANNUAL FEES FOR REACTOR OPERATING LICENSES, AND FUEL CYCLE LICENSES AND MATERIALS LICENSES, INCLUDING HOLDERS OF CERTIFICATES OF COMPLIANCE, REGISTRATIONS, AND QUALITY ASSURANCE PROGRAM APPROVALS AND GOVERNMENT AGENCIES LICENSED BY THE NRC

6. The authority citation for part 171 continues to read as follows:

Authority: Sec. 7601, Pub. L. 99–272, 100 Stat. 146, as amended by sec. 5601, Pub. L. 100–203, 101 Stat. 1330, as amended by Sec. 3201, Pub. L. 101–239, 103 Stat. 2106 as amended by sec. 6101, Pub. L. 101–508, 104 Stat. 1388 (42 U.S.C. 2213); sec. 301, Pub. L. 92–314, 86 Stat. 222 (42 U.S.C. 2201(w)); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 2903, Pub. L. 102–486, 106 Stat. 3125, (42 U.S.C. 2214 note).

7. In § 171.15, paragraph (d) is removed and reserved and paragraphs (a), (b), (c), and (e) are revised to read as follows:

§ 171.15 Annual Fees: Reactor operating licenses.

(a) Each person licensed to operate a power, test, or research reactor shall pay the annual fee for each unit for which the person holds an operating license at any time during the Federal FY in which the fee is due, except for those test and research reactors exempted in § 171.11 (a)(1) and (a)(2).

(b) The FY 1996 uniform annual fee for each operating power reactor which must be collected by September 30, 1996, is $2,747,000. This fee has been determined by adjusting the FY 1995 annual fee downward by approximately 6 percent. The FY 1995 annual fee was comprised of a base annual fee and an additional charge (surcharge). The activities comprising the base FY 1995 annual fee are as follows:

(1) Power reactor safety and safeguards regulation except licensing and inspection activities recovered under 10 CFR Part 170 of this chapter.

(2) Research activities directly related to the regulation of power reactors.

(3) Generic activities required largely for NRC to regulate power reactors, e.g., updating part 50 of this chapter, or operating the Incident Response Center.

(c) The activities comprising the FY 1995 surcharge are as follows:

(1) Activities not attributable to an existing NRC licensee or class of licensees; e.g., reviews submitted by other government agencies (e.g., DOE) that do not result in a license or are not associated with a license; international cooperative safety program and international safeguards activities; low-level waste disposal generic activities; uranium enrichment generic activities; and

(2) Activities not currently assessed under 10 CFR Part 170 licensing and inspection fees based on existing Commission policy, e.g., reviews and inspections conducted of nonprofit educational institutions, and costs that would not be collected from small entities based on Commission policy in accordance with the Regulatory Flexibility Act.

* * * * *

(d) [Reserved].

(e) The FY 1996 annual fees for licensees authorized to operate a nonpower (test and research) reactor licensed under Part 50 of this chapter, except for those reactors exempted from fees under § 171.11(a), are as follows:

Research reactor	$52,900
Test reactor	$52,900

* * * * *

8. In § 171.16, the introductory text of paragraph (c) and paragraphs (c)(1), (c)(4), (d), and (e) are revised to read as follows:

§ 171.16 Annual Fees: Materials Licensees, Holders of Certificates of Compliance, Holders of Sealed Source and Device Registrations, Holders of Quality Assurance Program Approvals and Government agencies licensed by the NRC.

* * * * *

(c) A licensee who is required to pay an annual fee under this section may qualify as a small entity. If a licensee qualifies as a small entity and provides the Commission with the proper certification, the licensee may pay reduced annual fees for FY 1996 as follows:

	Maximum annual fee per licensed category
Small Businesses Not Engaged in Manufacturing and Small Not-For-Profit Organizations (Gross Annual Receipts):	
$350,000 to $5 million	$1,800
Less than $350,000	400
Manufacturing entities that have an average of 500 employees or less:	
35 to 500 employees	1,800
Less than 35 employees	400
Small Governmental Jurisdictions (Including publicly supported educational institutions) (Population):	
20,000 to 50,000	1,800
Less than 20,000	400
Educational Institutions that are not State or Publicly:	
Supported, and have 500 Employees or Less:	
35 to 500 employees	1,800
Less than 35 employees	400

(1) A licensee qualifies as a small entity if it meets the size standards established by the NRC (See 10 CFR 2.810).

* * * * *

(4) For FY 1996, the maximum annual fee a small entity is required to pay is $1,800 for each category applicable to the license(s).

(d) The FY 1996 annual fees for materials licensees and holders of certificates, registrations or approvals subject to fees under this section are shown below. The FY 1996 annual fees, which must be collected by September 30, 1996, have been determined by adjusting downward the FY 1995 annual fees by approximately 6 percent. The FY 1995 annual fee was comprised of a base annual fee and an additional charge (surcharge). The activities comprising the FY 1995 surcharge are shown in paragraph (e) of this section.

SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY NRC

[See footnotes at end of table]

Category of materials licenses		Annual fees[1 2 3]
1. Special nuclear material:		
A.(1) Licenses for possession and use of U–235 or plutonium for fuel fabrication activities.		
(a) Strategic Special Nuclear Material:		
Babcock & Wilcox	SNM–42	$2,404,000
Nuclear Fuel Services	SNM–124	2,404,000
(b) Low Enriched Uranium in Dispersable Form Used for Fabrication of Power Reactor Fuel:		
Combustion Engineering (Hematite)	SNM–33	1,180,000

SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY NRC—Continued

[See footnotes at end of table]

Category of materials licenses		Annual fees [1 2 3]
General Electric Company	SNM–1097	1,180,000
Siemens Nuclear Power	SNM–1227	1,180,000
Westinghouse Electric Company	SNM–1107	1,180,000
(2) All other special nuclear materials licenses not included in Category 1.A.(1) which are licensed for fuel cycle activities.		
(a) Facilities with limited operations:		
B&W Fuel Company	SNM–1168	469,400
(b) All Others:		
General Electric	SNM–960	318,800
B. Licenses for receipt and storage of spent fuel at an independent spent fuel storage installation (ISFSI) ..		261,100
C. Licenses for possession and use of special nuclear material in sealed sources contained in devices used in industrial measuring systems, including x-ray fluorescence analyzers.		1,200
D. All other special nuclear material licenses, except licenses authorizing special nuclear material in unsealed form in combination that would constitute a critical quantity, as defined in § 150.11 of this chapter, for which the licensee shall pay the same fees as those for Category 1.A.(2).		2,800
E. Licenses for the operation of a uranium enrichment facility		[11] N/A
2. Source material:		
A.(1) Licenses for possession and use of source material for refining uranium mill concentrates to uranium hexafluoride.		598,100
(2) Licenses for possession and use of source material in recovery operations such as milling, in-situ leaching, heap-leaching, ore buying stations, ion exchange facilities and in processing of ores containing source material for extraction of metals other than uranium or thorium, including licenses authorizing the possession of byproduct waste material (tailings) from source material recovery operations, as well as licenses authorizing the possession and maintenance of a facility in a standby mode..		
Class I facilities [4]		57,000
Class II facilities [4]		32,200
Other facilities [4]		20,600
(3) Licenses that authorize the receipt of byproduct material, as defined in Section 11e.(2) of the Atomic Energy Act, from other persons for possession and disposal, except those licenses subject to the fees in Category 2.A.(2) or Category 2.A.(4).		41,800
(4) Licenses that authorize the receipt of byproduct material, as defined in Section 11e(2) of the Atomic Energy Act, from other persons for possession and disposal incidental to the disposal of the uranium waste tailings generated by the licensee's milling operations, except those licenses subject to the fees in Category 2.A.(2).		7,400
B. Licenses which authorize only the possession, use and/or installation of source material for shielding		450
C. All other source material licenses		8,100
3. Byproduct material:		
A. Licenses of broad scope for possession and use of byproduct material issued pursuant to parts 30 and 33 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution.		15,400
B. Other licenses for possession and use of byproduct material issued pursuant to part 30 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution.		5,200
C. Licenses issued pursuant to §§ 32.72, 32.73, and/or 32.74 of this chapter authorizing the processing or manufacturing and distribution or redistribution of radiopharmaceuticals, generators, reagent kits and/or sources and devices containing byproduct material. This category also includes the possession and use of source material for shielding authorized pursuant to part 40 of this chapter when included on the same license.		10,400
D. Licenses and approvals issued pursuant to §§ 32.72, 32.73, and/or 32.74 of this chapter authorizing distribution or redistribution of radiopharmaceuticals, generators, reagent kits and/or sources or devices not involving processing of byproduct material. This category also includes the possession and use of source material for shielding authorized pursuant to part 40 of this chapter when included on the same license..		4,100
E. Licenses for possession and use of byproduct material in sealed sources for irradiation of materials in which the source is not removed from its shield (self-shielded units).		2,900
F. Licenses for possession and use of less than 10,000 curies of byproduct material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes. This category also includes underwater irradiators for irradiation of materials in which the source is not exposed for irradiation purposes.		3,500
G. Licenses for possession and use of 10,000 curies or more of byproduct material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes. This category also includes underwater irradiators for irradiation of materials in which the source is not exposed for irradiation purposes.		18,200
H. Licenses issued pursuant to subpart A of part 32 of this chapter to distribute items containing byproduct material that require device review to persons exempt from the licensing requirements of part 30 of this chapter, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of part 30 of this chapter.		4,600

SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY NRC—Continued

[See footnotes at end of table]

Category of materials licenses		Annual fees[1 2 3]
I. Licenses issued pursuant to subpart A of part 32 of this chapter to distribute items containing byproduct material or quantities of byproduct material that do not require device evaluation to persons exempt from the licensing requirements of part 30 of this chapter, except for specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of part 30 of this chapter.	8,200	
J. Licenses issued pursuant to subpart B of part 32 of this chapter to distribute items containing byproduct material that require sealed source and/or device review to persons generally licensed under part 31 of this chapter, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under part 31 of this chapter.	3,500	
K. Licenses issued pursuant to subpart B of part 31 of this chapter to distribute items containing byproduct material or quantities of byproduct material that do not require sealed source and/or device review to persons generally licensed under part 31 of this chapter, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under part 31 of this chapter.	3,000	
L. Licenses of broad scope for possession and use of byproduct material issued pursuant to parts 30 and 33 of this chapter for research and development that do not authorize commercial distribution.	11,400	
M. Other licenses for possession and use of byproduct material issued pursuant to part 30 of this chapter for research and development that do not authorize commercial distribution.	5,100	
N. Licenses that authorize services for other licensees, except:		
(1) Licenses that authorize only calibration and/or leak testing services are subject to the fees specified in fee Category 3P; and		
(2) Licenses that authorize waste disposal services are subject to the fees specified in fee Categories 4A, 4B, and 4C.	5,600	
O. Licenses for possession and use of byproduct material issued pursuant to part 34 of this chapter for industrial radiography operations. This category also includes the possession and use of source material for shielding authorized pursuant to part 40 of this chapter when authorized on the same license.	13,000	
P. All other specific byproduct material licenses, except those in Categories 4A through 9D	1,600	
4. Waste disposal and processing:		
A. Licenses specifically authorizing the receipt of waste byproduct material, source material, or special nuclear material from other persons for the purpose of contingency storage or commercial land disposal by the licensee; or licenses authorizing contingency storage of low-level radioactive waste at the site of nuclear power reactors; or licenses for receipt of waste from other persons for incineration or other treatment, packaging of resulting waste and residues, and transfer of packages to another person authorized to receive or dispose of waste material.	94,400	
B. Licenses specifically authorizing the receipt of waste byproduct material, source material, or special nuclear material from other persons for the purpose of packaging or repackaging the material. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material.	13,300	
C. Licenses specifically authorizing the receipt of prepackaged waste byproduct material, source material, or special nuclear material from other persons. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material.	7,100	
5. Well logging:		
A. Licenses for possession and use of byproduct material, source material, and/or special nuclear material for well logging, well surveys, and tracer studies other than field flooding tracer studies.	7,500	
B. Licenses for possession and use of byproduct material for field flooding tracer studies	12,200	
6. Nuclear laundries:		
A. Licenses for commercial collection and laundry of items contaminated with byproduct material, source material, or special nuclear material.	13,600	
7. Human use of byproduct, source, or special nuclear material:		
A. Licenses issued pursuant to parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license.	9,500	
B. Licenses of broad scope issued to medical institutions or two or more physicians pursuant to parts 30, 33, 35, 40, and 70 of this chapter authorizing research and development, including human use of byproduct material except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license[9].	21,700	
C. Other licenses issued pursuant to parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, and/or special nuclear material except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license[9].	4,300	
8. Civil defense:		
A. Licenses for possession and use of byproduct material, source material, or special nuclear material for civil defense activities.	1,600	
9. Device, product, or sealed source safety evaluation:		
A. Registrations issued for the safety evaluation of devices or products containing byproduct material, source material, or special nuclear material, except reactor fuel devices, for commercial distribution.	6,700	

SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY NRC—Continued

[See footnotes at end of table]

Category of materials licenses		Annual fees[1 2 3]
B. Registrations issued for the safety evaluation of devices or products containing byproduct material, source material, or special nuclear material manufactured in accordance with the unique specifications of, and for use by, a single applicant, except reactor fuel devices.	3,400	
C. Registrations issued for the safety evaluation of sealed sources containing byproduct material, source material, or special nuclear material, except reactor fuel, for commercial distribution.	1,400	
D. Registrations issued for the safety evaluation of sealed sources containing byproduct material, source material, or special nuclear material, manufactured in accordance with the unique specifications of, and for use by, a single applicant, except reactor fuel.	720	
10. Transportation of radioactive material:		
A. Certificates of Compliance or other package approvals issued for design of casks, packages, and shipping containers.		
Spent Fuel, High-Level Waste, and	[6] N/A	
Other Casks	[6] N/A	
B. Approvals issued of 10 CFR part 71 quality assurance programs.		
Users and Fabricators	72,800	
Users	950	
11. Standardized spent fuel facilities	[6] N/A	
12. Special Projects	[6] N/A	
13. A. Spent fuel storage cask Certificate of Compliance	[6] N/A	
B. General licenses for storage of spent fuel under 10 CFR 72.210	261,100	
14. Byproduct, source, or special nuclear material licenses and other approvals authorizing decommissioning, decontamination, reclamation, or site restoration activities pursuant to 10 CFR parts 30, 40, 70, and 72.	[7] N/A	
15. Import and Export licenses	[8] N/A	
16. Reciprocity	[8] N/A	
17. Master materials licenses of broad scope issued to Government agencies	388,600	
18. Department of Energy:		
A. Certificates of Compliance	[10] 1,078,000	
B. Uranium Mill Tailing Radiation Control Act (UMTRCA) activities	1,813,000	

[1] Annual fees will be assessed based on whether a licensee held a valid license with the NRC authorizing possession and use of radioactive material during the fiscal year. However, the annual fee is waived for those materials licenses and holders of certificates, registrations, and approvals who either filed for termination of their licenses or approvals or filed for possession only/storage licenses prior to October 1, 1995, and permanently ceased licensed activities entirely by September 30, 1995. Annual fees for licensees who filed for termination of a license, downgrade of a license, or for a POL during the fiscal year and for new licenses issued during the fiscal year will be prorated in accordance with the provisions of § 171.17. If a person holds more than one license, certificate, registration, or approval, the annual fee(s) will be assessed for each license, certificate, registration, or approval held by that person. For licenses that authorize more than one activity on a single license (e.g., human use and irradiator activities), annual fees will be assessed for each category applicable to the license. Licensees paying annual fees under Category 1.A. (1). are not subject to the annual fees of Category 1.C and 1.D for sealed sources authorized in the license.

[2] Payment of the prescribed annual fee does not automatically renew the license, certificate, registration, or approval for which the fee is paid. Renewal applications must be filed in accordance with the requirements of parts 30, 40, 70, 71, or 72 of this chapter.

[3] For FYs 1997 and 1998, fees for these materials licenses will be calculated and assessed in accordance with § 171.13 and will be published in the FEDERAL REGISTER for notice and comments.

[4] A Class I license includes mill licenses issued for the extraction of uranium from uranium ore. A Class II license includes solution mining licenses (in-situ and heap leach) issued for the extraction of uranium from uranium ores including research and development licenses. An "other" license includes licenses for extraction of metals, heavy metals, and rare earths.

[5] Two licenses have been issued by NRC for land disposal of special nuclear material. Once NRC issues a LLW disposal license for byproduct and source material, the Commission will consider establishing an annual fee for this type of license.

[6] Standardized spent fuel facilities, parts 71 and 72 Certificates of Compliance, and special reviews, such as topical reports, are not assessed an annual fee because the generic costs of regulating these activities are primarily attributable to the users of the designs, certificates, and topical reports.

[7] Licensees in this category are not assessed an annual fee because they are charged an annual fee in other categories while they are licensed to operate.

[8] No annual fee is charged because it is not practical to administer due to the relatively short life or temporary nature of the license.

[9] Separate annual fees will not be assessed for pacemaker licenses issued to medical institutions who also hold nuclear medicine licenses under Categories 7B or 7C.

[10] This includes Certificates of Compliance issued to DOE that are not under the Nuclear Waste Fund.

[11] No annual fee has been established because there are currently no licensees in this particular fee category.

(e) The activities comprising the FY 1995 surcharge are as follows:

(1) LLW disposal generic activities;

(2) Activities not attributable to an existing NRC licensee or classes of licensees; e.g., international cooperative safety program and international safeguards activities; support for the Agreement State program; site decommissioning management plan (SDMP) activities and

(3) Activities not currently assessed under 10 CFR part 170 licensing and inspection fees based on existing law or Commission policy, e.g., reviews and inspections conducted of nonprofit educational institutions and Federal agencies; activities related to decommissioning and reclamation and costs that would not be collected from small entities based on Commission policy in accordance with the Regulatory Flexibility Act.

* * * * *

9. In § 171.19, paragraphs (b) and (c) are revised and a new paragraph (d) is added to read as follows:

§ 171.19 Payment.

* * * * *

(b) For FY 1996 through FY 1998, the Commission will adjust the fourth quarterly bill for operating power

reactors and certain materials licensees to recover the full amount of the revised annual fee. If the amounts collected in the first three quarters exceed the amount of the revised annual fee, the overpayment will be refunded. The NRC will refund any "flat" materials renewal fees payments received for renewal applications filed in FY 1996, as appropriate. All other licensees, or holders of a certificate, registration, or approval of a QA program will be sent a bill for the full amount of the annual fee upon publication of the final rule or on the anniversary date of the license. Payment is due on the invoice date and interest accrues from the date of the invoice. However, interest will be waived if payment is received within 30 days from the invoice date.

(c) For FYs 1996 through 1998, annual fees in the amount of $100,000 or more and described in the **Federal Register** notice pursuant to § 171.13 must be paid in quarterly installments of 25 percent as billed by the NRC. The quarters begin on October 1, January 1, April 1, and July 1 of each fiscal year.

(d) For FYs 1996 through 1998, annual fees of less than $100,000 must be paid as billed by the NRC. Beginning in FY 1996, materials license annual fees that are less than $100,000 will be billed on the anniversary of the license. The materials licensees that would be billed on the anniversary date of the license are those covered by fee categories 1.C. and 1.D.; 2.A.(2) through 2.C.; 3.A. through 3.P.; 4.B. through 9.D.; and 10.B. For annual fee purposes, the anniversary date of the license is considered to be the first day of the month in which the original license was issued by the NRC. During the transition year of FY 1996, licensees with license anniversary dates falling between October 1 and the effective date of the FY 1996 final rule would receive an annual fee bill payable on the effective date of the final rule, and licensees with license anniversary dates that fall on or after the effective date of the final rule would be billed on the anniversary of their license. Starting with the effective date of the FY 1996 final rule, licensees that are billed on the license anniversary date would be assessed the annual fee in effect on the anniversary date of the license.

Dated at Rockville, MD, this 19th day of January, 1996.

For the Nuclear Regulatory Commission.

James M. Taylor,

Executive Director for Operations.

Appendix A to this Proposed Rule Regulatory Flexibility Analysis for the Amendments to 10 CFR Part 170 (License Fees) and 10 CFR Part 171 (Annual Fees)

I. Background.

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*) establishes as a principle of regulatory practice that agencies endeavor to fit regulatory and informational requirements, consistent with applicable statutes, to a scale commensurate with the businesses, organizations, and government jurisdictions to which they apply. To achieve this principle, the Act requires that agencies consider the impact of their actions on small entities. If the agency cannot certify that a rule will not significantly impact a substantial number of small entities, then a regulatory flexibility analysis is required to examine the impacts on small entities and the alternatives to minimize these impacts.

To assist in considering these impacts under the Regulatory Flexibility Act (RFA), first the NRC adopted size standards for determining which NRC licensees qualify as small entities (50 FR 50241, December 9, 1985). These size standards were clarified November 6, 1991 (56 FR 56672). On April 7, 1994 (59 FR 16513), the Small Business Administration (SBA) issued a final rule changing its size standards. The SBA adjusted its receipts-based size standards levels to mitigate the effects of inflation from 1984 to 1994. On November 30, 1994 (59 FR 61293), the NRC published a proposed rule to amend its size standards. After evaluating the two comments received, a final rule that would revise the NRC's size standards as proposed was developed and approved by the SBA on March 24, 1995. The NRC published the final rule revising its size standards on April 11, 1995 (60 FR 18344). The revised standards became effective May 11, 1995. The revised standards adjusted the NRC receipts-based size standards from $3.5 million to $5 million to accommodate inflation and to conform to the SBA final rule. The NRC also eliminated the separate $1 million size standard for private practice physicians and applied a receipts-based size standard of $5 million to this class of licensees. This mirrored the revised SBA standard of $5 million for medical practitioners. The NRC also established a size standard of 500 or fewer employees for business concerns that are manufacturing entities. This standard is the most commonly used SBA employee standard and is the standard applicable to the types of manufacturing industries that hold an NRC license.

The NRC used the revised standards in the final FY 1995 fee rule and proposes to continue their use in this FY 1996 proposed rule. The small entity fee categories in § 171.16(c) of this proposed rule reflect the changes in the NRC's size standards adopted in FY 1995. A new maximum small entity fee for manufacturing industries with 35 to 500 employees was established at $1,800 and a lower-tier small entity fee of $400 was established for those manufacturing industries with less than 35 employees. The lower-tier receipts-based threshold of $250,000 was raised to $350,000 to reflect approximately the same percentage adjustment as that made by the SBA when they adjusted the receipts-based standard from $3.5 million to $5 million. The NRC believes that the proposal to continue these actions would reduce the impact of annual fees on small businesses in FY 1996. The NRC size standards are codified at 10 CFR 2.810.

Pub. L. 101–508, the Omnibus Budget Reconciliation Act of 1990 (OBRA–90), requires that the NRC recover approximately 100 percent of its budget authority, less appropriations from the Nuclear Waste Fund, for Fiscal Years (FY) 1991 through 1995 by assessing license and annual fees. OBRA–90 was amended in 1993 to extend the 100 percent recovery requirement for NRC through 1998. For FY 1991, the amount for collection was approximately $445.3 million; for FY 1992, approximately $492.5 million; for FY 1993 about $518.9 million; for FY 1994 about $513 million; for FY 1995 about $503.6 million and the amount to be collected in FY 1996 is approximately $462.3 million.

To comply with OBRA–90, the Commission amended its fee regulations in 10 CFR parts 170 and 171 in FY 1991 (56 FR 31472, July 10, 1991) in FY 1992, (57 FR 32691, July 23, 1992) in FY 1993 (58 FR 38666, July 20, 1993) in FY 1994 (59 FR 36895, July 20, 1994) and in FY 1995 (60 FR 32218, June 20, 1995) based on a careful evaluation of over 1,000 comments. These final rules established the methodology used by NRC in identifying and determining the fees assessed and collected in FYs 1991–1995.

The NRC indicated in the FY 1995 final rule that it would attempt to stabilize annual fees as follows. Beginning in FY 1996, it would adjust the annual fees only by the percentage change (plus or minus) in NRC's total budget authority unless there was a substantial change in the total NRC budget authority or the magnitude of the budget allocated to a specific class of licensees, in which case the annual fee base would be recalculated (60 FR 32225, June 20, 1995). The NRC also indicated that the percentage change would be adjusted based on changes in the 10 CFR part 170 fees and other receipts as well as an adjustment for the number of licensees paying the fees. As a result, the NRC is proposing that the FY 1996 annual fees for all licensees be established at 6.4 percent below the FY 1995 annual fees. The NRC believes that the proposed 6.4 percent downward adjustment to the FY 1995 annual fees is not a substantial enough change to warrant establishing a new baseline for FY 1996. Therefore, the NRC is proposing to establish the FY 1996 annual fees for all licensees at a level of about 6 percent below the FY 1995 fees.

The NRC is also proposing to continue the streamlining of the fee structure and process for materials licenses which began in FY 1995. Two changes are being proposed in this area.

First, the NRC is proposing to assess annual fees for certain materials licenses on

the anniversary date of the license. Billing certain materials licenses on the anniversary date of the license would allow NRC to make improved efficiencies in the billing process whereby approximately 500 annual fee invoices would be sent to materials licensees each month. The current practice of billing over 6,000 materials licensees at the same time in the fiscal year would be eliminated. The NRC believes that the efficiencies gained by billing certain materials annual fees on a monthly basis as well as materials licensees knowing exactly when they will be billed each year for the annual fee outweigh the inconveniences that may be caused during the FY 1996 transition period.

Second, the NRC is proposing to further streamline the materials fee program and improve the predictability of fees by eliminating the materials "flat" renewal fees in § 170.31. This proposed action is consistent with the NRC's recent Business Process Reengineering initiative to extend the duration of certain materials licenses. The NRC published a proposed rule in the **Federal Register** on September 8, 1995, explaining this initiative (60 FR 46784). In the proposed rule, certain materials licenses would be extended for five years beyond their expiration date. Additionally, comments were requested on the general topic of the appropriate duration of licenses. A final rule was published in the **Federal Register** on January 16, 1996 (61 FR 1109).

II. Impact on Small Entities

The comments received on the proposed FY 1991–1995 fee rule revisions and the small entity certifications received in response to the final FY 1991–1995 fee rules indicate that NRC licensees qualifying as small entities under the NRC's size standards are primarily those licensed under the NRC's materials program. Therefore, this analysis will focus on the economic impact of the annual fees on materials licensees.

The Commission's fee regulations result in substantial fees being charged to those individuals, organizations, and companies that are licensed under the NRC materials program. Of these materials licensees, about 18 percent (approximately 1,300 licensees) have requested small entity certification in the past. In FY 1993, the NRC conducted a survey of its materials licensees. The results of this survey indicated that about 25 percent of these licensees could qualify as small entities under the current NRC size standards.

The commenters on the FY 1991–1994 proposed fee rules indicated the following results if the proposed annual fees were not modified:

—Large firms would gain an unfair competitive advantage over small entities. One commenter noted that a small well-logging company (a "Mom and Pop" type of operation) would find it difficult to absorb the annual fee, while a large corporation would find it easier. Another commenter noted that the fee increase could be more easily absorbed by a high-volume nuclear medicine clinic. A gauge licensee noted that, in the very competitive soils testing market, the annual fees would put it at an extreme disadvantage with its much larger competitors because the proposed fees would be the same for a two-person licensee as for a large firm with thousands of employees.

—Some firms would be forced to cancel their licenses. One commenter, with receipts of less than $500,000 per year, stated that the proposed rule would, in effect, force it to relinquish its soil density gauge and license, thereby reducing its ability to do its work effectively. Another commenter noted that the rule would force the company and many other small businesses to get rid of the materials license altogether. Commenters stated that the proposed rule would result in about 10 percent of the well-logging licensees terminating their licenses immediately and approximately 25 percent terminating their licenses before the next annual assessment.

—Some companies would go out of business. One commenter noted that the proposal would put it, and several other small companies, out of business or, at the very least, make it hard to survive.

—Some companies would have budget problems. Many medical licensees commented that, in these times of slashed reimbursements, the proposed increase of the existing fees and the introduction of additional fees would significantly affect their budgets. Another noted that, in view of the cuts by Medicare and other third party carriers, the fees would produce a hardship and some facilities would experience a great deal of difficulty in meeting this additional burden.

Over the past five years, approximately 2,900 license, approval, and registration terminations have been requested. Although some of these terminations were requested because the license was no longer needed or licenses or registrations could be combined, indications are that other termination requests were due to the economic impact of the fees.

The NRC continues to receive written and oral comments from small materials licensees. These commenters previously indicated that the $3.5 million threshold for small entities was not representative of small businesses with gross receipts in the thousands of dollars. These commenters believe that the $1,800 maximum annual fee represents a relatively high percentage of gross annual receipts for these "Mom and Pop" type businesses. Therefore, even the reduced annual fee could have a significant impact on the ability of these types of businesses to continue to operate.

To alleviate the continuing significant impact of the annual fees on a substantial number of small entities, the NRC considered alternatives, in accordance with the RFA. These alternatives were evaluated in the FY 1991 rule (56 FR 31472, July 10, 1991) in the FY 1992 rule (57 FR 32691, July 23, 1992), in the FY 1993 rule (58 FR 38666, July 20, 1993); in the FY 1994 rule (59 FR 36895, July 20, 1994) and in the FY 1995 rule (60 FR 32218, June 20, 1995). The alternatives considered by the NRC can be summarized as follows.

—Base fees on some measure of the amount of radioactivity possessed by the licensee (e.g., number of sources).

—Base fees on the frequency of use of the licensed radioactive material (e.g., volume of patients).

—Base fees on the NRC size standards for small entities.

The NRC has reexamined the FY 1991–1995 evaluations of these alternatives. Based on that reexamination, the NRC continues to believe that establishment of a maximum fee for small entities is the most appropriate option to reduce the impact on small entities.

The NRC established, and is continuing for FY 1996, a maximum annual fee for small entities. The RFA and its implementing guidance do not provide specific guidelines on what constitutes a significant economic impact on a small entity. Therefore, the NRC has no benchmark to assist it in determining the amount or the percent of gross receipts that should be charged to a small entity. For FY 1996, the NRC will rely on the analysis previously completed that established a maximum annual fee for a small entity and the amount of costs that must be recovered from other NRC licensees as a result of establishing the maximum annual fees.

The NRC continues to believe that the 10 CFR part 170 license fees (application and amendment), or any adjustments to these licensing fees during the past year, do not have a significant impact on small entities. In issuing this proposed rule for FY 1996, the NRC concludes that the 10 CFR part 170 materials license fees do not have a significant impact on a substantial number of small entities and that the 10 CFR part 171 maximum annual small entity fee of $1,800 be continued.

By maintaining the maximum annual fee for small entities at $1,800, the annual fee for many small entities is reduced while at the same time materials licensees, including small entities, pay for most of the FY 1996 costs attributable to them. The costs not recovered from small entities are allocated to other materials licensees and to operating power reactors. However, the amount that must be recovered from other licensees as a result of maintaining the maximum annual fee is not expected to increase. Therefore, the NRC is continuing, for FY 1996, the maximum annual fee (base annual fee plus surcharge) for certain small entities at $1,800 for each fee category covered by each license issued to a small entity.

While reducing the impact on many small entities, the Commission agrees that the maximum annual fee of $1,800 for small entities, when added to the part 170 license fees, may continue to have a significant impact on materials licensees with annual gross receipts in the thousands of dollars. Therefore, as in FY 1992–1995, the NRC is continuing the lower-tier small entity annual fee of $400 for small entities with relatively low gross annual receipts. The lower-tier small entity fee of $400 also applies to manufacturing concerns, and educational institutions not State or publicly supported, with less than 35 employees. This lower-tier small entity fee was first established in the final rule published in the **Federal Register** on April 17, 1992 (57 FR 13625) and now includes manufacturing companies with a relatively small number of employees.

III. Summary

The NRC has determined the 10 CFR part 171 annual fees significantly impacts a substantial number of small entities. A maximum fee for small entities strikes a balance between the requirement to collect 100 percent of the NRC budget and the requirement to consider means of reducing the impact of the fee on small entities. On the basis of its regulatory flexibility analyses, the NRC concludes that a maximum annual fee of $1,800 for small entities and a lower-tier small entity annual fee of $400 for small businesses and not-for-profit organizations with gross annual receipts of less than $350,000, small governmental jurisdictions with a population of less than 20,000, small manufacturing entities that have less than 35 employees and educational institutions that are not State or publicly supported and have less than 35 employees reduces the impact on small entities. At the same time, these reduced annual fees are consistent with the objectives of OBRA–90. Thus, the revised fees for small entities maintain a balance between the objectives of OBRA–90 and the RFA. Therefore, the analysis and conclusions established in the FY 1991–1995 rules remain valid for this proposed rule for FY 1996.

[FR Doc. 96–1524 Filed 1–29–96; 8:45 am]
BILLING CODE 7590–01–P

FEDERAL RESERVE SYSTEM

12 CFR Part 226

[Regulation Z; Docket No. R-0913]

Truth in Lending

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Request for comments.

SUMMARY: The Board is soliciting comment on whether the Truth in Lending Act cost disclosure and other rules for open-end home-secured lines of credit provide adequate consumer protections. The Riegle Community Development and Regulatory Improvement Act of 1994 directs the Board to submit a report to the Congress regarding this matter. Under present law, creditors offering open-end home-equity lending programs have to provide detailed disclosures at the time a consumer applies for a line of credit. The law also imposes specific substantive limitations on how these programs may be structured; however they are not subject to the type of disclosure and restrictions imposed by the Home Ownership and Equity Act of 1994 for closed-end credit.

DATES: Comments must be received on or before April 1, 1996.

ADDRESSES: Comments should refer to Docket No. R–0913, and may be mailed to William W. Wiles, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW., Washington, DC 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 NW. (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 the availability of information.

FOR FURTHER INFORMATION CONTACT: Obrea Poindexter, Staff Attorney, Division of Consumer and Community Affairs, Board of Governors of the Federal Reserve System, at (202) 452–3667 or 452–2412. For users of Telecommunications Device for the Deaf (TDD), please contact Dorothea Thompson at (202) 452–3544.

SUPPLEMENTARY INFORMATION:

I. Background

The Home Ownership and Equity Protection Act (HOEPA) amendments to the Truth in Lending Act, contained in the Riegle Community Development and Regulatory Improvement Act of 1994 (RCDRIA) require special disclosures and impose substantive limitations on certain closed-end home-equity loans with rates or fees above a certain percentage or amount. The requirements and prohibitions contained in the HOEPA, which became effective in October 1995, do not apply to open-end home-secured lines of credit. The legislative history notes that congressional hearings on home-equity lending practices revealed little evidence of abusive practices in the open-end home-equity credit market. The legislative history also states that, if the market changes or if the Board finds that open-end credit plans are being used to circumvent the HOEPA, the Board has the authority to address abuses under section 152(d) of the HOEPA.

In addition, the RCDRIA directs the Board to conduct a study and submit a report to the Congress, including recommendations for legislation, on whether existing rules for open-end home-equity lending programs provide consumers obtaining home-equity lines of credit with adequate protections.

II. Current Rules for Home-Equity Lines of Credit

The Home Equity Loan Consumer Protection Act amendments to the Truth in Lending Act, enacted in November 1988, require creditors to give consumers extensive disclosures and an educational brochure for home-equity plans at the time an application is provided. For example, creditors must provide information about payment terms, fees imposed under the plans, and, for variable-rate plans, information about the index used to determine the rate and a fifteen-year history of changes in the index values. In addition, the law imposes certain substantive limitations on home-equity plans, such as limiting the right of creditors to terminate a plan and accelerate an outstanding balance or to change the terms of a plan after it has been opened.

The Board's Regulation Z (12 CFR part 226) implements the Truth in Lending Act. Regulation Z requirements for home-equity lines of credit closely mirror the statutory requirements. As the statute sets forth specific requirements that are restrictive in many cases, the rules implementing the statute are similarly restrictive.

Specific rules on home-equity lines of credit are contained in Regulation Z, §§ 226.5b, 226.6(e), 226.9(c)(3), and 226.16(d) and its accompanying commentary. Requirements for home-equity lines of credit apply to all open-end credit plans secured by a consumer's dwelling. The rules require creditors offering home-equity plans (and third-parties in some instances) to give specific disclosures about costs and terms and limits how creditors may structure programs.

Format and Timing of Disclosures

In most cases, at the time a consumer is provided with an application for a home-secured line of credit, disclosures must be given. These disclosures must be in writing, grouped together, and segregated from all unrelated information. Each consumer must also be given an educational pamphlet prepared by the Board entitled "When Your Home is On the Line: What You Should Know About Home Equity Lines of Credit," or a similar substitute. Program-specific initial disclosures must be given in writing before the first transaction is made under the plan.

Content of Disclosures

Creditors offering home-equity plans must provide information to consumers that is required under section 226.5b of the regulation. This includes, but is not limited to, the following:

(1) The payment terms, including the length of the draw and any repayment period, an explanation of how the minimum periodic payment will be determined and the timing of payments, and an example based on a $10,000

outstanding balance and a recent annual percentage rate (APR): [1]

(2) The APR;

(3) Fees imposed by the creditor and third parties;

(4) A statement that negative amortization may occur and that as a result a consumer's equity in a home may decrease; and

(5) Several statements, including a statement that loss of the home could occur in the event of default.

Subsequent Disclosures

Subject to certain limitations on changes in terms, creditors are generally required to send the consumer a fifteen-day advance notice if a term on the plan is changed. In addition, a notice must also be sent if additional extensions of credit are prohibited or if the credit limit is reduced; this notice must be sent no later than three business days after the action is taken. 12 CFR 226.9(c)

Limitations on Home-equity Plans

Regulation Z prescribes substantive limitations on the changes that a creditor can make in the annual percentage rate, termination of a plan, and any other change in the credit terms that were initially disclosed. For example, a creditor cannot terminate a plan and demand repayment of the entire outstanding balance unless the consumer has engaged in fraud or misrepresentation, failed to meet the repayment terms, or adversely affected the creditor's security by action or inaction. A creditor generally cannot change a term unless the change was provided for in the initial agreement, the consumer agrees to the change in writing, or the change is insignificant or "unequivocally beneficial" to the consumer throughout the remainder of the plan; and cannot apply a new index and margin unless the original index becomes unavailable. 12 CFR 226.5b(f)

Advertising

Creditors generally trigger additional disclosures, in advertisements, if they advertise account-opening disclosures relating to finance charges and other significant charges or repayment terms for a plan. If a home-equity plan advertisement contains a trigger term, creditors must also state the following:

(1) The periodic rate used to compute the finance charge (expressed as an APR);

(2) Loan fees that are a percentage of the credit limit, along with an estimate of other plan fees; and

(3) The maximum APR that could be imposed in a variable-rate plan.

If a minimum payment for the home-equity plan is stated, the advertisement must also state if a balloon payment will result. For a variable-rate plan, if the advertisement states a rate other than one based on the contract's index and margin, the advertisement must also state how long the introductory rate will be in effect. The introductory rate and the fully-indexed rate must be disclosed with equal prominence. In addition, creditors cannot advertise home-equity plans as "free money" (or using a similar term) and cannot discuss the tax consequences of interest deductions in a misleading way. 12 CFR 226.16(d)

III. Request for Comments

The Board requests comment on whether the existing home-equity lending rules provide adequate protections for consumers and whether any statutory or regulatory changes are warranted to ensure adequate disclosure and other consumer protections in connection with open-end home-equity lines of credit.

The Board will submit its report to the Congress in early fall 1996, based on the comments of interested parties and its own analysis.

By order of the Board of Governors of the Federal Reserve System, January 24, 1996.

William W. Wiles,

Secretary of the Board.

[FR Doc. 96–1651 Filed 1–29–96; 8:45 am]

BILLING CODE 6210–01–P

[1] The example must show the minimum periodic payment and the time it would take to repay the $10,000 balance if the consumer made only those payments and obtained no additional credit extensions.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

15 CFR Part 981

[Docket No. 951213299–5299–01]

RIN 0648–AI42

Ocean Thermal Energy Conversion Licensing Program

AGENCY: Office of Ocean and Coastal Resource Management (OCRM), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Proposed rule.

SUMMARY: The National Oceanic and Atmospheric Administration (NOAA) is proposing to remove Part 981 from Title 15 of the Code of Federal Regulations (Part 981). Part 981 implements the Ocean Thermal Energy Conversion (OTEC) Licensing Program, which was established under the Ocean Thermal Energy Conversion Act of 1980, as amended, (OTEC Act), 42 U.S.C. 9101 *et seq.* No applications under Part 981 for licenses of commercial OTEC facilities or plantships have yet been received by NOAA, and there has been a low level of NOAA activity under the OTEC Act. During this 15 year period of time, the availability and relatively low price of fossil fuels, coupled with the risks to potential investors, has limited the interest in the commercial development of OTEC projects. Removal of Part 981 at this time will allow NOAA to evaluate the appropriateness of these, or any other, regulations at such time as interest in the commercial development of OTEC projects occurs.

DATES: Comments on the proposed rule are invited and will be considered if submitted in writing to the address below on or before February 29, 1996.

ADDRESSES: Comments should be submitted to Karl Jugel, Chief, Ocean Minerals and Energy Division, Office of Ocean and Coastal Resource Management, National Ocean Service, National Oceanic and Atmospheric Administration, 1305 East-West Highway, 11th Floor, Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT: James Lawless, Deputy Director, Office of Ocean and Coastal Resource Management, at (301) 713–3155.

SUPPLEMENTARY INFORMATION:

I. Regulatory Review

The National Oceanic and Atmospheric Administration (NOAA) is proposing to remove Part 981 of 15 CFR, pursuant to the Regulatory Reform Initiative of President Clinton and the Ocean Thermal Energy Conversion Act of 1980, as amended.

In March 1995, President Clinton issued a directive to federal agencies regarding their responsibilities under his Regulatory Reform Initiative. This initiative is part of the National Performance Review and calls for immediate, comprehensive regulatory reform. The President directed all agencies to undertake, as part of this initiative, an exhaustive review of all their regulations—with an emphasis on eliminating or modifying those that are obsolete or otherwise in need of reform.

The Ocean Thermal Energy Conversion Act of 1980, as amended, (OTEC Act), 42 U.S.C. §§ 9101 *et seq.*, also requires that NOAA periodically review the regulations that apply to the licensing of OTEC facilities and

plantships. The fundamental purpose of the review is to determine if the regulations themselves impose an adverse impact on the development and commercialization of OTEC technology.

Comments are solicited from all interested persons on the proposed removal of Part 981. Comments are in particular invited on whether the OTEC regulations, or their removal at this time, impose an adverse impact on the development and commercialization of OTEC technology.

II. Ocean Thermal Energy Conversion Licensing Program

The principle behind Ocean Thermal Energy Conversion (OTEC) has been validated through experimental projects in the United States and elsewhere. However, many design and economic uncertainties remain with regard to a commercial scale plant.

The OTEC Act established a licensing and permitting system for the development of OTEC as a commercial energy technology. Without a legal framework, including the site security and predictability it provides, financing and insuring commercial OTEC operations may have been impossible. The OTEC Act applies to facilities located in U.S. territorial waters or connected to the United States by pipeline or cable. The law also applies to all OTEC plantships owned or operated by U.S. citizens and all OTEC facilities or plantships documented under U.S. law. The OTEC Act requires that a person obtain a license from NOAA in order to own, construct, or operate such a facility or plantship. The OTEC Act and the implementing regulations provide the framework for the development of a commercial OTEC industry.

Section 102(a) of the OTEC Act required NOAA to complete issuance of final implementing regulations by August 3, 1981. Section 102(a) also established certain criteria that the regulations must satisfy. NOAA is authorized, consistent with the purposes and provisions of the OTEC Act, to amend or rescind the OTEC regulations. In particular, section 117 of the OTEC Act requires NOAA to review the regulations on a periodic basis NOAA is authorized and directed to revise the regulations as necessary and appropriate to ensure that the regulations do not impede the development, evolution, and commercialization of OTEC technology.

After receiving comments from an advance notice of proposed rulemaking (45 FR 77038, November 21, 1980), NOAA proposed to issue minimal OTEC regulations upon considering three other approaches: (1) detailed regulation of OTEC activities, (2) moderate regulation of OTEC activities, and (3) no regulations. Under the "minimum regulation" approach proposed by NOAA on March 30, 1981 (46 FR 19418–19447), the OTEC licensing regulations would include only the general guidelines and performance standards specified in the OTEC Act. Detailed guidelines and specifications would not be provided in advance in the regulations. They would be introduced if deemed necessary on a site-specific, case-by-case basis to prevent significant adverse effects on the environment or to prevent other results contrary to law. The information submitted to NOAA with an application would include details of the proposed site, descriptions of the operating features of the plan, and assessments of the potential impacts of construction and operation. Thus, application for a license could be made before detailed design of the OTEC project was completed. NOAA would examine the applicant's assessments of the nature and potential magnitude of the impacts from construction and operation of the proposed project, and analyze in detail only those impacts that appeared to pose significant problems.

Under this approach, the incremental administrative costs to NOAA to process each application would be relatively modest. Maximum flexibility would be afforded OTEC project sponsors.

Most persons who commented on the proposed OTEC licensing regulations favored the "minimum regulation" approach as the approach which would best permit the innovation and flexibility necessary in the early years of implementation of a new technology. *See Final Regulatory Impact Analysis and Final Regulatory Flexibility Analysis for Regulations to Implement Public Law 96–320, The Ocean Thermal Energy Conversion Act of 1980,* July 1981, U.S. Dept. of Commerce, NOAA, Office of Ocean Minerals and Energy. NOAA's detailed analysis of potential regulatory impacts of various licensing regimes, prepared as part of the regulation development process, confirmed that the minimum regulation approach was the most cost-effective one that would satisfy the goals of the OTEC Act. Accordingly, it was adopted as the basis for the final licensing regulations issued by NOAA. NOAA published final regulations implementing the OTEC Act in the **Federal Register** on July 31, 1981 (46 FR 39388–39420). The licensing process developed by NOAA and specified in the final regulations was intended to provide the orderly, timely, and efficient review of OTEC proposals envisioned by the drafters of the OTEC Act.

In 1983 and 1984, NOAA undertook two reviews of the OTEC license procedures. Beginning with a notice in the **Federal Register** on May 11, 1983 (48 FR 21154–21156), NOAA reviewed the OTEC regulations to determine if the regulations themselves imposed an adverse impact on the development and commercialization of OTEC technology. A second review of the regulations was conducted by NOAA at the request of the Office of Management and Budget in accordance with the Paperwork Reduction Act. Also in 1984, Congress passed amendments to the OTEC Act. On November 21, 1985, NOAA published a proposed rule (50 FR 48097–48099) incorporating the 1984 amendments to the OTEC Act. This proposed rule reflected NOAA's conclusion, as a result of its regulatory review, that no additional regulatory modifications were necessary. A final rule was published in the **Federal Register** on June 10, 1986 (51 FR 20958–20960).

Also in 1985, NOAA published a *Guide to Permits and Regulations Applicable to Ocean Thermal Energy Conversion Projects—Hawaii Edition.* This permit guide was prepared in order to provide OTEC project sponsors with an overview of potential licenses, permits and authorizations required by federal, state and local agencies. It was intended as a reference guide for federal, state and local agencies processing OTEC permit applications.

No applications for licenses of commercial OTEC facilities or plantships have yet been received by NOAA, and there has been a low level of NOAA activity under the OTEC Act. Since FY 86, no appropriations have been requested by the present or past Administrations, or provided by the Congress, for NOAA OTEC activities. NOAA's last significant OTEC related activities were limited to the completion of two research studies in FY 87, both of which had been funded and initiated with previous appropriations. One was the impact of OTEC generated underwater sound on selected marine animals, and the second study was on the socioeconomic effects of an OTEC plant at Kahe Point, Oahu, Hawaii. Since that time, NOAA activities have been limited to responding to occasional requests for OTEC related technical and regulatory information. The overall availability and relatively low price of fossil fuels, coupled with the risks to potential investors, has limited the interest in the commercial development of OTEC projects.

Given that a commercial OTEC industry has yet to develop, Part 981 remains unused for the most part. Removal of Part 981 at this time is consistent with the purposes and provisions of the OTEC Act in that it will allow NOAA to evaluate the suitability of these regulations at such time as interest in the commercial development of OTEC projects occurs. At such time, NOAA will issue a proposed rule appropriate to the then current regulatory needs. Potential licensees will therefore be assured that any future OTEC regulations will be up to date, and will continue to provide innovation and flexibility necessary for an emerging OTEC industry.

NOAA is mindful of its responsibility for licensing of commercial OTEC facilities and plantships under the OTEC Act, however, and will take appropriate steps to review and process an application should one be made. For particular inquiries into the licensing of OTEC projects in the interim period, NOAA will provide copies of the provisions of these OTEC regulations in response to such inquiries. Thus, NOAA will provide actual and timely notice of applicable procedures and requirements to particular individuals. *See* 5 U.S.C. § 552(a). Accordingly, NOAA is proposing to remove Part 981, the OTEC regulations, from Title 15 of the CFR.

III. Miscellaneous Rulemaking Requirements

Executive Order 12612: Federalism Assessment

NOAA has concluded that this regulatory action does not have federalism implications sufficient to warrant the preparation of a Federalism Assessment under Executive Order 12612.

Executive Order 12866: Regulatory Impact

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

Regulatory Flexibility Act

No licenses have been issued for OTEC projects under 15 CFR Part 981. When commercial interest in OTEC projects occurs, NOAA will issue a proposed rule appropriate to the regulatory needs at that time. For particular inquiries into the licensing of OTEC projects in the interim period, NOAA will provide actual and timely notice of applicable procedures and requirements to particular individuals. *See* 5 U.S.C. § 552(a). For these reasons, the proposed removal of Part 981 is not expected to have a significant economic impact on a substantial number of small entities, and the Assistant General Counsel for legislation and Regulation of the Department of Commerce has so certified to the Chief Counsel for Advocacy of the Small Business Administration. As such, an initial Regulatory Flexibility Analysis was not prepared.

Paperwork Reduction Act

This rule does not contain an information collection requirement subject to review and approval by OMB under the Paperwork Reduction Act of 1980, 44 U.S.C. 3500 *et seq.*

National Environmental Policy Act

NOAA has concluded that this regulatory action does not constitute a major federal action significantly affecting the quality of the human environment. No applications for licenses of commercial OTEC facilities or plantships have yet been received by NOAA, and Part 981 remains unused for the most part. When commercial interest in OTEC projects occurs, NOAA will issue a proposed rule appropriate to the regulatory needs at that time. For particular inquiries into the licensing of OTEC projects in the interim period, NOAA will provide actual and timely notice of applicable procedures to particular individuals. *See* 5 U.S.C. 552(a). Therefore, an environmental impact statement is not required.

Authority: Ocean Thermal Energy Conversion Act of 1980, as amended, 42 U.S.C. 9101 *et seq.*

List of Subjects in 15 CFR Part 981

Administrative practice and procedure, Ocean thermal energy conversion licensing, Environmental protection, Marine resources, Penalties, Reporting and recordkeeping requirements.

Dated: January 24, 1996.

W. Stanley Wilson,

Assistant Administrator for Ocean Services and Coastal Zone Management.

Accordingly, for the reasons set forth above, Chapter IX of Title 15 of the Code of Federal Regulations is proposed to be amended as follows:

PART 981—OCEAN THERMAL ENERGY CONVERSION LICENSING PROGRAM—[REMOVED]

1. Under the authority of the Ocean Thermal Energy Conversion Act of 1980, Part 981 is removed.

[FR Doc. 96–1723 Filed 1–29–96; 8:45 am]
BILLING CODE 3510–22–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201, 208, 314, and 601

[Docket No. 93N–371W]

Prescription Drug Product Labeling; Public Patient Education Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of a public workshop.

SUMMARY: The Food and Drug Administration (FDA) is reannouncing a public patient education workshop to discuss methods and criteria for developing and evaluating prescription drug information for patients. Previously, in the **Federal Register** of December 8, 1995 (60 FR 63049), the agency announced this workshop which was scheduled for January 9 and 10, 1996. Due to inclement weather, the agency was forced to postpone the workshop. The agency has rescheduled the workshop for February 14 and 15, 1996. The purpose of this workshop is to obtain views and opinions concerning the criteria for useful patient information, and it is part of FDA's ongoing initiative to improve the distribution of adequate and useful prescription drug information to patients. FDA encourages health professionals, consumer groups, and other interested parties to participate in the workshop. FDA also invites the designers of primary information systems, which produce either written information or computer programs that generate prescription drug patient information, to display their systems for educational purposes.

DATES: The public patient education workshop will be held on February 14 and 15, 1996, from 8:30 a.m. to 5 p.m. Submit registration notices for participants by February 9, 1996. Submit registration notices for designers of information systems by February 7, 1996. Submit written comments by March 6, 1996.

ADDRESSES: The public patient education workshop will be held at the DoubleTree Hotel, 1750 Rockville Pike, Rockville, MD. Preregistration for workshop participants is encouraged, although not required, in order to facilitate logistical planning of the breakout discussion groups. There is no registration fee for this workshop. Registration forms can be obtained by calling 301–443–5470 or writing to the Office of Health Affairs, ATTN: Patient Education Workshop, Food and Drug Administration (HFY–40), 5600 Fishers

Lane, Rockville, MD 20857. Submit written views or comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. The designers of information systems should call the contact person (address below) for registration information. A more detailed agenda and written presentations will be placed in the docket, identified with the docket number found in brackets in the heading of this document, at the Dockets Management Branch, and will be available for review between 9 a.m. and 4 p.m., Monday through Friday. A transcript of the general sessions of the workshop will be available for review or purchase (10 cents per page) at the Dockets Management Branch approximately 5 business days after the meeting. The breakout sessions will not be transcribed.

FOR FURTHER INFORMATION CONTACT: Thomas J. McGinnis, Office of Health Affairs (HFY–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5470.

SUPPLEMENTARY INFORMATION: On January 9 and 10, 1996, FDA had intended to hold a public patient education workshop to discuss methods and criteria for developing and evaluating prescription drug information for patients. The agency was forced to postpone the workshop due to the closing of the Federal Government because of inclement weather in the metropolitan Washington, DC area. With this notice the agency is announcing the rescheduling of the workshop for February 14 and 15, 1996. The purpose and agenda for the meeting are identical to the previously scheduled workshop, with a few minor changes in the agenda due to the scheduling problems of the original invited presenters.

In the **Federal Register** of August 24, 1995 (60 FR 44182), FDA published a proposed rule that, if finalized, is intended to increase the dissemination of useful written prescription drug information to patients who receive drugs on an outpatient basis. In that proposal, the agency stated its belief that the quality of medical care could be enhanced and substantial costs from drug misadventures could be reduced by better informing patients about the use, side effects, and interactions of such drugs. At that time, the agency discussed a mandatory Federal program that would require such information to be distributed with most new prescriptions. However, the agency also stated that such a program would not be necessary if private sector efforts now underway accomplished the stated goal. Thus, FDA proposed, except where there is a serious and significant public health concern, to defer its program for several years.

To judge the success of those private efforts, the agency proposed goals (performance standards) that would define acceptable levels of information distribution and quality. To meet the performance standard for distribution of information, the agency proposed that by the year 2000 at least 75 percent of people receiving new prescriptions receive useful information. This goal was adapted from the Public Health Service's "Healthy People 2000" report. In addition, the agency proposed that by the year 2006, at least 95 percent of the people who receive new prescriptions receive useful information.

FDA proposed to periodically evaluate and report on the achievement of the goals. If the goals are not met in the specified timeframes, FDA proposed to either: (1) Implement a mandatory comprehensive medication guide program, or (2) seek public comment on whether a comprehensive program should be implemented, or whether, and what, other steps should be taken to meet the patient information goals.

To develop a performance standard for the quality of information distributed, FDA suggested seven specific components in its August 24 proposal for determining whether patient information is useful: Scientific accuracy, consistency with a standard format, nonpromotional tone and content, specificity, comprehensiveness, understandable language, and legibility. The agency defined these components of usefulness, as well as criteria that could be used to judge these components, and invited comments on their appropriateness. Because such criteria are of great interest to affected parties, and because there is substantial expertise in the development and communication of patient information, FDA also stated its intention to hold a public meeting that would allow the many interested groups and individuals to provide their recommendations directly to agency officials.

The agency will hold a public patient education workshop to discuss the methods and criteria for developing and evaluating the usefulness of written information. The patient education workshop will be designed to obtain recommendations from the public about the criteria that should be applied to help ensure that written information provided to patients is "useful."

The patient education workshop will be comprised of both formal presentations and open breakout discussion periods. Any interested person may attend and participate in the discussions. The workshop will include general sessions with presentations from FDA, health professional groups, consumer groups, the pharmaceutical industry, academicians, and parties with legal and regulatory expertise. The agency also intends to hold breakout sessions the morning of the second day to obtain broad participation and input from workshop attendees.

On Wednesday, February 14, 1996, there will be a series of presentations by consumer organizations, health professional organizations, researchers, and academicians. There will be time set aside for comments and questions from workshop participants. On Thursday, February 15, 1996, workshop participants will be divided into several breakout groups for discussions and development of recommendations regarding elements of useful information. These recommendations will then be presented to the workshop participants with time for comments and questions.

FDA believes that it would be helpful for workshop participants, including FDA staff, to learn about the design of current patient information systems, particularly programs that generate drug-specific patient information. The agency invites the designers of primary information systems, not the customizers of systems for retail outlets, to display their systems at the workshop for educational purposes only. No sales or solicitations may be made by exhibitors at the workshop site. Due to space limitations, FDA may be forced to limit the number of systems on display. In doing so, FDA would seek to permit display of the most representative/comprehensive systems available for patient information. However, the agency invites all interested persons to submit their views, comments, and descriptions of computer programs to the Dockets Management Branch (address above).

The agency notes that the comment period for the proposed rule that published in the **Federal Register** of August 24, 1995, closed on December 22, 1995 (60 FR 58025, November 24, 1995). Because this workshop will occur after the comment period has closed, the agency will accept additional comments to the proposed rule on the specific issues raised at the workshop. These comments will be considered as part of the agency's deliberations regarding further action on this rulemaking. For this limited purpose, written comments may be submitted to the Dockets Management Branch (address above)

until March 6, 1996. Comments are to be identified with the docket number found in brackets in the heading of this document.

A summary of the workshop will be included in a subsequent Federal Register notice related to this prescription drug labeling initiative.

Dated: January 22, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–1740 Filed 1–29–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF STATE

Bureau of Economic and Business Affairs

22 CFR Part 89

[Public Notice No. 2323]

Foreign Prohibitions on Longshore Work by U.S. Nationals

AGENCY: Department of State.

ACTION: Proposed rule; Extension of comment period.

SUMMARY: On November 24, 1995, the Department of State issued a proposed rulemaking regarding longshore work by foreign nationals in U.S. ports and waters. To assess the full effects of the proposed rule, the Department is extending the deadline for comments by 7 days, from January 26, 1996 to February 2, 1996.

DATES: Interested parties are invited to submit comments in triplicate no later than February 2, 1996.

ADDRESSES: Comments may be mailed to the Office of Maritime and Land Transport (EB/TRA/MA), Room 5828, Department of State, Washington, DC 20520–5816.

FOR FURTHER INFORMATION CONTACT: Richard T. Miller, Office of Maritime and Land Transport, Department of State, (202) 647–6961.

SUPPLEMENTARY INFORMATION: On November 24, 1995, the Department of State issued a proposed rulemaking (60 FR 58026) updating the list of longshore work by particular activity, of countries where performance of such a particular activity by crewmembers aboard United States vessels is prohibited by law, regulation or in practice in the country. The crews of ships registered in or owned by nationals of the countries on the list may not perform the activities enumerated on the list. On December 20, 1995, the Department extended the comment period by thirty days in response to requests from a number of parties (60 FR 65609). To assess the full effects of the proposed rule, the Department is further extending the deadline for comments by one week, from January 26, 1996 to February 2, 1996.

(8 U.S.C. 1288, Pub. L. 010–649, 104 Stat, 4878)

Dated: January 25, 1996.

Daniel K. Tarullo,

Assistant Secretary Economic and Business Affairs Department of State.

[FR Doc. 96–1821 Filed 1–26–96; 10:43 am]

BILLING CODE 4710–07–M

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Parts 630, 635 and 771

[FHWA Docket No. 96–3]

RIN 2125–AD58

Federal-Aid Project Agreement and Contract Procedures

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of proposed rulemaking (NPRM); request for comments.

SUMMARY: The FHWA proposes to amend its regulation on project agreements. The Intermodal Surface Transportation Efficiency Act (ISTEA) of 1991 modified the requirement that preliminary engineering and right-of-way projects must be advanced to the construction stage within certain time limits. Changes to the agreement provisions are being proposed to reflect these adjustments. Additionally, procedures would be added to provide flexibility in the format of the agreement document and to permit the development of a single document to serve as both the project authorization and project agreement document. Other changes would be made to shorten the agreement document and to add clarity to the process.

The FHWA also proposes to amend its regulation on contract procedures by incorporating into it provisions regarding overruns in contract time that would be removed from the project agreement regulation. The FHWA believes this material more appropriately belongs under contract procedures.

DATES: Written comments are due on or before April 1, 1996. Comments received after that date will be considered to the extent practicable.

ADDRESSES: All written, signed comments should refer to the docket number that appears at the top of this document and should be submitted to Federal Highway Administration, Office of Chief Counsel, Room 4232, HCC–10, 400 Seventh Street, SW., Washington, DC 20590. All comments and suggestions received will be available for examination at the above address between 8:30 a.m. and 3:30 p.m., e.t., Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped postcard.

FOR FURTHER INFORMATION CONTACT: Jack Wasley, Office of Engineering, 202–366–0450, or Wilbert Baccus, Office of the Chief Counsel, 202–366–0780, FHWA, 400 Seventh Street, SW., Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m. e.t., Monday through Friday except Federal holidays.

SUPPLEMENTARY INFORMATION: Under the provisions of 23 U.S.C. 110, a formal agreement between the State highway agency and the FHWA is required for Federal-aid highway projects. This agreement, referred to as the "project agreement," is in essence a written contract between the State and the Federal Government defining the extent of the work to be undertaken, the State and the Federal shares of a project's cost, and commitments concerning maintenance of the project.

The present regulation, 23 CFR 630, subpart C, provides further requirements concerning the project agreement. It includes detailed instructions on preparation of the project agreement, a standard form for the agreement, and an assemblage of agreement provisions that are part of the standard form. This is a longstanding regulation and no significant changes have been made to it in several years.

It is the FHWA's desire to update and modify the existing regulation to incorporate needed changes to reflect adjustments made by the ISTEA, Pub. L. 102–240, 105 Stat. 1914, to streamline the project agreement form and provisions, and to allow more versatility in its use. The proposed changes are discussed in the following section-by-section analysis.

Section-by-Section Analysis

Section 630.301 Purpose

The statement of purpose would be revised with minor changes for clarity.

Section 630.302 Definitions

It is proposed to remove § 630.302. The terms *calendar day, contract time, incentives/disincentives for early completion, liquidated damages,* and *workday* would be relocated to 23 CFR 635.102. The terms *bond issue project,*

Federal-aid highway project, and *highway planning and research project* have such commonly recognized meanings that they would be removed from the regulation.

Since it is proposed to move § 630.305, Agreement provisions regarding overrun in contract time, without modification to 23 CFR 635.127, definitions relevant to § 630.305, i.e., *certification acceptance project*, *Division Administrator*, and *State highway agency*, would be removed from § 630.302.

Section 630.303 Policy

Section 630.303 would be combined with § 630.304 to create a new § 630.303, Preparation of agreement. A State would continue to be required to prepare a project agreement for each Federal-aid highway and FHWA planning and research project. However, it is proposed to eliminate Form PR–2 (Federal-Aid Project Agreement) and the instructions on its preparation. Instead, a State would develop its own form for the project agreement, provided it contains information identified as necessary by the regulation.

Additionally, the current practice of allowing the project agreement and project authorization (as required under 23 CFR 630, subpart A) to be combined into one document would be incorporated into the regulation. This section also would allow the use of electronic forms and signatures as developed and implemented by the FHWA.

Although the Form PR–2 would be eliminated from the regulation, it is anticipated a sample project agreement form would be added as nonregulatory guidance in the Federal-Aid Policy Guide. For illustrative purposes only, a copy of a sample project agreement is shown in Figure 1.

Section 630.304 Preparation of Agreement

This section would be eliminated because of the proposal to combine § 630.304 with § 630.303 to create a new § 630.303 with the section heading, Preparation of agreement. As discussed, the regulation would no longer provide for use of a specific form. Instead, a State would be allowed the flexibility to use whatever format is suitable to provide the information required for a project agreement document.

Section 630.305 Agreement Provisions Regarding Overruns in Contract Time

This section, which covers provisions regarding overruns in contract time, would be relocated to 23 CFR 635.127, without modification. Because these provisions deal with aspects of contract administration, they would more appropriately be included in FHWA's regulation on contract procedures, 23 CFR 635, subpart A.

Section 630.306 Modification of Original Agreement

It is proposed to revise this section and redesignate it as new § 630.305 with retention of the same section heading. A State would continue to be required to prepare a modification to a project agreement as changes occur. However, it is proposed to eliminate the specified Form PR–2A (Modification of Federal-Aid Project Agreement). Instead, a State could develop its own form for modification of project agreement, provided it contains necessary information as identified by the regulation.

Although the Form PR–2A would be eliminated from the regulation, it is anticipated that a sample form for a modification of project agreement would be added as nonregulatory guidance in FHWA's Federal-Aid Policy Guide (available for copying and inspection as prescribed at 49 CFR Part 7, appendix D). For illustrative purposes only, a copy of a sample modification of project agreement is shown in Figure 2.

Section 630.307 Agreement Provisions

A new section would be added identifying the provisions that must be a part of each agreement. Currently, the Form PR–2 contains 20 boilerplate provisions. These provisions take up three pages and add considerably to the bulk of the form. In addition, many provisions just restate requirements of law that apply to Federal-aid projects in general.

It is FHWA's desire to simplify the project agreement by eliminating all the boilerplate provisions from the agreement itself. The provisions that are necessary would be included in this section of the regulation. The simplified project agreement would then, by reference to this section, incorporate the provisions into each agreement. The following discussion covers each of the existing 20 boilerplate provisions and describes what deletions or revisions are being proposed.

Provision 1, Responsibility for Work, would be eliminated and replaced with the general provision that now appears on the top front of the sample project agreement form. (This would appear as § 630.307(a) in the proposed regulation.) Under this general provision, the State agrees to comply with title 23, United States Code (U.S.C.), the regulations implementing title 23, and the policies and procedures established by the FHWA. In addition, language has been added reflecting that States must also comply with all other applicable Federal laws and regulations. This general provision is broad in scope and there is little need for other provisions, such as, Provision 1 which covers only a limited feature of title 23, U.S.C.

Provision 2, Highway Planning and Research Project, would be eliminated. Requirements concerning planning, research funding, and projects are set forth in 23 CFR 420. In light of proposed new Provision 1 and its broad scope, there is no need for Provision 2.

Provision 3, Project for Acquisition of Rights-of-Way, would be retained (proposed § 630.307(c)(1)) because it corresponds to a requirement in 23 U.S.C. 108(a) that the agreement between the State and the FHWA shall include a provision that construction shall begin within a specified period of time. However, Provision 3 would be modified to change the specified time period from 10 years to 20 years. This reflects an amendment to 23 U.S.C. 108(a) resulting from passage of section 1017(a) of the ISTEA.

Provision 4, Preliminary Engineering Projects, would be retained (proposed § 630.307(c)(2)) but modified. Prior to passage of the ISTEA, this provision represented an administrative decision by the FHWA to require repayment of Federal-aid highway funds authorized for preliminary engineering if right-of-way acquisition or actual construction had not begun within 5 years after authorization of the preliminary engineering. The general concept of this provision is now found in the statute; section 1016(a) of the ISTEA incorporated this provision into 23 U.S.C. 102(b). One significant difference between the statutory provision and the existing FHWA practice is that 10 years instead of 5 years must pass before payback is required. Provision 4 would be modified to reflect the 10-year payback period.

Provision 5, Interstate System Project, would be eliminated. Requirements for agreements relating to use of and access to rights-of-way on the Interstate system are contained in 23 U.S.C. 111. In light of proposed new Provision 1 and its broad scope, there is no need for Provision 5.

Provision 6, Project for Construction in Advance of Apportionment, would be eliminated. The requirement in Provision 6(a) is adequately covered in 23 U.S.C. 115. Provision 6(b) is considered superfluous.

Provision 7, Stage Construction, would be eliminated. This is dated policy that is no longer appropriate in many cases.

Provision 8, Bond Issue Projects, would be eliminated. Requirements concerning bond projects are found in 23 U.S.C. 122 and the implementing regulation 23 CFR 630, subpart G. In light of proposed new Provision 1 and its broad scope, there would be no need for Provision 8.

Provision 9, Special Highway and Planning Research Project, would be eliminated. Requirements on planning and research projects are set forth in 23 CFR 420. In light of proposed new Provision 1 and its broad scope, there would be no need for Provision 9.

Provision 10, Parking Regulation and Traffic Control, would be eliminated. The State is ultimately responsible for any project undertaken with the cooperation of another government agency (23 CFR 1.3) and for maintenance of the project (23 U.S.C. 116 and 23 CFR 1.27). Adequately maintaining a project includes the issue of parking regulations and traffic control. In light of proposed new Provision 1 and its broad scope, there would be no need for Provision 10.

Provision 11, Signing and Marking, would be eliminated. The FHWA believes that 23 U.S.C. 109(d) and the implementing regulations in 23 CFR 655 adequately address this issue. In light of proposed new Provision 1 and its broad scope, there would be no need for Provision 11.

Provision 12, Maintenance, would be eliminated. Maintenance requirements for Federal-aid highway projects are found in 23 U.S.C. 116. In light of proposed new Provision 1 and its broad scope, there would be no need for Provision 12.

Provision 13, Liquidated Damages, would be eliminated. Requirements concerning liquidated damages are contained in FHWA regulations (presently in 23 CFR 630, subpart C, although this proposed rulemaking would transfer these requirements to 23 CFR 635, subpart A). In light of proposed new Provision 1 and its broad scope, there would be no need for Provision 13.

Provision 14, Implementation of Clear Air Act and Federal Water Pollution Control Act, would be eliminated. These are requirements of Federal law and they apply to Federal-aid projects in general. The existing reference in the project agreement to these other Federal laws serves no legal purpose and is considered extraneous information that could be removed from the form.

Provisions 15, 16 and 17, covering Equal Opportunity, Nondiscrimination, and Minority Business Enterprises, would be eliminated. These same requirements are expressed in 23 CFR 200, 230, and 633 subpart A. The three provisions have been updated and incorporated into the Form FHWA–1273, "Required Contract Provisions, Federal-Aid Construction Contracts." Subpart A of part 633 contains the regulatory requirements for Form FHWA–1273. In light of proposed new Provision 1 and its broad scope, there would be no need for Provisions 15, 16 and 17.

Provision 18, Bicycle Transportation and Pedestrian Walkways, would be eliminated. The requirements of this provision are found in 23 U.S.C. 217 and 23 CFR 652. In light of proposed new Provision 1 and its broad scope, there would be no need for Provision 18.

Provision 19, Modified or Terminated Highway Projects, would be eliminated. This provision merely highlights exceptions to the payback requirements that are found in other existing regulations. In light of proposed new Provision 1 and its broad scope, there would not be a need for Provision 19.

Provision 20, Environmental Impact Mitigation Features, would be removed from 23 CFR Part 630 and moved to 23 CFR Part 771. The requirements of this provision ensure that State Highway agencies comply with Federal mitigation standards as directed by the Council on Environmental Quality (CEQ) regulations for implementing National Environmental Policy Act (NEPA)(40 CFR 1505.3). The State Highway agencies would then be required to comply with 23 CFR 771 through the broad scope of proposed new Provision 1.

New provisions would be added to require that certain certifications be given to the FHWA. These certifications would be: § 630.307(c)(3) for drug-free workplace certification required by 49 CFR 29.630, § 630.307 (c)(4) for suspension/debarment certification required by 49 CFR 29.510, and § 630.307(c)(5) for lobbying certification required by 49 CFR 20.110. States must provide these certifications for each project. Placing language in the project agreement as part of the general provisions is considered an effective solution to providing a separate certification action for every project.

The FHWA is considering whether specific requirements of applicable Federal laws and regulations should be expressly covered in the proposed regulation. Proposed § 630.307(a) provides that the States generally agree, in the project agreement process, to comply with all other applicable Federal laws and regulations. This general provision would include laws such as title VI of the 1964 Civil Rights Act. The FHWA is considering whether reference should be made to specific laws, such as title VI. One possible option, for example, would be to have the regulation require certification to the FHWA by the State that it has met the Standard DOT title VI Assurance requirements, just as the proposed rule would require certification for a drug-free work-place or lobbying. Another option would be to list on the revised project agreement certain Federal laws, such as title VI, with which the State agrees to comply by signing the agreement itself. Comment is solicited on the need to specifically refer to other non-title 23 Federal laws and regulations with which the States must comply, such as through a statement incorporating those laws and regulations by reference or listing them directly on the project agreement form.

Appendix A—Federal-Aid Project Agreement, Form PR–2

The existing Form PR–2 would be eliminated. No specific form for the project agreement would be specified. Instead, a State would have the flexibility to develop its own form provided it includes the appropriate information. For illustrative purposes only, a copy of a sample project agreement is shown in Figure 1.

Appendix B—Modification of Federal-Aid Project Agreement, Form PR–2A

The existing Form PR–2A would be eliminated. No specific form for the modification of project agreement would be specified. Instead, a State would have the flexibility to develop its own form provided it includes the appropriate information. For illustrative purposes only, a copy of a sample modification of project agreement is shown in Figure 2.

Appendix C—Federal-Aid Project Agreement (National Cooperative Highway Research Program), Form PR–2.1.

This form would be eliminated. It is no longer needed because the greater flexibility for the project agreement process would allow for planning and research project requirements.

Section 635.102 Definitions

This section would incorporate the definitions contained in § 630.302(b), (d), (h), (i), and (k). These definitions apply to § 630.305, Agreement provisions regarding overrun in contract time. Due to the proposal to move § 630.305 to § 635.127, the definitions contained in § 630.302(b), (d), (h), (i), and (k) would be moved and inserted in alphabetical order into the definitions

currently in this section. The term *Secondary Road* Plan would be removed as this plan no longer exists.

Section 635.127 Agreement Provisions Regarding Overruns in Contract Time

It is proposed to redesignate § 630.305 as § 635.127. The text of the section would remain unchanged.

The following table is provided to assist the user in locating regulatory paragraph changes proposed by this rulemaking:

Old section	New section
630.301	630.301.
630.302	Removed (except (b), (d), (h), (i), and (k).
630.302(b)	635.102.
630.302(d)	635.102.
630.302(h)	635.102.
630.302(i)	635.102.
630.302(k)	635.102.
630.303	630.303.
630.304	630.303.
630.305	635.127.
630.306	630.305.
Appendix A	Removed.
Prov. 1	Removed.
Prov. 2	Removed.
Prov. 3	630.307(c)(1).
Prov. 4	630.307(c)(2).
Prov. 5 through 19	Removed.
Prov. 20	771.109(d).
Appendix B	Removed.
Appendix C	Removed.

BILLING CODE 4910–22–P

Figure 1

TO BE COMPLETED BY FHWA	FEDERAL-AID PROJECT AGREEMENT U.S. Department of Transportation Federal Highway Administration	STATE COUNTY PROJECT NO.

The State stipulates that as a condition to payment of the Federal funds obligated, it accepts and will comply with the agreement provisions set forth in 23 CFR 630.307.

PROJECT TERMINI

PROJECT CLASSIFICATION OR PHASE OF WORK	EFFECTIVE DATE OF AUTHORIZATION
FHWA PLANNING AND RESEARCH	
PRELIMINARY ENGINEERING	
RIGHTS-OF-WAY	
CONSTRUCTION	

OTHER (Specify)

ESTIMATED TOTAL COST OF PROJECT	IDENTIFY FEDERAL SHARE	AMOUNT OF FEDERAL FUNDS
$	☐ Pro Rata _____ % ☐ Lump Sum	$

_____
(Official name of Highway Agency)

By_____

_____
(Title)

By_____

_____
(Title)

By_____

_____
(Title)

U.S. DEPARTMENT OF TRANSPORTATION
FEDERAL HIGHWAY ADMINISTRATION

By_____
(Division Administrator)

Date executed by
Division Administrator _____

Figure 2

TO BE COMPLETED BY FHWA			
MONTHLY TRANSACTION NUMBER	U.S. Department of Transportation Federal Highway Administration	**MODIFICATION OF FEDERAL-AID PROJECT AGREEMENT**	State
PROJECT REPORT NUMBER			County
MODIFICATION NUMBER			Project Number

The Project Agreement for the above-referenced project entered into between the undersigned parties and executed by the Division Administrator on _____, 19 ____ is hereby modified as follows:.

	Former Amount	Revised Amount
Estimated total cost of project	$_____	$_____
Federal funds	$_____	$_____
Other revisions		

This modification is made for the following reasons:

All other terms and conditions of the Project Agreement will remain in full force and effect.

This modification is effective as of the _____ day of _____, 19 ____

_____
(Official name of Highway Agency)

By _____

_____
(Title)

By _____

_____
(Title)

By _____

_____
(Title)

U.S. DEPARTMENT OF TRANSPORTATION
FEDERAL HIGHWAY ADMINISTRATION

By _____
(Division Administrator)

BILLING CODE 4910-22-C

Rulemaking Analyses and Notices

All comments received before the close of business on the comment closing date indicated above will be considered and will be available for examination in the docket at the above address. Comments received after the comment closing date will be filed in the docket and will be considered to the extent practicable, but the FHWA may issue a final rule at any time after the close of the comment period. In addition to late comments, the FHWA will also continue to file relevant information in the docket as it becomes available after the comment closing date, and interested persons should continue to examine the docket for new material.

Executive Order 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures

The FHWA has determined that this action is not a significant regulatory action within the meaning of Executive Order 12866 or significant within the meaning of Department of Transportation regulatory policies and procedures. The proposed amendments would update the Federal-aid project agreement regulation to conform to recent laws, regulations, or guidance and to clarify existing policies. It is anticipated that the economic impact of this rulemaking will be minimal; therefore, a full regulatory evaluation is not required.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (5 U.S.C. 601–612), the FHWA has evaluated the effects of this rule on small entities. Based on the evaluation, the FHWA certifies that this action will not have a significant economic impact on a substantial number of small entities. The proposed amendments would clarify or simplify procedures used by State highway agencies in accordance with existing laws, regulations, or guidance.

Executive Order 12612 (Federalism Assessment)

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

Executive Order 12372 (Intergovernmental Review)

Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.

Paperwork Reduction Act

The information collection requirements associated with this rulemaking in § 630.303 have been approved by the Office of Management and Budget under control number OMB 2125–0529 and expire June 30, 1997. The information collection requirements associated with this rulemaking would update and modify existing requirements to reflect statutory changes to the project agreement process enacted by the ISTEA, streamline the project agreement form and provisions, and allow more versatility in its use.

National Environmental Policy Act

The agency has analyzed this action for the purpose of the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq.) and has determined that this action would not have any effect on the quality of the environment.

Regulation Identification Number

A regulation identification number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading of this document can be used to cross reference this action with the Unified Agenda.

List of Subjects in 23 CFR Parts 630, 635, and 771

Government contracts, Grant programs—Transportation, Highways and roads, Project agreement procedures.

In consideration of the foregoing, the FHWA proposes to amend Title 23, Code of Federal Regulations, by revising Parts 630, 635, and 771 as set forth below.

Issued on: January 12, 1996.

Rodney E. Slater,

Federal Highway Administrator.

PART 630—PRECONSTRUCTION PROCEDURES

1. The authority citation for part 630 is revised to read as follows and all other authority citations which appear throughout part 630 are removed:

Authority: 23 U.S.C. 105, 106, 109, 110, 115, 315, 320, and 402(a); 23 CFR 1.32; 49 CFR 1.48(b).

PART 635—[AMENDED]

2. The authority citation for part 635 is revised to read as follows:

Authority: 23 U.S.C. 101(note), 109, 112, 113, 114, 116, 117, 119, 128, and 315; 31 U.S.C. 6506; 42 U.S.C. 3334, 4601 *et seq.*; 23 CFR 1.32; 49 CFR 1.48(b); sec. 1041(a), Pub. L. 102–240, 105 Stat. 1914.

§ 630.305 [Redesignated as § 635.127]

3. Section 630.305 is redesignated as § 635.127.

4. Part 630, subpart C is revised to read as follows:

Subpart C—Project Agreements

Sec.

§ 630.301 Purpose.

The purpose of this subpart is to prescribe the procedures for the execution of the project agreement required by 23 U.S.C. 110(a) for Federal-aid projects, except for forest highway projects pursuant to 23 U.S.C. 204, and for non-highway public mass transit projects administered by the Federal Transit Administration.

§ 630.303 Preparation of agreement.

(a) The State highway agency (SHA) shall prepare a project agreement for each Federal-aid highway and FHWA planning and research project eligible for Federal-aid funding.

(b) The SHA may develop the project agreement in a format acceptable to both the SHA and the FHWA provided the following are included:

(1) A description of the project location including State and project termini;

(2) The Federal-aid project number;

(3) The phases of work covered by the agreement along with the effective date of authorization for each phase;

(4) The total project cost and amount of Federal funds under agreement;

(5) The Federal share expressed as either a pro rata percentage or a lump sum;

(6) A statement that the State accepts and will comply with the agreement provisions set forth in 23 CFR 630.307; and

(7) Signatures of officials from both the State and the FHWA and date executed.

(c) The project agreement may be combined with the project authorization required under 23 CFR 630, Subpart A.

(d) The SHA may use an electronic version of the agreement as provided by the FHWA.

(Approved by the Office of Management and Budget under control number 2125–0529)

§ 630.305 Modification of original agreement.

(a) When changes are needed to the original project agreement, a modification of agreement shall be prepared.

(b) The SHA may develop the modification of project agreement in a format acceptable to both the SHA and the FHWA provided the following are included:

(1) The Federal-aid project number and State;

(2) A sequential number identifying the modification;

(3) A reference to the date of the original project agreement to be modified;

(4) The original total project cost and the original amount of Federal funds under agreement;

(5) The revised total project cost and the revised amount of Federal funds under agreement;

(6) The reason for the modifications; and,

(7) Signatures of officials from both the State and the FHWA and date executed.

(c) The SHA may use an electronic version of the modification of project agreement as provided by the FHWA.

§ 630.307 Agreement provisions.

(a) The State, through its highway agency, accepts and agrees to comply with the applicable terms and conditions set forth in Title 23, United States Code, Highways, the regulations issued pursuant thereto, the policies and procedures promulgated by the FHWA relative to the designated project in which the FHWA authorized certain work to proceed, and all other applicable Federal laws and regulations.

(b) Federal funds obligated for the project must not exceed the amount agreed to on the project agreement, the balance of the estimated total cost being an obligation of the State. Such obligation of Federal funds extends only to project costs incurred by the State after the FHWA authorization to proceed with the project involving such costs.

(c) The State must stipulate that as a condition to payment of the Federal funds obligated, it accepts and will comply with the following applicable provisions:

(1) *Project for acquisition of rights-of-way.* In the event that actual construction of a road on this right-of-way is not undertaken by the close of the twentieth fiscal year following the fiscal year in which the project is authorized, the SHA will repay to the FHWA the sum or sums of Federal funds paid to the highway agency under the terms of the agreement.

(2) *Preliminary engineering project.* In the event that right-of-way acquisition for, or actual construction of, the road for which this preliminary engineering is undertaken is not started by the close of the tenth fiscal year following the fiscal year in which the project is authorized, the SHA will repay to the FHWA the sum or sums of Federal funds paid to the highway agency under the terms of the agreement.

(3) *Drug-free workplace certification.* The SHA agrees that it will provide a drug-free workplace by:

(i) Publishing a statement notifying its employees that the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance is prohibited in the SHA's workplace and specifying the actions that will be taken against employees for violation of such prohibition;

(ii) Establishing an ongoing drug-free awareness program to inform its employees about—

(A) The dangers of drug abuse in the workplace;

(B) The SHA's policy of maintaining a drug-free workplace;

(C) Any available drug counseling, rehabilitation, and employment assistance programs; and

(D) The penalties that may be imposed upon employees for drug abuse violations occurring at the workplace;

(iii) Making it a requirement that each of its employees engaged in the performance of the work covered by the project agreement be given a copy of the statement required by paragraph (c)(3)(i) of this section;

(iv) Notifying its employees in the statement required by paragraph (c)(3)(i) of this section that, as a condition of employment on work covered by the project agreement, the employee will—

(A) Abide by the terms of the statement; and

(B) Notify the employer in writing of his/her conviction for a violation of a criminal drug statute occurring in the workplace no later than 5 calendar days after such conviction;

(v) Notifying the FHWA Division Administrator in writing, within 10 calendar days after receiving notice under paragraph (c)(3)(iv)(B) of this section from an employee or otherwise receiving actual notice of such conviction. Such notification shall include the employee's position title and the identification number(s) of the project(s) employed on;

(vi) Taking one of the following actions, within 30 calendar days of receiving notice under paragraph (c)(3)(iv)(B), with respect to any of its employees so convicted—

(A) Taking appropriate personnel action against such an employee, up to and including termination, consistent with the requirements of the Rehabilitation Act of 1973, Public Law 93–112, 87 Stat. 355, as amended; or

(B) Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purpose by a Federal, State, or local health, law enforcement, or other appropriate agency;

(vii) Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (c)(1) through (c)(5) of this section.

(4) *Suspension and debarment certification.* The SHA agrees that its principals engaged in the performance of the work covered by the project agreement:

(i) Are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded by any Federal Department or Agency;

(ii) Have not within a 3-year period preceding the agreement been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State or local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;

(iii) Are not presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State or local) with commission of any of the offenses enumerated in paragraph (c)(4)(ii) of this section; and

(iv) Have not within a 3-year period preceding the agreement had one or more public transactions (Federal, State or local) terminated for cause or default.

(5) *Lobbying certification.* The SHA agrees that:

(i) No Federal appropriated funds have been paid or will be paid, by or on behalf of the SHA, to any person for influencing or attempting to influence an officer or employee of a Federal agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any contract, or modification of any contract covered by the project agreement;

(ii) If any funds, other than Federal appropriated funds, have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any Federal agency, a Member of Congress, or an employee of a Member of Congress in connection with work covered by the project agreement, the SHA shall complete and submit to the FHWA Division Administrator Standard Form-LLL,[1] Disclosure Form to Report Lobbying, in accordance with its instructions;

(iii) The language of this certification shall be included in the award documents for all contracts and subcontracts, covered by the project agreement, which exceed $100,000 and all recipients of such contracts and subcontracts shall be required to certify and disclose accordingly.

PART 635—CONSTRUCTION AND MAINTENANCE [AMENDED]

5. Subpart A of part 635 is amended by revising § 635.102 to read as follows:

§ 635.102 Definitions.

As used in this subpart:

Administrator means the Federal Highway Administrator.

Calendar day means each day shown on the calendar but, if another definition is set forth in the State contract specifications, that definition will apply.

Certification acceptance means the alternative procedure which may be used for administering certain highway projects involving Federal funds pursuant to 23 U.S.C. 117.

Contract time means the number of workdays or calendar days specified in a contract for completion of the contract work. The term includes authorized time extensions.

Division Administrator means the chief FHWA official assigned to conduct business in a particular State. A State is as defined in 23 U.S.C. 101.

Force account means a basis of payment for the direct performance of highway construction work with payment based on the actual cost of labor, equipment, and materials furnished and consideration for overhead and profit.

Formal approval means approval in writing or the electronic transmission of such approval.

Incentive/disincentive for early completion as used in this subpart, describes a contract provision which compensates the contractor a certain amount of money for each day identified critical work is completed ahead of schedule and assesses a deduction for each day the contractor overruns the incentive/disincentive time. Its use is primarily intended for those critical projects where traffic inconvenience and delays are to be held to a minimum. The amounts are based upon estimates of such items as traffic safety, traffic maintenance, and road user delay costs.

Liquidated damages means the daily amount set forth in the contract to be deducted from the contract price to cover additional costs incurred by a State highway agency because of the contractor's failure to complete the contract work within the number of calendar days or workdays specified. The term may also mean the total of all daily amounts deducted under the terms of a particular contract.

Local public agency means any city, county, township, municipality, or other political subdivision that may be empowered to cooperate with the State highway agency in highway matters.

Major change or major extra work means a change which will significantly affect the cost of the project to the Federal Government or alter the termini, character or scope of the work.

Materially unbalanced bid means a bid which generates a reasonable doubt that award to the bidder submitting a mathematically unbalanced bid will result in the lowest ultimate cost to the Federal Government.

Mathematically unbalanced bid means a bid containing lump sum or unit bid items which do not reflect reasonable actual costs plus a reasonable proportionate share of the bidder's anticipated profit, overhead costs, and other indirect costs.

Public agency means any organization with administrative or functional responsibilities which are directly or indirectly affiliated with a governmental body of any nation, State, or local jurisdiction.

Publicly owned equipment means equipment previously purchased or otherwise acquired by the public agency involved primarily for use in its own operations.

Specialty items means work items identified in the contract which are not normally associated with highway construction and require highly specialized knowledge, abilities or equipment not ordinarily available in the type of contracting organizations qualified and expected to bid on the contract; in general these items are to be limited to minor components of the overall contract.

State highway agency (SHA) means that department, commission, board, or official of any State charged by its laws with the responsibility for highway construction. The term "State" should be considered equivalent to "State highway agency" if the context so implies.

Workday means a calendar day during which construction operations could proceed for a major part of a shift, normally excluding Saturdays, Sundays, and State-recognized legal holidays.

PART 771—ENVIRONMENTAL IMPACT AND RELATED PROCEDURES

6. The authority citation for part 771 is revised to read as follows and all other authority citations which appear throughout part 771 are removed:

Authority: 42 U.S.C. 4321 et seq.; 23 U.S.C. 109, 110, 128, 138 and 315; 49 U.S.C. 303(c), 5301(e), 5323, and 5324; 40 CFR part 1500 et seq.; 49 CFR 1.48(b) and 1.51.

§ 771.109 [Amended]

7. Section 771.109 is amended by adding paragraph (d) to read as follows:

* * * * *

(d) When entering into Federal-aid project agreements pursuant to 23 U.S.C. 110, it shall be the responsibility of the State highway agency to ensure that the project is constructed in accordance with and incorporates all committed environmental impact mitigation measures listed in approved environmental documents unless the State requests and receives written Federal Highway Administration approval to modify or delete such mitigation features.

[FR Doc. 96–1156 Filed 1–29–96; 8:45 am]
BILLING CODE 4910–22–P

[1] The FHWA Division Office can provide the latest information on the availability of this form.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[FRL–5321–5]

Approval and Promulgation of Implementation Plans and Designation of Areas for Air Quality Planning Purposes; State of Massachusetts; Change in National Policy Regarding Applicability of Conformity Requirements to Redesignation Requests

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA proposes to approve the State Implementation Plan (SIP) revision submitted by the State of Massachusetts to redesignate the Boston area from nonattainment to attainment

for carbon monoxide (CO). Under the Clean Air Act as amended in 1990 (CAA), designations can be revised if sufficient data is available to warrant such revisions.

In addition, EPA is proposing approval of two related State Implementation Plan (SIP) submissions by Massachusetts DEP. On November 15, 1993, Massachusetts DEP submitted a final 1990 base year emission inventory for CO emissions, which includes emissions data for all sources of CO in Massachusetts' CO nonattainment areas, as well as CO emissions for the entire State. On October 29, 1993, Massachusetts DEP submitted an oxygenated fuel program for the Boston consolidated metropolitan statistical area (CMSA).

In the Final Rules Section of this **Federal Register**, EPA is approving the CO emissions inventory and the oxygenated fuels program as a direct final rule.

In addition, EPA is also approving Massachusetts' redesignation request as a direct final rule without prior proposal. A detailed rationale for the action is set forth in the direct final rule, including a modification in national policy regarding the need for a conformity SIP submission prior to redesignation of an area. If no adverse comments are received in response to that direct final rule, no further activity is contemplated in relation to this proposed rule. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this notice. Any parties interested in commenting on this notice should do so at this time.

DATES: Comments must be received by February 29, 1996.

ADDRESSES: Written comments should be sent to Susan Studlien, Acting Director of the Air, Pesticides and Toxics Management Division, at the EPA Regional Office listed below. Copies of the redesignation request and the State of Massachusetts' submittal are available for public review during normal business hours at the addresses listed below.

Air and Radiation Docket and Information Center, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, and; Environmental Protection Agency, One Congress Street, Boston, MA 02203.

FOR FURTHER INFORMATION CONTACT: Wing Chau of the EPA Region I Air, Pesticides and Toxics Management Division at (617) 565–3240. Dated: September 29, 1995.

John P. DeVillars,

Regional Administrator, Region I.

[FR Doc. 96–1590 Filed 1–29–96; 8:45 am]

BILLING CODE 6560–50–P

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40 CFR Parts 52 and 81

[SIPTRAX NO. PA075–4001b; PA075–4002b; PA024–4005b; FRL–5329–2]

Approval and Promulgation of Implementation Plans; Designation of Areas for Air Quality Planning Purposes; Redesignation of the Philadelphia County Carbon Monoxide Area to Attainment and Approval of the Area's Maintenance Plan and the Philadelphia County 1990 Base Year Carbon Monoxide Emission Inventory; Commonwealth of Pennsylvania

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve the State Implementation Plan (SIP) revision submitted by the Commonwealth of Pennsylvania for the purpose of approving a maintenance plan, the 1990 base year carbon monoxide (CO) emissions inventory for Philadelphia County and a request to redesignate the Philadelphia County carbon monoxide nonattainment area, from nonattainment to attainment for CO. In the Final Rules section of this **Federal Register**, EPA is approving the Commonwealth's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial SIP revision and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this proposed rule, no further activity is contemplated in relation to this rule. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time.

DATES: Comments must be received in writing by February 29, 1996.

ADDRESSES: Written comments on this action should be addressed to Marcia L. Spink, Associate Director, Air Programs, Mailcode 3AT00, U.S. Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, Pennsylvania 19107. Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air, Radiation, and Toxics Division, U.S. Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, Pennsylvania 19107; Pennsylvania Department of the Environment, Bureau of Air Quality, P.O. Box 8468, 400 Market Street, Harrisburg, Pennsylvania 17105 and Philadelphia Department of Public Health, Air Management Services, 321 University Avenue, Philadelphia, Pennsylvania 19104.

FOR FURTHER INFORMATION CONTACT: Kelly L. Bunker, (215) 597–4554.

SUPPLEMENTARY INFORMATION: See the information provided in the Direct Final action, titled, Approval and Promulgation of Implementation Plans; Designation of Areas for Air Quality Planning Purposes; Redesignation of the Philadelphia County Carbon Monoxide Area to Attainment and Approval of the Area's Maintenance Plan and the Philadelphia County 1990 Base Year Carbon Monoxide Emission Inventory; Commonwealth of Pennsylvania, which is located in the Rules and Regulations Section of this **Federal Register**.

List of Subjects in

40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements.

40 CFR Part 81

Air pollution control.

Authority: 42 U.S.C. 7401–7671q.

Dated: October 31, 1995.

Stanley Laskowski,

Acting Regional Administrator, Region III.

[FR Doc. 96–1103 Filed 1–29–96; 8:45 am]

BILLING CODE 6560–50–P

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40 CFR Parts 52 and 81

[FRL–5325–1]

Approval and Promulgation of Implementation Plans; Designation of Areas for Air Quality Planning Purposes; Redesignation of the Metropolitan Washington Carbon Monoxide Area to Attainment and Approval of the Area's Maintenance Plan and Emission Inventory; Commonwealth of Virginia, District of Columbia and the State of Maryland

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve the State Implementation Plan (SIP) revision submitted on October 4, 1995 and October 12, 1995, by the Commonwealth of Virginia and the State of Maryland and the District of Columbia, respectively, for the purpose of approving a maintenance plan and a request to redesignate the Metropolitan Washington area; including the Counties of Alexandria and Arlington, Virginia; Prince Georges and Montgomery Counties in Maryland, and the District of Columbia (the "Washington Carbon Monoxide (CO) nonattainment area") from nonattainment to attainment for CO. In the Final Rules section of this **Federal Register**, EPA is approving the State's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial SIP revision and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this proposed rule, no further activity is contemplated in relation to this rule. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time.

DATES: Comments must be received in writing by February 29, 1996.

ADDRESSES: Written comments on this action should be addressed to Marcia L. Spink, Associate Director, Air Programs, Mailcode 3AT00, U.S. Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, Pennsylvania 19107. Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air, Radiation, and Toxics Division, U.S. Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, Pennsylvania 19107; District of Columbia Department of Consumer and Regulatory Affairs, 2100 Martin Luther King Avenue, SE., Washington, DC 20020; Maryland Department of the Environment, 2500 Broening Highway, Baltimore, Maryland, 21224; Virginia Department of Environmental Quality, 629 East Main Street, Richmond, Virginia, 23219.

FOR FURTHER INFORMATION CONTACT: Kelly A. Sheckler, (215) 597–6863.

SUPPLEMENTARY INFORMATION: See the information provided in the Direct Final action, titled, Approval and Promulgation of Implementation Plans; Designation of Areas for Air Quality Planning Purposes; Redesignation of the Washington Metropolitan Carbon Monoxide Area to Attainment and Approval of the Area's Maintenance Plan and Emission Inventory; Commonwealth of Virginia, States of Maryland and the District of Columbia, which is located in the Rules and Regulations Section of this **Federal Register**.

Authority: 42 U.S.C. 7401–7671q.

Dated: October 23, 1995.

Stanley Laskowski,

Acting Regional Administrator, Region III.

[FR Doc. 96–1591 Filed 1–29–96; 8:45 am]

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40 CFR Part 70

[NJ001; FRL–5403–8]

Clean Air Act Proposed Interim Approval of Operating Permit Program; New Jersey

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed interim approval.

SUMMARY: EPA proposes source category-limited interim approval of the operating permit program submitted by the State of New Jersey for the purpose of complying with federal requirements which mandate that states develop, and submit to EPA, programs for issuing operating permits to all major stationary sources and to certain other sources.

DATES: Comments on this proposed action must be received in writing by February 29, 1996.

ADDRESSES: Written comments on this action should be addressed to Steven C. Riva, Chief, Permitting/Toxics Supports Section, Air Compliance Branch, at the EPA Region 2 office listed below. Copies of New Jersey's submittal and other supporting information used in developing the proposed interim approval are available for inspection during normal business hours at the following location: U.S. Environmental Protection Agency, Region 2, 290 Broadway, 21st Floor, New York, NY 10007–1866.

FOR FURTHER INFORMATION CONTACT: Ms. Suilin Chan, Air and Waste Management Division, U.S. Environmental Protection Agency, Region 2, 290 Broadway, 21st Floor, New York, NY 10007–1866, (212) 637–4019.

SUPPLEMENTARY INFORMATION:

I. Background and Purpose

A. Introduction

As required under title V of the Clean Air Act ("the Act") as amended by the 1990 Clean Air Act Amendments, EPA promulgated rules on July 21, 1992 (57 FR 32250), that define the minimum elements of an approvable state operating permit program and the corresponding standards and procedures by which EPA will approve, oversee, and withdraw approval of state operating permit programs. These rules are codified at 40 Code of Federal Regulations (CFR) Part 70. Title V and Part 70 require that states develop, and submit to EPA, programs for issuing operating permits to all major stationary sources and to certain other sources.

The Act requires states to develop and submit these programs to EPA by November 15, 1993, and EPA to approve or disapprove such program within one year after receiving the complete submittal. If the State's submission is materially changed during the one-year review period, 40 CFR § 70.4(e)(2) allows EPA to extend the review period for no more than one year following receipt of the additional materials. EPA reviews state operating permit programs pursuant to section 502 of the Act and 40 CFR Part 70, which together outline the criteria for approval or disapproval. Where a program substantially, but not fully, meets the requirements of Part 70, EPA may grant the program interim approval for a period of up to two years. Additionally, where a state can demonstrate to the satisfaction of EPA that reasons exist to justify granting a source category-limited interim approval, EPA may so exercise its authority. A program with a source category-limited interim approval is one that substantially meets the requirements of Part 70 and that applies to at least 60% of all affected sources which account for 80% of the total emissions within the state. If EPA has not fully approved a program by November 15, 1995, or by the end of an interim program, it must establish and implement a federal operating permit program for that state.

EPA received New Jersey's title V operating permit program submittal initially on November 19, 1993. However, EPA found that submittal to be incomplete. In a February 4, 1994 letter to the New Jersey Department of Environmental Protection (NJDEP), EPA informed New Jersey of the incompleteness determination and listed the deficiencies that must be corrected. EPA received New Jersey's

August 10th, 1995, revised program submittal on August 21, 1995 which EPA determined to be complete on September 5, 1995.

B. Federal Oversight and Sanctions

Following the granting of final interim approval, if New Jersey failed to submit a complete corrected program for full approval by the date six months before expiration of the interim approval or if EPA disapproved New Jersey's corrected program submittal, EPA would start an 18-month clock for mandatory sanctions in either situation. If and when the 18 months expire and New Jersey fails to submit a complete corrected program to address the deficiencies identified in the interim approval or identified in the disapproval, whichever the case may be, EPA would be required to apply one of the sanctions in section 179(b) of the Act. In either case, the sanction would remain in effect until EPA determines that New Jersey had corrected the deficiencies that triggered the mandatory sanctions clock. If six months after application of the first sanction, New Jersey still had not submitted the requisite complete program, a second sanction would be applied. Moreover, if the Administrator found a lack of good faith on the Part of New Jersey, both sanctions under section 179(b) would apply after the expiration of the 18-month period until the Administrator determines that New Jersey had come into compliance.

In addition, discretionary sanctions may be applied where warranted any time after an interim approval expires and a state has failed to submit a timely and complete corrected program or EPA has disapproved a corrected program. Moreover, if a state does not have in place an approved full program by the expiration date of its interim approval or an approved program by the time the federal operating permit program, to be codified at 40 CFR Part 71, is promulgated, EPA is mandated to administer and enforce the federal program for that state.

II. Proposed Action and Implications

EPA has concluded that the operating permit program submitted by New Jersey substantially meets the requirements of title V and Part 70. Based upon EPA's review of New Jersey's request for source category-limited interim approval and the substantiation submitted thereto and of New Jersey's operating permit program in its entirety, EPA proposes to grant source category-limited interim approval to the New Jersey program. For detailed information on the analysis of the State's submission, please refer to the Technical Support Document (TSD) contained in the docket at the address noted above.

A. Analysis of State Submission

1. Support Materials

Pursuant to section 502(d) of the Act, each state must develop and submit to the Administrator an operating permit program under state or local law or under an interstate compact meeting the requirements of title V of the Act. On November 19, 1993, EPA received the title V operating permit program submitted by the State of New Jersey and supplemental information submitted on August 10, 1995, and August 28, 1995. The New Jersey Department of Environmental Protection (NJDEP) requested, under the signature of the New Jersey Governor's designee, Commissioner Robert C. Shinn Jr. of the NJDEP, a source category-limited interim approval of New Jersey's operating permit program with full authority to administer the program in all areas of the State of New Jersey.

The following documents which were submitted by the State of New Jersey in support of its request for a source category-limited interim approval have been reviewed by EPA and have been found to substantially meet the Part 70 requirements.

1. Pursuant to 40 CFR § 70.4(b)(1), a complete program description is presented under Chapter 3 of Volume I providing detailed discussions on how the state intends to carry out its title V responsibilities.

2. Pursuant to 40 CFR § 70.4(b)(2), the regulations that comprise the permitting program is submitted under *Appendix A* of Volume II and copies of all applicable state or local statutes and regulations are included in *Appendix* C of Volume II.

3. Pursuant to 40 CFR § 70.4(b)(3), a legal opinion from the State Attorney General is presented in *Appendix B* of Volume II. New Jersey has demonstrated that the NJDEP has adequate authority to carry out all aspects of New Jersey's operating permit program.

4. Pursuant to 40 CFR § 70.4(b)(4), copies of the permit application forms and relevant guidance that will assist in the State's implementation of the operating permit program are presented in *Appendices F and G* of Volume II. No permit form has been submitted by New Jersey since each permit will be issued with conditions specific to the source's operation. The contents of an operating permit is listed in N.J.A.C. 7:27–22.16.

5. Pursuant to 40 CFR § 70.4(b)(5), a complete description of the State's compliance tracking and enforcement program is presented in Chapter 6 of Volume I. This document describes how New Jersey will use its data management system (AIMS) to track and report enforcement activities. It also reaffirms New Jersey's commitment to continue to follow air enforcement strategies stipulated in previous enforcement agreements it has entered with the EPA.

6. Pursuant to 40 CFR § 70.4(b)(6) and § 70.4(b)(8), a description of the state permit procedures and a statement on adequate personnel and funding is presented in Chapter 4 of Volume I. This chapter describes how the permit application reviews will be coordinated with the other offices with NJDEP and what the duties of the agency personnel will be for implementing the program.

7. Pursuant to 40 CFR § 70.4(b)(7), a fee demonstration and a workload analysis are presented in *Appendices D and E* of Volume II. New Jersey adopted the presumptive minimum fee of $25 per ton of pollutant per year (adjusted by the Consumer Price Index based on the 1989 value) and is presumed to have adequate funding for the development and implementation of its operating permit program.

8. Pursuant to 40 CFR § 70.4(b)(9), New Jersey committed to provide quarterly reports on enforcement activities via its data management system as discussed in Chapter 5 of Volume I.

9. Pursuant to 40 CFR § 70.4(b)(11), a transition plan is presented in Chapter 2 of Volume I describing the application submittal schedule and the permitting timeframe for the initial permits. Also discussed in this chapter is New Jersey's rationale for requesting source category-limited interim approval. New Jersey has demonstrated in this chapter that its operating permit program will meet the 60/80 percent tests which require that the interim program applies to at least 60% of the total number of Part 70-affected sources in New Jersey and that these sources account for at least 80% of the total emissions.

2. Regulations and Program Implementation

The State of New Jersey adopted regulations in Subchapter 22 of Chapter 27 of the New Jersey Administrative Code (N.J.A.C. 7:27–22) for the implementation of the requirements of 40 CFR Part 70. This rule, which was initially adopted on October 3, 1994, was re-proposed with changes and adopted in August 10, 1995. There is sufficient evidence such as responses to comments showing that the rule adoptions were procedurally correct as required by 40 CFR § 70.4(b)(2). The New Jersey operating permit rule which

contains the lists of exempt activities, insignificant operations, and two tables of excluded emissions are included in *Appendix A* of Volume II. The other applicable state statutes and regulations are included in *Appendix C* of Volume II. Based on EPA's review, none of the applicable state statutes or regulations restricts implementation of the New Jersey operating permit program. New Jersey's rule meets the main requirements of Part 70 as described below:

a. Applicability (40 CFR § 70.2 and § 70.3):

(1) New Jersey's rule requires facilities with the potential-to-emit of any pollutants at major source threshold levels to obtain operating permits. Facilities subject to requirements that are not listed in N.J.A.C. 7:27–22.2(a) will not be subject to the New Jersey operating permit program (i.e., non-major sources subject to § 111 or § 112 of the Act (NSPS or NESHAP)). New Jersey has elected to defer these non-major sources until EPA completes rulemaking with respect to future applicability. This is consistent with 40 CFR § 70.3(b)(1). However, 40 CFR § 70.3(b)(2) states that non-major sources subject to standards promulgated after July 21, 1992 are required to obtain an operating permit unless the standard itself contains specific language that would exempt them from Part 70 requirements. EPA interprets this Part 70 provision to mean that if the standard were promulgated without the exemption clause, a Part 70 exemption for non-major sources is assumed not to exist and all sources covered under that standard are required to obtain an operating permit. Although New Jersey's rule in N.J.A.C. 7:27–22.2(b) alludes to an EPA rulemaking as the triggering factor for title V applicability to non-major sources, it does provide NJDEP with the necessary regulatory authority to permit under Part 70 those non-major sources that are not exempt from post-1992 standards based on its reference to 40 CFR § 70.3(b)(2). Therefore, EPA does not find this to be a problem for granting interim approval. In addition, section 22.5(i) of New Jersey's rule provides the mechanism under which non-major sources would be required to submit an application. To ensure that national consistency is maintained in the implementation of 40 CFR § 70.3(b)(2), EPA will require New Jersey to submit a commitment in the corrected program asserting that New Jersey will require non-major sources subject to section 111 and 112 standards promulgated after July 21, 1992 to apply for an operating permit as required by the Administrator. Applications from these sources should be submitted in accordance with the schedule specified in the standard and/or rulemaking. This commitment must be submitted in order to receive full program approval.

(2) New Jersey's rule excludes activities such as office equipment, water storage tanks, and other minimally emitting facilities from the operating permit application. The entire list of exempt activities is included in the definition section of the New Jersey rule (N.J.A.C. 7:27–22.1). Since these facilities either do not emit any air pollutants or are not part of a source's production process, EPA finds it appropriate to exclude them from the operating permit application. EPA believes exclusion of the listed activities from the application is highly unlikely to interfere with determining applicability of or imposing any applicable requirements. In addition, N.J.A.C. 7:27–22.6(f)(5) requires that permit applications contain all information needed to determine the applicability of or to impose any applicable requirement. Therefore, EPA proposes to approve the list of exempt activity as defined in N.J.A.C. 7:27–22.1 from New Jersey's operating permit program. This list may be expanded with prior EPA input and approval during the state rulemaking process for the rule revision consistent with 40 CFR § 70.4(i).

(3) Consistent with the Part 70 regulations, New Jersey's rule requires inclusion of fugitive emissions only if the source belongs to one of the 27 source categories listed in 40 CFR § 70.2.

(4) New Jersey's rule at N.J.A.C 7:27–22.2 did not include the "support facility test" as an additional criterion for separating the R & D facility from the primary source operation. EPA does not find this to be an issue for program approval since New Jersey's R&D definition requires that the R&D facility not be "engaged in the manufacture of products for commercial sale, except in a de minimis manner". However, it is EPA's understanding of New Jersey's intention that if the R&D facility is not connected to the manufacturing process except in a de minimis capacity that the R&D facility would not be a support facility to the manufacturing process. Thus, if the R&D facility is contributing to the manufacturing process in a material, rather than de minimis capacity, it would be a support facility to the manufacturing process. Under the support facility test, co-located and commonly owned sources would be considered one source (and therefore their emissions aggregated) if the output of one is more than 50 percent devoted to support the other.

(5) New Jersey's rule at N.J.A.C.7:27–22.2(d) allows sources with equipment that can be operated in both R&D and manufacturing modes to segregate emissions attributable to the R&D operation from the source's potential to emit when determining whether the source is major. In many cases, the segregation could result in separating a facility into a minor facility and a R&D facility which would render the source as a whole not subject to Part 70. In order for the entire facility to be excluded from the Part 70 requirements, federally enforceable permit conditions must be obtained by the source. As in other synthetic minor situations, New Jersey plans to use its SIP-approved new source review preconstruction permit program to provide the federally enforceable permit limitations necessary to cap source emissions at below the title V major source threshold levels. New Jersey provided a supplement to the August 10, 1995 title V operating permit program which describes in detail how these sources will be capped out of the New Jersey operating permit program. Based upon EPA's review, the mechanism to be used by New Jersey to limit emissions from such "dual equipment" is federally and practicably enforceable and is sufficient to prevent Part 70 circumvention.

The "dual equipment" type sources are subject to federally enforceable NSR requirements if the source (and its associated process units) meets the criteria set out in the NSR regulations of New Jersey's rule (N.J.A.C. 7:27–8). Most of these types of sources become subject to New Jersey's NSR requirements because they process more than 50 pounds per hour of all materials combined with the exclusion of air and water. The permit issued to such sources is called a "Dual Permit" which consists of two sections, one specific to the R&D operation and the other to the manufacturing operation. The permit also contains common emission caps for each pollutant with recordkeeping requirements to monitor when the emission limits will be reached. When the emission limits are reached, the source is required to cease operation of all equipment or process covered under the permit or apply for a permit revision to raise the emission limits, at which time additional requirements such as installation of the state-of-the-art controls may be required. Although it has the legal authority to do so, NJDEP has not issued a dual permit that covers the entire facility. It is EPA's belief that in situations where the facility has the flexibility to change operation at will,

facility-wide emission caps or summation of individual permits at a source is essential to prevent circumvention of the Part 70 regulations.

b. Permit Application (40 CFR § 70.5):

(1) Consistent with EPA's policy as discussed in the July 10th, 1995 "White Paper for Streamlined Development of Part 70 Permit Applications", New Jersey's rule streamlines the application requirements for emitting activities that meet the definition of insignificant source operations. Such emitting activities or units are not required to be listed individually on the application; they may be listed by source type. On the application, an estimate of the total emissions from all of the insignificant source operations shall be listed for each criteria pollutant with the applicable requirements which generally apply to them. The list of insignificant source operations which EPA hereby approves is defined in N.J.A.C. 7:27–22.1. This list may be changed with prior EPA input and approval during the state rulemaking process for the rule revision consistent with 40 CFR § 70.4(i).

(2) New Jersey's rule also provides for some streamlining for significant source operations that have extremely small emissions. For emitting activities or units that meet the definition of significant source operations and have emission rates that are less than those listed in Tables A and B of *Appendix I* of New Jersey's operating permit rule, their emissions are only required to be listed as "de minimis". The emissions levels listed under these tables are so small that EPA does not have any objections to requiring a listing of these emission units without their specific emission rates.

c. Permit Content (40 CFR § 70.6):

(1) Part 70 requires prompt reporting of deviations from the permit requirements. 40 CFR § 70.6(a)(3)(iii)(B) requires the permitting authority to define "prompt" in relation to the degree and type of deviation likely to occur and the applicable requirements. Where "prompt" is defined in the individual permit but not in the program regulations, EPA may veto permits that do not contain sufficiently prompt reporting of deviations. The State of New Jersey has defined "prompt" in its regulations at N.J.A.C. 7:27–22.19 in the manner discussed below. Immediate reporting on the NJDEP hotline is required if the air contaminants are released in a quantity or concentration which poses a potential threat to public health, welfare or the environment. Where the air contaminants are released in a quantity or concentration which poses no potential threat to public health, welfare, or the environment but the permittee intends to assert an affirmative defense for the deviation, the instance must be reported within 2 days. Deviations that were discovered during source emissions testing must be reported in 30 days as part of the testing report. Other reporting obligations required by the permit including deviations recorded by the emissions monitors are to be submitted semi-annually. EPA finds New Jersey's definition of "prompt" reporting of deviations as delineated above to be inadequate. In order for EPA to consider this definition adequate for protecting public health and safety, New Jersey must add a provision requiring reporting of deviations within 10 days where the air contaminants are released in a quantity or concentration that pose no potential threat to public health, welfare, or the environment and the permittee does not intend to assert affirmative defense for the deviation.

(2) Alternative operating scenarios may be made part of the initial permit or added via a significant modification, a minor modification or a 7-day notice change. Sources that are allowed to operate under different scenarios are required to operate within the range or limit specified for each operating parameter in the approved operating scenario. The New Jersey rule (N.J.A.C. 7:27–22.27(a)(2)) allows the addition of new alternative operating scenarios to an existing operating permit via a 7-day notice change provided the emission limit for the source operation included in the scenario does not exceed the maximum allowable emission limits in the existing permit. Another provision in N.J.A.C. 7:27–22.22(b)(5) disallows Title I modifications from being incorporated into the existing permit via the 7-day notice procedure. These two provisions in effect assure that a new NSR permit could not be added to the existing permit through the 7-day notice procedure by calling it an alternative operating scenario bypassing the minor or significant permit modification procedures. In addition, N.J.A.C. 7:27–22.26(b) rules out the possibility that a source might try to incorporate a MACT standard into the existing permit via a 7-day notice change by calling it an alternative operating scenario. Based on EPA's review of the New Jersey rule, the alternative operating scenario provisions are consistent with 40 CFR § 70.6(a)(9).

(3) New Jersey's Act permits an affirmative defense for start-ups, shut-downs, equipment maintenance and malfunctions. New Jersey's legislation (N.J.S.A. 26:2C–19.1 and 19.2) allows such a defense and sections 22.3(nn) and 22.16(l) of the rule discuss when it can be used. The Part 70 regulations allows an affirmative defense in emergency situations only and do not extend this defense to start-ups, shut-downs, equipment maintenance or malfunctions per se. Because start-up, shut-down, and malfunction events will not always qualify as an "emergency," as defined in part 70, NJ's rule and legislation are inconsistent with 40 CFR § 70.6(g). EPA finds this to be an impediment to full program approval. In addition, both NJ's legislation and rule are also inconsistent with 40 CFR § 70.6(g) because they do not limit the application of the affirmative defense to technology-based emission limits. 40 CFR § 70.6(g) provides that the emergency affirmative defense is only applicable to technology-based emission limits and not health-based emission limits. Therefore, EPA has determined that the NJ legislation as stated in N.J.S.A. 26:2C–19.1 and 19.2 and/or the NJ rule provisions on affirmative defenses as stated in N.J.A.C. 7:27–22.3(nn) and 22.16(l) must be revised to clarify its law to conform with 40 CFR § 70.6(g).

d. Public Participation (40 CFR § 70.7): Consistent with the Part 70 regulations, the public will be provided with notice of, and an opportunity to comment on, draft permits related to initial permit issuance, permit renewals, and significant modifications (N.J.A.C. 7:27–22.11).

e. Permit Modification (40 CFR 70.7):

(1) New Jersey's rule provides the following mechanism for modifying an operating permit: administrative amendments, changes to insignificant source operations (these are similar to Part 70's off-permit changes), 7-day notice changes, minor modifications, and significant modifications. Each of these procedures requires a different level of review/processing time to complete. Public review is required for significant modifications but is discretionary for minor modifications. No public review is afforded within the other types of permit modification procedures. The criteria for determin the proper procedure for a modification are addressed in the specific sections of the New Jersey rule for each type of modification (N.J.A.C. 7:27–22.20, 22.21, 22.22, 22.23, and 22.24). These procedures are consistent with the requirements of 40 CFR 70.7 and the provisions of 40 CFR 70.4(b)(12) and 40 CFR 70.4(b)(14).

(2) Under New Jersey's administrative amendment procedure (N.J.A.C. 7:27–22.20(b)(7)), provisions of a

preconstruction permit may be incorporated into the operating permit if the preconstruction permit was issued through public participation requirements substantially equivalent to those for operating permits as stipulated in N.J.A.C. 7:27–22.11 (public comment) and 22.12 (EPA comment). As written, New Jersey's rule is inconsistent with 40 CFR § 70.7(d)(1)(v). Instead of requiring the preconstruction permit to have gone through procedures of N.J.A.C. 7:27–22.11 and 22.12, it only requires the permit to have undergone procedures that are "substantially equivalent." This might allow New Jersey to decide what "substantially equivalent" means on a case by case basis. This discretion is not contemplated by 40 CFR § 70.7(d)(1)(v). In fact, it expressly contravenes the language of that section, which says that the preconstruction review "program" can be substantially equivalent. In other words, incorporation by administrative amendment can occur even if the procedures of the NSR program do not match part 70 exactly, if they are nevertheless approved by EPA as being substantially equivalent. Therefore, in order to receive full program approval, New Jersey must either:

i. Specify in § 7:27–22.20(b)(7) the procedures under which preconstruction permits must have been issued (§§ 70.7 and .8) and permit content (§ 70.6) requirements the permit must meet in order to be eligible for incorporation by administrative amendment, or

ii. Codify those procedural and permit content requirements into the preconstruction review regulations and obtain EPA's approval of those regulations.

(3) One characteristic of New Jersey's minor and significant modification procedures, which is not prohibited or required by the Part 70 regulations, is the integration of the preconstruction permit review process with the operating permit review. For significant modifications, draft permits covering respectively, the preconstruction and operating permit requirements will be issued for public review at the same time. At the conclusion of the public comment period, the final preconstruction approval will be issued to the applicant and the proposed operating permit will be submitted to EPA for a 45-day review. For minor modifications, public review is not required but the EPA and affected states will have 45 days to object to the proposed minor modification. If no objection is received, New Jersey will issue the preconstruction approval and the revised portion of the operating permit in final.

f. EPA oversight (40 CFR § 70.8): Each permit, renewal, and minor or significant modification is subject to EPA review/veto prior to issuance. New Jersey's rule states that if NJDEP fails to revise a permit based on an EPA objection or if EPA objects (in response to a public petition) to the proposed permit after final permit issuance, EPA would take action to issue the revised permit or re-issue the permits under federal operating permit regulations to be promulgated at 40 CFR Part 71. In these situations, before EPA takes any action pursuant to the Part 71 regulations, NJDEP must take action to withdraw approval of the operating permit upon receipt of EPA's veto. EPA will then revise and re-issue such permits in accordance with 40 CFR Part 71.

g. Enforcement authority (40 CFR § 70.11): New Jersey's Air Pollution Control Act provides NJDEP with adequate enforcement authority and penalties for civil and criminal violations of permits and rules. Penalties may be assessed in the maximum amount of $10,000 per day per violation. This also covers violations associated with the applicant's failure to pay the required fees.

h. Initial application submittal and issuance (40 CFR § 70.4(b)(11) (i) and (ii): While 40 CFR 70 requires all applications to be submitted within the first 12 months after state program approval, New Jersey has divided its subject sources into seven groups in an effort to maintain a smooth phase-in at the beginning of a new program. With an interim program approval, New Jersey is required to receive, during the first year, applications from 60% of the sources subject to the interim program. Permits for these sources will be issued one-third (of the 60%) each year during the first three years of program approval. The remaining 40% of the subject sources will submit applications during the first year of full program approval. The permits for these source will be issued one-third (of the 40%) each year during the initial three years after full approval. Based on Table 2–3 of page 2–8 of Chapter 2, New Jersey would have received four "waves" of applications from subject sources by November 15, 1996. This would cover 57.2 percent of all sources as opposed to 60%. To ensure that the 60% is met, New Jersey encouraged early submission of applications in February 1995 (6 months prior to program submittal). Also, since New Jersey's interim approval will not take place until at least February 1996, two months into the fifth waves of application submittal, it is certain that New Jersey would have received 60% of all applications by February 1997. As such, EPA does not consider this to be an issue for program approval.

3. Permit Fee Demonstration

New Jersey's title V fee program consists of four types of fees which includes an emissions based fee, an initial application fee, permit modification fee, and a surcharge for rebuilding the infrastructure of its Air Programs. New Jersey has adopted the presumptive minimum of $25 per ton per year (to be adjusted by the consumer price index annually) as its emissions based fee.

It should be noted, however that the actual appropriation for the New Jersey program has been limited by the fee legislation to $9.51 million dollars per year from the collected fees. EPA acknowledges that the program costs and fee revenue figures submitted in New Jersey's fee demonstration are only projections based on New Jersey's current experience with similar permitting programs. A more accurate assessment of the actual program costs will not be possible until the state has had the opportunity to implement the program. Therefore, EPA is requiring New Jersey to re-submit a more refined fee demonstration that assures sufficient funding for the operating permit program prior to EPA granting full approval. Should the revised fee demonstration show that the $9.51 million dollar funding level is insufficient, New Jersey must correct the deficiency prior to submitting the corrected program. New Jersey is aware of the need to revisit the fee demonstration and has committed to re-evaluate the fee program during the interim approval period and take all necessary steps to ensure sufficient funding for the operating permit program.

With respect to New Jersey's intention to use fees collected in excess of $9.51 million in reengineering NJDEP's Air Program, EPA does not find that to be a problem for interim approval for two reasons. First of all, based on the restricted use of the "Air Surcharge Reengineering Fund" as stipulated in New Jersey's legislation, the "excess title V fees are not used for activities that are totally unrelated to title V. EPA has thoroughly reviewed the activities listed in the legislation that are earmarked for the "Air Surcharge Reengineering Fund" and found them to be related to the development and maintenance of the infrastructure for implementing New Jersey's operating permit program. The costs associated with those activities are indirect costs to

the title V program. Therefore, EPA finds it acceptable for New Jersey to use "excess" title V fees to fund those activities. In addition, this is consistent with guidance issued by EPA on August 4, 1993 and July 21, 1994, which stated that "Title V does not limit a jurisdiction's discretion to collect fees pursuant to independent state authority beyond the minimum amount required by Title V". These guidance documents clearly allow a state to charge fees in excess of that which are needed to run the operating permit program.

EPA also notes that New Jersey requires fee payments from all title V affected sources including title IV Phase I units. There is one Phase I unit in the State of New Jersey. The Part 70 regulation (40 CFR § 70.9(b)(4)) states that "during the years 1995 through 1999 inclusive, no fee for purposes of title V shall be required to be paid with respect to emissions from any affected unit under section 404 of the Act". This Part 70 provision, however, does not restrict the state from collecting title V fees from Phase I units based on emissions that occurred prior to January 1, 1995 or after December 31, 1999. It also does not restrict a state from collecting non-title V related emissions based fee or non-emission based title V related fees from these units. Therefore, in this notice, EPA is proposing to grant interim approval to New Jersey's fee program. New Jersey may assess fees from any title IV Phase I units provided these fees are not used for purposes of title V.

4. Provisions Implementing the Requirements of Other Titles of the Act

a. Authority for Section 112 Implementation

New Jersey has demonstrated in its program submittal adequate legal authority to implement and enforce all section 112 requirements through its title V operating permit program. The implementing rule which is found in N.J.A.C. 7:27–22 includes section 112 requirements in the definition of applicable federal requirements with which all subject sources must comply. New Jersey has sufficient legislative and regulatory authorities to issue permits that assure compliance with the following section 112 requirements:

i. Early reductions: N.J.A.C 7:27–22.34 authorizes New Jersey to allow sources that achieved sufficient early reductions of hazardous air pollutants (HAP) emissions to delay compliance with the MACT or GACT standard for six years from the original compliance date if all of the conditions of the operating permit are met and the reductions are maintained throughout the six-year period.

ii. Case-by-case MACT determinations: In the event that no applicable emissions limitations have been established by the Administrator, N.J.A.C. 7:27–22.26 allows New Jersey to make case-by-case MACT determinations as required under section 112 (g) and (j) of the Act.

iii. Implementation of section 112(r): N.J.A.C 7:27–22.9 requires applicants submitting an initial operating permit application to include in its proposed compliance plan a statement certifying that the permittee will ensure the compliance of the facility with the accidental release provisions at 42 U.S.C. 7412(r). Annual certification of compliance with each applicable requirement that pertains to the facility is required under N.J.A.C. 7:27–22.19.

b. Implementation of Section 112(g) Upon Program Approval

Case-by-case MACT determinations: In the event that no applicable emissions limitations for the hazardous air pollutants have been established by the Administrator, NJDEP will make case-by case Maximum Achievable Control Technology (MACT) determinations as required under Sections 112(j) and (g) of the Act. The EPA issued an interpretive notice on February 14, 1995 (60 FR 8333), which outlines EPA's revised interpretation of 112(g) applicability. The notice postpones the effective date of 112(g) until after EPA has promulgated a rule addressing that provision. The notice sets forth in detail the rationale for the revised interpretation.

The Section 112(g) interpretive notice explains that EPA is still considering whether the effective date of Section 112(g) should be delayed beyond the date of promulgation of the Federal rule so as to allow states time to adopt rules implementing the Federal rule, and that EPA will provide for any such additional delay in the final Section 112(g) rulemaking. NJDEP has provided broad language in its regulation that will allow the implementation of 112(g) immediately after EPA promulgates its rule. The permitting mechanism to be used by the state of New Jersey to implement these requirements during the period before EPA promulgates the final federal rule and after New Jersey's title V program becomes effective is the State's preconstruction process (as stated in N.J.A.C. 7:27–22.33). In the event that EPA's final rulemaking under § 112(g) requires changes in New Jersey's operating permit rule/program to assure compliance with federal requirements, New Jersey has committed to making all necessary changes in a timely manner.

In this notice, EPA proposes to approve New Jersey's preconstruction review program found in N.J.S.A.26:2C–1 et. seq. under the authority of title V and Part 70 solely for the purpose of implementing section 112(g) of the Act. However, this approval does not have any effect on previous actions taken by EPA on the New Jersey preconstruction review program found in N.J.S.A.26:2C–1 et. seq. Also, this approval will be without effect if EPA decides in the final section 112(g) rule that sources are not subject to the requirements of the rule until State regulations are adopted. The duration of this approval is limited to 18 months following promulgation by EPA of the section 112(g) rule to provide adequate time for the State to adopt regulations consistent with the federal requirements.

c. Program for Delegation of Section 112 Standards as Promulgated

Section 112(l): Requirements for approval specified in 40 CFR § 70.4(b), encompass Section 112(l)(5) approval requirements for delegation of Section 112 standards as they apply to Part 70 sources. Section 112(l)(5) requires that the state's program contain adequate authorities, adequate resources for implementation, an expeditious compliance schedule, and adequate enforcement ability, which are also requirements under Part 70. In a letter dated November 15, 1995, from William O'Sullivan, Administrator of the Air Quality Permitting Program of the NJDEP requested delegation through 112(l) of all existing 112 standards for Part 70 sources and infrastructure programs. With respect to future section 112 standards, NJDEP intends to review every standard within 45 days of receiving notice from EPA and determine whether to accept the delegation of a standard on a case-by-case basis. In this letter, NJDEP demonstrated that it has sufficient legal authorities, adequate resources, capability for automatic delegation of future standards, and adequate enforcement ability for implementation of Section 112 of the Act for Part 70 sources. Therefore, the EPA is proposing to grant approval under Section 112(l)(5) and 40 CFR Part 63.91 to New Jersey for its program mechanism for receiving delegation of all existing and future 112(d) standards for Part 70 sources.

d. Commitment To Implement Title IV of the Act

As stated in N.J.A.C. 7:27–22.29, the state of New Jersey has already adopted

and incorporated by reference the provisions of 40 CFR Part 72, and any subsequent amendments thereto, for purposes of implementing an acid rain program that meets the requirements of title IV of the Act. It further stated that if provisions or requirements of 40 CFR Part 72 conflict with or are not included in New Jersey's rule that the Part 72 provision and requirements shall apply and take precedence.

B. Proposed Actions

EPA proposes source category-limited interim approval of the operating permit program initially submitted by the state of New Jersey on November 15, 1993, and revised on August 10, 1995. Under this approval, New Jersey may collect fees from any title IV Phase I facilities, provided that these are not used to meet the presumptive title V fee level for the interim program.

In accordance with 40 CFR § 70.4(b), this approval encompasses EPA's approval under section 112(l)(5) and 40 CFR § 63.91 to the state of New Jersey for its program mechanism for receiving delegation of all existing and future section 112(d) standards for all Part 70 sources. In order to receive full program approval, the State of New Jersey must submit a corrected program that addresses the following deficiencies six months before expiration of the interim approval:

1. Deferral of Non-Major Sources

As a condition for full program approval, New Jersey must submit a commitment in the corrected program asserting that New Jersey will require non-major sources subject to § 111 or § 112 standards promulgated after July 21, 1992 to apply for an operating permit under New Jersey's full program unless EPA exempts such sources in future rulemaking or promulgation of future requirements. Applications from these sources should be submitted in accordance with the schedule found under N.J.A.C. 7:27–22.5(i).

2. Definition of Prompt Reporting of Deviations

In order to receive full program approval, the reporting requirement in N.J.A.C. 7:27–22.19 must be revised to ensure adequate protection of public health and safety. New Jersey must add a provision requiring reporting of deviations within 10 days if the air contaminants are released in a quantity or concentration that poses no potential threat to public health, welfare, or the environment and the permittee does not intend to assert an affirmative defense for the deviation.

3. Affirmative Defense

In order to receive full program approval, the New Jersey legislation as stated in N.J.S.A. 26:2C–19.1 and 19.2 and/or the New Jersey rule provisions on affirmative defenses as stated in N.J.A.C. 7:27–22.3(nn) and 22.16(l) must be revised to clarify its law to conform with 40 CFR § 70.6(g).

4. Administrative Amendments

In order to receive full program approval, New Jersey must revise its operating permit rule to ensure that the administrative amendment procedure is properly used for incorporating preconstruction permits into the operating permit. Specifically, New Jersey must either:

i. Specify in § 7:27–22.20(b)(7) the procedures under which preconstruction permits must have been issued (§§ 70.7 and .8) and permit content (§ 70.6) requirements the permit must meet in order to be eligible for incorporation by administrative amendment, or

ii. Codify those procedural and permit content requirements into the preconstruction review regulations and obtain EPA's approval of those regulations. the following changes must be made to N.J.A.C. 7:27–22.20(b)(7)(i) and (ii):

5. Permit Fees

In order to receive full program approval, New Jersey must submit a revised fee demonstration showing that $9.51 million is adequate to administer the operating permit program during the initial four years of full program implementation. Should the cap of $9.51 million fall short of the actual program costs, New Jersey must take all necessary actions (including legislative changes) to correct the problem prior to submitting the corrected program.

C. Options for Approval/Disapproval and Implications

This interim approval, which may not be renewed, extends for a period of up to two years. During the interim approval period, New Jersey is protected from sanctions for failure to have a program, and EPA is not obligated to promulgate a federal operating permit program in the State. Permits issued under a program with interim approval have full standing with respect to Part 70, and the one-year time period for submittal of permit applications by subject sources begins upon interim approval, as does the three-year time period for processing the initial permit applications.

The scope of New Jersey's Part 70 program that EPA proposes to grant interim approval in this notice would apply to all Part 70 sources as listed in New Jersey's operating permit rule (N.J.A.C. 7:27–22.5) and transition plan.

As discussed above in section II.A.4.c., EPA also proposes to grant approval under section 112(l)(5) and 40 CFR 63.91 to New Jersey's program for receiving delegation of section 112 standards that are unchanged from federal standards as promulgated. In addition, EPA proposes to delegate existing standards under 40 CFR Parts 61 and 63.

III. Administrative Requirements

A. Request for Public Comments

EPA requests comments on all aspects of this proposed interim approval. Copies of the State's submittal and other information relied upon for the proposed interim approval are contained in docket number NJ–95–01 maintained at the EPA Regional Office. The docket is an organized and complete file of all the information submitted to, or otherwise considered by, EPA in the development of this proposed interim approval. The principal purposes of the docket are:

(1) To allow interested parties a means to identify and locate documents so that they can effectively participate in the approval process; and

(2) To serve as the record in case of judicial review. EPA will consider any comments received by February 29, 1996.

B. Executive Order 12866

The Office of Management and Budget has exempted this action from Executive Order 12866 review.

C. Regulatory Flexibility Act

EPA's actions under section 502 of the Act do not create any new requirements, but simply address operating permit programs submitted to satisfy the requirements of 40 CFR Part 70. Because this action does not impose any new requirements, it does not have a significant impact on a substantial number of small entities.

D. Unfunded Mandates Act

Under section 202 of the Unfunded Mandates Reform Act of 1995 ("Unfunded Mandates Act"), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate; or to the private sector, of $100 million or more. Under section 205, EPA must select the most cost effective and least burdensome

alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the proposed approval action promulgated today does not include a federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This federal action approves pre-existing requirements under State or local law, and imposes no new federal requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

List of Subjects in 40 CFR Part 70

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Operating permits, Reporting and recordkeeping requirements.

Authority: 42 U.S.C. 7401–7671q.

Dated: December 18, 1996.

Jeanne M. Fox,

Regional Administrator.

[FR Doc. 96–1712 Filed 1–29–96; 8:45 am]

BILLING CODE 6560–50–P

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40 CFR Part 81

[Region II Docket No.147; NJ24–1–7249b, FRL–5404–9]

Air Quality Designations: Deletion of TSP Designations From New Jersey, New York, Puerto Rico and Virgin Islands

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to delete from the State-by-State lists contained in 40 CFR part 81 the attainment status designations, including designations of attainment, unclassifiable and nonattainment, affected by the original national ambient air quality standards (NAAQS) for particulate matter measured as total suspended particulate (TSP). In accordance with section 107(d)(3)(B) of the Clean Air Act, the Administrator has determined that the selected area designations for TSP are no longer necessary for implementing the requirements for prevention of significant deterioration (PSD) of air quality for particulate matter since EPA has adopted equivalent PSD increments for particulate matter with an aerodynamic diameter less than 10 microns (PM10), which became effective on June 3, 1994. In the Final Rules Section of this Federal Register, the EPA is deleting the TSP area designations for New Jersey, New York, Puerto Rico, and Virgin Islands, as identified therein, as a direct final rule without prior proposal because the Agency views this as a noncontroversial revision amendment and anticipates no adverse comments. A detailed rationale for this action is set forth in the direct final rule. If no adverse comments are received in response to that direct final rule no further activity is contemplated in relation to this proposed rule. If the EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule.

The EPA will not institute a second comment period on this document. Any parties interested in commenting on this document should do so at this time.

DATES: Comments must be received on or before February 29, 1996.

ADDRESSES: All comments should be addressed to: William S. Baker, Chief, Air Programs Branch, Environmental Protection Agency, Region II Office, 290 Broadway, New York, New York 10007–1866

Copies of the documents relevant to this action are available for inspection during normal business hours at the following address:

Environmental Protection Agency, Region II Office, Air Programs Branch, 290 Broadway, 20th Floor, New York, New York 10007–1866

FOR FURTHER INFORMATION CONTACT: Kirk J. Wieber, Air Programs Branch, Environmental Protection Agency, 290 Broadway, 20th Floor, New York, New York 10278, (212) 637–4249.

SUPPLEMENTARY INFORMATION: For additional information see the direct final rule which is published in the rules section of this Federal Register.

Dated: December 18, 1996.

Jeanne M. Fox,

Regional Administrator.

[FR Doc. 96–1587 Filed 1–29–96; 8:45 am]

BILLING CODE 6560–50–P

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40 CFR Parts 260 through 265, and 270

[FRL–5468–8]

Military Munitions Rule: Hazardous Waste Identification and Management; Explosives Emergencies; Redefinition of On-Site

AGENCY: Environmental Protection Agency (EPA).

ACTION: Extension of Public Comment Period for Proposed Rule.

SUMMARY: EPA is today extending the public comment period on its proposed military munitions rule (60 FR 56468, November 8, 1995) to February 2, 1996.

DATES: Written comments on these proposed rules will be accepted until 4 pm, February 2, 1996.

ADDRESSES: Written comments [one original and two copies] should be addressed to: EPA RCRA Docket #F–95–MMP-FFFFF, Mail Code 5305W, 401 M Street SW, Washington, DC 20460. Comments also may be submitted electronically by sending electronic mail (e-mail) through the Internet system to: RCRA-Docket@epamail.epa.gov. All electronic comments must be submitted as an ascii file avoiding the use of special characters and any form of encryption. The comments should be identified with the above docket number.

The official action for this record will be kept in paper form. Accordingly, EPA will convert all documents received electronically into printed paper form as they are received and will place the paper copies in the official record, which will also include all comments submitted directly in writing. The official record is the paper record kept in the RCRA Docket. (Comments submitted on paper will not be transferred to electronic format. These comments may be viewed only in the RCRA Docket as described here.)

Public comments and the supporting information used for this rule are available for public inspection and copying in the RCRA Information Center (RIC) located in Crystal Gateway, First Floor, 1235 Jefferson Davis Highway, Arlington, Virginia. The RIC is open from 9:00 a.m. to 4:00 p.m., Monday through Friday, excluding federal holidays. To review docket materials, the public must make an appointment by calling 703–603–9230.

FOR FURTHER INFORMATION CONTACT: The RCRA Hotline between 9 am - 6 pm EST, toll-free, at 800–424–9346; 703–412–9810 from Government phones or if in the Wash, DC local calling area; or 800–553–7672 for the hearing impaired; or Ken Shuster, U.S. EPA (5303W), Washington, DC 20460, 703–308–8759.

SUPPLEMENTARY INFORMATION:

I. Legal Authority

These regulations are proposed under authority of sections 2002, 3001–3007 (including 3004(y)), 3010, 7003, and 7004 of the Solid Waste Disposal Act of 1965, as amended, including amendments by RCRA and the FFCA

(42 U.S.C. 6912, 6921–7, 6930, and 6973–4).

II. Today's Action

In response to Section 107 of the Federal Facility Compliance Act (FFCA) of l992 which added a new subsection 3004(y) to the Resource Conservation and Recovery Act (RCRA) (42 U.S.C. section 6924(y)), EPA proposed a rule (60 FR 56468, November 8, 1995) that identifies when conventional and chemical military munitions become a hazardous waste under RCRA, and that provides for the safe storage and transport of such waste. The proposal would also amend existing regulations regarding emergency responses involving military munitions and other explosives, by non-military or private personnel, as well as by the military. The proposal would also revise the definition of "on-site," which applies to all generators of hazardous waste. Because of the partial shutdown of the Federal government, EPA is today extending the end of the public comment period from January 8 to February 2, 1996.

Dated: January 18, 1996.

Elaine Cotsworth,

Acting Director, Office of Solid Waste.

[FR Doc. 96–1711 Filed 1–29–96; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

Federal Motor Vehicle Safety Standards

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Denial of petition for rulemaking.

SUMMARY: This document denies a petition for rulemaking submitted by Herzlich Consulting, Inc. Herzlich asked that the tire standards be amended to require that tires be designed to provide a visual indication when the tread depth reaches 3/32 inch. Herzlich also asked that the agency define legal tire wear out as having 3/32 inch tread depth with no bald areas. The petitioner asserted that this change would improve wet traction, improve antilock brake system (ABS) performance, result in fewer landfill scrap tires, provide a better supply of undamaged tire casings for retreading, and improve tire safety enforcement.

NHTSA has decided to deny the Herzlich petition. The agency believes that there is no safety need to remove tires at 3/32 inch, that more rather than fewer scrap tires would be generated if tires were removed sooner, that passenger car tires are not retreaded in sufficient numbers to compensate for the greater number of scrap tire casings that would result from earlier tire removal, and that enforcement efforts would not be greatly enhanced if tires were removed when tread depth reaches 3/32 inches instead of when it reaches 2/32 inches.

FOR FURTHER INFORMATION CONTACT: For technical issues: Robert M. Clarke, Office of Vehicle Safety Standards, National Highway Traffic Safety Administration, 400 Seventh Street, SW, Room 5307, Washington, DC 20590; telephone (202) 366–5278, facsimile (202) 366–4329.

For legal issues: Walter Myers, Office of the Chief Counsel, National Highway Traffic Safety Administration, 400 Seventh Street, SW, Room 5219, Washington, DC 20590; telephone (202) 366–2992, facsimile (202) 366–3820.

Background Information

Current Regulatory Requirements

Federal motor vehicle safety standards (Standards) 109, *New pneumatic tires* (49 CFR 571.109), and 119, *New pneumatic tires for motor vehicles other than passenger cars* (49 CFR 571.119) both require treadwear indicators that provide visual indication when the tire has been worn to a tread depth of 1/16 inch. For motorcycle tires, Standard No. 119 requires tread depth indicators at 1/32 inch.

Specifically, paragraph S4.2(d), Standard No. 109 provides that:

> If manufactured on or after August 1, 1968, [each tire] shall incorporate a tread wear indicator that will provide a visual indication that the tire has worn to a tread depth of 1/16 inch.

With respect to new pneumatic tires for motor vehicles other than passenger cars, paragraph S6.4 of Standard No. 119 provides that:

> Except as specified below, each tire shall have at least six treadwear indicators spaced approximately equally around the circumference of the tire that enable a person inspecting the tire to determine visually whether the tire has worn to a tread depth of one sixteenth of an inch. Tires with 12-inch or smaller rim diameter shall have at least three such treadwear indicators. Motorcycle tires shall have at least three such indicators which permit visual determination that the tire has worn to a tread depth of one-thirty-second of an inch.

No Federal motor vehicle safety standard requires that tires be removed from a vehicle at those or any other tread depths. However, § 570.9(a) of part 570, *Vehicle in use inspection standards*, specifies that tread depth of any tire on a vehicle with a gross vehicle weight rating (GVWR) of 10,000 pounds or less shall be not less than 2/32 inches. For vehicles with a higher GVWR, § 570.62(a) specifies a tread depth of not less than 4/32 inches for front tires and not less than 2/32 inches for all other tires. However, the agency has specified tread depth limits for tires on vehicles-in-use in its vehicle-in-use standards. Pursuant to a statutory mandate, the agency issued those standards for implementation by the States as part of their highway safety programs under 23 U.S.C. 402.

The Petition

Pursuant to 49 CFR part 552, Herzlich Consulting, Inc., of Las Vegas, NV (Herzlich) petitioned NHTSA to amend the tire standards to require that tires be designed to provide a visual indication when the tread depth reaches 3/32 inch. Herzlich also asked that the agency define legal tire wearout as having 3/32 inch tread depth with no bald areas.

Herzlich stated that it is a "rule of thumb" that approximately 80 percent of tire road hazard failures occur in the final 20 percent of tread life. He asserted that tire technology must now address new needs that include tire interaction with ABS, decreased rolling resistance and improved retreading. He stated that when a tread reaches a depth of 2/32 inch, it will not have sufficient tread remaining to meet wet skid resistance requirements. He further stated that when a tire reaches a tread depth of 2/32 inch, there are already areas that are below that depth and some spots are even bald. In addition, petitioner stated that the suggested amendments would provide better tire safety enforcement, provide the retread industry a better supply of casings, and reduce environmental concerns about so many scrap tires in landfills. Finally, petitioner stated that because individual tire manufacturers cannot themselves make such changes if they want to remain competitive, NHTSA should, and has a unique opportunity to, mandate such changes.

Agency Decision

The 2/32 inch figure specified in Standards 109 and 199 for the tires for most types of vehicles is based on early studies that showed that tire treads essentially lose their traction capabilities at about 1/16 inch. In a report entitled *Skidding Accidents on Runways and Highways Can Be Reduced*, prepared by W. B. Horne of

the National Aeronautics and Space Administration's Langley Research Center for publication in the August, 1967 issue of the Journal of Astronautics and Aeronautics, the author stated:

> Research indicates that grooved or treaded tires behave like bald or smooth tires when the groove depth is decreased by wear to about 1/16 inch of tread remaining.

The same conclusion was reached in a study entitled *Vehicle-in-Use Limit Performance and Tire Factors—The Tire In Use*, prepared in March, 1975 for NHTSA by Paul S. Fancher and James E. Bernard, report no. DOT HS–801 438. The report stated in pertinent part:

> Our recommendation, based on the results of this investigation * * *, is that tires should be replaced when they reach a groove depth of 2/32 of an inch.

Those studies, among others, confirmed a long-standing practice in the tire industry that tires should be replaced when the tread reached a depth of 1/16 inch (the "rule of thumb" was to place a penny in the tire groove and if you could see the top of Lincoln's head, it was time to replace or retread the tire). NHTSA adopted the industry practice in specifying the treadwear indicator height in Standard Nos. 109 and 119 at 1/16 inch.

Herzlich cited his own forensic experience in asserting that a tread depth of 2/32 inch is inadequate to maintain effective wet skid resistance. However, he cited no pertinent data in support of his forensic experience. Further, NHTSA is unaware of any data that would suggest that a tread depth of 2/32 inch is unsafe or that treadwear indicators should be raised.

The petitioner asserted that tire technology must now service new tire needs such as ABS, but did not explain the implications of ABS technology and performance for tire technology and tire tread depths. NHTSA has issued extensive rulemaking in recent years on ABS technology (see e.g., final rule on heavy truck ABS, 60 FR 13216, March 10, 1995). Theoretically, by preventing wheel lockup, ABS should be able to prevent tires from "flat spotting" or developing bald areas, thereby increasing tire life. Further, based on its experience with ABS, NHTSA does not believe that increasing the height of the treadwear indicators would measurably improve any function associated with ABS.

Petitioner also stated that tire technology must help provide decreased rolling resistance. Again, petitioner did not elaborate on this, nor provide any data to suggest that raising the treadwear indicators would have any effect on rolling resistance. NHTSA knows of no such correlation. Thus, although NHTSA agrees that tire technology must be responsive to new needs, the agency does not see how raising the treadwear indicators would contribute to the reduction of rolling resistance.

Petitioner alluded to the potential for improved recycling because there would be fewer landfill junk tires and by providing retreaders a better supply of usable casings. The January 1995 issue of *Modern Tire Dealer* magazine stated that approximately 228,200,000 passenger car tires are shipped nationwide per year, while only 5,850,000 retreaded passenger car tires are shipped. Thus, if tire life were shortened by removing tires from vehicles before reaching a tread depth of 2/32 inch, there should logically be more rather than fewer tires in landfills. NHTSA does not know of any data suggesting that tire casings are sounder for retreading purposes with 3/32 inch tread remaining than those with 2/32 inch tread remaining, or that more tires would be retreaded if more tread remained on the casing prior to retreading. Even assuming that there might be a small increase in the number of tires retreaded if tires had more tread remaining when they were retired, the agency has no data, and the petitioner provided none, on how many additional tires could be expected to be retreaded compared to the additional number of tires that would be removed and discarded upon reaching a tread depth of 3/32 inch.

In summary, NHTSA knows of no data suggesting either a safety or an environmental need to raise the treadwear indicators to 3/32 inch, and the petitioner has presented none. Neither has the petitioner submitted any data to support his assertions that a tread depth of 3/32 inch would improve ABS wet skid interaction, provide retreaders a better supply of undamaged tire casings, result in fewer scrap tires in landfills, or that tire safety enforcement would be improved. There is no reasonable probability that the requested amendments would be issued at the end of a rulemaking proceeding. Accordingly, the petition of Herzlich Consulting, Inc. is denied.

Authority: 49 U.S.C. 322, 30111, and 30162; delegation of authority at 49 CFR 1.50.

Issued on January 24, 1996.

Barry Felrice,

Associate Administrator for Safety Performance Standards.

[FR Doc. 96–1654 Filed 1–29–96; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 301

[Docket No. 960111003–6008–02; I.D. 122095C]

RIN 0648–AI48

Pacific Halibut Fisheries; Catch Sharing Plan

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

ACTION: Proposed catch sharing plan; request for comment.

SUMMARY: NMFS proposes to approve and implement a catch sharing plan (CSP) in accordance with the Northern Pacific Halibut Act of 1982 (Halibut Act). The CSP would apportion the catch limit specified by the International Pacific Halibut Commission (IPHC) for Regulatory Area 4 among subareas 4A, 4B, 4C, 4D, and 4E in and off the State of Alaska. The proposed CSP is based on the recommendations of the North Pacific Fishery Management Council (Council). This action is necessary to provide a basis for allocating the Pacific halibut resources of the Bering Sea and Aleutian Islands area among U.S. fishers who harvest these resources in accordance with the Individual Fishing Quota (IFQ) Program and Community Development Quota (CDQ) Program. The action is intended to carry out the fishery management objectives of the Council under the provisions of the Halibut Act and is consistent with the resource management objectives of the IPHC.

DATES: Comments on the CSP must be received before the close of business on February 1, 1996.

ADDRESSES: Send comments to Ronald J. Berg, Chief, Fishery Management Division, NMFS, Alaska Region, P.O. Box 21668, Juneau, AK 99802–1668, Attention: Lori Gravel. A copy of the Environmental Assessment, Regulatory Impact Review, and Initial Regulatory Flexibility Analysis (IRFA) may be obtained from the North Pacific Fishery Management Council, 605 W. 4th Ave., Suite 306, Anchorage, AK 99501–2252.

FOR FURTHER INFORMATION CONTACT: Jay J. C. Ginter, 907–586–7228.

SUPPLEMENTARY INFORMATION:

Background

The Secretary of Commerce (Secretary) is responsible for implementing the Halibut Convention

between the United States and Canada as provided by the Halibut Act, at 16 U.S.C. 773c. Section 773c(c) also authorizes the regional fishery management council for the geographical area concerned to develop regulations governing the allocation of Pacific halibut among U.S. fishers. Such regulations may be in addition to, but must not conflict with, regulations developed by the IPHC for primarily biological conservation purposes and must be approved by the Secretary before being implemented. Accordingly, the Council developed a halibut fishery management regime for IPHC Areas 2C through 4E establishing an IFQ limited access system and, for IPHC Areas 4B through 4E, a CDQ program for certain western Alaska communities. The IFQ and CDQ programs were designed to allocate specific harvesting privileges among U.S. fishers to resolve conservation and management problems that stem from "open access" management and to promote the development of the seafood industry in western Alaska. Both programs were approved by the Secretary on January 29, 1993, and were initially implemented by rules published in the **Federal Register** on November 9, 1993 (58 FR 59375). Fishing for halibut under the IFQ and CDQ programs began on March 15, 1995.

In February 1995, the IPHC informed the Council that there was no basis other than allocation for the historical distribution of the catch limits among Regulatory Areas 4C, 4D, and 4E. Further, the IPHC informed the Council of IPHC policy to distribute harvest in proportion to estimated biomass in each subarea because IPHC staff scientists perceived no stock separation among the subareas. Therefore, the IPHC staff recommended a harvest distribution for Area 4 based on estimated habitat and catch per unit of effort (CPUE) data. Alternatively, the IPHC suggested combining subareas 4C, 4D, and 4E. IPHC staff scientists recommended an equal exploitation rate strategy for the halibut resource in subareas 4A and 4B in which they perceive considerable stock separation. The IPHC staff presented this information to the Council because both alternatives would substantially affect the halibut catch limit allocations prescribed by the IFQ and CDQ programs.

The Council initially discussed the IPHC recommendations at the September 1995 meeting of the Council. The IPHC staff indicated at that meeting that it was reviewing its methods of calculating biomass based on habitat and CPUE estimates and that it was 1 to 2 years from making final recommendations for a biological basis for apportioning the Area 4 catch limit among the subareas. The IPHC staff also acknowledged no evidence of harm to the Area 4 halibut resource due to the traditional method of apportioning the catch limit among subareas. Apportionment of the Area 4 catch limit in 1995, prescribed at 50 CFR 301.10, has been approximately the same since 1984.

The current subareas and historical apportionment of catch limits among them is important to achieve the socioeconomic objectives of the IFQ and CDQ programs. The Halibut Act authorizes the Council to develop regulations that have allocation of harvesting privileges as the primary objective. Hence, the Council began to develop the CSP during its meeting of September 27 through October 2, 1995, by directing its staff to draft the analysis of CSP alternatives. The alternatives included (1) the status quo or "do nothing" alternative, and (2) an alternative that would establish the same subarea proportions as were established in 1995. These proportions of the total Area 4 catch limit were 33 percent for subarea 4A, 39 percent for subarea 4B, 13 percent for subarea 4C, 13 percent of subarea 4D, and 2 percent for subarea 4E. The Council also included an option under Alternative 2 that would assign the first 80,000 lb (36.3 metric tons (mt)) of catch limit greater than the total Area 4 catch limit to Area 4E, and distribute any additional catch limit among all Area 4 subareas in proportion to the 1995 apportionments. The total catch limit of halibut in Area 4 in 1995 was 5,920,000 lb (2,685.3 mt). The purpose of the option was to provide CDQ fishermen in subarea 4E with additional harvesting opportunity. The entire subarea 4E catch limit is assigned to the CDQ reserve and subsequently allocated to qualifying CDQ groups. The Council agreed with representatives from some of these CDQ groups that the subarea 4E catch limit has been unreasonably constrained in recent years.

The analysis of CSP alternatives was made available by the Council staff for public review on November 9, 1995. At its meeting December 6 through 10, 1995, the Council decided to recommend Alternative 2, including the option, to NMFS for implementation.

The Proposed CSP

Introduction: This CSP would constitute a framework that would be applied to the annual Area 4 catch limit established by the IPHC. The purpose of the CSP is to establish subareas within Area 4, and to provide for the apportionment of the Area 4 catch limit among the subareas as necessary to carry out the objectives of the IFQ and CDQ programs that allocate halibut among U.S. fishers. The IPHC, consistent with its responsibilities, is scheduled to implement the measures specified in this CSP at its annual meeting in January 1996, based on an assumption that the CSP will be approved by NMFS. If the CSP is not approved, then the IPHC will reconsider alternative ways to manage the Area 4 catch limit. If approved, this CSP would continue in effect until amended by the Council or superseded by action of the IPHC.

Area 4 subareas: Regulatory Areas 4A, 4B, 4C, 4D, and 4E would be established as they are defined currently at paragraphs (f), (g), (h), (i), and (j), respectively, at 50 CFR 301.6. For the convenience of the reader, definitions of these subareas are set out as follows:

Area 4A includes all waters in the Gulf of Alaska west of Area 3B defined in § 301.6(e) and in the Bering Sea west of the closed area, defined in § 301.9, that are east of 172°00′00″ W. long. and south of 56°20′00″ N. lat.

Area 4B includes all waters in the Bering Sea and the Gulf of Alaska west of Area 4A and south of 56°20′00″ N. lat.

Area 4C includes all waters in the Bering Sea north of Area 4A and north of the closed area defined in § 301.9, that are east of 171°00′00″ W. long., south of 58°00′00″ N. lat., and west of 168°00′00″ W. long.

Area 4D includes all waters in the Bering Sea north of Areas 4A and 4B, north and west of Area 4C, and west of 168°00′00″ W. long.

Area 4E includes all waters in the Bering Sea north and east of the closed area defined in § 301.9, east of 168°00′00″ W. long., and south of 65°34′00″ N. lat.

Catch limit apportionments: Apportionment of the Area 4 catch limit specified annually by the IPHC would be as follows:

subarea 4A—33 percent
subarea 4B—39 percent
subarea 4C—13 percent
subarea 4D—13 percent
subarea 4E—2 percent

An exception to this CSP apportionment schedule is provided when the Area 4 catch limit is greater than 5,920,000 lb (2,685.3 mt) and less than or equal to 6,000,000 lb (2,721.6 mt). In this event, the amount of the Area 4 catch limit that is greater than 5,920,000 lb (2,685.3 mt) but less than or equal to 6,000,000 lb (2, 721.6 mt) would be assigned to subarea 4E. The

amount of the Area 4 catch limit that is greater than 6,000,000 lb (2,721.6 mt) would be distributed among all Area 4 subareas according to the CSP apportionment schedule.

Example 1: If the IPHC specifies the Area 4 catch limit to be 5,980,000 lb (2,712.5 mt), then 5,920,000 lb (2,685.3 mt) would be distributed among the Area 4 subareas according to the CSP apportionment schedule, and 60,000 lb (27.2 mt) would be added to subarea 4E as follows:

Subarea				lb	Mt
4A	.33 ×	5,920,000	=	1,953,600	886.1
4B	.39 ×	5,920,000	=	2,308,800	1,047.3
4C	.13 ×	5,920,000	=	769,600	349.1
4D	.13 ×	5,920,000	=	769,600	349.1
4E	.02 ×	5,920,000 + 60,000	=	178,400	80.9
Totals	1.00			5,980,000	2,712.5

Example 2: If the IPHC specifies the Area 4 catch limit to be 6,100,000 lb (2,766.9 mt), then 5,920,000 lb (2,685.3 mt) plus the amount that is greater than 6,000,000 lb (2,721.6 mt) (i.e. 100,000 lb (45.4 mt)) would be distributed among the Area 4 subareas according to the CSP apportionment schedule, and the 80,000 lb (36.3 mt) remainder would be added to subarea 4E as follows:

Subarea				lb	Mt
4A	.33 ×	6,020,000	=	1,986,600	901.1
4B	.39 ×	6,020,000	=	2,347,800	1,064.9
4C	.13 ×	6,020,000	=	782,600	355.0
4D	.13 ×	6,020,000	=	782,600	355.0
4E	.02 ×	6,020,000 + 80,000	=	200,400	90.9
Totals	1.00			6,100,000	2,766.9

Classification

The IRFA prepared by the Council for this proposed CSP indicates that, if approved, the CSP could cause IFQ and CDQ halibut fishers in subareas 4A through 4D to forego up to an average of $143 each due to the potential 80,000 lb (36.3 mt) that would be redistributed from these areas to subarea 4E. About 88 CDQ halibut fishermen in subarea 4E would gain an average of $1,559 each from landing up to 80,000 lb (36.3 mt) more than otherwise would be possible if Area 4 apportionments did not change from 1995. The analysis indicated that the potentially foregone amounts of halibut from subareas 4A through 4D would amount to less than 5 percent of the annual gross revenues for fishers in these subareas. The proposed CSP would not increase compliance costs for any IFQ or CDQ fisher. Therefore, the Assistant General Counsel for Legislation and Regulation certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed CSP would not have a significant economic impact on a substantial number of small entities and does not require a regulatory flexibility analysis under the Regulatory Flexibility Act. Copies of the IRFA are available (see **ADDRESSES**).

This CSP would have been published in December 1995, but the government shutdown delayed publication until now. Consequently, the public comment period is reduced for this action to assure that the NMFS decision on whether to approve the CSP is made, and, if approved, a final CSP is effective before the Area 4 halibut fishery that is likely to begin in March 1996. Further, the affected public was notified and had opportunity to comment on the proposed CSP alternatives at the December 1995 meeting of the Council. The proposed CSP allocation scheme for the Area 4 catch limit is scheduled for discussion at the public IPHC meeting in January 1996. Furthermore, the timely issuance of IFQ shares necessitates a shortened comment period. Additional time for public comment would be redundant and potentially counterproductive.

This action has been determined to be not significant for purposes of E.O. 12866.

Dated: January 24, 1996.

Gary Matlock,

Program Management Officer, National Marine Fisheries Service.

[FR Doc. 96–1659 Filed 1–25–96; 11:52 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 61, No. 20
Tuesday, January 30, 1996

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

Animal and Plant Health Inspection Service

[Docket No. 95–094–1]

Availability of Environmental Assessments and Findings of No Significant Impact

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that two environmental assessments and findings of no significant impact have been prepared by the Animal and Plant Health Inspection Service relative to the issuance of permits to allow the field testing of genetically engineered organisms. The environmental assessments provide a basis for our conclusion that the field testing of the genetically engineered organisms will not present a risk of introducing or disseminating a plant pest and will not have a significant impact on the quality of the human environment. Based on its findings of no significant impact, the Animal and Plant Health Inspection Service has determined that environmental impact statements need not be prepared.

ADDRESSES: Copies of the environmental assessments and findings of no significant impact are available for public inspection at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect those documents are requested to call ahead on (202) 690–2817 to facilitate entry into the reading room.

FOR FURTHER INFORMATION CONTACT: Dr. Arnold Foudin, Deputy Director, Biotechnology Permits, BBEP, APHIS, Suite 5B05, 4700 River Road Unit 147, Riverdale, MD 20737–1237; (301) 734–7612. For copies of the environmental assessments and findings of no significant impact, write to Mr. Clayton Givens at the same address. Please refer to the permit numbers listed below when ordering documents.

SUPPLEMENTARY INFORMATION: The regulations in 7 CFR part 340 (referred to below as the regulations) regulate the introduction (importation, interstate movement, and release into the environment) of genetically engineered organisms and products that are plant pests or that there is reason to believe are plant pests (regulated articles). A permit must be obtained or a notification acknowledged before a regulated article may be introduced into the United States. The regulations set forth the permit application requirements and the notification procedures for the importation, interstate movement, and release into the environment of a regulated article.

In the course of reviewing each permit application, APHIS assessed the impact on the environment that releasing the organisms under the conditions described in the permit application would have. APHIS has issued permits for the field testing of the organisms listed below after concluding that the organisms will not present a risk of plant pest introduction or dissemination and will not have a significant impact on the quality of the human environment. The environmental assessments and findings of no significant impact, which are based on data submitted by the applicants and on a review of other relevant literature, provide the public with documentation of APHIS' review and analysis of the environmental impacts associated with conducting the field tests.

Environmental assessments and findings of no significant impact have been prepared by APHIS relative to the issuance of permits to allow the field testing of the following genetically engineered organisms:

Permit No.	Permittee	Date issued	Organisms	Field test location
95–205–01	Bejo Seeds, Incorporated	11–09–95	Chicory plants genetically engineered to express male sterility and tolerance to glufosinate herbicide as a marker	California.
95–234–01	Agritope, Incorporated	12–11–95	Raspberry plants genetically engineered to express delayed ripening	California.

The environmental assessments and findings of no significant impact have been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321 *et seq.*), (2) Regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372; 60 FR 6000–6005, February 1, 1995).

Done in Washington, DC, this 24th day of January 1996.

Terry L. Medley,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 96–1668 Filed 1–29–96; 8:45 am]

BILLING CODE 3410–34–P

Forest Service

Eastern Washington Cascades Provincial Interagency Executive Committee (PIEC), Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Eastern Washington PIEC Advisory Committee that had been scheduled for January 18, 1996 in the River Room at Campbells Resort,

Chelan, Washington has been rescheduled to occur on February 29 at the same location. The meeting will begin at 9 a.m. and continue until 4 p.m. This meeting will primarily focus on land management agency response to committee advice on Dry Forest Health issues, and riparian zone management under the Northwest Forest Plan. All Eastern Washington Cascades Province Advisory Committee meetings are open to the public. Interested citizens are welcome to attend.

FOR FURTHER INFORMATION CONTACT: Direct questions regarding this meeting to Paul Hart, Designated Federal Official, USDA, Wenatchee National Forest, P.O. Box 811, Wenatchee, Washington 98807, 509–662–4335.

Dated: January 9, 1996.

Paul Hart,

Designated Federal Official, Wenatchee National Forest.

[FR Doc. 96–1660 Filed 1–29–96; 8:45 am]

BILLING CODE 3410–11–M

Southwest Washington Provincial Advisory Committee Meeting Notice

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Southwest Washington Provincial Advisory Committee will meet on February 13, 1996, in Longview, Washington. The meeting will begin at 9 a.m. and continue until 4:30 p.m. An Advisory Committee Subcommittee on the Forest Monitoring Program will meet on February 9, 1996, in Vancouver, Washington.

The purpose of the Advisory Committee meeting is to utilize the Province Health Matrix to advise on proposed Timber sales for the Cowlitz, Lewis, Wind River, and White Salmon Basins. Agenda items to be covered include: (1) 1996 and 1997 Timber Sale Program, (2) Updates from Subcommittees on the Social and Economic Indicators of Basin Health and Forest Monitoring Program, (3) Cispus AMA Technical Panel establishment, (4) Replacements for vacated seats, (5) Flood damage report, and (6) Public Open Forum.

The purpose of the Monitoring Subcommittee meeting is to develop a proposal on components of the Forest Monitoring Program. All Southwest Washington Provincial Advisory Committee meetings are open to the public. Interested citizens are encouraged to attend. The "open forum" provides opportunity for the public to bring issues, concerns, and discussion topics to the Advisory Committee. The "open forum" is scheduled as part of agenda item (1) for this meeting. Interested speakers will need to register prior to the open forum period. The committee welcomes the public's written comments on committee business at any time.

FOR FURTHER INFORMATION CONTACT: Direct questions regarding this meeting to Mark Maggiora, Public Affairs, at (360) 750–5007, or write Forest Headquarters Office, Gifford Pinchot National Forest, 6926 E. Fourth Plain Blvd., PO Box 8944, Vancouver, WA 98668–8944.

Dated: January 22, 1996.

Ted C. Stubblefield,

Forest Supervisor.

[FR Doc. 96–1636 Filed 1–29–96; 8:45 am]

BILLING CODE 3410–11–M

ASSASSINATION RECORDS REVIEW BOARD

Notice of Formal Determinations and Corrections

AGENCY: Assassination Records Review Board.

SUMMARY: The Assassination Records Review Board (Review Board) met in a closed meeting on January 5, 1996, and made formal determinations on the release of records under the President John F. Kennedy Assassination Records Collection Act of 1992 (JFK Act). By issuing this notice, the Review Board complies with the section of the JFK Act that requires the Review Board to publish the results of its decisions on a document-by-document basis in the **Federal Register** within 14 days of the date of the decision. (The date has been extended by six days due to weather related shutdowns of the Federal government.) This notice document also contains two minor corrections from previous notices.

FOR FURTHER INFORMATION CONTACT: T. Jeremy Gunn, General Counsel and Associate Director for Research and Analysis, Assassination Records Review Board, Second Floor, 600 E Street NW, Washington, DC 20530, (202) 724–0088, fax (202) 724–0457.

SUPPLEMENTARY INFORMATION: This notice complies with the requirements of the President John F. Kennedy Assassination Records Collection Act of 1992, 44 U.S.C. 2107.9(c)(4)(A) (1992). On January 5, 1996, the Review Board made formal determinations on records it reviewed under the JFK Act.

These determinations are listed below. The assassination records are identified by the record identification number assigned in the President John F. Kennedy Assassination Records Collection database maintained by the National Archives. For each document, the number of releases of previously redacted information is noted as well as the number of sustained postponements.

Record No.	ARRB release	Sustained postponements	Status of document	Action date
FBI Documents:				
124–10017–10252	3	0	Open in Full	n/a
124–10035–10119	4	0	Open in Full	n/a
124–10050–10395	5	0	Open in Full	n/a
124–10170–10115	4	0	Open in Full	n/a
124–10241–10111	6	0	Open in Full	n/a
124–10255–10334	4	0	Open in Full	n/a
CIA Documents:				
104–10015–10033	11	6	Postponed in Part	01/1996
104–10015–10159	9	0	Open in Full	n/a
104–10015–10215	4	0	Open in Full	n/a
104–10015–10225	7	2	Postponed in Part	01/2006
104–10015–10230	4	4	Postponed in Part	03/1996
104–10015–10243	12	2	Postponed in Part	01/2006
104–10015–10255	7	3	Postponed in Part	03/1996
104–10015–10346	29	5	Postponed in Part	01/2006
104–10015–10372	6	2	Postponed in Part	03/1996

Record No.	ARRB release	Sustained postponements	Status of document	Action date
104–10015–10386	8	1	Postponed in Part	03/1996
104–10015–10400	3	2	Postponed in Part	01/2006
104–10015–10420	9	1	Postponed in Part	01/2006
104–10015–10425	5	0	Open in Full	n/a
104–10015–10444	2	2	Postponed in Part	03/1996
104–10016–10011	23	15	Postponed in Part	03/1996
104–10016–10012	5	2	Postponed in Part	01/1996
104–10016–10025	7	2	Postponed in Part	03/1996
104–10016–10026	16	1	Postponed in Part	03/1996
104–10017–10022	4	0	Open in Full	n/a
104–10017–10033	8	0	Open in Full	n/a
104–10017–10036	4	3	Postponed in Part	01/2006
104–10017–10040	5	4	Postponed in Part	03/1996
104–10017–10049	7	3	Postponed in Part	03/1996
104–10017–10057	7	0	Open in Full	n/a
104–10017–10058	17	2	Postponed in Part	01/2006
104–10017–10073	6	2	Postponed in Part	01/2006
104–10018–10001	1	2	Postponed in Part	03/1996
104–10018–10007	9	2	Postponed in Part	01/2006
104–10018–10042	9	4	Postponed in Part	01/2006
104–10018–10076	7	4	Postponed in Part	01/2006
104–10018–10080	9	5	Postponed in Part	01/2006
104–10018–10088	8	0	Open in Full	n/a
104–10018–10089	8	2	Postponed in Part	03/1996
104–10018–10091	6	2	Postponed in Part	03/1996
HSCA Documents:				
180–10070–10273	0	2	Postponed in Part	01/2006
180–10070–10276	0	2	Postponed in Part	01/2006
180–10071–10164	2	0	Open in Full	n/a
180–10075–10118	0	2	Postponed in Part	01/2006
180–10076–10049	76	0	Open in Full	n/a
180–10080–10131	1	2	Postponed in Part	2017
180–10080–10276	4	1	Postponed in Part	01/2006
180–10082–10451	0	2	Postponed in Part	01/2006
180–10085–10498	0	2	Postponed in Part	01/2006
180–10086–10342	6	5	Postponed in Part	01/2006
180–10087–10190	0	2	Postponed in Part	01/2006
180–10090–10122	1	0	Open in Full	n/a
180–10090–10128	1	0	Open in Full	n/a
180–10090–10134	1	0	Open in Full	n/a
180–10093–10026	2	0	Open in Full	n/a
180–10094–10459	0	1	Postponed in Part	2017
180–10096–10460	1	0	Open in Full	n/a
180–10104–10324	1	0	Open in Full	n/a
180–10106–10100	1	3	Postponed in Part	01/2006
180–10108–10349	1	0	Open in Full	n/a
180–10108–10350	2	0	Open in Full	n/a
180–10118–10129	1	0	Open in Full	n/a
180–10140–10022	0	186	Postponed in Part	2017
NARA Documents:				
179–40001–10073	2	0	Open in Full	n/a
179–40001–10432	1	0	Open in Full	n/a
179–40002–10050	2	0	Open in Full	n/a
179–40002–10171	1	0	Open in Full	n/a
179–40002–10314	1	0	Open in Full	n/a

Corrections

On December 12 and 13, 1996, the Review Board made formal determinations that were published in the Tuesday, January 2, 1996, **Federal Register** (FR Doc. 95–31560, 61 FR 48), reflecting those determinations. For that notice make the following corrections:

On page 51, in the second, third, and fourth columns of the HSCA documents table, make the following corrections:

Record No.	Previously published	Corrected information
180–10087–10362	3,0, Open in Full, n/a.	2,1 Postponed in Part, 2017.

In its implementation of the JFK Act, the Federal Bureau of Investigation (FBI) inadvertently assigned two record identification numbers—124–10087–10334 and 124–10027–10011—to the same assassination record. The Review Board's final determinations regarding this assassination record were published in the Monday, December 4, 1995, **Federal Register** (see FR Doc. 95–29839, 60 FR 62066) under record identification number 124–10087–10334. The FBI subsequently notified the Review Board of the prior inadvertent assignment of two record identification numbers to that assassination record, and of the FBI's

decision to use 124–10027–10011 as the sole record identification number for that assassination record for further processing under the JFK Act. Accordingly, the assassination record in question is being processed and released to the public, pursuant to the Review Board's determinations, as record identification number 124–10027–10011.

Dated: January 25, 1996.

David G. Marwell,

Executive Director.

[FR Doc. 96–1687 Filed 1–29–96; 8:45 am]

BILLING CODE 6118–01–U

DEPARTMENT OF COMMERCE

Bureau of the Census

1997 Economic Census Covering Wholesale Trade, Retail Trade, and Food Services, Drinking Places, and Accommodations Sectors; Proposed Agency Information Collection Activity; Comment Request

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before April 1, 1996.

ADDRESSES: Direct all written comments to Margaret L. Woody, Department of Commerce, Room 5327, 14th and Constitution Avenue NW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to John Trimble for Wholesale Trade, Bureau of the Census, Room 2682, Building 3, Washington, DC 20233 on (301) 457–2725 and to Fay Dorsett for Retail Trade and Food Services, Drinking Places, and Accommodations, Bureau of the Census, Room 2679, Building 3, Washington, DC 20233 on (301) 457–2687.

SUPPLEMENTARY INFORMATION:

I. Abstract

The Census Bureau is the preeminent collector and provider of timely, relevant and quality data about the people and economy of the United States. Economic data are the Census Bureau's primary program commitment during nondecennial census years. The economic census, conducted under authority of Title 13 USC, is the primary source of facts about the structure and functioning of the Nation's economy and features unique industry and geographic detail. Economic census statistics serve as part of the framework for the national accounts and provide essential information for government, business and the general public. The 1997 Economic Census will cover virtually every sector of the U. S. economy including more than .5 million wholesale establishments, more than 1.1 million retail establishments, and more than .5 million food services, drinking places, and accommodations establishments.

II. Method of Collection

The wholesale trade, retail trade, and food services, drinking places, and accommodations sectors of the economic census will select establishments for their mail canvasses from a frame given by the Census Bureau's Standard Statistical Establishment List. To be eligible for selection, an establishment will be required to satisfy the following conditions: (i) it must be classified in the wholesale trade, retail trade, or food services, drinking places, and accommodations sector; (ii) it must be an active operating establishment of a multi-establishment firm, or it must be a single-establishment firm with payroll; and (iii) it must be located in one of the 50 states or the District of Columbia. Mail selection procedures will distinguish the following groups of establishments:

A. Establishments of Multi-Establishment Firms

Selection procedures will assign all active wholesale, retail, food services, drinking places, and accommodations operating establishments of multi-establishment firms to the mail component of the potential respondent universe. We estimate that the census mail canvass for 1997 will include approximately 155,000 wholesale multi-establishment firms, 422,000 retail multi-establishment firms, and 151,000 food services, drinking places, and accommodations multi-establishment firms.

B. Single-Establishment Firms With Payroll

As an initial step in the selection process, we will conduct a study of the potential respondent universe for wholesale trade, retail trade, and food services, drinking places, and accommodations. Wholesale trade agents, brokers, and commission merchants will be exempted from this process and will all receive a standard form. The study of potential respondents will produce a set of industry-specific payroll cutoffs that we will use to distinguish large versus small single-establishment firms within each industry or kind of business. This payroll size distinction will affect selection as follows:

1. Large Single-Establishment Firms

Selection procedures will assign large single-establishment firms having annualized payroll (from Federal administrative records) that equals or exceeds the cutoff for their industry to the mail component of the potential respondent universe. We estimate that the census mail canvass for 1997 will include approximately 229,000 merchant wholesale firms, 238,000 retail firms, and 165,000 food services, drinking places, and accommodations firms in this category.

2. Small Single-Establishment Firms

Selection procedures will assign a sample of small single-establishment firms having annualized payroll below the cutoff for their industry to the mail component of the potential respondent universe. Sampling strata and corresponding probabilities of selection will be determined by a study of the potential respondent universe conducted shortly before mail selection operations begin. We estimate that the census mail canvass for 1997 will include approximately 11,000 merchant wholesale firms, 78,000 retail firms, and 17,000 food services, drinking places, and accommodations firms in this category.

Small single-establishment merchant wholesale firms not selected in the foregoing sample will receive a wholesale short form, which will collect basic statistics and other essential information that is not available from administrative records. We estimate that the census mail canvass for 1997 will include approximately 105,000 merchant wholesale firms in this category.

All single-establishment agents, brokers, and commission merchant firms will receive a wholesale standard form. We estimate that the census mail canvass will include approximately 45,000 firms in this category.

All remaining single-establishment firms with payroll will be represented in the census by data from Federal administrative records. Generally, we will not include these small employers in the census mail canvass. However, administrative records sometimes have

fundamental deficiencies that make them unsuitable for use in producing detailed industry statistics by geographic area. When we find such a deficiency, we will mail the firm a census short form to collect basic information needed to resolve the problem. We estimate that the census mail canvass for 1997 will include approximately 340,000 retail firms and 202,000 food services, drinking places, and accommodations firms in this category.

III. Data

The information collected from businesses in these sectors of the economic census will produce basic statistics by kind of business for number of establishments, sales, payroll, and employment. It also will yield a variety of subject statistics, including sales by commodity and merchandise line, sales by class of customer, and other industry-specific measures. Primary strategies for reducing burden in Census Bureau economic data collections are to increase electronic reporting through broader use of computerized self-administered census questionnaires, electronic data interchange, and other electronic data collection methods.

OMB Number: Not Available.

Form Number: The forms used to collect information from businesses in these sectors of the economic census are tailored to specific business practices and are too numerous to list separately in this notice. You can obtain information on the proposed content of the forms by calling Yvonne Wade on (301) 457–2661.

Type of Review: Regular review.

Affected Public: Businesses or Other for Profit, Non-profit Institutions, Small Businesses or Organizations, and State or Local Governments.

Estimated Number of Respondents:

Wholesale Trade (Standard Form)—395,000
Wholesale Trade (Short Form)—105,000
Retail Trade (Standard Form)—738,000
Retail Trade (Short Form)—333,000
Food Services, Drinking Places, and Accommodations (Standard Form)—340,000
Food Services, Drinking Places, and Accommodations (Short Form)—202,000

Estimated Time Per Response:

Wholesale Trade (Standard Form)—1.25 hrs
Wholesale Trade (Short Form)—.50 hrs
Retail Trade (Standard Form)—.85 hours
Retail Trade (Short Form)—.20 hours
Food Services, Drinking Places, and Accommodations (Standard Form)—.85 hours
Food Services, Drinking Places, and Accommodations (Short Form)—.20 hours

Estimated Total Annual Burden Hours:

Wholesale Trade (Standard Form)—493,750
Wholesale Trade (Short Form)—52,500
Retail Trade (Standard Form)—627,300
Retail Trade (Short Form)—66,600
Food Services, Drinking Places, and Accommodations (Standard Form)—289,000
Food Services, Drinking Places, and Accommodations (Short Form)—40,400

Estimated Total Annual Cost: The cost to the government for this work is included in the total cost of the 1997 Economic Census, estimated to be $218 million.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: January 24, 1996.

Margaret L. Woody,

Office of Management and Organization.

[FR Doc. 96–1759 Filed 1–29–96; 8:45 am]

BILLING CODE 3510–07–P

Bureau of Export Administration

Regulations and Procedures Technical Advisory Committee; Notice of Partially Closed Meeting

A meeting of the Regulations and Procedures Technical Advisory Committee will be held March 19, 1996, 9:00 a.m., in the Herbert C. Hoover Building, Room 3884, 14th Street between Constitution and Pennsylvania Avenues NW., Washington, D.C. The Committee advises the Office of the Assistant Secretary for Export Administration on implementation of the Export Administration Regulations (EAR) and provides for continuing review to update the EAR as needed.

Agenda

Open Session

1. Opening Remarks by the Chairman.
2. Presentation of Papers or Comments by the Public.
3. Update on the Enhanced Proliferation Control Initiative (EPCI).
4. Presentation/discussion on reform of the Export Administration Regulations (EAR).
5. Discussion on the Executive Order for the Administration of Export Controls.

Closed Session

6. Discussion of matters properly classified under Executive Order 12958, dealing with the U.S. export control program and strategic criteria related thereto.

The General Session of the meeting will be open to the public and a limited number of seats will be available. To the extent that time permits, members of the public may present oral statements to the Committee. Written statements may be submitted at any time before or after the meeting. However, to facilitate the distribution of public presentation materials to the Committee members, the Committee suggests that presenters forward the public presentation materials two weeks prior to the meeting date to the following address: Ms. Lee Ann Carpenter, TAC Unit/OAS/EA, Room 3886C, Bureau of Export Administration, U.S. Department of Commerce, Washington, D.C. 20230.

The Assistant Secretary for Administration, with the concurrence of the delegate of the General Counsel, formally determined on December 22, 1994, pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended, that the series of meetings or portions of meetings of the Committee and of any Subcommittees thereof, dealing with the classified materials listed in 5 U.S.C. 552b(c)(1) shall be exempt from the provisions relating to public meetings found in section 10 (a)(1) and (a)(3), of the Federal Advisory Committee Act. The remaining series of meetings or portions thereof will be open to the public.

A copy of the Notice of Determination to close meetings or portions of meetings of the Committee is available for public inspection and copying in the Central Reference and Records

Inspection Facility, Room 6020, U.S. Department of Commerce, Washington, D.C. For further information, call Lee Ann Carpenter at (202) 482–2583.

Dated: January 25, 1996.

Lee Ann Carpenter,

Director, Technical Advisory Committee Unit.

[FR Doc. 96–1746 Filed 1–29–96; 8:45 am]

BILLING CODE 3510–DT–M

Foreign-Trade Zones Board

[Docket 6–96]

Foreign-Trade Zone 14—Little Rock, AR Application for Subzone; Cedar Chemical Corporation (Agricultural and Specialty Chemicals) West Helena, AR

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the Little Rock Port Authority on behalf of the State of Arkansas Department of Industrial Development, grantee of FTZ 14, requesting special-purpose subzone status for the agricultural and specialty chemical manufacturing facility of Cedar Chemical Corporation (Cedar) (wholly-owned subsidiary of Trans-Resources, Inc.), in West Helena, Arkansas. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally filed on January 19, 1996.

The Cedar plant (48 acres) is located within the Helena/West Helena Industrial Park at Hwy. 242 South, West Helena (Phillips County), Arkansas, some 120 miles east of Little Rock. The facility is used to produce agricultural chemicals, chemicals for the pharmaceutical industry and other specialty chemical products. A substantial portion of the plant's activity involves contract manufacturing. The main products currently manufactured at the plant are Diuron Technical and Linuron Technical bulk herbicides and Trometamol, a pH buffering agent for pharmaceutical and industrial applications and a custom-manufactured herbicide intermediate for a global agricultural chemical producer. Some 50 percent of the Cedar-brand products are exported.

Zone procedures would exempt Cedar from Customs duty payments on foreign materials used in production for export. On domestic shipments, the company or its customers (operating under zone procedures) would be able to choose the duty rates that apply to the finished products instead of the duty-rates that would otherwise apply to the foreign-sourced materials. The HTSUS category and duty rates for the final products and associated inputs are as follows:

Final product/input	HTSUS No.	Duty rate
DIURON TECHNICAL/3,4-dichlorophenyl isocyanate	2924.21.1600	12.8%
	2929.10.3000	$0.026/kg + 15.2%
LINURON TECHNICAL/3,4-dichlorophenyl isocyanate	2924.21.1600	12.8%
	2929.10.3000	$0.026/kg + 15.2%
HERBICIDE (for customer)/benzoic acid compounds	2935.00.1300	duty-free
	2916.31.5000	$0.03/kg + 16.8%
TROMETAMOL/nitromethane	2922.21.1600	duty-free
	2904.20.5000	7.4%

At the outset, the main use of zone procedures would be to allow a customer (operating under zone procedures) choose the duty rate that applies to its finished product (duty-free) rather than the duty rate that would otherwise apply to the foreign-sourced item ($0.03/kg + 16.8%). The application indicates that the savings from zone procedures will help improve the international competitiveness of Cedar and its customers.

In accordance with the Board's regulations, a member of the FTZ Staff has been designated examiner to investigate the application and report to the Board.

Public comment is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is April 1, 1996. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period (to April 15, 1996.)

A copy of the application and accompanying exhibits will be available for public inspection at each of the following locations:

U.S. Department of Commerce District Office, TCBY Tower Bldg., Suite 700, 425 West Capitol Ave., Little Rock, Arkansas 72201

Office of the Executive Secretary, Foreign-Trade Zones Board, U.S. Department of Commerce, Room 3716, 14th and Pennsylvania Avenue, NW., Washington, DC 20230

Dated: January 22, 1996.

John J. Da Ponte, Jr.,

Executive Secretary.

[FR Doc. 96–1612 Filed 1–29–96; 8:45 am]

BILLING CODE 3510–DS–P

[Docket 5–96]

Foreign-Trade Zone 25—Broward County, FL; Application for Subzone Status; Federal-Mogul World Trade, Inc. (Vehicle Components) Ft. Lauderdale, FL

An application has been submitted to the Foreign-Trade Zones Board (the Board) by Broward County, Florida, grantee of FTZ 25, requesting special-purpose subzone status for the warehouse/distribution facility of Federal-Mogul World Trade, Inc. (Federal-Mogul), in Ft. Lauderdale, Florida. (The Federal-Mogul site is currently being operated as part of the general-purpose zone on a temporary basis (until 12–1–96)). The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a-81u), and the regulations of the Board (15 CFR part 400). It was formally filed on January 19, 1996.

The Federal-Mogul facility (200,000 sq. ft. on 17 acres, 109 employees) is located at 1600 North Park Drive, Fort Lauderdale (Broward County), Florida. It is used to warehouse and distribute vehicle components, such as bearings, brakes, pistons, valves, shocks, gaskets and water pumps. Over 90 percent of the products are reexported, primarily to Latin America.

FTZ procedures would exempt Federal-Mogul from Customs duty payments on the foreign items that are reexported. On its domestic sales, the company would be able to defer Customs duties until the foreign items are shipped from the plant. The application indicates that subzone status would help to improve the company's international competitiveness.

In accordance with the Board's regulations, a member of the FTZ Staff has been designated examiner to investigate the application and report to the Board.

Public comment is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is April 1, 1996. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period (to April 15, 1996.

A copy of the application and accompanying exhibits will be available for public inspection at each of the following locations:

U.S. Export Assistance Center, 5600 NW 36th St., Suite 617, Miami, Florida 33166

Office of The Executive Secretary, Foreign-Trade Zones Board, U.S. Department of Commerce, Room 3716, 14th and Constitution Avenue, NW., Washington, DC 20230

Dated: January 22, 1996.

John J. Da Ponte, Jr.,

Executive Secretary.

[FR Doc. 96–1613 Filed 1–29–96; 8:45 am]

BILLING CODE 3510–DS–P

National Oceanic and Atmospheric Administration

[I.D. 012296B]

Pacific Fishery Management Council; Public Meetings

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

ACTION: Notice of public meetings.

SUMMARY: The Pacific Fishery Management Council's Pacific Whiting Allocation Committee will hold public meetings.

DATES: The first of two meetings will be held on February 5 beginning at 1:00 p.m. The meeting may go into the evening until business for the day is completed and continue on February 6 from 8:00 a.m. until 5:00 p.m. The second meeting will be held on February 26 beginning at 1:00 p.m. The meeting may go into the evening until business for the day is completed and continue on February 27 from 8:00 a.m. until 5:00 p.m.

ADDRESSES: The meetings will be held at the Pacific Fishery Management Council, 2130 SW Fifth Avenue, Suite 224, Portland, OR 97201.

FOR FURTHER INFORMATION CONTACT: Jim Glock, Groundfish Fishery Management Coordinator; telephone: (503) 326–6352.

SUPPLEMENTARY INFORMATION: The primary purpose of these meetings is to work towards developing a consensus recommendation to manage the whiting fishery after the current allocation expires at the end of 1996. At the first meeting, analysts will report on the status of economic and social impact analyses as well as the results of the 1995 whiting survey. The committee will develop management alternatives for further consideration. At the second meeting, the committee will continue to work towards narrowing the alternatives to the two that will be presented to the Council at its March meeting. A third meeting, as yet unscheduled, will be held after the Council meeting, at which time the committee will be directed to agree on a single proposal.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Eric Greene at (503) 326–6352 at least 5 days prior to the meeting date.

Dated: January 24, 1996.

Richard W. Surdi,

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

[FR Doc. 96–1640 Filed 1–25–96; 9:35 am]

BILLING CODE 3510–22–F

[I.D. 012396D]

South Atlantic Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The South Atlantic Fishery Management Council (Council) will convene a public meeting of its Snapper-Grouper Assessment Group.

DATES: The meeting will be held on February 5, 1996, from 1:00 p.m. until 5:00 p.m. and continue on February 6, 1996, from 8:30 a.m. until 12:00 noon.

ADDRESSES: The meetings will be held at the Council office. One Southpark Circle, Suite 306, Charleston, SC 29407–4699.

FOR FURTHER INFORMATION CONTACT: Susan Buchanan, Public Information Officer; telephone: (803) 571–4366; fax: (803) 769–4520.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to review biological and fishery date on the condition of wreckfish (*Polyprion Americanus*) in the management unit, and to make recommendations to the Council for wreckfish framework actions (e.g. 1996–97 wreckfish total allowable catch).

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Council office (see **ADDRESSES**) by January 31, 1996.

Dated: January 24, 1996.

Richard W. Surdi,

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

[FR Doc. 96–1726 Filed 1–25–96; 1:27 pm]

BILLING CODE 3510–22–F

[I.D. 012296D]

Marine Mammals

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

ACTION: Receipt of application to modify permit no. 873 (P77(2)#63).

SUMMARY: Notice is hereby given that the Southwest Fisheries Science Center, NMFS, P.O. Box 271, La Jolla, CA 92038–0271, has requested a modification to Permit No. 873.

DATES: Written comments must be received on or before February 29, 1996.

ADDRESSES: The modification request and related documents are available for review upon written request or by appointment in the following office(s):

Permits Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13130, Silver Spring, MD 20910 (301/713–2289);

Director, Southwest Region, NMFS, 501 West Ocean Blvd, Suite 4200, Long Beach, CA 90802–4213 (310/980–4001); and

Coordinator, Pacific Area Office, Southwest Region, National Marine Fisheries Service, 2570 Dole Street, Room 106, Honolulu, HI 96822–2396 (808/973–2987).

Written data or views, or requests for a public hearing on this request should be submitted to the Chief, Permits Division, F/PR1, Office of Protected Resources, Silver Spring, MD 20910. Those individuals requesting a hearing should set forth the specific reasons

why a hearing on this particular request would be appropriate.

FOR FURTHER INFORMATION CONTACT: Trevor Spradlin, 301/713–2289.

SUPPLEMENTARY INFORMATION: The subject modification is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered fish and wildlife (50 CFR part 222).

Permit No. 873 authorizes the Permit Holder to biopsy several species of bow-riding cetaceans off the coasts of Washington, Oregon, California, and Mexico, and to import biopsy tissues collected outside of U.S. waters. The Permit Holder now seeks authorization to import biopsy samples from three additional cetacean species/stocks (i.e., bowhead whale (*Balaena mysticetus*), western Pacific gray whale (*Eschrichtius robustus*), and beluga whale (*Delphinapterus leucas*) from Russian territorial waters. The applicant proposes to initiate this work upon issuance of the modification.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of this application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: January 23, 1996.

Ann D. Terbush,

Chief, Permits and Documentation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 96–1724 Filed 1–29–96; 8:45 am]

BILLING CODE 3510–22–F

[I.D. 012296C]

Marine Mammals and Endangered Species

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

ACTION: Receipt of application for a scientific research permit (P5I).

SUMMARY: Notice is hereby given that Dr. Donald B. Siniff, Department of Ecology, Evolution and Behavior, University of Minnesota, 1987 Upper Buford Circle, St. Paul, MN 55108, has applied in due form for a permit to conduct scientific research on Hawaiian monk seals (*Monachus schauinslandi*).

DATES: Written comments must be received on or before February 29, 1996.

ADDRESSES: The application and related documents are available for review upon written request or by appointment in the following office(s):

Permits Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13130, Silver Spring, MD 20910 (301/713–2289);

Director, Southwest Region, NMFS, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802–4213 (310/980–4001); and

Coordinator, Pacific Area Office, Southwest Region, NMFS, 2570 Dole Street, Room 106, Honolulu, HI 96822–2396 (808/955–8831).

Written data or views, or requests for a public hearing on this request, should be submitted to the Director, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13130, Silver Spring, MD 20910. Those individuals requesting a hearing should set forth the specific reasons why a hearing on this particular request would be appropriate.

FOR FURTHER INFORMATION CONTACT: Jeannie Drevenak, Permits Division, 301/713–2289.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered fish and wildlife (50 CFR parts 217–222). The applicant is requesting to harass (i.e., capture, instrument, release, and recapture for instrument removal) up to 35 adult male and female Hawaiian monk seals (*Monachus schauinslandi*) from the population at French Frigate Shoals, over an 18-month period. The objective of this research is to investigate Hawaiian monk seal movements and foraging patterns using satellite-linked time-depth recorders to characterize habitat use. The applicant wishes to begin research in February 1996.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of this application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: January 23, 1996.

Ann D. Terbush,

Chief, Permits and Documentation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 96–1725 Filed 1–29–96; 8:45 am]

BILLING CODE 3510–22–F

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Announcement of Import Limits and Guaranteed Access Levels for Certain Cotton, Wool and Man-Made Fiber Textile Products Produced or Manufactured in Costa Rica

January 24, 1996.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs establishing limits and guaranteed access levels.

EFFECTIVE DATE: January 31, 1996.

FOR FURTHER INFORMATION CONTACT: Jennifer Aldrich, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 927–5850. For information on embargoes and quota re-openings, call (202) 482–3715.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

The import restraint limits for textile products, produced or manufactured in Costa Rica and exported during the period January 1, 1996 through December 31, 1996 are based on limits notified to the Textiles Monitoring Body pursuant to the Uruguay Round Agreements Act and the Uruguay Round Agreement on Textiles and Clothing (ATC). The Guaranteed Access Levels are being established pursuant to a Memorandum of Understanding dated December 23, 1993 between the Governments of the United States and Costa Rica.

In the letter published below, the Chairman of CITA directs the Commissioner of Customs to establish limits and guaranteed access levels for 1996.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 60 FR 65299, published on December 19, 1995).

Requirements for participation in the Special Access Program are available in **Federal Register** notices 51 FR 21208, published on June 11, 1986; 52 FR 26057, published on July 10, 1987; and

54 FR 50425, published on December 6, 1989; and 55 FR 21047, published on May 22, 1990.

The letter to the Commissioner of Customs and the actions taken pursuant to it are not designed to implement all of the provisions of the Uruguay Round Agreements Act and the ATC, but are designed to assist only in the implementation of certain of their provisions.

Troy H. Cribb,

Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

January 24, 1996.

Commissioner of Customs,
Department of the Treasury, Washington, DC 20229.

Dear Commissioner: Under the terms of section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854), the Uruguay Round Agreements Act and the Uruguay Round Agreement on Textiles and Clothing (ATC); and in accordance with the provisions of Executive Order 11651 of March 3, 1972, as amended, you are directed to prohibit, effective on January 31, 1996, entry into the United States for consumption and withdrawal from warehouse for consumption of cotton, wool and man-made fiber textile products in the following categories, produced or manufactured in Costa Rica and exported during the twelve-month period beginning on January 1, 1996 and extending through December 31, 1996, in excess of the following restraint limits:

Category	Twelve-month limit
340/640	889,229 dozen.
342/642	328,264 dozen.
347/348	1,498,547 dozen.
443	209,152 numbers.
447	11,277 dozen.

Imports charged to these category limits for the period January 1, 1995 through December 31, 1995 shall be charged against those levels of restraint to the extent of any unfilled balances. In the event the limits established for that period have been exhausted by previous entries, such goods shall be subject to the levels set forth in this directive.

The limits set forth above are subject to adjustment in the future according to the provisions of the Uruguay Round Agreements Act, the ATC, and any administrative arrangement notified to the Textiles Monitoring Body.

Pursuant to the Memorandum of Understanding dated December 23, 1993 between the Governments of the United States and Costa Rica; and under the terms of the Special Access Program, as set forth in 51 FR 21208 (June 11, 1986), 52 FR 26057 (July 10, 1987) and 54 FR 50425 (December 6, 1989), you are directed to establish guaranteed access levels for properly certified cotton, wool and man-made fiber textile products in the following categories which are assembled in Costa Rica from fabric formed and cut in the United States and re-exported to the United States from Costa Rica during the period beginning on January 1, 1996 and extending through December 31, 1996:

Category	Guaranteed access level
340/640	650,000 dozen.
342/642	250,000 dozen.
347/348	1,500,000 dozen.
443	200,000 numbers.
447	4,000 dozen.

Any shipment for entry under the Special Access Program which is not accompanied by a valid and correct certification and Export Declaration in accordance with the provisions of the certification requirements established in the directive of May 15, 1990 shall be denied entry unless the Government of Costa Rica authorizes the entry and any charges to the appropriate specific limit. Any shipment which is declared for entry under the Special Access Program but found not to qualify shall be denied entry into the United States.

In carrying out the above directions, the Commissioner of Customs should construe entry into the United States for consumption to include entry for consumption into the Commonwealth of Puerto Rico.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception of the rulemaking provisions of U.S.C.553(a)(1).

Sincerely,

Troy H. Cribb,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc.96–1743 Filed 1–29–96; 8:45 am]

BILLING CODE 3510–DR–F

Announcement of an Import Restraint Limit for Certain Cotton and Man-Made Fiber Textile Products Produced or Manufactured in Fiji

January 24, 1996.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs establishing a limit.

EFFECTIVE DATE: February 1, 1996.

FOR FURTHER INFORMATION CONTACT:

Ross Arnold, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212. For information on the quota status of this limit, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 927–5850. For information on embargoes and quota re-openings, call (202) 482–3715.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

The Governments of the United States and Fiji agreed to extend their current agreement for two consecutive one-year periods beginning on January 1, 1996 and extending through December 31, 1997.

In the letter published below, the Chairman of CITA directs the Commissioner of Customs to establish limits for the 1996 period.

This limit will be subject to revision pursuant to the Uruguay Round Agreements Act and the Uruguay Round Agreement on Textiles and Clothing (ATC) on the date that Fiji becomes a member of the World Trade Organization.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 60 FR 65299, published on December 19, 1995).

The letter to the Commissioner of Customs and the actions taken pursuant to it are not designed to implement all of the provisions of the bilateral agreement, but are designed to assist only in the implementation of certain of its provisions.

Troy H. Cribb,

Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

January 24, 1996.

Commissioner of Customs,
Department of the Treasury, Washington, DC 20229.

Dear Commissioner: Under the terms of section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854); pursuant to the Bilateral Textile Agreement, effected by exchange of notes dated May 24, 1991 and August 20, 1991, as amended and extended, between the Governments of the United States and Fiji; and in accordance with the provisions of Executive Order 11651 of March 3, 1972, as amended, you are directed to prohibit, effective on February 1, 1996, entry into the United States for consumption and withdrawal from warehouse for consumption of cotton and manmade fiber textile products in Categories 338/339/638/639, produced or manufactured in Fiji and exported during the twelve-month period beginning on January 1, 1996 and extending through December 31, 1996, in excess of 1,071,914 dozen[1] of which not more than

[1] The limit has not been adjusted to account for any imports exported after December 31, 1995.

893,262 dozen shall be in Categories 338–S/339–S/638–S/639–S.[2]

Imports charged to this category limit for the period January 1, 1995 through December 31, 1995 shall be charged against that level of restraint to the extent of any unfilled balance. In the event the limit established for that period has been exhausted by previous entries, such goods shall be subject to the level set forth in this directive.

Should Fiji become a member of the World Trade Organization (WTO), the limit set forth above will be subject to adjustment in the future pursuant to the provisions of the Uruguay Round Agreements Act, the Uruguay Round Agreement on Textiles and Clothing and any administrative arrangements notified to the Textiles Monitoring Body.

In carrying out the above directions, the Commissioner of Customs should construe entry into the United States for consumption to include entry for consumption into the Commonwealth of Puerto Rico.

The Committee for the Implementation of Textile Agreements has determined that this action falls within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

Troy H. Cribb,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 96–1744 Filed 1–29–96; 8:45 am]

BILLING CODE 3510–DR–M

Announcement of Import Limits for Certain Cotton, Wool, Man-Made Fiber, Silk Blend and Other Vegetable Fiber Textiles and Textile Products Produced or Manufactured in Taiwan

January 24, 1996.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs establishing limits.

EFFECTIVE DATE: February 1, 1996.

FOR FURTHER INFORMATION CONTACT: Jennifer Aldrich, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 927–6718. For information on embargoes and quota re-openings, call (202) 482–3715.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

In a Memorandum of Understanding (MOU) dated December 29, 1995, the American Institute in Taiwan (AIT) and the Taipei Economic and Cultural Representative Office (TECRO) agreed to amend and extend their current agreement for two consecutive one-year periods beginning on January 1, 1996 and extending through December 31, 1997.

In the letter published below, the Chairman of CITA directs the Commissioner of Customs to establish limits for the 1996 period.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 60 FR 65299, published on December 19, 1995).

The letter to the Commissioner of Customs and the actions taken pursuant to it are not designed to implement all of the provisions of the MOU, but are designed to assist only in the implementation of certain of its provisions.

Troy H. Cribb,

Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

January 24, 1996.

Commissioner of Customs,
Department of the Treasury, Washington, DC 20229.

Dear Commissioner: Under the terms of section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854); pursuant to Memorandum of Understanding (MOU) dated December 29, 1995 between the American Institute in Taiwan and the Taipei Economic and Cultural Representative Office (TECRO); and in accordance with the provisions of Executive Order 11651 of March 3, 1972, as amended, you are directed to prohibit, effective on February 1, 1996, entry into the United States for consumption and withdrawal from warehouse for consumption of cotton, wool, man-made fiber, silk blend and other vegetable fiber textiles and textile products in the following categories, produced or manufactured in Taiwan and exported during the twelve-month period which begins on January 1, 1996 and extends through December 31, 1996, in excess of the following restraint limits:

Category	Twelve-month limit
Group 1:	
200–224, 225/317/326, 226, 227, 229, 300/301/ 607, 313–315, 360–363, 369–L/670–L/870,[1] 369–S,[2] 369–O,[3] 400–414, 464–469, 600–606, 611, 613/614/615/617, 618, 619/620, 621–624, 625/626/627/628/629, 665, 666, 669–P,[4] 669–T,[5] 669–O,[6] 670–H,[7] and 670–O,[8] as a group.	561,758,816 square meters equivalent.
Sublevels in Group 1:	
218	20,114,129 square meters.
225/317/326	35,702,525 square meters.
226	6,478,868 square meters.

[2] Category 338–S: only HTS numbers 6103.22.0050, 6105.10.0010, 6105.10.0030, 6105.90.8010, 6109.10.0027, 6110.20.1025, 6110.20.2040, 6110.20.2065, 6110.90.9068, 6112.11.0030 and 6114.20.0005; Category 339–S: only HTS numbers 6104.22.0060, 6104.29.2049, 6106.10.0010, 6106.10.0030, 6106.90.2510, 6106.90.3010, 6109.10.0070, 6110.20.1030, 6110.20.2045, 6110.20.2075, 6110.90.9070, 6112.11.0040, 6114.20.0010 and 6117.90.9020; Category 638–S: all HTS numbers except 6109.90.1007, 6109.90.1009, 6109.90.1013 and 6109.90.1025; Category 639–S: all HTS numbers except 6109.90.1050, 6109.90.1060, 6109.90.1065 and 6109.90.1070.

Category	Twelve-month limit
300/301/607	1,640,166 kilograms of which not more than 1,366,804 kilograms shall be in Category 300; not more than 1,366,804 kilograms shall be in Category 301; and not more than 1,366,804 kilograms shall be in Category 607.
363	11,965,746 numbers.
369–L/670–L/870	46,172,659 kilograms.
611	2,899,234 square meters.
613/614/615/617	17,980,761 square meters.
619/620	13,216,138 square meters.
625/626/627/628/629	17,197,317 square meters.
669–P	312,641 kilograms.
669–T	1,016,150 kilograms.
670–H	17,680,750 kilograms.
Group I Subgroup:	
200, 219, 313, 314, 315, 361, 369–S and 604, as a group.	136,210,756 square meters equivalent.
Within Group I subgroup:	
200	649,926 kilograms.
219	14,791,664 square meters.
313	64,691,319 square meters.
314	26,347,876 square meters.
315	20,189,186 square meters.
361	1,305,558 numbers.
369–S	447,967 kilograms.
604	218,873 kilograms.
Group II:	
237, 239, 330–332, 333/334/335, 336, 338/339, 340–345, 347/348, 349, 350/650, 351, 352/652, 353, 354, 359–C/659–C,[9] 359–H/659–H,[10] 359–O,[11] 431–444, 445/446, 447/448, 459, 630–632, 633/634/635, 636, 638/639, 640, 641–644, 645/646, 647/648, 649, 651, 653, 654, 659–S,[12] 659–O,[13] 831–844 and 846–859, as a group.	755,000,000 square meters equivalent.
Sublevels in Group II:	
237	634,985 dozen.
239	5,467,216 kilograms.
331	502,181 dozen pairs.
336	108,183 dozen.
338/339	760,244 dozen.
340	1,116,676 dozen.
345	113,039 dozen.
347/348	1,064,931 dozen of which not more than 1,064,931 dozen shall be in Categories 347–W/348–W.[14]
352/652	2,870,220 dozen.
349–C/659–C	1,447,633 kilograms.
359–H/659–H	4,747,826 kilograms.
433	14,792 dozen.
434	10,271 dozen.
435	24,389 dozen.
436	4,855 dozen.
438	27,409 dozen.
440	5,309 dozen.
442	43,607 dozen.
443	41,414 numbers.
444	58,981 numbers.
445/446	134,077 dozen.
631	4,678,788 dozen pairs.
633/634/635	1,634,440 dozen of which not more than 959,317 dozen shall be in Categories 633/634 and not more than 850,077 dozen shall be in Category 635.
638/639	6,565,058 dozen
640	1,058,909 dozen of which not more than 281,710 dozen shall be in Category 640–Y.[15]
642	777,133 dozen.
643	492,845 numbers.
644	688,863 numbers.
645/646	4,107,691 dozen.
647/648	5,248,544 zone of which not more than 5,248,544 dozen shall be in Categories 647–W/648–W.[16]
659–S	1,601,702 kilograms.
835	18,103 dozen.
Group II Subgroup:	
333/334/335, 341, 342, 350/650, 351, 447/448, 636, 641 and 651, as a group.	74,639,669 square meters equivalent.
Within Group II Subgroup:	
333/334/335	278,326 dozen of which not more than 150,760 dozen shall be in Category 335.

Category	Twelve-month limit
341	334,872 dozen.
342	209,196 dozen.
350/650	132,691 dozen.
351	348,033 dozen.
447/448	20,212 dozen.
636	372,236 dozen.
641	728,891 dozen of which not more than 255,112 dozen shall be in Category 641–Y.[17]
651	436,458 dozen.
Group III:	
Sublevel in Group III—845	849,513 dozen.

[1] Category 870; Category 369–L; only HTS numbers 4202.12.4000, 4202.12.8020, 4202.12.8060, 4202.92.1500, 4202.92.3015 and 4202.92.6090; Category 670–L; only HTS numbers 4202.12.8030, 4202.12.8070, 4202.92.3020, 4202.92.3030 and 4202.92.9025.

[2] Category 369–S: only HTS number 6307.10.2005.

[3] Category 369–O: all HTS numbers except 4202.12.4000, 4202.12.8020, 4202.12.8060, 4202.92.1500, 4202.92.3015, 4202.92.6090 (Category 369–L); and 6307.10.2005 (Category 369–S).

[4] Category 669–P: only HTS numbers 6305.32.0010, 6305.32.0020, 6305.33.0010, 6305.33.0020 and 6305.39.0000.

[5] Category 669–T: only HTS numbers 6306.12.0000, 6306.19.0010 and 6306.22.9030.

[6] Category 669–O; all HTS numbers except 6305.32.0010, 6305.32.0020, 6305.33.0010, 6305.33.0020, 6305.39.0000 (Category 669–P); 6306.12.0000, 6306.19.0010 and 6306.22.9030 (Category 669–T).

[7] Category 670–H; only HTS numbers 4202.22.4030 and 4202.22.8050.

[8] Category 670–O: all HTS numbers except 4202.22.4030 4202.22.8050 (Category 670–H); 4202.12.8030, 4202.12.8070, 4202.92.3020, 4202.92.3030 and 4202.92.9025 (Category 670–L).

[9] Category 359–C: only HTS numbers 6103.42.2025, 6103.49.8034, 6104.62.1020, 6104.69.8010, 6114.20.0048, 6114.20.0052, 6203.42.2010, 6203.42.2090, 6204.62.2010, 6211.32.0010, 6211.32.0025 and 6211.42.0010; Category 659–C: only HTS numbers 6103.23.0055, 6103.43.2020, 6103.43.2025, 6103.49.2000, 6103.49.8038, 6104.63.1020, 6104.63.1030, 6104.69.1000, 6104.69.8014, 6114.30.3044, 6114.30.3054, 6203.43.2010, 6203.43.2090, 6203.49.1010, 6203.49.1090, 6204.63.1510, 6204.69.1010, 6210.10.9010, 6211.33.0010, 6211.33.0017 and 6211.43.0010.

[10] Category 359–H: only HTS numbers 6505.90.1540 and 6505.90.2060; Category 659–H: only HTS numbers 6502.00.9030, 6504.00.9015, 6504.00.9060, 6505.90.5090, 6505.90.6090, 6505.90.7090 and 6505.90.8090.

[11] Category 359–O: all HTS numbers except 6103.42.2025, 6103.49.8034, 6104.62.1020, 6104.69.8010, 6114.20.0048, 6114.20.0052, 6203.42.2010, 6203.42.2090, 6204.62.2010, 6211.32.0010, 6211.32.0025 and 6211.42.0010 (Category 359–C); 6505.90.1540 and 6505.90.2060 (Category 359–H).

[12] Category 659–S: only HTS numbers 6112.31.0010, 6112.31.0020, 6112.41.0010, 6112.41.0020, 6112.41.0030, 6112.41.0040, 6112.11.1010, 6111.11.1020, 6111.12.1010, and 6211.12.1020.

[13] Category 659–O: all HTS numbers except 6103.23.0055, 6103.43.2020, 6103.43.2025, 6103.49.2000, 6103.49.8038, 6104.63.1020, 6104.63.1030, 6104.69.1000, 6104.69.8014, 6114.30.3044, 6114.30.3054, 6203.43.2010, 6203.43.2090, 6203.49.1010, 6203.49.1090, 6204.63.1510, 6204.69.1010, 6210.10.9010, 6211.33.0010, 6211.33.0017, and 6211.43.0010 (Category 659–C); 6502.00.9030, 6504.00.9015, 6504.00.9060, 6505.90.5090, 6505.90.6090, 6505.90.6090, 6505.90.7090, 6205.90.8090 (Category 659–H); 6112.31.0010, 6112.31.0020, 6112.41.0010, 6112.41.0020, 6112.41.0030, 6112.41.0040, 6211.11.1010 6211.11.1020, 6211.12.1010 and 6211.12.1020 (Category 659–S).

[14] Category 347–W: only HTS numbers 6203.19.1020, 6203.19.9020, 6203.22.3020, 6203.22.3030, 6203.42.4005, 6203.42.4010, 6203.42.4015, 6203.42.4025, 6203.42.4035, 6203.42.4045, 6203.42.4050, 6203.42.4060, 6203.49.8020, 6210.40.9033, 6211.20.1520, 6211.20.3810, and 6211.32.0040; Category 348–W: only HTS numbers 6204.12.0030, 6204.19.8030; 6204.22.3040, 6204.22.3050, 6204.29.4034, 6204.62.3000, 6204.62.4005, 6204.62.4010, 6204.62.4020, 6204.62.4030, 6204.62.4040, 6204.62.4050, 6204.62.4055, 6204.62.4065, 6204.69.6010, 6204.69.9010, 6210.50.9060, 6211.20.1550, 6211.20.6810, 6211.42.0030 and 6217.90.9050.

[15] Category 640–Y: only HTS numbers 6205.30.2010, 6205.30.2020, 6205.30.2050 and 6205.30.2060.

[16] Category 647–W: only HTS numbers 6203.23.0060, 6203.23.0070, 6203.29.2030, 6230.29.2035, 6203.43.2500, 6203.43.3500, 6203.43.4010, 6203.43.4020, 6203.43.4030, 6203.43.4040, 6203.49.1500, 6203.49.2015, 6203.49.2030, 6203.49.2045, 6203.49.2060, 6203.49.8030, 6210.40.5030, 6211.20.1525, 6211.20.3820 and 6211.33.0030; Category 648–W: only HTS numbers 6204.23.0040, 6204.23.0045, 6204.29.2020, 6204.29.2025, 6204.29.4038, 6204.63.2000, 6204.63.3000, 6204.63.3510, 6204.63.3530, 6204.63.3532, 6204.63.3540, 6204.69.2510, 6204.69.2530, 6204.69.2540, 6204.69.2560, 6204.69.6030, 6204.69.9030, 6210.50.5035, 6211.20.1555, 6211.20.6820, 6211.43.0040 and 6217.90.9060.

[17] Category 641–Y: only HTS numbers 6204.23.0050, 6204.29.2030, 6206.40.3010 and 6206.40.3025.

Imports charged to these category limits for the period January 1, 1995 through December 31, 1995 shall be charged against those levels of restraint to the extent of any unfilled balances. In the event the limits established for that period have been exhausted by previous entries, such good shall be subject to the levels set forth in this directive.

The limits set forth above are subject to adjustment in the future according to the provisions of the current bilateral textile agreement, effected by exchange of notes dated August 21, 1990 and September 28, 1990, as amended and extended. The conversion factors are as follows:

Category	Conversion factors (square meters equivalent/ category unit)
300/301/607	8.5
333/334/335	33.75
352/652	11.3
359–C/659–C	10.1
359–H/659–H	11.5
369–L/670–L/870	3.8
633/634/635	34.1
638/639	12.5

In carrying out the above directions, the Commissioner of Customs should construe entry into the United States for consumption to include entry for consumption into the Commonwealth of Puerto Rico.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

Troy H. Cribb,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 96–1745 Filed 1–29–96; 8:45 am]

BILLING CODE 3510–DR–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Privacy Act of 1974; Notice to Add a System of Records

AGENCY: Department of Defense.

ACTION: Notice to add a system of records.

SUMMARY: The Office of the Secretary of Defense is proposing to add one system of records notice to its inventory of

Privacy Act systems of records notices subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: The addition is effective February 29, 1996, unless comments are received that would result in a contrary determination.

ADDRESSES: Send comments to the OSD Privacy Act Officer, Washington Headquarter Services, Correspondence and Directives Division, Records Management Division, 1155 Defense Pentagon, Room 5C315, Washington, DC 20301–1155.

FOR FURTHER INFORMATION CONTACT: Mr. Dan Cragg at (703) 695–0970.

SUPPLEMENTARY INFORMATION: The Office of the Secretary of Defense systems of records notices subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on January 5, 1996, to the Committee on Government Reform and Oversight of the House of Representatives, the Committee on Governmental Affairs of the Senate, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, 'Federal Agency Responsibilities for Maintaining Records About Individuals,' dated July 25, 1994 (59 FR 37906, July 25, 1994).

Dated: January 23 1996.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

DHA 07

SYSTEM NAME:

Defense Medical Information System (DMIS).

SYSTEM LOCATION:

Primary location: Directorate of Information Management, Building 1422, Fort Detrick, MD 21702–5000.

Secondary location: Service Medical Treatment Facility Medical Centers and Hospitals, and Uniformed Services Treatment Facilities. For a complete listing of all facility addresses write to the system manager.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Uniformed services medical beneficiaries enrolled in the Defense Enrollment Eligibility Reporting System (DEERS) or those who receive medical care at one or more of DoD's medical treatment facilities (MTFs) or one of the Uniformed Services Treatment Facilities (USTFs), or who have care provided under the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) program.

CATEGORIES OF RECORDS IN THE SYSTEM:

Selected data elements extracted from the DEERS beneficiary and enrollment records. Electronic files containing beneficiary identifier, date of birth, gender, sponsor status (active duty or retired), relationship of patient to sponsor, pay grade of sponsor, state or country, zip code, and enrollment and eligibility status.

Individual patient hospital discharge records. Electronic files containing patient ID, date of birth, gender, sponsor status (active duty or retired), relationship to sponsor, pay grade of sponsor, state or country, zip code, health care dates and services, provider, service status, health status, billed amount, allowed amount, amount paid by beneficiary, amount applied to deductible, and amount paid by government.

Selected data elements extracted from the CHAMPUS medical claims records. Electronic files containing patient ID, date of birth, gender, sponsor status (active duty or retired), relationship to sponsor, pay grade of sponsor, state or country, zip code, health care dates and services, provider, service status, health status, billed amount, allowed amount, amount paid by beneficiary, amount applied to deductible, and amount paid by government.

Data elements extracted from the DEERS electronic Non-availability Statement (NAS) application. Records containing beneficiary ID, date and types of health care services not covered by the issuing entity (MTFs, etc.), along with other demographic and issuing entity information.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 1102 and E.O. 9397.

PURPOSE(S):

DMIS collects data from multiple DoD electronic medical systems and processes and integrates the data in a manner that permits health management policy analysts to study, evaluate, and recommend changes to DoD health care programs. Analysis of beneficiary utilization of military medical and other program resources is possible using DMIS. Statistical and trend analysis permits changes in response to health care demand and treatment patterns. The system permits the projection of future Medical Health Services System (MHSS) beneficiary population, utilization requirements, and program costs to enable health care management concepts and programs to be responsive and up to date.

The detailed patient level data at the foundation of DMIS permits analysis of virtually any aspect of the military health care system.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

To the Health Care Finance Administration for conducting demographic and financial analytical studies.

To the Congressional Budget Office for projecting costs and workloads associated with DoD Medical benefits.

To the Department of Veterans Affairs (DVA) for coordinating cost sharing activities between the DoD and DVA.

The 'Blanket Routine Uses' set forth at the beginning of OSD's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on optical and magnetic media.

RETRIEVABILITY:

Records may be retrieved by individual's Social Security Number, sponsor's Social Security Number, Beneficiary ID (sponsor's ID, patient's name, patient's DOB, and family member prefix or DEERS dependent suffix).

SAFEGUARDS:

Automated records are maintained in a controlled area accessible only to authorized personnel. Entry to this area is restricted to personnel with a valid requirement and authorization to enter. Physical entry is restricted by the use of a cipher lock on the only entrance to the computer room. Personal data maintained at the back-up site is stored in a locked room.

Access to DMIS records is restricted to individuals who require the data in the performance of official duties. Access is controlled through use of passwords.

RETENTION AND DISPOSAL:

Records are permanent. They are transferred to the National Archives

when no longer needed. Records are depersonalized by replacing identifiers with non-indexed control numbers before transfer to the National Archives.

SYSTEM MANAGER(S) AND ADDRESS:

Corporate Executive Information System Program Office, Six Skyline Place, Suite 698, 5109 Leesburg Pike, Falls Church, VA 22041–3201.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the Corporate Executive Information System Program Office, Six Skyline Place, Suite 698, 5109 Leesburg Pike, Falls Church, VA 22041–3201.

Requests should contain the full names of the beneficiary and sponsor, sponsor Social Security Number, sponsor service, beneficiary date of birth, beneficiary sex, treatment facility(ies), and fiscal year(s) of interest.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system of records should address written requests to Corporate Executive Information System Program Office, Six Skyline Place, Suite 698, 5109 Leesburg Pike, Falls Church, VA 22041–3201.

Requests should contain the full names of the beneficiary and sponsor, sponsor Social Security Number, sponsor service, beneficiary date of birth, beneficiary sex, treatment facility(ies) that have provided care, and fiscal year(s) of interest.

CONTESTING RECORD PROCEDURES:

The OSD rules for accessing records, for contesting contents and appealing initial agency determinations are contained in OSD Administrative Instruction 81; 32 CFR part 311; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

The individual data records that are assembled to form the DMIS data base are submitted by the Military Departments, the Defense Enrollment Eligibility Reporting System, the Office of the Civilian Health and Medical Program for the Uniformed Services, the Uniformed Service Treatment Facility Managed Care System, and the Health Care Finance Administration.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 96–01615 Filed 01–29–96; 8:45 am]

BILLING CODE 5000–04–F

Department of the Navy

Community Redevelopment Authority and Available Surplus Buildings and Land at Military Installations Designated for Closure: Naval Research Laboratory, Underwater Sound Reference Detachment, Orlando, FL (NRLUSRDO)

SUMMARY: This Notice provides information regarding the redevelopment authority that has been established to plan the reuse of the NRLUSRDO and the surplus property that is located at that base closure site.

FOR FURTHER INFORMATION CONTACT: John J. Kane, Director, Department of the Navy, Real Estate Operations, Naval Facilities Engineering Command, 200 Stovall Street, Alexandria, VA 22332–2300, telephone (703) 325–0474, or Mr. E.R. Nelson, Director, Real Estate Division, Southern Division, Naval Facilities Engineering Command, North Charleston, SC 29419–9010, telephone (803) 820–7494. For more detailed information regarding particular properties identified in this Notice (i.e., acreage, floor plans, sanitary facilities, exact street address, etc.), contact Mr. Gary Woods, Naval Research Laboratory, PO Box 568337, Orlando, FL 32856–8337, telephone (407) 857–5140.

SUPPLEMENTARY INFORMATION: In 1995, the NRLUSRDO, was designated for closure pursuant to the Defense Base Closure and Realignment Act of 1990, Pub. L. 101–510, as amended. Pursuant to this designation, on September 28, 1995, land and facilities at this installation were declared excess to the Department of the Navy and available for use by other federal agencies. No interest has been expressed.

Notice of Surplus Property

Pursuant to paragraph (7)(B) of section 2905(b) of the Defense Base Closure and Realignment Act of 1990, as amended by the Base Closure Community Redevelopment and Homeless Assistance Act of 1994 (Pub. L. 103–421), the following information regarding the redevelopment authority and surplus property at the NRLUSRDO is published in the **Federal Register**.

Redevelopment Authority

The redevelopment authority for the NRLUSRDO for purposes of implementing the provisions of the Defense Base Closure and Realignment Act of 1990, as amended, is Orange County, FL. The points of contact are Mr. Robert E. Wiegers, Orange County Planning Department, and Ms. Ceretha Leon, Assistant County Administrator, 201 S. Rosalind Ave., Orlando, FL 32802, telephone (407) 836–5600 or (407) 836–5362.

Surplus Property Descriptions

The following is a listing of the land and facilities at the NRLUSRDO that are surplus to the federal government.

Land

Approximately 10.50 acres of improved fee simple land, of which 7 acres is submerged land at the NRLUSD in Orange County, FL and approximately 7.5 acres of fee simple land in Lake County, FL. In general, all areas will be available upon the closure of the Laboratory, anticipated for March 1997.

Buildings

The following is a summary of the facilities located on the above described land which will also be available when the Laboratory closes in March 1997, unless otherwise indicated. Property numbers are available on request.

Miscellaneous facilities (27 structures) Comments: Approx. 79,394 square feet. Includes administrative, storage, and laboratory facilities.

—Paved areas. Comments: Includes roads, sidewalks, and parking areas.

Expressions of Interest

Pursuant to paragraph 7(C) of section 2905(b) of the Defense Base Closure and Realignment Act of 1990, as amended by the Base Closure Community Redevelopment and Homeless Assistance Act of 1994, state and local governments, representatives of the homeless, and other interested parties located in the vicinity of the NRLUSRDO shall submit to Orange County, FL a notice of interest, of such governments, representatives and parties in the above described surplus property, or any portion thereof. A notice of interest shall describe the need of the government, representative, or party concerned for the desired surplus property. Pursuant to paragraphs 7(C) of said section 2905(b), Orange County shall assist interested parties in evaluating the surplus property for the intended use and publish in a newspaper of general circulation in Florida the date by which expressions of interest must be submitted.

Dated: January 19, 1996.

Michael A. Waters,

LCDR, JAGC, USN, Federal Register Liaison Officer.

[FR Doc. 96–1662 Filed 1–29–96; 8:45 am]

BILLING CODE 3810–FF–P

Community Redevelopment Authority and Available Surplus Buildings and Land at Military Installations Designated for Closure: Naval Reserve Center, Sheboygan, WI

SUMMARY: This Notice provides information regarding the redevelopment authority that has been established to plan the reuse of the Naval Reserve Center, Sheboygan, WI, and the surplus property that is located at that base closure site.

FOR FURTHER INFORMATION CONTACT: John J. Kane, Director, Department of the Navy, Real Estate Operations, Naval Facilities Engineering Command, 200 Stovall Street, Alexandria, VA 22332–2300, telephone (703) 325–0474, or Mr. E.R. Nelson, Director, Real Estate Division, Southern Division, Naval Facilities Engineering Command, North Charleston, SC 29419–9010, telephone (803) 820–7494. For more detailed information regarding particular properties identified in this Notice (i.e., acreage, floor plans, sanitary facilities, exact street address, etc.), contact Mr. Steve Campbell at the above North Charleston address and at telephone (803) 820–7492.

SUPPLEMENTARY INFORMATION: In 1995, the Naval Reserve Center, Sheboygan, WI, was designated for closure pursuant to the Defense Base Closure and Realignment Act of 1990, Public Law 101–510, as amended. Pursuant to this designation, on 28 September 1995, land and facilities at this installation were declared excess to the Department of the Navy and available for use by other federal agencies. No interest has been expressed.

Notice of Surplus Property

Pursuant to paragraph (7)(B) of Section 2905(b) of the Defense Base Closure and Realignment Act of 1990, as amended by the Base Closure Community Redevelopment and Homeless Assistance Act of 1994 (Pub. L. 103–421), the following information regarding the redevelopment authority and surplus property at the Naval Reserve Center, Sheboygan, WI is published in the **Federal Register**:

Redevelopment Authority

The redevelopment authority for the Naval Reserve Center, Sheboygan, WI for purposes of implementing the provisions of the Defense Base Closure and Realignment Act of 1990, as amended, is the City of Sheboygan, WI. The Director of City Development is Mr. Robert Peterson, 807 Center Avenue, Sheboygan, WI 53081–4414, telephone (414) 459–3377.

Surplus Property Descriptions

The following is a listing of the land and facilities at the Naval Reserve Center, Sheboygan, WI that are surplus to the federal government.

Land

Approximately 1.20 acres of improved fee simple land at the Naval Reserve Center, Sheboygan, WI. In general, all areas will be available upon the closure of the Center, anticipated for September 1996.

Buildings

The following is a summary of the facilities located on the above described land which will also be available when the Center closes in September 1996, unless otherwise indicated. Property numbers are available on request.

—Office/administration building. Comments: Approx. 14,200 square feet.

—Paved areas. Comments: Includes roads, sidewalks, and parking areas.

Expressions of Interest

Pursuant to paragraph 7(C) of Section 2905(b) of the Defense Base Closure and Realignment Act of 1990, as amended by the Base Closure Community Redevelopment and Homeless Assistance Act of 1994, state and local governments, representatives of the homeless, and other interested parties located in the vicinity of the Naval Reserve Center, Sheboygan, Wisconsin shall submit to the City of Sheboygan a notice of interest, of such governments, representatives and parties in the above described surplus property, or any portion thereof. A notice of interest shall describe the need of the government, representative, or party concerned for the desired surplus property. Pursuant to paragraphs 7(C) of said Section 2905(b), the City of Sheboygan shall assist interested parties in evaluating the surplus property for the intended use and publish in a newspaper of general circulation in Wisconsin the date by which expressions of interest must be submitted.

Dated: January 19, 1996.

M.A. Waters,

LCDR, JAGC, USN, Federal Register Liaison Officer.

[FR Doc. 96–1663 Filed 1–29–96; 8:45 am]

BILLING CODE 3810–FF–P

Community Redevelopment Authority and Available Surplus Buildings and Land at Military Installations Designated for Closure: Point Molate Fuel Department, Richmond, CA

SUMMARY: This Notice provides information regarding the redevelopment authority that has been established to plan the reuse of the Point Molate Fuel Department, located in Richmond, Contra Costa County, California, and the surplus property that is located at that base closure site.

FOR FURTHER INFORMATION CONTACT: John J. Kane, Director, Department of the Navy, Real Estate Operations, Naval Facilities Engineering Command, 200 Stovall Street, Alexandria, VA 22332–2300, telephone (703) 325–0474, or Mr. William R. Carsillo, Real Estate Center, Engineering Field Activity West, 900 Commodore Drive, San Bruno, CA 94066–5006, telephone (415) 244–3815, facsimile (415) 244–3803. For more detailed information regarding particular properties identified in this Notice (i.e., acreage, floor plans, sanitary facilities, exact street address, etc.), contact Lieutenant Commander Rich Iannicca, Base Closure Officer, Fleet and Industrial Supply Center Oakland, 250 Executive Way, Oakland, CA 94625–5000, telephone (510) 302–5377, facsimile (510) 302–5381.

SUPPLEMENTARY INFORMATION: In 1995, Point Molate Fuel Department, Richmond, CA, was designated for closure pursuant to the Defense Base Closure and Realignment Act of 1990, Public Law 101–510, as amended. Pursuant to this designation, on 28 September 1995, land and facilities at this installation were declared excess to the Department of Navy and made available for use by other federal public agencies. No interest has been expressed.

Notice of Surplus Property

Pursuant to paragraph (7)(B) of section 2905(b) of the Defense Base Closure and Realignment Act of 1990, as amended by the Base Closure Community Redevelopment and Homeless Assistance Act of 1994, the following information regarding the redevelopment authority for and surplus property at Point Molate Fuel Department, Richmond, CA is published in the **Federal Register**:

Redevelopment Authority

The redevelopment authority for Point Molate Fuel Department, Richmond, CA for purposes of implementing the provisions of the Defense Base Closure and Realignment Act of 1990, as amended, is the LRA for

Point Molate. Day to day operations of the Commission are handled by a professional staff. The address of the redevelopment authority: LRA for Point Molate, 2600 Barret Avenue, Richmond, California 94804, telephone (510) 620–6952.

Surplus Property Descriptions

The following is a listing of the land and facilities at Point Molate Fuel Department, Richmond, CA, that are surplus to the Federal government.

Land

Approximately 413 acres of improved and unimproved fee simple land at the Point Molate Fuel Department, located in the City of Richmond, Contra Costa County, California. In general, all areas will be available upon the closure of the facility, anticipated for 1998.

Buildings

The following is a summary of the facilities located on the above described land which will also be available when the facility closes in 1998, unless otherwise indicated. Property numbers are available on request.

—Petroleum product storage and distribution systems. 17 miles of aboveground and underground pipeline with associated facilities, and 23 above and below ground tanks with a total capacity of 1.1 million barrels.
—Piers and moorings. (3 structures.)
—Warehouse/storage. (9 structures). 336,308 square feet.
—Office/administration. (1 structure). 6,136 square feet.
—Fire station. (1 structure). 4,236 square feet.
—Housing. (29 single-family units). 32,928 square feet.
—Garages. (6 structures). 6,325 square feet.
—Heating plant. (1 structure). 2,255 square feet.
—Public works shops. (3 structures). 8,141 square feet.
—Laboratory. (1 structure). 8,900 square feet.
—Vehicle maintenance. (1 structure). 1,711 square feet.
—Utilities. Gas, electrical, water, telephone, sewer.
—Railroad. 4.3 miles of track.

Expressions of Interest

Pursuant to paragraph 7(C) of section 2905(b) of the Defense Base Closure and Realignment Act of 1990, as amended by the Base Closure Community Redevelopment and Homeless Assistance Act of 1994, State and local governments, representatives of the homeless, and other interested parties located in the vicinity of the Point Molate Fuel Department, Richmond, CA, shall submit to the said redevelopment authority (LRA for Point Molate) a notice of interest, of such governments, representatives and parties in the above described surplus property, or any portion thereof. A notice of interest shall describe the need of the government, representative, or party concerned for the desired surplus property. Pursuant to paragraphs 7(C) of said Section 2905(b), the redevelopment authority shall assist interested parties in evaluating the surplus property for the intended use and publish in a newspaper of general circulation in Richmond, California the date by which expressions of interest must be submitted.

Dated: January 19, 1996.

M.A. Waters,

LCDR, JAGC, USN, Federal Register Liaison Officer.

[FR Doc. 96–1661 Filed 1–29–96; 8:45 am]

BILLING CODE 3810–FF–P

Notice of Public Hearing for the Draft Environmental Impact Statement for the Disposal and Reuse of Naval Base Philadelphia, Philadelphia, PA

SUMMARY: Pursuant to Council on Environmental Quality regulations (40 CFR parts 1500–1508) implementing procedural provisions of the National Environmental Policy Act, the Department of the Navy has prepared and filed with the U.S. Environmental Protection Agency the Draft Environmental Impact Statement (DEIS) for the Disposal and Reuse of Naval Base Philadelphia, Philadelphia, PA. This action is being conducted in accordance with the Defense Base Closure and Realignment Act of 1990 (Pub. L. 101–510).

The DEIS has been distributed to various federal, state, and local agencies, elected officials, special interest groups, the media, and the South Philadelphia Branch of the Free Library of Philadelphia; 1700 South Broad Street, Philadelphia. A limited number of single copies are available at the address listed at the end of this notice for public review and comment. A public hearing to inform the public of the DEIS findings and to solicit comments will be held on February 15, 1996, beginning at 7:30 p.m., at the South Philadelphia Community Center, 2600 South Broad Street (corner of Broad St. and Oregon Ave.), Philadelphia, Pennsylvania. Please call the point of contact listed below or the Community Center at (610) 467–1500 in the case of inclement weather to confirm that the meeting will take place.

Federal, state, local agencies and interested parties are invited and urged to be present or represented at the hearing. Oral statements will be heard and transcribed by a stenographer; however, to ensure accuracy of the record, all statements should be submitted in writing. All statements, both oral and written, will become part of the public record on this study. Equal weight will be given to both oral and written statements.

ADDRESSES: Written comments on the DEIS should be mailed to the address noted below, and must be postmarked by March 4, 1996 to become part of the official record. Additional information concerning this notice may be obtained by contacting Ms. Tina Deininger, (Code 202), Northern Division, Naval Facilities Engineering Command, 10 Industrial Highway, MSC 82, Lester, PA, 19113, telephone (610) 595–0759, facsimile (610) 595–0778.

Dated: January 25, 1996.

M.D. Schetzsle,

LT, JAGC, USNR, Alternate Federal Register Liaison Officer.

[FR Doc. 96–1669 Filed 1–29–96; 8:45 am]

BILLING CODE 3810–FF–M

Notice of Intent To Prepare an Environmental Impact Statement on General Development at the Acoustic Research Detachment, Bayview, ID

SUMMARY: Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969, as implemented by the Council on Environmental Quality regulations (40 CFR parts 1500–1508), the Department of the Navy announces its intent to prepare an Environmental Impact Statement (EIS) to evaluate the environmental effects of implementing a plan for General Development at the Naval Surface Warfare Center, Acoustic Research Detachment (ARD) in Bayview, Idaho. Bayview is situated on Scenic Bay in the southern end of Lake Pend Oreille in Kootenai County, Idaho. Bayview is approximately 70 miles northeast of Spokane, Washington, 35 miles north of Coeur D'Alene, Idaho, and approximately 75 miles south of the Canadian border.

The mission of the ARD is to support underwater acoustic research experiments. Lake Pend Oreille provides certain characteristics that provide an ideal acoustic and water quality environment for research experiments. The ARD operates facilities ashore and in Lake Pend Oreille. The shore facilities are generally

divided into the Waterfront Industrial Area and Upland Base. The Waterfront Industrial Area, located along the lake shoreline, is suited to water access, berthing, and equipment maintenance facilities. The Upland Base, located on a bluff above the shoreline, is suited to administrative facilities. Currently, functions and facilities are scattered among dispersed facilities causing inefficiency in operations. Planning for future operations at ARD has identified a need to consolidate dispersed facilities and functions, bringing together related functions for an increased operations efficiency.

Two alternative programs for improvements to both the Waterfront Industrial Area and the Upland Base have been identified to accomplish this goal. These alternatives will focus on design and configuration options for two principal developmental projects. These projects are the construction and operation of a Model Engineering and Support Facility (MESF) and an Acoustic Test and Analysis Center (ATAC). The EIS will address the environmental impacts of these two projects and associated capital improvements in comparative analysis. The EIS will also address ARD operations supported by these facilities, including acoustic experimentation in Lake Pend Oreille. The No Action alternative would result in continuing operations at ARD and using the existing facilities without change.

The proposed MESF is needed to improve waterborne operational efficiency. It would incorporate an interior model life well, storage, maintenance shop, and laboratory space. It would replace an existing barge which is not adequate to support mission requirements of storage and handling capacity. As proposed, the MESF is a pile-supported structure over a dredged slip area used for retrieving models from the lake. Several design options are available for environmental analysis, including a pile support option, a floating barge support option, and no-dredge model slip option.

The proposed ATAC would consolidate project management, computer centers, record storage, and conference facilities with Waterfront Industrial area shop functions in a new facility located near the present site of Building 1. The proposed ATAC would replace the existing Building 1 and provide additional vehicle maneuverability and laydown space along the shoreline within the Waterfront Industrial Area. Building 1 would be demolished. In the alternative design option for this facility project, management, computer, storage, and conference functions would be located in a new facility in the Upland Base. The Waterfront Industrial Area shops would be consolidated in a new building to be located near Building 1; Building 1 would also be demolished under this alternative.

In addition to construction of these facilities, the proposed action includes a number of other associated capital improvements in the Waterfront Industrial Area and Upland Base. Improvements in the Waterfront Industrial Area would include extension of the floating log-boom wave diffuser, construction of a pier to the existing model support platform, and relocation and construction of a new hazardous materials handling facility. The new construction would require removal of 1940's vintage buildings and other temporary structures. Associated with these improvements are bank stabilization projects to protect the lake and Navy resources. Improvements to the Upland Base would include the relocation of the main gate and entry road, expansion of the main parking lot, and construction of a new recreation activity area.

The EIS will discuss environmental impacts resulting from construction and operation of these facilities, mitigation measures, and indirect environmental impacts to area land use patterns. Significant environmental issues that will be addressed in the EIS will include, but not limited to, impacts on water quality, shoreline habitat, threatened and endangered species, groundwater, land use, transportation, noise, utilities, aesthetics, air quality, cultural resources, and environmental justice. Cumulative impacts associated with the implementation of the proposed action, including associated operations, will also be considered.

Federal, State and local agencies, and interested individuals are encouraged to participate in the scoping process to determine the range of issues and general development of alternatives to be addressed by the EIS. A public scoping meeting to receive oral and written comments will be held on Tuesday, February 27, 1996, at the Bayview Community Center, 16304 Perimeter Road, Bayview, Idaho 83803, at 7 p.m. In the interest of available time, each speaker will be asked to limit oral comments to five minutes. To be most helpful, scoping comments should clearly describe specific issues or topics which the commentor believes the EIS should address.

ADDRESSES. Written comments should be sent to the address listed below and submitted no later than March 15, 1996 to become part of the official record. Questions regarding the scoping process should also be addressed to: Commanding Officer, Engineering Field Activity Northwest; Naval Facilities Engineering Command, 19917 Seventh Avenue NE, Poulsbo, WA 98370–7579 (Attn: Mr. Peter Havens, Code 232PH), telephone (360) 396–0916, fax (360) 396–0854.

Dated: January 25, 1996.

M.D. Schetzsle,

Lt, JAGC, USNR, Alternate Federal Register Liaison Officer.

[FR Doc. 96–1670 Filed 1–29–96; 8:45 am]

BILLING CODE 3810–FF–M

DEPARTMENT OF EDUCATION

National Assessment Governing Board

AGENCY: National Assessment Governing Board; Education.

ACTION: Notice of Teleconference meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of a forthcoming meeting of the Executive Committee of the National Assessment Governing Board. This notice also describes the functions of the Board. Notice of this meeting is required under Section 10(a)(2) of the Federal Advisory Committee Act. This document is intended to notify the general public of their opportunity to attend.

DATES: February 2, 1996.

TIME: 1:00 p.m.–2:30 p.m. (e.s.t.).

LOCATION: 800 North Capitol Street, NW, Suite 825, Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Mary Ann Wilmer, Operations Officer, National Assessment Governing Board, Suite 825, 800 North Capitol Street, N.W., Washington, D.C., 20002–4233, Telephone: (202) 357–6938.

SUPPLEMENTARY INFORMATION: The National Assessment Governing Board is established under section 412 of the National Education Statistics Act of 1994 (Title IV of the Improving America's Schools Act of 1994).

The Board is established to formulate policy guidelines for the National Assessment of Educational Progress. The Board is responsible for selecting subject areas to be assessed, developing assessment objectives, identifying appropriate achievement goals for each grade and subject tested, and establishing standards and procedures for interstate and national comparisons.

The Executive Committee of the National Assessment Governing Board will meet February 2, 1996 from 1:00

p.m. until 2:30 p.m. Because this is a teleconference meeting, facilities will be provided so the public will have access to the Committee's deliberations. The Committee will review and approve the agenda for the March meeting of the Board; review progress of Planning Initiative; discuss priorities for 1997 and 1998 assessments, and plans for the release of the 1996 math report.

Records are kept of all Board proceedings and are available for public inspection at the U.S. Department of Education, National Assessment Governing Board, Suite 825, 800 North Capitol Street, N.W., Washington, D.C., from 8:30 a.m. to 5:00 p.m.

Dated: January 25, 1996.

Roy Truby,

Executive Director, National Assessment Governing Board.

[FR Doc. 96–1727 Filed 1–29–96; 8:45 am]

BILLING CODE 4000–01–M

DEPARTMENT OF ENERGY

[FE Docket No. EA–98–A]

Application To Amend Electricity Export Authorization; Western Systems Power Pool

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of application.

SUMMARY: The Western Systems Power Pool (WSPP) filed an application to amend its authorization to export electricity to Canada by adding the names of ten new member companies to the list of authorized exporters.

DATES: Comments, protests or requests to intervene must be submitted on or before February 29, 1996.

ADDRESSES: Comments, protests or requests to intervene should be addressed as follows: U.S. Department of Energy, Office of Fossil Energy (FE–52), 1000 Independence Avenue, SW Washington, DC 20585–0350.

FOR FURTHER INFORMATION CONTACT: Ellen Russell (Program Office) 202–586–9624 or Mike Skinker (Program Attorney) 202–586–6667.

SUPPLEMENTARY INFORMATION: Exports of electricity from the United States to a foreign country are regulated and require authorization under section 202(e) of the Federal Power Act.

On September 2, 1994, in Order No. EA–98, the Office of Fossil Energy (FE) authorized 22 members of the Western System Power Pool (WSPP) in order to transmit electric energy from the United States to Canada. Specifically, the Order authorized each of the 22 entities to individually export electric energy to British Columbia Hydro and Power Authority (BC Hydro), or other future Canadian members of the WSPP, under the terms and conditions of the WSPP's pooling agreement and service schedules approved by the Federal Energy Regulatory Commission (FERC). The order further authorized that the electric energy be transmitted using the international transmission facilities of the Bonneville Power Administration.

On December 29, 1995, WSPP, on behalf of the following member companies, filed a request to amend Order No. EA–98 by adding their names to the list of authorized exporters in this docket:

Coastal Electric Services Company
Englehard Power Marketing, Inc.
Enron Power Marketing
Entergy Power, Inc.
Equitable Power Services Company
Heartland Energy Services
Illinova Power Marketing, Inc.
Koch Power Services, Inc.
LG&E Power Marketing Inc.
Valero Power Services Company

By this joint application, each of the participating Pool members seeks an export authorization allowing them to enter into transactions with BC Hydro which involve the exportation of electricity from the United States. All such transactions would occur pursuant to the terms and conditions of the WSPP's pooling agreement and service schedules approved by the FERC.

Procedural Matters

Any person desiring to be heard or to protest this application should file a petition to intervene or protest at the address provided above in accordance with §§ 385.211 or 385.214 of the Rules of Practice and Procedure (18 CFR 385.211, 385.214).

Any such petitions and protests should be filed with the DOE on or before the date listed above. Additional copies of such petitions to intervene or protests also should be filed directly with Michael E. Small, Wright & Talisman, Suite 600, 1200 G Street, NW, Washington, DC 20005–3802

Pursuant to 18 CFR 385.211, protests and comments will be considered by the DOE 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 must file a petition to intervene under 18 CFR 385.214. Section 385.214 requires that a petition to intervene must state, to the extent known, the position taken by the petitioner and the petitioner's interest in sufficient factual detail to demonstrate either that the petitioner has a right to participate because it is a State Commission; that it has or represents an interest which may be directly affected by the outcome of the proceeding, including any interest as a consumer, customer, competitor, or a security holder of a party to the proceeding; or that the petitioner's participation is in the public interest.

A final decision will be made on this application after a determination is made by the DOE that the proposed action will not impair the sufficiency of electric supply within the United States or will not impede or tend to impede the coordination in the public interest of facilities in accordance with section 202(e) of the Federal Power Act.

Before an export authorization may be issued, the environmental impacts of the proposed DOE action (i.e., granting the export authorization, with any conditions and limitations, or denying it) must be evaluated pursuant to the National Environmental Policy Act of 1969.

Copies of this application will be made available, upon request, for public inspection and copying at the address provided above.

Issued in Washington, DC, on January 22, 1996.

Anthony J. Como,

Director, Office of Coal & Electricity, Office of Fuels Programs, Office of Fossil Energy.

[FR Doc. 96–1607 Filed 1–29–96; 8:45 am]

BILLING CODE 6450–01–P

Environmental Management Site-Specific Advisory Board, Fernald

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: Pursuant to the provisions of the Federal Advisory Committee Act (Public Law 92–463, 86 Stat. 770) notice is hereby given of the following Advisory Committee meeting: Environmental Management Site-Specific Advisory Board (EM SSAB), Fernald.

DATES: Saturday, February 10, 1996: 8:30 a.m.–12:00 p.m.

ADDRESS: The Joint Information Center, 6025 Dixie Highway, Route 4, Fairfield, Ohio.

FOR FURTHER INFORMATION CONTACT: John S. Applegate, Chair of the Fernald Citizens Task Force, P.O. Box 544, Ross, Ohio 45061, or call the Fernald Citizens Task Force office (513) 648–6478.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE and its regulators in the areas of future use, cleanup levels, waste

disposition and cleanup priorities at the Fernald site.

Tentative Agenda: Saturday, February 10, 1996

8:30 a.m. Call to Order; Chair's Remarks
8:45 a.m. Committee Chairs' Reports
9:00 a.m. Discussion of On-Site Disposal Cell Issues
10:30 a.m. Break
10:45 a.m. Develop Recommendations
11:45 a.m. Opportunity for Public Input
12:00 a.m. Adjourn

A final agenda will be available at the meeting, Saturday, February 10, 1996.

Public Participation: The meeting is open to the public. Written statements may be filed with the Task Force chair either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact the Task Force chair at the address or telephone number listed above. Requests must be received 5 days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Designated Federal Official, Gary Stegner, Public Affairs Officer, Ohio Field Office, U.S. Department of Energy, is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Each individual wishing to make public comment will be provided a maximum of 5 minutes to present their comments. This notice is being published less than 15 days before the date of the meeting, due to programmatic issues that had to be resolved prior to publication.

Minutes: The minutes of this meeting will be available for public review and copying at the Freedom of Information Public Reading Room, 1E–190, Forrestal Building, 1000 Independence Avenue, SW, Washington, DC 20585 between 9:00 a.m. and 4:00 p.m., Monday-Friday, except Federal holidays. Minutes will also be available by writing to John S. Applegate, Chair, the Fernald Citizens Task Force, P.O. Box 544, Ross, Ohio 45061 or by calling the Task Force message line at (513) 648–6478.

Issued at Washington, DC on January 25, 1996.

Rachel Murphy Samuel,

Acting Deputy Advisory Committee Management Officer.

[FR Doc. 96–1730 Filed 1–29–96; 8:45 am]

BILLING CODE 6450–01–P

Environmental Management Site-Specific Advisory Board, Hanford Site

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: Pursuant to the provisions of the Federal Advisory Committee Act (Public Law 92–463, 86 Stat. 770) notice is hereby given of the following Advisory Committee meeting: Environmental Management Site-Specific Advisory Board (EM SSAB), Hanford Site.

DATES: Thursday, February 1, 1996: 9 a.m.–5:15 p.m. Friday, February 2, 1996: 8:30 a.m.–4:30 p.m.

ADDRESSES: Ramada Inn, 435 Clover Island, Kennewick, Washington.

FOR FURTHER INFORMATION CONTACT: Jon Yerxa, Public Participation Coordinator, Department of Energy Richland Operations Office, P.O. Box 550, Richland, WA, 99352.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE and its regulators in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda

February Meeting Topics

The Hanford Advisory Board will receive information on and discuss issues related to: Strategic Planning Update and Proposal, Proposed Advice on 1995 Budget Reallocations, Risk Data Sheets, Recommendations on 300 Area Cleanup, Groundwater Strategy Document, and an Update on N Springs Wall. The Committee will also receive updates from various Subcommittees, including reports on: the Environmental Protection Agency's Budget and Reorganization, National Waste Management Programmatic Environmental Impact Statement, Tank Waste Remediation System Tri-Party Agreement Change Negotiations, M–33 Status of Negotiations, M&I Contract Status, and Workforce Restructuring.

Public Participation

The meeting is open to the public. Written statements may be filed with the Committee either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Jon Yerxa's office at the address or telephone number listed above. The Designated Federal Official is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Each individual wishing to make public comment will be provided a maximum of 5 minutes to present their comments. Due to programmatic issues that had to be resolved, the **Federal Register** notice is being published less than fifteen days before the date of the meeting.

Minutes

The minutes of this meeting will be available for public review and copying at the Freedom of Information Public Reading Room, 1E–190, Forrestal Building, 1000 Independence Avenue, SW, Washington, DC 20585 between 9:00 a.m. and 4 p.m., Monday–Friday, except Federal holidays. Minutes will also be available by writing to Jon Yerxa, Department of Energy Richland Operations Office, P.O. Box 550, Richland, WA 99352, or by calling him at (509) 376–9628.

Issued at Washington, DC on January 24, 1996.

Rachel Murphy Samuel,

Acting Deputy Advisory Committee Management Officer.

[FR Doc. 96–1609 Filed 1–29–96; 8:45 am]

BILLING CODE 6450–01–P

Environmental Management Site-Specific Advisory Board, Monticello Site

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) notice is hereby given of the following Advisory Board Committee Meeting: Environmental Management Site-Specific Advisory Board, Monticello Site.

DATE AND TIME: Tuesday, April 16, 1996 6 p.m.–8 p.m.

ADDRESS: Monticello City Office, 17 North 1st East, Monticello, Utah 84535.

FOR FURTHER INFORMATION CONTACT: Audrey Berry, Public Affairs Specialist, Department of Energy Grand Junction Projects Office, P.O. Box 2567, Grand Junction, CO, 81502 (303) 248–7727.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to advise DOE and its regulators in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda: Reports from subcommittees on local training and hiring, health and safety, and future land use.

Public Participation: The meeting is open to the public. Written statements may be filed with the Committee either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Audrey Berry's office at the address or telephone number listed above. Requests must be received 5 days prior to the meeting and reasonable

provision will be made to include the presentation in the agenda. The Designated Federal Official is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Each individual wishing to make public comment will be provided a maximum of 5 minutes to present their comments.

Minutes: The minutes of this meeting will be available for public review and copying at the Freedom of Information Public Reading Room, 1E–190, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585 between 9 a.m. and 4 p.m., Monday–Friday, except Federal holidays. Minutes will also be available by writing to Audrey Berry, Department of Energy Grand Junction Projects Office, P.O. Box 2567, Grand Junction, CO 81502, or by calling her at (303) 248–7727.

Issued at Washington, DC, on January 25, 1996.

Rachel Murphy Samuel,

Acting Deputy Advisory Committee Management Officer.

[FR Doc. 96–1731 Filed 1–29–96; 8:45 am]

BILLING CODE 6450–01–P

Privacy Act of 1974; Establishment of a New System of Records

AGENCY: Department of Energy (DOE).

ACTION: Proposed establishment of a new Privacy Act system of records.

SUMMARY: The Department of Energy (DOE) proposes to establish a new system of records entitled "DOE–88 Epidemiologic and Other Health Studies, Surveys and Surveillances." The Department has established an epidemiology and health surveillance program to determine the health effects of the Department's activities on workers and populations having access, or in proximity, to the Department's facilities. Federal Agencies are required by the Privacy Act of 1974 and Office of Management and Budget Circular A–130, Transmittal Memorandum No. 2, July 15, 1994, to publish notice in the **Federal Register** of proposed systems of records.

DATES: The proposed new system of records will become effective without further notice 40 days after publication in the **Federal Register** (March 11, 1996) unless comments are received on or before that date that would result in a contrary determination and a notice is published to that effect.

ADDRESSES: Written comments should be directed to the following address: Director, FOIA/Privacy Act Division, Office of Executive Secretariat, U.S. Department of Energy, HR–78, 1000 Independence Avenue, SW, Washington, DC 20585. Any written comments received will be available for inspection at the above address between the hours of 9 a.m. and 4 p.m.

FOR FURTHER INFORMATION CONTACT: (1) Heather Stockwell, Acting Director, Office of Epidemiologic Studies, EH–62, U.S. Department of Energy, 19901 Germantown Road, Germantown, MD 20874–1290, (301) 903–3721; or (2) GayLa D. Sessoms, Director, FOIA/Privacy Act Division, HR–78, U.S. Department of Energy, 1000 Independence Avenue, SW, Washington, DC 20585, (202) 586–5955; or (3) Harold Halpern, Office of General Counsel, GC–80, U.S. Department of Energy, 1000 Independence Avenue, SW, Washington, DC 20585, (202) 586–7406.

SUPPLEMENTARY INFORMATION: The DOE proposes to establish a new system of records entitled "DOE–88 Epidemiological and Other Health Studies, Surveys and Surveillances". The Department has established an epidemiology and health surveillance program to determine the health effects of the Department's activities on workers and populations having access, or in proximity, to the Department's facilities. Epidemiological studies are an important means of determining the status of, and improving, public health. Epidemiological studies permit the scientific evaluation of the effects of exposure to potentially harmful materials by determining and quantifying health effects associated with such exposures. Health surveys, which are used to assess immediate health issues, are designed to discover the occupational source of outbreaks of illness, injury, or death, and to describe the extent of exposure to specific substances at a single point in time. Surveillance is used to identify new and emerging health problems by monitoring groups of workers, who have the same job or exposures, for changes in their illness and injury patterns over time.

Information in the proposed new system will assist the Department in studying and monitoring individual employee and aggregate population health risks from exposures to radiation, chemicals, or other hazards that may have occurred as a result of the Department's operations and other energy-related activities. The studies should provide information that is necessary for long-range energy planning pursuant to continued development of the national energy strategy. The health studies include all Department facilities and workers and other special populations that have relevance to the Department's mission.

Pursuant to the Memoranda of Understanding with the Department of Health and Human Services ("HHS"), 56 FR 9701, March 7, 1991, and the Agency for Toxic Substances and Disease Registry ("ATSDR"), October 10, 1990, studies, surveys and surveillances will be conducted for DOE by units of the Public Health Service, the National Institute for Occupational Safety and Health, the National Center for Environmental Health, and ATSDR, and their contractors, grantees, and cooperative agreement holders. States also may perform studies as the Department's or the Department of Health and Human Services' contractors, grantees, or cooperative agreement holders.

Records in the new system will have the following routine uses, among others:

(1) A record from this system of records may be disclosed to facilitate health hazard evaluations, epidemiological studies, or public health activities required by law performed by personnel, contractor personnel, grantees, and cooperative agreement holders of components of the Department of Health and Human Services, including the National Institute for Occupational Safety and Health, the National Center for Environmental Health of the Centers for Disease Control and Prevention, and the Agency for Toxic Substances and Disease Registry pursuant to Memoranda of Understanding between the Department and the Department of Health and Human Services or its components.

(2) Subject to the same Privacy Act limitations applicable to employees of the Department, a record from this system of records may be disclosed as a routine use to contractors, grantees, participants in cooperative agreements, collaborating researchers, or their employees, in performance of health studies or related health or environmental duties pursuant to their contracts, grants, and cooperating or collaborating research agreements. In order to perform such studies, the Department, its contractors, grantees, participants in cooperative agreements, and collaborating researchers may disclose a record: to Federal, State, and local health and medical agencies or authorities; to subcontractors in order to determine a subject's vital status or cause of death; to health care providers to verify a diagnosis or cause of death; or to third parties to obtain current addresses for participants in health-

related studies, surveys, and surveillances. All recipients of such records are required to comply with the Privacy Act, to follow prescribed measures to protect personal privacy, and to disclose or use personally identifiable information only for the above described research purposes.

(3) A record from this system of records may be disclosed to members of Department advisory committees, the Department of Health and Human Services Advisory Committee on Projects Related to Department of Energy Facilities, and to designated employees of Federal, State, or local government, or government-sponsored entities, authorized to provide advice to the Department concerning health, safety, or environmental issues. All recipients of such records are required to comply with the Privacy Act, to follow prescribed measures to protect personal privacy, and to disclose or use personally identifiable information only for the purpose of providing advice to the Department or to the Department of Health and Human Services.

The proposed new system of records should not have adverse privacy consequences. Health studies tend to benefit persons in the studied populations by identifying increases in adverse health effects following exposure to toxic agents. Individuals are never identified in published studies and the studies are not used to support determinations concerning any individual's rights, benefits, or privileges. Regarding current and former employees of the Department, its predecessors and their contractors, the proposed system will contain information gathered from other Department systems permitting disclosure for health studies as routine uses, as well as information gathered from individuals and employers.

Furthermore, privacy interests will be protected by a number of means. As a condition of releasing individually identifiable information for studies, surveys, or surveillances conducted for DOE, persons conducting studies will, consistent with the routine uses, be required to: (1) Keep personal information confidential; (2) use personal information only for purposes of studies in which there is no publication of the identity of any individual subject; (3) consult with DOE prior to any release of personally identifiable information obtained from DOE; (4) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record; (5) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project under these same conditions and with written authorization of the Department, (c) for disclosure to an authorized person for the purpose of an audit related to the research project, and (d) when required by law. Additionally, the Department will secure a written statement attesting to the recipient's understanding of, and willingness to abide by, these provisions. The provisions in this paragraph apply to DOE collaborating researchers, not those studies being performed by the Department of Health and Human Services.

Privacy safeguards are in place regarding the studies to be conducted pursuant to the Memoranda of Understanding with Department of Health and Human Services or its components. Department of Health and Human Services has agreed: (1) Not to use or disclose any personally-identifiable information obtained from DOE or its contractors and grantees except for research purposes; (2) not to use information in identifiable form to make any determination about the rights, benefits, or privileges of any individual; (3) to use and disclose information in accord with agreements under which the personally-identifiable information was obtained by the Department or its contractors and provided such use or disclosure is consistent with applicable law; (4) to notify the Department of any efforts to use or obtain personally-identifiable information for purposes other than research or other public health activities required by law; (5) to use and take appropriate steps to prevent improper disclosure; (6) to establish or modify Privacy Act systems of records broadening the "Categories of Individuals" section to specifically address information provided by DOE, as necessary, and consult with the Department concerning provisions of Privacy Act systems of records notices. Additionally, Department of Health and Human Services requires its contractors, grantees, and cooperative agreement holders performing epidemiological studies to abide by conditions similar to those imposed by the Department, as described in this paragraph.

The proposed system will contain records gathered from other Department of Energy systems of records having routine uses that permit disclosure for health studies. *See* 60 FR 33510 (June 28, 1995) (amending routine uses in DOE–1, DOE–5, DOE–13, DOE–33, DOE–35, DOE–36, DOE–38, DOE–40, DOE–67, DOE–71, DOE–72, and DOE–73). The types of records needed will be determined by the design and goals of each particular study. Examples of possible types of data needed from other Department systems of records include, questionnaires, demographic information, work history, medical and reproductive history, birth data, radiation and other exposure history, laboratory test results, data from prior health studies, surveys, and surveillances, and alcohol and tobacco use history. Such data are found in records such as health study or personnel files and lists, training files, medical records, legal case files, bioassay records, industrial hygiene files, radiation and other hazard exposure records, occupational and industrial accident records, employee medical insurance claims, personnel security clearance questionnaires, and employee and visitor access control records.

The new system of records may contain data concerning current and former employees of DOE, its predecessor agencies, and their contractors and subcontractors, as well as other designated individuals included in authorized epidemiologic or other health studies, surveys, and surveillances pertaining to any potential health hazard (including electromagnetic fields) associated with energy production, transmission, or use. The system may also contain data about individuals exposed to radiation or other industrial toxicants as a result of living or working in proximity to DOE facilities. Members of the general population selected as control groups may also be included.

DOE is submitting the report required by Office of Management and Budget Circular A–130 concurrently with the publication of this notice. The text of the systems notice is set forth below.

Issued in Washington, DC this 19th day of January 1996.

Archer L. Durham,

Assistant Secretary for Human Resources and Administration.

DOE–88

SYSTEM NAME:

Epidemiologic and Other Health Studies, Surveys and Surveillances.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION(S):

U.S. Department of Energy, Office of Environment, Safety and Health, Office of Health Studies (EH–62), Germantown, MD 20874–1290. Portions may also be located with contractors, other entities involved in conducting or

managing health studies, surveys, and surveillances, or other Department offices listed below:

1. U.S. Department of Energy, Alaska Power Administration, 2770 Sherwood Lane, Juneau, AK 99801–8545
2. U.S. Department of Energy, Albuquerque Operations Office, P.O. Box 5400, Albuquerque, NM 87185–5400
3. U.S. Department of Energy, Bartlesville Project Office, 220 North Virginia Avenue, P.O. Box 1398, Bartlesville, OK 74003
4. U.S. Department of Energy, Bonneville Power Administration, P.O. Box 3621, Portland, OR 97208
5. U.S. Department of Energy, Chicago Operations Office, 9800 South Cass Avenue, Argonne, IL 60439
6. U.S. Department of Energy, Golden Field Office, 1617 Cole Boulevard, Golden, CO 80401
7. U.S. Department of Energy, Grand Junction, P.O. Box 2567, Grand Junction, CO 81502–2567
8. U.S. Department of Energy, Headquarters, 1000 Independence Avenue, SW., Washington, DC 20585
9. U.S. Department of Energy, Idaho Operations Office, 785 DOE Place, Idaho Falls, ID 83401
10. U.S. Department of Energy, Morgantown Energy Technology Center, 3610 Collins Ferry Road, P.O. Box 880, Morgantown, WV 26507–0880
11. U.S. Department of Energy, Nevada Operations Office, P.O. Box 98518, Las Vegas, NV 89193–8518
12. U.S. Department of Energy, Oak Ridge Operations Office, P.O. Box 2001, Oak Ridge, TN 37831
13. U.S. Department of Energy, Oakland Operations Office, 1301 Clay Street, Oakland, CA 94612–5208
14. U.S. Department of Energy, Ohio Field Office, 1 Mound Road, Miamisburg, OH 45342
15. U.S. Department of Energy, Pittsburgh Energy Technology Center, P.O. Box 10940, Pittsburgh, PA 15236–0940
16. U.S. Department of Energy, Pittsburgh Naval Reactors, P.O. Box 109, West Mifflin, PA 15122–0109
17. U.S. Department of Energy, Richland Operations Office, 825 Jadwin Avenue, P.O. Box 550, Richland, WA 99352
18. U.S. Department of Energy, Rocky Flats Office, P.O. Box 928, Golden, CO 80402–0928
19. U.S. Department of Energy, Savannah River Operations Office, P.O. Box A, Aiken, SC 29801
20. U.S. Department of Energy, Schenectady Naval Reactors Office, P.O. Box 1069, Schenectady, NY 12301
21. U.S. Department of Energy, Southeastern Power Administration, Samuel Elbert Building, Public Square, Elberton, GA 30635
22. U.S. Department of Energy, Southwestern Power Administration, P.O. Box 1619, Tulsa, OK 74101
23. U.S. Department of Energy, Strategic Petroleum Reserve Project Office, 900 Commerce Road East, New Orleans, LA 70123
24. U.S. Department of Energy, Western Area Power Administration, P.O. Box 3402, Golden, CO 80401

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The system includes data about individuals who were included in any authorized epidemiologic or other health study, survey, or surveillance. Such persons include current and former employees of the Department, its predecessor agencies, and their contractors and subcontractors, as well as other individuals included in health studies, surveys, and surveillances pertaining to any potential health hazard (including electromagnetic fields) associated with energy production, transmission, or use. Accordingly, persons having access, or in proximity, to the Department's facilities, persons involved in or effected by energy production activities, and members of the general population selected as control groups may also be included. Personal information in this system of records concerning current and former employees of the Department, its predecessors, and their contractors is derived from other Department of Energy systems of records having routine uses permitting disclosure for health studies, as well as from other sources.

CATEGORIES OF RECORDS IN THE SYSTEM:

The specific types of records collected and maintained are determined by the needs of the individual study, survey, or surveillance. Examples include, but are not limited to, questionnaires, demographic information, work history, medical and reproductive history, birth data, radiation and other exposure history, laboratory test results, data from prior studies, surveys, and surveillances, alcohol and tobacco use history, and illness absence information. Information may be collected directly from individuals, as well as extracted as necessary from personnel files and lists, training files, medical records, legal case files, bioassay records, industrial hygiene files, payroll and leave records, radiation and other hazard exposure records, occupational and industrial accident records, employee insurance claims, personnel security clearance questionnaires, personnel assurance program records, and related sources.

Authority:

5 U.S.C. 301, Pub. L. 89–554, 89 Stat. 379 (1966); authority incorporated by reference in Title III of the Department of Energy Organization Act at 42 U.S.C. 7151 and 7297, Pub. L. 95–91, 91 Stat. 565 (1977), including 42 U.S.C. 2201(c), 2201(i)(3), 5813 and 5817;

PURPOSE:

This system will contain data for epidemiological and other health studies, surveys and surveillances, performed by the Department and the Department of Health and Human Services performing studies for the Department, their contractors, grantees, and collaborating researchers. The health studies pertain to individual and aggregate population health risks from exposures to radiation, or other chemical, physical, or biological hazards that may occur or may have occurred as a result of the Department's, its predecessor agencies', and their contractors' operations, or as a result of energy production, transmission, or use. Individually identifiable information does not appear in published epidemiological studies or other published health studies, surveys, and surveillances. However, the system will contain records compiled in completing published and unpublished studies, surveys, and surveillances from which information may be retrieved by name or other personal identifier.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

(1) A record from this system of records may be disclosed to facilitate health hazard evaluations, epidemiological studies, or public health activities required by law performed by personnel, contractor personnel, grantees, and cooperative agreement holders of components of the Department of Health and Human Services, including the National Institute for Occupational Safety and Health, the National Center for Environmental Health of the Centers for Disease Control and Prevention, and the Agency for Toxic Substances and Disease Registry pursuant to the Memoranda of Understanding between the Department and the Department of Health and Human Services or its components.

(2) Subject to the same Privacy Act limitations applicable to employees of

the Department, a record from this system of records may be disclosed as a routine use to contractors, grantees, participants in cooperative agreements, collaborating researchers, or their employees, in performance of health studies or related health or environmental duties pursuant to their contracts, grants, and cooperating or collaborating research agreements. In order to perform such studies, the Department, its contractors, grantees, participants in cooperative agreements, and collaborating researchers may disclose a record: To Federal, State, and local health and medical agencies or authorities; to subcontractors in order to determine a subject's vital status or cause of death; to health care providers to verify a diagnosis or cause of death; or to third parties to obtain current addresses for participants in health-related studies, surveys and surveillances. All recipients of such records are required to comply with the Privacy Act, to follow prescribed measures to protect personal privacy, and to disclose or use personally identifiable information only for the above described research purposes.

(3) A record from this system of records may be disclosed to members of Department advisory committees, the Department of Health and Human Services Advisory Committee on Projects Related to Department of Energy Facilities, and to designated employees of Federal, State, or local government, or government-sponsored entities, authorized to provide advice to the Department concerning health, safety, or environmental issues. All recipients of such records are required to comply with the Privacy Act, to follow prescribed measures to protect personal privacy, and to disclose or use personally identifiable information only for the purpose of providing advice to the Department or to the Department of Health and Human Services.

(4) A record from this system of records may be disclosed, as a routine use, to DOE contractors in performance of their contracts, and their officers and employees who have a need for the record in the performance of their duties subject to the same limitations applicable to DOE officers and employees under the Privacy Act.

(5) A record from this system of records may be disclosed to the Department of Justice when: (a) DOE or any component thereof; (b) any DOE employee, or employee of a DOE predecessor agency, in an official capacity; (c) the United States Government; (d) any current or former DOE contractor, or employee of such contractor, is a party to or has an interest in litigation and DOE determines that the records are both relevant and necessary and the use of such records by the Department of Justice is deemed by DOE to be compatible with the purpose for which DOE collected the records.

(6) A record from this system of records may be disclosed to the Archivist of the United States, the National Archives and Records Administration or to the General Services Administration for records management conducted under 44 U.S.C. 2904 and 2906.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Electromagnetic storage material, microfilm, paper records, and computer printouts.

RETRIEVABILITY:

By name, study/surveillance-assigned control number, or social security number. Some of these records may be entered into a database. Records in a database may be retrieved by name, or other personal identifier, as dictated by the needs of the particular researcher.

SAFEGUARDS:

During business hours, records at Department sites are maintained in secured buildings with access limited to those whose official duties require access; during nonbusiness hours, the records are in guarded, secured rooms. Paper records are maintained in labeled cabinets. Access to secured records is limited to individuals having a need-to-know as determined by the Department's Office of Epidemiology and Health Surveillances. Magnetic disk or tape records will be secured in a computer storage area. Printed or readable reports will be under the control of a custodian and stored and processed as sensitive unclassified material.

RETENTION AND DISPOSAL:

After data needed for a study or surveillances is collected and processed, the system manager will give written authorization for destruction of personal identifiers and source documents, unless the information is needed for further research or other purposes. Records retention and disposal authorities are contained in the General Records Schedule and DOE records schedules which have been approved by the National Archives and Records Administration. See DOE Order 1324.5B. Records within the DOE are destroyed by shredding, burning, or burial in a sanitary landfill, as appropriate.

SYSTEM MANAGER AND ADDRESS:

U.S. Department of Energy, Director, Office of Epidemiologic Studies, EH–62, Germantown, Md. 20874–1290.

NOTIFICATION PROCEDURES:

a. Requests by an individual to determine if a system or records contains information about him/her should be directed to: Director, Freedom of Information and Privacy Act Division, U.S. Department of Energy, Washington, DC 20585, or the Freedom of Information and Privacy Officer at the operations offices listed above in accordance with DOE's Privacy Act regulations (10 CFR part 1008, 45 FR 61576, September 16, 1980).

b. Required identifying information: Individual's name; address; employer(s), and employment dates at the time of any exposure that was, or may have been, the focus of a study, survey, or surveillance; social security number; current name; address; and telephone number.

RECORD ACCESS PROCEDURES:

Same as notification procedures.

CONTESTING RECORD PROCEDURES:

Same as notification procedures.

RECORD SOURCE CATEGORIES:

Subject individual and subject individual's employer, including DOE and its predecessor agencies and their contractors and subcontractors.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 96–1608 Filed 1–29 –96; 8:45 am]
BILLING CODE 6450–01–P

Federal Energy Regulatory Commission

[Docket No. TM96–2–97–002]

Chandeleur Pipe Line Company; Notice of Compliance Filing

January 24, 1996.

Take notice that on January 17, 1996, Chandeleur Pipe Line Company (Chandeleur) tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1, the following sheets, to become effective January 1, 1996; Third Revised Sheet No. 5, First Revised Sheet No. 8, First Revised Sheet No. 14 and Original Sheet No. 64A, implementing a provision for Fuel and Line Loss Allowance fixed retention percentage.

Chandeleur states that the purpose of this filing is to comply with the

Commission's order issued December 29, 1995, in TM96–2–97–000, which directed Chandeleur to file, within 15 days of such order, to revise its tariff to identify the affected rate schedules and specify the step-by-step arithmetic averaging formula it uses to compute the fixed retention percentage. The Commission also directed Chandeleur to indicate the beginning and ending months of the 12-month base period used in the percentage formula, how underrecoveries or overrecoveries will be factored into its annual reconciliation, and to include in the step-by-step explanation of its methodology the allocation and classification of the fuel use and line loss gas it uses. Specifically, Chandeleur has revised Section 5 of Rate Schedules FT and IT and added Section 21 to the General Terms and Conditions to clarify Chandeleur's intentions, and has included the methodology and timing of any fuel reimbursement percentage adjustments and which rate schedules will be subject to such adjustments.

Chandeleur states that it is serving copies of the filing to its customers, State Commissions and interested parties.

Any person desiring to protest this filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with 18 CFR 385.211 of the Commission's Rules and Regulations. All such protests must be filed as provided in Section 154.210 of the Commission's Regulations. 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. 96–1705 Filed 1–29–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket Nos. RP94–96–016 and RP94–213–013 (Consolidated)]

CNG Transmission Corporation; Notice of Proposed Changes in FERC Gas Tariff

January 22, 1996.

Take notice that on January 17, 1996, CNG Transmission Corporation (CNG), tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1, and its FERC Gas Tariff, Original Volume No. 2A, various tariff sheets. CNG requested an effective date on July 1, 1994, for certain of these sheets, and a January 1, 1996 effective date for the remainder. CNG states that it has also submitted intervening sheets with various effective dates, as indicated in Attachment A to the transmittal letter of CNG's filing.

CNG states that the purpose of its filing is to submit the remainder of the tariff sheets from appendices to the June 28. Stipulation, and intervening sheets that were filed by CNG in various dockets and approved by the Commission, subsequent to the captioned proceedings. CNG further states that it has made one formatting improvement to the rate tariff sheets enclosed: to more clearly state the rates for CNG services on Sheet Nos. 31 through 37 of its tariff, CNG has revised the designation of rates so that each rate will be expressed as dollars per Dt, rather than a combination of rate components expressed in terms of dollars per Dt and cents per Dt.

CNG states that copies of this letter of transmittal and enclosures are being mailed to parties to the captioned proceeding, and to CNG's customers and interested state commissions.

Any person desiring to protest this filing should file a protest with the Federal Energy Regulatory Commission, Washington, DC, 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed as provided in Section 154.210 of the Commission's Regulations. 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. 96–1698 Filed 1–29–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP96–74–001]

Colorado Interstate Gas Company; Notice of Compliance Filing

January 24, 1996.

Take notice that on January 16, 1996, Colorado Interstate Gas Company (CIG), tendered for filing workpapers further supporting its stranded Account No. 858 surcharge filing made with the Federal Energy Regulatory Commission (FERC) on December 1, 1995. The filing was made pursuant to the Commission's letter order dated December 28, 1995 in Docket No. RP96–74–000 which directed CIG to provide additional workpapers which shows information supporting the derivation of instant surcharge adjustment.

CIG states that copies of the filing were served upon the company's intervening jurisdictional customers and interested state commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed as provided in Section 154.210 of the Commission's Regulations. 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. 96–1702 Filed 1–29–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP95–408–005]

Columbia Gas Transmission Corporation; Notice of Proposed Changes in FERC Gas Tariff

January 24, 1996.

Take notice that on January 17, 1996, Columbia Gas Transmission Corporation (Columbia) tendered for filing to become part of its FERC Gas Tariff, Second Revised Volume No. 1, the following substitute tariff sheet, to be effective February 1, 1996:

2nd Substitute Eleventh Revised Sheet No. 25

On December 29, 1995, Columbia submitted a filing in compliance with the Commission's "Suspension Order" issued on August 31, 1995 in Docket RP95–408, proposing tariff sheets to become effective February 1, 1996. Due to a clerical error the incremental surcharge associated with the total rate charge to Equitable Gas Company was misstated on Substitute Eleventh Revised Sheet No. 25. Footnote 5 on this sheet indicates that the incremental surcharge applicable to the assignees under the seller's former Rate Schedule X–70 is $1.525/Dth for the Reservation Charge and 8.70¢/Dth for the commodity rate. The correct incremental surcharge is $.857/Dth for the Reservation Charge and 7.11¢ for the commodity rate. No other rates or tariffs sheets are affected since the error was limited to Footnote 5 which occurred

following the preparation of the overall rate design.

Columbia states that copies of its filing have been mailed to all firm customers interested interruptible customers, affected state regulatory commissions and the official service list in this proceeding.

Any person desiring to protest this filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed as provided in Section 154.210 of the Commission's Regulations. 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. 96–1699 Filed 1–29–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP96–63–001]

Iroquois Gas Transmission System, L.P.; Notice of Proposed Changes in FERC Gas Tariff

January 24, 1996.

Take notice that on January 16, 1996, Iroquois Gas Transmission System, L.P. (Iroquois) tendered for filing to become part of its FERC Gas Tariff, First Revised Volume No. 1, the following revised tariff sheets, with a proposed effective date of January 1, 1996:

Substitute First Revised Sheet No. 38
Substitute Original Sheet No. 57B
Substitute Third Revised Sheet No. 59
Substitute Original Sheet No. 59A
Substitute Second Revised Sheet No. 60
Substitute First Revised Sheet No. 61

Iroquois states that the purpose of the instant filing is to comply with the Commission's December 29, 1995 order conditionally accepting certain tariff sheets filed on November 30, 1995. The revised tariff sheets reflect when sharing of revenues under Rate Schedule PAL will begin and clarify that 25 MDT of system linepack flexibility will be reserved for point operators that receive service under operational balancing agreements.

Iroquois states that copies of its filing were served on all parties to the proceeding as well as all jurisdictional customers and interested state commissions.

Any person desiring to protest said filing should file protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with 18 CFR 385.211 of the Commission's Rules and Regulations. All such protests must be filed as provided in Section 154.210 of the Commission's Regulations. 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. 96–1701 Filed 1–29–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. ER96–373–000]

MP Energy, Inc., Notice of Filing

January 24, 1996.

Take notice that on January 16, 1996, MP Energy, Inc. tendered for filing an amendment in the above-referenced docket.

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, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before February 5, 1996. 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 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. 96–1692 Filed 1–29–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. CP96–149–000]

NorAm Gas Transmission Co.; Notice of Request Under Blanket Authorization

January 24, 1996.

Take notice that on January 19, 1996, NorAm Gas Transmission Company (NGT), 1600 Smith Street, Houston, Texas 77002, filed in Docket No. CP96–149–000 a request pursuant to Sections 157.205 and 157.211 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157.211) for authorization to construct and operate facilities in Sebastian County, Arkansas under NGT's blanket certificate issued in Docket No. CP82–384–000, *et al.*, pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

NGT proposes to construct and operate a 2-inch tap and 1-inch first-cut regulator on NGT's Line 0 in Section 6, Township 5 North, Range 31 West, to deliver gas to ARKLA a distribution division of NorAm Energy Corp. The estimated volumes to be delivered are approximately 1,150 MMBtu annually and 5 MMBtu on a peak day. The estimated cost of construction is $3,500 and ARKLA agrees to reimburse NGT for these costs.

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 Section 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. 96–1691 Filed 1–29–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. CP96–148–000]

Northern Natural Gas Co.; Notice of Request Under Blanket Authorization

January 24, 1996.

Take notice that on January 16, 1996, Northern Natural Gas Company (Northern), 1111 South 103rd Street, Omaha, Nebraska 68124–1000, filed in Docket No. CP96–148–000, a request pursuant to Sections 157.205, 157.212, and 157.216(b) of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157.212, and 157.216(b)) for authorization to (1) upgrade its existing Columbus #4 TBS delivery point, and (2) abandon and remove the Eddie Beck Farm Tap, both of which are located in Sec. 26–T17N–

R1E, Platte County, Nebraska, under Northern's blanket certificate issued in Docket No. CP82–401–000, pursuant to Section 7(c) 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.

Northern states that it is currently providing service to UtiliCorp United Inc. (UCU) at the Columbus #4 TBS delivery point for Minnesota Corn Processors (MCP) for use at their Columbus Plant. Northern requests authorization to upgrade this delivery point to accommodate increased natural gas deliveries for transportation directly to MCP. Northern relates that MCP requested the upgrade of the delivery point and throughput service. Northern states that deliveries will be made pursuant to Northern's currently effective throughput service agreements with MCP. Northern estimates the cost of upgrading the delivery point to be $128,000, and indicates that will be financed in accordance with the General Terms and Conditions of Northern's FERC Gas Tariff, Fifth Revised Volume No. 1.

Northern states that the proposed increase in volumes to be delivered to MCP at the Columbus #4 TBS delivery point are 8,943 MMBtu on a peak day and 3,200,300 MMBtu on an annual basis. Northern advises that the total volumes to be delivered after the request do not exceed the total volumes authorized prior to the request. Northern states that the proposed activity is not prohibited by its existing tariff and that it has sufficient capacity to accommodate the changes proposed herein without detriment or disadvantage to Northern's other customers.

Northern has included in the filing letters from both UCU and MCP consenting to the abandonment of the Eddie Beck Farm Tap, as service will be provided through the Columbus #4 TBS delivery point instead.

Northern states that it has notified UCU and the affected state Commission of this request.

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 Section 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 therefore, 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. 96–1690 Filed 1–29–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TM96–2–86–001]

Pacific Gas Transmission Company; Notice of Supplemental Compliance Filing

January 24, 1996.

Take notice that on January 17, 1996, Pacific Gas Transmission Company (PGT) tendered for filing as part of its FERC Gas Tariff, First Revised Volume No. 1–A, Third Revised Sheet No. 6C. PGT requests the above-referenced sheet become effective January 1, 1996.

PGT asserts that the purpose of this filing is to reflect a change to the Gas Research Institute (GRI) funding unit adjustment component for PGT's Parking Service and Authorized Imbalance Service, in compliance with the Commission's October 13, 1995 GRI funding Order in Docket No. RP95–374–000.

PGT further states a copy of this filing has been served upon its jurisdictional customers and interested state regulatory agencies, as well as the official service list compiled by the Secretary in this proceeding.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Section 385.211 of the Commission's Rules of Practice and Procedure. All such protests must be filed as provided in Section 154.210 of the Commission's Regulations. 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. 96–1704 Filed 1–29–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP96–51–001]

Panhandle Eastern Pipe Line Company; Notice of Compliance Filing

January 24, 1996.

Take notice that on January 18, 1996, Panhandle Eastern Pipe Line Company (Panhandle) tendered for filing as part of its FERC Gas Tariff, First Revised Volume No. 1, the tariff sheets listed on Appendix A to the filing, to become effective January 1, 1996. Panhandle asserts that the purpose of this filing is to comply with the Commission's order issued December 29, 1995, in Docket No. RP96–51–000.

Panhandle states that the tariff sheets submitted herewith reflect that gas parking service will be scheduled after, and interrupted before, all other firm and interruptible services. Panhandle's filing also provides support for the derivation of the minimum daily parking rate.

Panhandle states that copies of this filing are being served on all affected customers, applicable state regulatory agencies and all parties to this proceeding.

Any person desiring to protest this filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with 18 CFR 385.211 of the Commission's Rules and Regulations. All such protests must be filed as provided in Section 154.210 of the Commission's Regulations. 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. 96–1700 Filed 1–29–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. GT96–44–000]

Texas Eastern Transmission Corporation; Notice of Proposed Changes in FERC Gas Tariff

January 24, 1996.

Take notice that on January 19, 1996, Texas Eastern Transmission Corporation (Texas Eastern) tendered for filing as part of its FERC Gas Tariff, Sixth Revised Volume No. 1, second revised tariff sheets listed in the filing letter. The proposed effective date of these second revised tariff sheets is December 1, 1995.

Texas Eastern states that the purpose of this filing is to update its index of firm customers through December 1, 1995.

Texas Eastern states that copies of its filing have been served on all firm customers of Texas Eastern and interested state commissions.

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, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Sections 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed as provided in Section 154.210 of the Commission's Regulations. 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 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. 96–1693 Filed 1–29–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP96–117–000]

Texas Eastern Transmission Corporation; Notice of Proposed Changes in FERC Gas Tariff

January 24, 1996.

Take notice that on January 19, 1996, Texas Eastern Transmission Corporation (Texas Eastern) tendered for filing as part of its FERC Gas Tariff, Sixth Revised Volume No. 1 and Original Volume No. 2, the tariff sheets listed on Appendix A to the filing to become effective February 18, 1996. Texas Eastern asserts that the purpose of this filing is to comply with the Commission's order issued September 28, 1995 in Docket No. RM95–3–000.

Texas Eastern states that the purpose of this filing is to bring its FERC Gas Tariff into compliance with the Commission's updated Regulations set forth in Order No. 582 (Final Rule) issued September 28, 1995 in Docket No. RM95–3–000, Filing and Reporting Requirements for Interstate Natural Gas Company Rate Schedules and Tariffs. Specifically, Texas Eastern is: (a) adding telephone and facsimile numbers as well as street address to the respective title pages of each volume of the tariff; (b) revising Section 11 to address Texas Eastern's policy on financing or construction of pipeline laterals; (c) adding a statement describing the order in which Texas Eastern discounts its rates; (d) including a description of periodic reports required by Commission orders or settlements in proceedings initiated under Part 154 or 284 of the Commission's Regulations; (e) updating references to Part 154 of the Commission's Regulations; and (f) adding the Index of Firm Customers to the Table of Contents. Copies of the filing were served on firm customers of Texas Eastern and interested state commissions.

Any person desiring to be heard or to protest this filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First 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 must be filed as provided in § 154.210 of the Commission's Regulations. 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 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. 96–1703 Filed 1–29–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. MT96–3–000]

Transcontinental Gas Pipe Line Corporation; Notice of Filing

January 24, 1996.

Take notice that on January 19, 1996, Transcontinental Gas Pipe Line Corporation (Transco) tendered for filing to become part of its FERC Gas Tariff, Third Revised Volume No. 1, Sixth Revised Sheet No. 344, with the proposed effective date January 1, 1996, together with revisions to its corporate Code of Conduct in compliance with Order No. 497, as amended by Order No. 636.

Transco states that the revisions to the tariff sheet and to the Code of Conduct reflect (1) changes to its list of marketing affiliates, occasioned by the merger of Transco Energy Company (Transco's former parent company) with a subsidiary of The Williams Companies, Inc. (Williams) effective May 1, 1995; and (2) changes to its list of shared directors and officers, also necessitated as a result of the above-referenced merger.

Transco states that it is serving copies of the instant filing to its customers, State Commissions, and other interested parties.

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, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Sections 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed as provided in Section 154.210 of the Commission's Regulations. 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 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. 96–1694 Filed 1–29–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP85–181–010]

Texas Gas Transmission Corporation; Notice of Filing of Refund Report and Request To Terminate Proceedings

January 24, 1996.

Take notice that on January 11, 1996, Texas Gas Transmission Corporation (Texas Gas) filed a report of an agreement and refund report with Columbia Gas Transmission Corporation (Columbia) to resolve the issues and disputes in Docket No. RP85–181 and the related appeals pending before the United States Court of Appeals for the District of Columbia Circuit (Panhandle Eastern v. FERC No. 94–1727). Under the agreement, Texas Gas states that it will refund to Columbia a principal amount of $11,948,555.73, $1,468,424.44 in interest for the period 2/11/94 to the date of refund, and additional interest of $850,000 for the period prior to 2/11/94.

Texas Gas states Columbia and Texas Gas have filed with the United States Court of Appeals to withdraw their pending appeals cited above. Texas Gas and Columbia request that the Commission issue an order accepting the refund report and terminating the proceedings in Docket No. RP85–181, conditioned, as necessary, upon an order of the United States Court of Appeals for the District of Columbia

granting the motions to withdraw the appeals of the orders issued in Docket No. RP85–181.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C., 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. Any person wishing to protest said filing, must file a protest on or before January 31, 1996. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make portestants 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. 96–1695 Filed 1–29–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. CP96–144–000]

Williams Natural Gas Co.; Notice of Request Under Blanket Authorization

January 24, 1996.

Take notice that on January 18, 1996, Williams Natural Gas Company (WNG), P.O. Box 3288, Tulsa, Oklahoma 74101, filed in Docket No. CP96–144–000 a request pursuant to Sections 157.205 and 157.216 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157.216) for authorization to abandon measurement and appurtenant facilities at 11 locations in Nowata and Washington Counties, Oklahoma and Chautauqua, Labette, and Montgomery Counties, Kansas under WNG's blanket certificate issued in Docket No. CP82–479–000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

WNG proposes to abandon the transportation of natural gas and to reclaim facilities originally installed for delivery of sales gas at four locations: J&S Feed, Seed & Supply in Washington County, Oklahoma, Clarence Graybill in Labette County, Kansas, Union Gas Elk City town border in Montgomery County, Kansas, and the KC Crude setting in Montgomery County, Kansas. WNG also proposes to abandon by reclaim facilities originally installed to receive transportation gas at seven locations: Bayou PLD in Nowata County, Oklahoma, the MDA PLD and Petro D–3 in Montgomery County, Kansas, the Central Plains PLD and Highwood PLD in Labette County, Kansas, and the Flamco Energy PLD and SE Kansas Gas #2 in Chautauqua County, Kansas. WNG states that the affected customers have agreed to the reclaim of the facilities or the companies no longer exist. WNG estimates that the total reclaim costs are $16,056 with a salvage value of $0.

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 Section 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. 96–1689 Filed 1–29–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP90–137–029]

Williston Basin Interstate Pipeline Company; Notice of Refund Report

January 24, 1996.

Take notice that on January 5, 1996, Williston Basin Interstate Pipeline Company (Williston Basin), tendered for filing with the Commission, under protest, its Refund Report made in compliance with ordering Paragraph (D) of the Commission's "Order Denying Rehearing, Granting Requests for Exemptions and Ordering Refunds" issued December 6, 1995 in Docket Nos. RP90–137–020 RP90–137–021, RP90–137–022, RP90–137–023, RP90–137–025 and RP90–137–026.

Williston Basin states that on December 22, 1995, refunds were sent to applicable shippers for the take-or-pay volumetric surcharge amounts previously collected through transportation rates charged for the gas placed in storage in accordance with Rate Schedule S–2 Service Agreements between Williston Basin and such applicable shippers. These refunds, for the period November 1, 1990 through August 31, 1995, also include interest through December 22, 1995, in accordance with Section 154.501 of the Commission's Regulations.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with 18 CFR 385.211 of the Commission's Rules and Regulations. All such protests must be filed on or before January 31, 1996. 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. 96–1696 Filed 1–29–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP90–137–029]

Williston Basin Interstate Pipeline Company; Notice of Refund Report

January 31, 1996.

Take notice that on January 5, 1996, Williston Basin Interstate Pipeline Company (Williston Basin), tendered for filing with the Commission, under protest, its Refund Report made in compliance with ordering Paragraph (D) of the Commission's "Order Denying Rehearing, Granting Requests for Exemptions and Ordering Refunds" issued December 6, 1995 in Docket Nos. RP90–137–020 RP90–137–021, RP90–137–022, RP90–137–023, RP90–137–025 and RP90–137–026.

Williston Basin states that on December 22, 1995, refunds were sent to applicable shippers for the take-or-pay volumetric surcharge amounts previously collected through transportation rates charged for the gas placed in storage in accordance with Rate Schedule S–2 Service Agreements between Williston Basin and such applicable shippers. These refunds, for the period November 1, 1990 through August 31, 1995, also include interest through December 22, 1995, in accordance with Section 154.501 of the Commission's Regulations.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with 18 CFR 385.211 of the Commission's Rules and Regulations. All such protests must be filed on or before January 31, 1996. 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. 96–1697 Filed 1–29–96; 8:45 am]

BILLING CODE 6717–01–M

Office of Arms Control and Nonproliferation Policy

Proposed Subsequent Arrangement

AGENCY: Department of Energy.

ACTION: Subsequent Arrangement.

SUMMARY: Pursuant to section 131 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2160) notice is hereby given of a proposed "subsequent arrangement" to be carried out in the Republic of Korea under the Agreement for Cooperation between the Government of the United States of America and the Government of the Republic of Korea Concerning Civil Uses of Atomic Energy, signed November 24, 1972, as amended.

The subsequent arrangement to be carried out under the above-mentioned agreement involves the joint determination, pursuant to Article VIII (c) of that Agreement, that the provisions of Article XI may be effectively applied for the alteration in form or content of U.S.-origin nuclear material contained in pressurized water reactor fuels, CANDU fuels, and research reactor fuels at the Post Irradiation Examination Facility and the Irradiated Materials Examination Facility at the Headquarters of the Korea Atomic Energy Research Institute in accordance with the plan contained in KAERI/AR–417/95, Rev-1, dated May, 1995. The aforementioned determination will be made, and the approval for the post-irradiation examination for the agreed upon program will be granted, for the period ending December 31, 2001.

In accordance with section 131 of the Atomic Energy Act of 1954, as amended, it has been determined that this subsequent arrangement will not be inimical to the common defense and security.

This subsequent arrangement will take effect no sooner than fifteen days after the date of publication of this notice.

Dated: January 22, 1996.

For the Department of Energy.

Edward T. Fei,

Deputy Director, International Policy and Analysis Division, Office of Arms Control and Nonproliferation.

[FR Doc. 96–1610 Filed 1–29–96; 8:45 am]

BILLING CODE 6450–01–P

Office of Energy Efficiency and Renewable Energy

Energy Conservation Program for Consumer Products: Granting of the Application for Interim Waiver and Publishing of the Petition for Waiver of Thermo Products Inc. From the DOE Furnace Test Procedure. (Case No. F–083)

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice.

SUMMARY: Today's notice grants an Interim Waiver to Thermo Products Inc. (Thermo Products) from the existing Department of Energy (DOE or Department) test procedure regarding blower time delay for the company's CHA-upflow and CCA-downflow condensing gas furnaces.

Today's notice also publishes a "Petition for Waiver" from Thermo Products. Thermo Products Petition for Waiver requests DOE to grant relief from the DOE furnace test procedure relating to the blower time delay specification. Thermo Products seeks to test using a blower delay time of 45 seconds for its CHA-upflow and CCA-downflow condensing gas furnaces instead of the specified 1.5-minute delay between burner on-time and blower on-time. The Department is soliciting comments, data, and information respecting the Petition for Waiver.

DATES: DOE will accept comments, data, and information not later than February 29, 1996.

ADDRESSES: Written comments and statements shall be sent to: Department of Energy, Office of Energy Efficiency and Renewable Energy, Case No. F–083, Mail Stop EE–43, Room 1J–108, Forestall Building, 1000 Independence Avenue, SW, Washington, D.C. 20585, (202) 586–7140.

FOR FURTHER INFORMATION CONTACT:

Cyrus H. Nasseri, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Mail Station EE–431, Forestall Building, 1000 Independence Avenue, SW., Washington, D.C. 20585–0121, (202) 586–9138

Eugene Margolis, Esq., U.S. Department of Energy, Office of General Counsel, Mail Station GC–72, Forestall Building, 1000 Independence Avenue, SW., Washington, D.C. 20585–0103, (202) 586–9507

SUPPLEMENTARY INFORMATION: The Energy Conservation Program for Consumer Products (other than automobiles) was established pursuant to the Energy Policy and Conservation Act, as amended (EPCA), which requires DOE to prescribe standardized test procedures to measure the energy consumption of certain consumer products, including furnaces. The intent of the test procedures is to provide a comparable measure of energy consumption that will assist consumers in making purchasing decisions. These test procedures appear at Title 10 CFR Part 430, Subpart B.

The Department amended the test procedure rules to provide for a waiver process by adding Section 430.27 to Title 10 CFR Part 430. 45 FR 64108, September 26, 1980. Subsequently, DOE amended the waiver process to allow the Assistant Secretary for Energy Efficiency and Renewable Energy (Assistant Secretary) to grant an Interim Waiver from test procedure requirements to manufacturers that have petitioned DOE for a waiver of such prescribed test procedures. Title 10 CFR Part 430, Section 430.27(a)(2).

The waiver process allows the Assistant Secretary to waive temporarily test procedures for a particular basic model when a petitioner shows that the basic model contains one or more design characteristics which prevent testing according to the prescribed test procedures, or when the prescribed test procedures may evaluate the basic model in a manner so unrepresentative of its true energy consumption as to provide materially inaccurate comparative data. Waivers generally remain in effect until final test procedure amendments become effective, resolving the problem that is the subject of the waiver.

An Interim Waiver will be granted if it is determined that the applicant will experience economic hardship if the Application for Interim Waiver is denied, if it appears likely that the Petition for Waiver will be granted, and/or the Assistant Secretary determines that it would be desirable for public policy reasons to grant immediate relief pending a determination on the Petition for Waiver. Title 10 CFR Part 430, Section 430.27(g). An Interim Waiver remains in effect for a period of 180 days or until DOE issues its determination on the Petition for

Waiver, whichever is sooner, and may be extended for an additional 180 days, if necessary.

On November 29, 1995, Thermo Products filed an Application for Interim Waiver and a Petition for Waiver regarding blower time delay. Thermo Products Application seeks an Interim Waiver from the DOE test provisions that require a 1.5-minute time delay between the ignition of the burner and starting of the circulating air blower. Instead, Thermo Products requests the allowance to test using a 45-second blower time delay when testing its CHA-upflow and CCA-downflow condensing gas furnaces. Thermo Products states that the 45-second delay is indicative of how these furnaces actually operate. Such a delay results in an increase in AFUE improvement of up to 2.0 percent. Since current DOE test procedures do not address this variable blower time delay, Thermo Products asks that the Interim Waiver be granted.

The Department has published a Notice of Proposed Rulemaking on August 23, 1993, (58 FR 44583) to amend the furnace test procedure, which addresses the above issue.

Previous Petitions for Waiver for this type of time blower delay control have been granted by DOE to Coleman Company, 50 FR 2710, January 18, 1985; Magic Chef Company, 50 FR 41553, October 11, 1985; Rheem Manufacturing Company, 53 FR 48574, December 1, 1988, 56 FR 2920, January 25, 1991, 57 FR 10166, March 24, 1992, 57 FR 34560, August 5, 1992; 59 FR 30577, June 14, 1994, and 59 FR 55470, November 7, 1994; Trane Company, 54 FR 19226, May 4, 1989, 56 FR 6021, February 14, 1991, 57 FR 10167, March 24, 1992, 57 FR 22222, May 27, 1992, 58 FR 68138, December 23, 1993, and 60 FR 62835, December 7, 1995; Lennox Industries, 55 FR 50224, December 5, 1990, 57 FR 49700, November 3, 1992, 58 FR 68136, December 23, 1993, and 58 FR 68137, December 23, 1993; Inter-City Products Corporation, 55 FR 51487, December 14, 1990, and 56 FR 63945, December 6, 1991; DMO Industries, 56 FR 4622, February 5, 1991, and 59 FR 30579, June 14, 1994; Heil-Quaker Corporation, 56 FR 6019, February 14, 1991; Carrier Corporation, 56 FR 6018, February 14, 1991, 57 FR 38830, August 27, 1992, 58 FR 68131, December 23, 1993, 58 FR 68133, December 23, 1993, 59 FR 14394, March 28, 1994, and 60 FR 62832, December 7, 1995; Amana Refrigeration Inc., 56 FR 27958, June 18, 1991, 56 FR 63940, December 6, 1991, 57 FR 23392, June 3, 1992, and 58 FR 68130, December 23, 1993; Snyder General Corporation, 56 FR 54960, September 9, 1991; Goodman Manufacturing Corporation, 56 FR 51713, October 15, 1991, 57 FR 27970, June 23, 1992 and 59 FR 12586, March 17, 1994; The Ducane Company Inc., 56 FR 63943, December 6, 1991, 57 FR 10163, March 24, 1992, and 58 FR 68134, December 23, 1993; Armstrong Air Conditioning, Inc., 57 FR 899, January 9, 1992, 57 FR 10160, March 24, 1992, 57 FR 10161, March 24, 1992, 57 FR 39193, August 28, 1992, 57 FR 54230, November 17, 1992, and 59 FR 30575, June 14, 1994; Thermo Products, Inc., 57 FR 903, January 9, 1992; Consolidated Industries Corporation, 57 FR 22220, May 27, 1992; Evcon Industries, Inc., 57 FR 47847, October 20, 1992, and 59 FR 46968, September 13, 1994; Bard Manufacturing Company, 57 FR 53733, November 12, 1992, and 59 FR 30578, June 14, 1994; and York International Corporation, 59 FR 46969, September 13, 1994, 60 FR 100, January 3, 1995, 60 FR 62834, December 7, 1995, and 60 FR 62837, December 7, 1995.

Thus, it appears likely that this Petition for Waiver for blower time delay will be granted. In those instances where the likely success of the Petition for Waiver has been demonstrated based upon DOE having granted a waiver for a similar product design, it is in the public interest to have similar products tested and rated for energy consumption on a comparable basis.

Therefore, based on the above, DOE is granting Thermo Products an Interim Waiver for its CHA-upflow and CCA-downflow condensing gas furnaces. Thermo Products shall be permitted to test its CHA-upflow and CCA-downflow condensing gas furnaces on the basis of the test procedures specified in Title 10 CFR Part 430, Subpart B, Appendix N, with the modification set forth below:

(I) Section 3.0 in Appendix N is deleted and replaced with the following paragraph:

3.0 Test Procedure. Testing and measurements shall be as specified in Section 9 in ANSI/ASHRAE 103–82 with the exception of Sections 9.2.2, 9.3.1, and 9.3.2, and the inclusion of the following additional procedures:

(ii) Add a new paragraph 3.10 in Appendix N as follows:

3.10 Gas- and Oil-Fueled Central Furnaces. After equilibrium conditions are achieved following the cool-down test and the required measurements performed, turn on the furnace and measure the flue gas temperature, using the thermocouple grid described above, at 0.5 and 2.5 minutes after the main burner(s) comes on. After the burner start-up, delay the blower start-up by 1.5 minutes (t-) unless: (1) the furnace employs a single motor to drive the power burner and the indoor air circulation blower, in which case the burner and blower shall be started together; or (2) the furnace is designed to operate using an unvarying delay time that is other than 1.5 minutes, in which case the fan control shall be permitted to start the blower; or (3) the delay time results in the activation of a temperature safety device which shuts off the burner, in which case the fan control shall be permitted to start the blower. In the latter case, if the fan control is adjustable, set it to start the blower at the highest temperature. If the fan control is permitted to start the blower, measure time delay (t-) using a stop watch. Record the measured temperatures. During the heat-up test for oil-fueled furnaces, maintain the draft in the flue pipe within ±0.01 ινψη οφ ςατερ ψολθμν οφ της μανθφαψτθρερ∓σ ρεψομμενδεδ ον-περιοδ δραφτ.

This Interim Waiver is based upon the presumed validity of statements and all allegations submitted by the company. This Interim Waiver may be removed or modified at any time upon a determination that the factual basis underlying the Application is incorrect.

The Interim Waiver shall remain in effect for a period of 180 days or until DOE acts on the Petition for Waiver, whichever is sooner, and may be extended for an additional 180-day period, if necessary.

Thermo Products's Petition for Waiver requests DOE to grant relief from the DOE furnace test procedure relating to the blower time delay specification. Thermo Products seeks to test using a blower delay time of 45 seconds for its CHA-upflow and CCA-downflow condensing gas furnaces instead of the specified 1.5-minute delay between burner on-time and blower on-time. Pursuant to paragraph (b) of Title 10 CFR Part 430.27, DOE is hereby publishing the "Petition for Waiver" in its entirety. The Petition contains no confidential information. The Department solicits comments, data, and information respecting the Petition.

Christine A. Ervin,

Assistant Secretary, Energy Efficiency and Renewable Energy.

Thermo Pride

Heating, Cooling, Electronic Air Cleaning and Humidification Equipment

November 29, 1995.

The Assistant Secretary for Conservation and Renewable Energy,

United States Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585

Subject: *Petition for Waiver and Application for Interim Waiver*

Gentlemen: This is a Petition for Waiver and Application for Interim Waiver which are submitted pursuant to Title 10 CFR 430.27. Waiver is requested from Test Procedures for Measuring the Energy Consumption of Furnace found in Appendix N to Subpart B of Part 430.

The test procedure requires a 1.5 minute delay between burner and blower start-up. Thermo Products requests a waiver from the specified 1.5 minute delay and requests approval to use a 45-second delay for our Series CHA- upflow and CCA- downflow condensing type residential gas fired furnaces.

An electronic fan control is being used on these products that incorporate a fixed timing.

Current test procedures do not credit Thermo Products for the energy savings associated with the shorter blower timing. The shorter timed on fan delay reduces flue losses therefor increasing furnace efficiency. Test data for these furnaces utilizing a 45-second timing indicates an increase in AFUE up to 2%. Confidential supporting test data is available upon request.

Thermo Products is confident that this Waiver will be granted, as several other manufacturers of gas furnaces received DOE granted waivers such as Carrier, Lennox Industries, Inter-City Products, Amana, Rheem Manufacturing and others based on timed blower operation.

Manufacturers that domestically market similar products are being sent a copy of this Petition for Waiver and Application for Interim Waiver.

Sincerely,

Everett E. James,

Director of Engineering.

[FR Doc. 96–1728 Filed 1–29–96; 8:45 am]

BILLING CODE 6450–01–P

[Case No. F–084]

Energy Conservation Program for Consumer Products: Granting of the Application for Interim Waiver and Publishing of the Petition for Waiver of Goodman Manufacturing Company From the DOE Furnace Test Procedure

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice.

SUMMARY: Today's notice grants an Interim Waiver to Goodman Manufacturing Company (Goodman) from the existing Department of Energy (DOE or Department) test procedure regarding blower time delay for the company's GSU series central furnaces.

Today's notice also publishes a "Petition for Waiver" from Goodman. Goodman's Petition for Waiver requests DOE to grant relief from the DOE furnace test procedure relating to the blower time delay specification. Goodman seeks to test using a blower delay time of 30 seconds for its GSU series central furnaces instead of the specified 1.5-minute delay between burner on-time and blower on-time. The Department is soliciting comments, data, and information respecting the Petition for Waiver.

DATES: DOE will accept comments, data, and information not later than February 29, 1996.

ADDRESSES: Written comments and statements shall be sent to: Department of Energy, Office of Energy Efficiency and Renewable Energy, Case No. F–084, Mail Stop EE–43, Room 1J–108, Forestall Building, 1000 Independence Avenue, SW, Washington, D.C. 20585, (202) 586–7140.

FOR FURTHER INFORMATION CONTACT:

Cyrus H. Nasseri, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Mail Station EE–431, Forestall Building, 1000 Independence Avenue, SW., Washington, D.C. 20585–0121, (202) 586–9138

Eugene Margolis, Esq., U.S. Department of Energy, Office of General Counsel, Mail Station GC–72, Forestall Building, 1000 Independence Avenue, SW., Washington, D.C. 20585–0103, (202) 586–9507

SUPPLEMENTARY INFORMATION: The Energy Conservation Program for Consumer Products (other than automobiles) was established pursuant to the Energy Policy and Conservation Act, as amended (EPCA), which requires DOE to prescribe standardized test procedures to measure the energy consumption of certain consumer products, including furnaces. The intent of the test procedures is to provide a comparable measure of energy consumption that will assist consumers in making purchasing decisions. These test procedures appear at Title 10 CFR Part 430, Subpart B.

The Department amended the test procedure rules to provide for a waiver process by adding Section 430.27 to Title 10 CFR Part 430. 45 FR 64108, September 26, 1980. Subsequently, DOE amended the waiver process to allow the Assistant Secretary for Energy Efficiency and Renewable Energy (Assistant Secretary) to grant an Interim Waiver from test procedure requirements to manufacturers that have petitioned DOE for a waiver of such prescribed test procedures. Title 10 CFR Part 430, Section 430.27(a)(2).

The waiver process allows the Assistant Secretary to waive temporarily test procedures for a particular basic model when a petitioner shows that the basic model contains one or more design characteristics which prevent testing according to the prescribed test procedures, or when the prescribed test procedures may evaluate the basic model in a manner so unrepresentative of its true energy consumption as to provide materially inaccurate comparative data. Waivers generally remain in effect until final test procedure amendments become effective, resolving the problem that is the subject of the waiver.

An Interim Waiver will be granted if it is determined that the applicant will experience economic hardship if the Application for Interim Waiver is denied, if it appears likely that the Petition for Waiver will be granted, and/or the Assistant Secretary determines that it would be desirable for public policy reasons to grant immediate relief pending a determination on the Petition for Waiver. Title 10 CFR Part 430, Section 430.27 (g). An Interim Waiver remains in effect for a period of 180 days or until DOE issues its determination on the Petition for Waiver, whichever is sooner, and may be extended for an additional 180 days, if necessary.

On July 19, 1995, Goodman filed an Application for Interim Waiver and a Petition for Waiver regarding blower time delay. Goodman's Application seeks an Interim Waiver from the DOE test provisions that require a 1.5-minute time delay between the ignition of the burner and starting of the circulating air blower. Instead, Goodman requests the allowance to test using a 30-second blower time delay when testing its GSU series central furnaces. Goodman states that the 30-second delay is indicative of how these furnaces actually operate. Such a delay results in an increase in AFUE of 1.0 percentage point. Since current DOE test procedures do not address this variable blower time delay, Goodman asks that the Interim Waiver be granted.

The Department has published a Notice of Proposed Rulemaking on August 23, 1993, (58 FR 44583) to amend the furnace test procedure, which addresses the above issue.

Previous Petitions for Waiver for this type of time blower delay control have been granted by DOE to Coleman Company, 50 FR 2710, January 18, 1985; Magic Chef Company, 50 FR 41553, October 11, 1985; Rheem Manufacturing Company, 53 FR 48574, December 1, 1988, 56 FR 2920, January 25, 1991, 57 FR 10166, March 24, 1992, 57 FR 34560, August 5, 1992; 59 FR 30577, June 14, 1994, and 59 FR 55470, November 7, 1994; Trane Company, 54 FR 19226, May 4, 1989, 56 FR 6021, February 14, 1991, 57 FR 10167, March 24, 1992, 57

FR 22222, May 27, 1992, 58 FR 68138, December 23, 1993, and 60 FR 62835, December 7, 1995; Lennox Industries, 55 FR 50224, December 5, 1990, 57 FR 49700, November 3, 1992, 58 FR 68136, December 23, 1993, and 58 FR 68137, December 23, 1993; Inter-City Products Corporation, 55 FR 51487, December 14, 1990, and 56 FR 63945, December 6, 1991; DMO Industries, 56 FR 4622, February 5, 1991, and 59 FR 30579, June 14, 1994; Heil-Quaker Corporation, 56 FR 6019, February 14, 1991; Carrier Corporation, 56 FR 6018, February 14, 1991, 57 FR 38830, August 27, 1992, 58 FR 68131, December 23, 1993, 58 FR 68133, December 23, 1993, 59 FR 14394, March 28, 1994, and 60 FR 62832, December 7, 1995; Amana Refrigeration Inc., 56 FR 27958, June 18, 1991, 56 FR 63940, December 6, 1991, 57 FR 23392, June 3, 1992, and 58 FR 68130, December 23, 1993; Snyder General Corporation, 56 FR 54960, September 9, 1991; Goodman Manufacturing Corporation, 56 FR 51713, October 15, 1991, 57 FR 27970, June 23, 1992 and 59 FR 12586, March 17, 1994; The Ducane Company Inc., 56 FR 63943, December 6, 1991, 57 FR 10163, March 24, 1992, and 58 FR 68134, December 23, 1993; Armstrong Air Conditioning, Inc., 57 FR 899, January 9, 1992, 57 FR 10160, March 24, 1992, 57 FR 10161, March 24, 1992, 57 FR 39193, August 28, 1992, 57 FR 54230, November 17, 1992, and 59 FR 30575, June 14, 1994; Thermo Products, Inc., 57 FR 903, January 9, 1992; Consolidated Industries Corporation, 57 FR 22220, May 27, 1992; Evcon Industries, Inc., 57 FR 47847, October 20, 1992, and 59 FR 46968, September 13, 1994; Bard Manufacturing Company, 57 FR 53733, November 12, 1992, and 59 FR 30578, June 14, 1994; and York International Corporation, 59 FR 46969, September 13, 1994, 60 FR 100, January 3, 1995, 60 FR 62834, December 7, 1995, and 60 FR 62837, December 7, 1995.

Thus, it appears likely that this Petition for Waiver for blower time delay will be granted. In those instances where the likely success of the Petition for Waiver has been demonstrated based upon DOE having granted a waiver for a similar product design, it is in the public interest to have similar products tested and rated for energy consumption on a comparable basis.

Therefore, based on the above, DOE is granting Goodman an Interim Waiver for its GSU series condensing furnaces. Goodman shall be permitted to test its GSU series condensing furnaces on the basis of the test procedures specified in Title 10 CFR Part 430, Subpart B, Appendix N, with the modification set forth below:

(I) Section 3.0 in Appendix N is deleted and replaced with the following paragraph:

3.0 Test Procedure. Testing and measurements shall be as specified in Section 9 in ANSI/ASHRAE 103–82 with the exception of Sections 9.2.2, 9.3.1, and 9.3.2, and the inclusion of the following additional procedures:

(ii) Add a new paragraph 3.10 in Appendix N as follows:

3.10 Gas- and Oil-Fueled Central Furnaces. After equilibrium conditions are achieved following the cool-down test and the required measurements performed, turn on the furnace and measure the flue gas temperature, using the thermocouple grid described above, at 0.5 and 2.5 minutes after the main burner(s) comes on. After the burner start-up, delay the blower start-up by 1.5 minutes (t-) unless: (1) the furnace employs a single motor to drive the power burner and the indoor air circulation blower, in which case the burner and blower shall be started together; or (2) the furnace is designed to operate using an unvarying delay time that is other than 1.5 minutes, in which case the fan control shall be permitted to start the blower; or (3) the delay time results in the activation of a temperature safety device which shuts off the burner, in which case the fan control shall be permitted to start the blower. In the latter case, if the fan control is adjustable, set it to start the blower at the highest temperature. If the fan control is permitted to start the blower, measure time delay (t-) using a stop watch. Record the measured temperatures. During the heat-up test for oil-fueled furnaces, maintain the draft in the flue pipe within ± 0.01 inch of water column of the manufacturer's recommended on-period draft.

This Interim Waiver is based upon the presumed validity of statements and all allegations submitted by the company. This Interim Waiver may be removed or modified at any time upon a determination that the factual basis underlying the Application is incorrect.

The Interim Waiver shall remain in effect for a period of 180 days or until DOE acts on the Petition for Waiver, whichever is sooner, and may be extended for an additional 180-day period, if necessary.

Goodman's Petition for Waiver requests DOE to grant relief from the DOE furnace test procedure relating to the blower time delay specification. Goodman seeks to test using a blower delay time of 30 seconds for its GSU series condensing furnaces instead of the specified 1.5-minute delay between burner on-time and blower on-time. Pursuant to paragraph (b) of Title 10 CFR Part 430.27, DOE is hereby publishing the "Petition for Waiver" in its entirety. The Petition contains no confidential information. The Department solicits comments, data, and information respecting the Petition.

Christine A. Ervin,

Assistant Secretary, Energy Efficiency and Renewable Energy.

July 19, 1995.

Assistant Secretary, Conservation and Renewable Energy,

United States Department of Energy, 1000 Independence Ave., SW., Washington, DC 20585

Re: Petition for Waiver and Application for Interim Waiver

Gentlemen: This is a Petition for Waiver and Application for Interim Waiver submitted pursuant to Title 10 CFR 430.27. Waiver is requested from the test procedure for measuring Furnace Energy Consumption as found in Appendix H to Subpart B of 430.

The current test procedure requires a 1.5 minute delay between burner ignition and the start of the circulating air blower. Goodman Manufacturing Co., L.P. is requesting waiver and authorization to use a 30 second delay instead of the specified 1.5 minutes for the blower to start after main burner ignition. Goodman Manufacturing intends to use a fixed timing control on our GSU series central furnaces to gain additional energy savings that are achieved with the use of shorter blower on times.

Test data for these furnaces with a 30 second day delay indicated an increase in AFUE of 1.0 percentage point. The use of a 30 second delay reduces the appliance flue losses and therefore increases the furnace efficiency. Copies of confidential test data confirming this energy savings will be provided to you at your request.

The current test procedure does not give Goodman Manufacturing credit for energy savings that can be obtained using fixed blower timings. The proposed ASHRAE 103–1988 that is under consideration by D.O.E. addresses the use of timed blower operation.

Goodman Manufacturing is confident that this Waiver will be granted, and therefore we request an Interim Waiver be granted until a final ruling is made. Goodman, as well as other manufacturers of domestic furnaces. have been granted similar waivers.

Manufacturers that domestically market similar products have been sent a copy of this Petition for Waiver and Application for Interim Waiver.

Sincerely,

Peter H. Alexander,

Executive Vice President.

[FR Doc. 96–1729 Filed 1–29–95; 8:45 am]

BILLING CODE 6450–01–P9

Office of Energy Research

Energy Research Financial Assistance Program Notice 96–06: Global Change Integrated Assessment Research

AGENCY: Department of Energy (DOE).

ACTION: Notice inviting grant applications.

SUMMARY: The Office of Health and Environmental Research (OHER) of the Office of Energy Research, U.S. Department of Energy (DOE) hereby announces its interest in receiving applications to support research and analysis of Global Change Assessment Research. This notice is a follow on to two previous notices published in the **Federal Register** (Notice 93–4 published December 9, 1992, entitled Economics of Global Change Research Program and Notice 95–12 published December 29, 1994, entitled Global Change Assessment Research Program). The program has expanded since 1992 to include core support for integrated assessment activities and research on assessment in direct support of global change policy. The research program supports the Department's Global Change Research Program, the U.S. Global Change Research Program (USGCRP), and the Administration's goals to understand and mitigate the rise in greenhouse gases.

DATES: Formal applications submitted in response to this notice must be received by 4:30 p.m., EST, March 20, 1996, to permit timely consideration for awards in Fiscal Year 1996 and Fiscal Year 1997.

ADDRESSES: Formal applications referencing Program Notice 96–06 should be forwarded to: U.S. Department of Energy, Office of Energy Research, Grants and Contracts Division, ER–64, 19901 Germantown Road, Germantown, MD 20874–1290, ATTN: Program Notice 96–06. The following address must be used when submitting applications by U.S. Postal Service Express Mail, any commercial mail delivery service, or when hand-carried by the applicant: U.S. Department of Energy, Office of Energy Research, Grants and Contracts Division, ER–64, 19901 Germantown Road, Germantown, MD 20874–1290.

FOR FURTHER INFORMATION CONTACT: Dr. John C. Houghton, Office of Health and Environmental Research, Environmental Sciences Division, ER–74 (GTN), U.S. Department of Energy, Germantown, MD 20874–1290 (301) 903–8288, fax (301) 903–7363, or by Internet address, john.houghton@oer.doe.gov.

SUPPLEMENTARY INFORMATION: There are two topics that are included in the DOE Global Change Integrated Assessment Research program for FY 1996 and FY 1997. Approximately 80 percent of the funds are expected to be allocated to the first topic; 20 percent for the second topic.

The determination of energy policy, such as that contained in the Department of Energy's National Energy Policy Plan and-the President's Climate Change Action Plan, as well as the policy actions taken in response to the first Conference of the Parties in Berlin, is tied to understanding the benefits and costs of potential actions with respect to the control of greenhouse gases and possible climate change. The research described in this notice supports the analysis of those benefits and costs as well as helps in presenting the results of the U.S. Global Change Research Program to the policy-setting process.

This research will be judged in part on its potential to improve and/or support the analytical basis for policy development. For instance, research that supports integrated assessment, which in turn supports the policy process, is considered relevant. More broadly applicable research will be preferred to narrowly focussed research on, for example, particular energy technologies, or narrowly-defined geographic regions. One of the requirements of the application is to define the linkage to policy questions that the research expects to address. Applications that involve development of analytical models and computer codes will be judged in part on the basis of proposed tasks to prepare documentation and make the models and codes available to other groups.

A background document that describes the supplementary information in more detail is available from Dr. Houghton. Applicants are expected to be familiar with literature on global climate change. A representative list of relevant literature is also available from Dr. Houghton.

A. Integrated Assessment of Climate Change

Integrated assessment (IA) of climate change is the analysis of climate change from the cause, such as greenhouse gas emissions, through impacts, such as changed energy requirements for space conditioning due to temperature changes. The analysis should include feedbacks and be oriented to evaluating policy options. IA is sometimes, but not always, implemented as a computer model. Under this topic, the Integrated Assessment program will support research that either (a) develops IA's for use by the policy-setting process, or (b) conducts more narrowly defined research topics, the results of which would be used by the IA community. Note that the research supports the development of methodologies or information rather than the exercise of a model to evaluate specific policy options. In case (a), a criterion for selecting awards will be the potential contribution to the policy decision process and the added value of that particular proposed IA effort (particularly for new IA models) over other ongoing IA activities. In case (b), a criterion will be the importance of the research results to the IA community.

The following categories are examples of focused research topics that would support IA. They are listed in order of importance.

1. Technology Innovation and Diffusion. This category has been a primary focus of the Integrated Assessment program for the last three years. Potential research projects include such issues as:

- The representation of technology innovation and diffusion in IA models. This might include studies such as (a) The expected impact of increased R&D programs on technology innovation, (b) decomposing technology improvements into various factors, including a residual such as the autonomous energy efficiency improvement index, (c) capital vintaging and embodied technology in capital stock, and d) analysis of the "top/down versus bottom/up controversy",
- The rate of technology diffusion from the US to developing countries and the prediction of the energy-use path for developing countries, including the influence that future technology improvements in developed countries will have on developing countries, and
- The translation of existing literature on the economics of technology innovation into a representation that could be adapted for IA models.

2. Representing Non-Market Impacts in Integrated Assessments: A major challenge before the integrated assessment modeling community is to expand the range of representations in integrated assessment models of the response of ecosystems, socio-economic systems, human health, and other sectors to potential climate changes. This is especially true for estimates of the consequences of climate change on the "non-market" goods and services provided by ecosystems. This topic will emphasize the interface between impacts sectors and integrated assessment rather than process modeling of the sectors. Of particular importance are analyses that attempt to predict the change of unmanaged ecosystems to transient climate change rather than, for instance, static doubled carbon dioxide regime.

3. Reduced Form Models: This category would support the development of selected simplified models that portray an important aspect

of the overall problem and can be used by several of the IA modelers. This category would also support research that addresses paradigms for coordinating research on process studies so that they are more easily reformulated as reduced form models.

4. Uncertainty. Research subjects include how to estimate uncertainty in IA models, how uncertainty affects the effectiveness of policy options, the utility of different representations of uncertainty including surprises, and the value of research on different topics based on an analysis of the utility of uncertainty reduction.

5. Scale Differences: In linking the physical, biological, and social science systems together, information and sub-models are often collected and constructed at different geographical scales and timeframes. For example, impacts averaged across large latitude and longitude cells do not correspond to nations, which are often the appropriate unit in political science models of international negotiating. This category includes research on combining different scales in a consistent manner.

6. Data: Some data sets are so important and common to so many assessment activities that support for collection of that data would prevent duplication. This category includes two subjects. The first is to conduct the research necessary to define specific data sets that are needed by the IA community. The second is to conduct the research necessary to collect and provide a needed data set.

7. Driving Forces: This research will help understand the underlying economic forces that drive global change and that form a foundation for most economic modeling of global change.

B. Assessment in Direct Support of Policy

The following subject areas are defined by categories of policy concerns rather than by research categories themselves. Successful research applications in this area will concentrate on the broader issues of policy activities rather than, for example, specific policy proposals. Although particular examples or case studies may be important to understanding the broader theme, the major goal is the general understanding that can be applied to the broad policy. The categories are listed in order of importance.

1. U.S. Emission Abatement Strategies: The research would help predict the direct and indirect effectiveness of emission abatement strategies, such as cost, impacts, and timing. For example, assessing effectiveness of voluntary actions would be important for some short-term abatement actions.

2. R&D as a Policy Option: Investment or other policies to encourage research and development are options for increasing abatement and improving adaptation. Research in this category would investigate such subjects as how to predict the success of research programs and the effectiveness of alternative modes of implementation, such as direct grants, cooperative research projects, etc.

3. Global Change in the Context of Other Social and Environmental Policy Options: Often global change policy issues are discussed in the context of broader social and environmental goals. This category would support the extension of global change assessment to include measures and concepts that would benefit the broader debate, such as international trade, job formation, and economic competitiveness.

4. International Negotiations: This category includes research on past roles or future prospects for science and integrated assessments in international environmental negotiating processes and the formation and stability of international agreements, for instance, whether agreements can be generated that are both effective in reducing emissions and that do not encourage countries to "drop out".

Potential applications are strongly encouraged to submit a brief preapplication in accordance with 10 CFR 600.10(d)(2), which consists of two to three pages of narrative describing research objectives. Preapplications will be used to identify potential opportunities for coordinated research, to enable DOE to advise potential applicants of DOE's interest in their research ideas, and to serve as a basis for arranging reviews of formal applications.

Preapplications should include no more than two to three double-spaced pages (10 pt.), including proposed research; names and telephone numbers for all principal investigators (PIs), coprincipal investigators, and collaborators; and telefax number, Internet address (if available) and mail address for the PI. Preapplications referencing Program Notice 96–06 should be sent to Dr. Houghton, Office of Health and Environmental Research, ER–74, Germantown, MD 20874–1290, or to john.houghton@oer.doe.gov. Preapplications arriving close to the deadline for submission of applications may not receive adequate attention.

Preapplications and formal applications will be reviewed relative to the DOE interests described by this notice and in reference to scope and research priorities of the U.S. Global Climate Change Research Program (USGCRP). Preapplications will be reviewed for relevance to Program needs and interests. Formal applications will be subjected to merit review and will be evaluated against the evaluation criteria set forth in 10 CFR Part 605 as well as the specifics referenced above.

It is anticipated that approximately $2 million will be available for grant awards in Fiscal Years 1996 and 1997, contingent upon availability of appropriated funds. Previous awards for this type of research have ranged from $30,000 up to $250,000 per year, with most not exceeding $150,000. While most awards are expected to range from $50,000 to $150,000 per year, a few larger awards may be granted for large integrated assessment activities, which may be funded at up to $500,000 per year. Funding of multiple year grant awards of up to three years is available and is also contingent upon availability of appropriated funds.

Information about the development and submission of applications, eligibility, limitations, evaluation, selection process, and other policies and procedures, may be found in 10 CFR Part 605, and in the Application Guide for the Office of Energy Research Financial Assistance Program. The Application Guide is available from the U.S. Department of Energy, Office of Health and Environmental Research, Environmental Sciences Division, ER–74, Germantown, MD 20874–1290. Telephone requests may be made by calling (301) 903–4902. Electronic access to ER's Financial Assistance Guide is possible via the Internet using the following e-mail address: http://www.er.doe.gov.

Related Funding Opportunities

Investigators may wish to obtain information about the following related funding opportunities:

National Science Foundation: In concert with other US/GCRP agencies, NSF has established Methods and Models for Integrated Assessment to sponsor high-quality, fundamental and methodological research in two related categories: (1) Research that advances the development of methodologies and models that will integrate or couple multiple component systems; and (2) research that develops and enhances the scientific components of the integrated approach. For both research categories, NSF encourages participation and collaboration of researchers from all appropriate scientific and engineering disciplines, including the mathematical

sciences. In FY 1995, NSF awarded approximately $3.4 M through the special MMIA competition. Funding in FY 1996 is anticipated at approximately the same level, depending on availability of funds. Proposals submitted for this competition must be postmarked no later than March 11, 1996. For more information on this program, please contact; Dr. Robin Cantor, Directorate for Social, Behavioral, and Economic Sciences, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230, PH: (703) 306–1757, FAX: (703) 306–0485, Internet: rcantor@nsf.gov.

National Oceanic and Atmospheric Administration: Within the context of its Economics and Human Dimensions of Climate Fluctuations Program, the Office of Global Programs of the National Oceanic and Atmospheric Administration will support research that identifies and analyzes social and economic impacts associated with seasonal, year-to-year and intradecadal climate variability, improves our understanding of factors that determine human vulnerability to such fluctuations, and identifies options for reducing vulnerability. The program is particularly interested in learning how advanced climate information, as well as an improved understanding of current coping mechanisms, could be used for reducing vulnerability and providing for more efficient adjustment to these variations. Notice of this program is included in the Program Announcement for NOAA's Climate and Global Change Program, which is published each spring in the **Federal Register**. The deadline for proposals to be considered in Fiscal Year 1997 is expected to be in late summer 1996. For further information, contact: Claudia Nierenberg; Office of Global Programs; National Oceanic and Atmospheric Administration; 1100 Wayne Ave., Suite 1225; Silver Spring, MD 20910; Phone: (301) 427–2089, Ext. 46; Internet: nierenberg@ogp.noaa.gov.

The Catalog of Federal Domestic Assistance Number for this program is 81.049, and the solicitation control number is ERFAP 10 CFR part 605.

John Rodney Clark,

Associate Director for Resource Management, Office of Energy Research.

[FR Doc. 96–1611 Filed 1–29–96; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–5407–3]

Agency Information Collection Activities: New Source Performance Standards (NSPS) for Bulk Gasoline Terminals

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this notice announces that EPA is planning to submit the following proposed and/or continuing Information Collection Requests (ICRs) to the Office of Management and Budget (OMB). Before submitting the ICRs to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collections as described below.

DATES: Comments must be submitted on or before April 1, 1996.

ADDRESSES: U.S. Environmental Protection Agency, 401 M Street SW., Mail Code 2223A, OECA/OC/METD, Washington, DC 20460. A copy of these ICRs may be obtained without charge from Sandy Farmer (202) 260–2740.

FOR FURTHER INFORMATION CONTACT: Peter Bahor at (202) 564–7029 or Julie Tankersley at (202) 564–7002 for NSPS subpart XX, Bulk Gasoline Terminals. The fax number for either contact is (202) 564–0050.

SUPPLEMENTARY INFORMATION: Affected entities: Entities potentially affected by this action are those which are subject to NSPS subpart XX, Bulk Gasoline Terminals.

Title: NSPS subpart XX, Bulk Gasoline Terminals, OMB number 2060–0006, expires March 31, 1996.

Abstract: Owners or operators of the affected facilities described must make the following one-time-only reports: notification of the date of construction or reconstruction; notification of the anticipated and actual dates of start-up; notification of any physical or operational change to an existing facility which may increase the regulated pollutant emission rate; notification of the date of the initial performance test; and the results of the initial performance test. Owners or operators are also required to maintain records of the occurrence and duration of any start-up, shutdown, or malfunction in the operation of an affected facility. These notifications, reports and records are required, in general, of all sources subject to NSPS.

Monitoring requirements specific to bulk gasoline terminals consist mainly of identifying and documenting vapor tightness for each gasoline tank truck that is loaded at the affected facility, and notifying the owner or operator of each tank truck that is not vapor tight. The owner or operator must also perform a monthly visual inspection for liquid or vapor leaks, and maintain records of these inspections at the facility for a period of two years.

The reporting requirements for this industry currently include only the initial notifications and initial performance test report listed above. All reports are sent to the delegated State or local authority. In the event that there is no such delegated authority, the reports are sent directly to the EPA Regional Office. Notifications are used to inform the Agency or delegated authority when a source becomes subject to the standard. The reviewing authority may then inspect the source to ensure that the pollution control devices are properly installed and operated. Performance test reports are needed as these are the Agency's record of a source's initial capability to comply with the emission standard, and note the operating conditions under which compliance was achieved.

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR Part 9.

The EPA would like to solicit comments to:

(i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(ii) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) enhance the quality, utility, and clarity of the information to be collected; and

(iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Burden Statement: The estimate was based on the assumption that there are 49 sources in existence and there would be three new affected facilities each year. For reporting requirements it is

estimated that it will take one person-hour to read the instructions. The ICR uses 60 burden hours for the initial performance test this includes the burden to write the report of the performance test. It is assumed that 20% of all affected facilities will have to repeat performance tests.

The following is a breakdown used in the ICR. Burden is calculated as two hours each for respondents to gather existing information and write the reports for; notification of construction/modification, notification of anticipated start-up, and notification of initial performance test. The burden is calculated as one hour for respondents to gather existing information and write a report for notification of actual start-up. These are all one time only burdens. These notifications, reports and records are required in general, of all sources subject to NSPS.

Recordkeeping is the only ongoing burden associated with this ICR. The recordkeeping burden—time to enter information—records of start-up, shutdown, malfunction, or any periods during which the monitoring system is inoperative is estimated to be one and one half hours 50 times per year or about one occurrence per week.

The burden to enter records of tank identification numbers is 0.1 of an hour with the assumption it takes six minutes to enter each tank truck identification number. It is estimated there will be approximately 2,100 truck loadings per year based on six tank trucks each day multiplied by 350 days per year. It is estimated that leak detection records from monthly inspection of control equipment is one person-hour every two years.

This estimate includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Dated: January 24, 1996.

Elaine G. Stanley,

Director, Office of Compliance.

[FR Doc. 96–1708 Filed 1–29–96; 8:45 am]

BILLING CODE 6560–50–P

[FRL–5407–6]

Standards of Performance for New Stationary Sources, Supplemental Delegation of Authority to Alabama

AGENCY: Environmental Protection Agency (EPA).

ACTION: Informational notice.

SUMMARY: On June 10, 1991, and August 14, 1995, the Alabama Department of Environmental Management (ADEM) requested that EPA delegate authority for implementation and enforcement of additional categories of New Source Performance Standards (NSPS). Since EPA's review of Alabama's pertinent laws, rules, and regulations showed them to be adequate and effective procedures for the implementation and enforcement of these Federal standards, EPA has made the delegation as requested.

EFFECTIVE DATE: The effective date of these delegations of authority are June 10, 1991, and November 29, 1995.

ADDRESSES: Copies of the request for delegation of authority and EPA's letter of delegation are available for public inspection during normal business hours at the following locations:

Environmental Protection Agency, Region IV, Air Programs Branch, 345 Courtland Street, Atlanta, Georgia 30365.

Alabama Department of Environmental Management, 1751 Congressman W. L. Dickinson Drive, Montgomery, Alabama 36109.

Effective immediately, all requests, applications, reports and other correspondence required pursuant to the newly delegated standards should not be submitted to the Region 4 office, but should instead be submitted to the following address: Alabama Department of Environmental Management, 1751 Congressman W. L. Dickinson Drive, Montgomery, Alabama 36109.

FOR FURTHER INFORMATION CONTACT: Kimberly Bingham, Regulatory Planning and Development Section, Air Programs Branch, United States Environmental Protection Agency, Region 4, 345 Courtland Street N.E., Atlanta, Georgia 30365, (404) 347–3555, x4195.

SUPPLEMENTARY INFORMATION: Section 301, in conjunction with Sections 110 and 111(c)(1) of the Clean Air Act as amended November 15, 1990, authorizes EPA to delegate authority to implement and enforce the standards set out in 40 CFR Part 60, New Source Performance Standards (NSPS).

On August 5, 1976, EPA initially delegated the authority for implementation and enforcement of the NSPS programs to the State of Alabama. On June 10, 1991, and August 14, 1995, Alabama requested a delegation of authority for implementation and enforcement of the following NSPS categories found in 40 CFR Part 60.

40 CFR Part 60

1. Standard of Performance for Sewage Treatment Plants, as specified in 40 CFR part 60, Subpart O, as amended by 59 FR 5107, February 3, 1994, as adopted March 16, 1995. Section 61.174(a) within Subpart O cannot be delegated.

2. Standard of Performance for Automobile and Light-Duty Truck Surface Coating Operations, as specified in 40 CFR part 60, Subpart MM, as amended by 59 FR 51383 October 11, 1994, as adopted March 16, 1995.

3. Standard of Performance for Volatile Organic Compound (VOC) Emissions from the Synthetic Organic Chemical Manufacturing Industry (SOCMI) Reactor Processes, as amended by 58 FR 45948 (August 31, 1993), as specified in 40 CFR part 60, Subpart RRR, and as adopted March 16, 1995. Section 60.703(e) of Subpart RRR cannot be delegated.

4. Volatile Organic Compound Emissions from the Synthetic Organic Chemical Manufacturing Industry (SOCMI) Air Oxidation Unit Processes, as amended by 55 FR 26912 (June 29, 1990) and 55 FR (September 7, 1990), as specified in 40 CFR part 60, Subpart III. Section 60.613(e) of Subpart III cannot be delegated.

5. Standard of Performance for Volatile Organic Compound (VOC) Emissions from the Synthetic Organic Chemical Manufacturing Industry (SOCMI) Distillation Operations, as amended by 55 FR 26931 (June 29, 1990) and 55 FR 36932 (September 7, 1990), as specified in 40 CFR part 60, Subpart NNN. Section 60.663(e) of Subpart NNN cannot be delegated.

6. Standard of Performance for Small Industrial-Commercial-Institutional Steam Generating Units, as amended by 55 FR 37674 (September 12, 1990), as specified in 40 CFR part 60, Subpart Dc. Section 60.48c(a)(4) cannot be delegated.

7. Standard of Performance for Petroleum Refineries, as amended by 55 FR 40171 (October 2, 1990), as specified in 40 CFR part 60, Subpart J. Sections 60.105(a)(13)(iii) and 60.106(i)(12) cannot be delegated.

After a thorough review of the request, the Regional Administrator determined that such a delegation was appropriate for this source category with the conditions set forth in the original delegation letter of August 5, 1976 and

subsequent delegation letters of March 29, 1982; April 5, 1985; June 2, 1987; December 2, 1988; and February 20, 1991. Alabama sources subject to the requirements of this subpart will now be under the jurisdiction of Alabama.

Since review of the pertinent Alabama laws, rules, and regulations showed them to be adequate for the implementation and enforcement of the aforementioned categories of NSPS and NESHAPs, the EPA hereby notifies the public that it has delegated the authority for the source categories listed above on June 10, 1991, and November 20, 1995. The Office of Management and Budget has exempted this rule from the requirements of section 6 of Executive Order 12866.

Authority: This notice is issued under the authority of sections 101, 110, 111, 112, and 301 of the Clean Air Act, as Amended (42 U.S.C. 7401, 7410, 7411, 7412, and 7601).

Dated: January 12, 1996.

Phyllis P. Harris,

Acting Regional Administrator.

[FR Doc. 96–1717 Filed 1–29–96; 8:45 am]

BILLING CODE 6560–50–P

[FRL–5406–9]

Accidental Release Prevention Requirements: Risk Management Programs Under Section 112(r)(7) of the Clean Air Act as Amended; Draft Guidances

AGENCY: Environmental Protection Agency.

ACTION: Notice of availability.

SUMMARY: Section 112(r)(7) of the Clean Air Act (CAA), as amended, requires the Environmental Protection Agency (EPA) to develop guidance documents, including model risk management plans, to assist stationary sources in the development of risk management programs. The following three draft guidance documents are available for review in Docket No. A–91–73 Category VIII–A: "Offsite Consequence Assessment"; "Generic Guidance Risk Management Program (RMP) for Ammonia Refrigeration Facilities"; and "Risk Management Plan Data Elements." The Agency is interested in continued dialogue on the guidances with interested members of the public and will issue guidance at the time it promulgates the Risk Management Program regulations.

DATES: Those who wish to express their views concerning the material contained in the guidances should submit written comments by February 29, 1996, to Docket A–91–73 Category VIII–B, at the address below, or via e-mail to A-and-R-Docket@epamail.epa.gov.

ADDRESSES: *Docket.* These documents are in Docket A–91–73 Category VIII–A and available for public inspection and copying between 8 a.m. and 5:30 p.m., Monday through Friday, including all non-Governmental holidays, at EPA's Air and Radiation Docket and Information Center, room M1500, U.S. Environmental Protection Agency (6102), 401 M Street SW., Washington, DC 20460.

Electronic Access. These documents can be accessed in electronic format through the Internet system and through EPA's Technology Transfer Network (TTN), a network of electronic bulletin boards operated by the Office of Air Quality Planning and Standards. The Internet address of EPA's gopher server is GOPHER.EPA.GOV. This information is also available using File Transfer Protocol (FTP) on FTP.EPA.GOV or using World Wide Web (WWW) (http://earth1.epa.gov/ceppo). The TTN service is free, except for the cost of a phone call. To access the TTN, dial (919) 541–5742 for up to a 14,400 bits per second (bps) modem. If more information on TTN is needed, contact the systems operator at (919) 541–5382.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: A-and-R-Docket@epamail.epa.gov. Electronic comments must be submitted as ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number A–91–73 Category VIII–B. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic comments on this draft guidance may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: For technical information on the "Generic Guidance Risk Management Program (RMP) for Ammonia Refrigeration Facilities" or the draft "Risk Management Data Elements", contact Lyse Helsing, (202) 260–6128. For technical information on the draft "Offsite Consequence Assessment", contact Craig Matthiessen, (202) 260–9781. To order copies of these documents, please FAX requests to the Emergency Planning and Community Right-to-Know Information Hotline (Hotline) at (703) 412–3333. The Hotline is also available to answer questions at (800) 535–0202 or (703) 412–9877 when calling from local Washington, DC area.

SUPPLEMENTARY INFORMATION: EPA announces the availability of draft guidances that will assist stationary sources in complying with the provisions of CAA section 112(r)(7)(B), including the requirement to prepare risk management plans. The documents made available today are drafts of guidances and would not, when finalized, create any obligations on the part of entities subject to CAA section 112(r)(7)(B); thus, these documents are neither regulations nor proposed regulations.

EPA proposed Risk Management Program regulations to implement CAA section 112(r)(7) on October 20, 1993 (58 FR 54190) and March 13, 1995 (60 FR 13528). For information on the proposed regulations, please see the above-referenced notices. Furthermore, for information on chemicals, sources, and processes subject to CAA section 112(r)(7), please see 40 CFR part 68 and the notice establishing these provisions (59 FR 4478, January 31, 1994).

The draft "Offsite Consequence Assessment" guidance contains all the methodologies and reference tables that would be necessary to develop and analyze the consequences of worst case and more likely ("alternative case") scenarios for the regulations under CAA section 112(r)(7)(B). This guidance is designed to help those sources subject to section 112(r)(7) comply with the offsite consequence requirements without specific expertise or access to computer-based and more sophisticated modeling tools. EPA contemplates that sources will be able to use the modeling results contained in a final guidance or other appropriate modeling results in complying with the section 112(r)(7) regulations.

The draft "Generic Guidance Risk Management Program (RMP) for Ammonia Refrigeration Facilities" is a model program and plan that will help owners and operators of ammonia refrigeration facilities comply with the CAA section 112(r). The draft guidance includes a section on hazard assessment and on emergency response, and four appendices: (A) Selection of scenarios; (B) background information on ammonia modeling; (C) effect of ammonia releases on structures; and (D) refrigerated ammonia release modeling.

The Risk Management Program regulation will require submission of risk management plans. The draft Risk Management Data Elements maps out the kinds of information that would be submitted by each source as its risk management plan. The draft includes an executive summary, registration, data on worst case and alternative releases for toxics and for flammables, five-year

accident history, prevention program, and emergency response program.

Dated: January 23, 1996.

Jim Makris,

Director, Chemical Emergency Preparedness and Prevention Office.

[FR Doc. 96–1706 Filed 1–29–96; 8:45 am]

BILLING CODE 6560–50–P

[FRL–5406–8]

Regulatory Reinvention (XL) Pilot Projects: XL Community Pilot Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice correction.

On December 12, 1995 the Environmental Protection Agency published the **Federal Register** Notice 60 FR 63711 (FRL–5344–5) in error. Please refer to the November 1, 1995 **Federal Register** Notice 60 FR 55569 (FRL–5322–9) for the correct and complete description of the XL Community (XLC) Pilot Program. Additional information on the XL Community Pilot Program may be obtained by calling 703–934–3241. To request that XLC documents be sent or faxed please call the XL program's automated telephone system at 202–260–8590.

Dated: January 19, 1996.

John Wilson,

OPPE/OSEC.

[FR Doc. 96–1714 Filed 1–29–96; 8:45 am]

BILLING CODE 6560–50–P

[FRL–5407–7]

Underground Injection Control Program: Class I Non-Hazardous Waste Disposal Injection Restrictions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of intent to grant a case-by-case extension.

The U.S. Environmental Protection Agency is granting the request from Abbott Laboratories, Wichita, Kansas, for a case-by-case extension of the RCRA land disposal restriction (LDR) treatment standards applicable to total organic carbon (TOC), EPA Hazard Code D001. This final decision provides for a one year extension period beginning September 19, 1995, and allows Abbott to continue injecting its wastestream into their Underground Injection Control (UIC) Class I injection well until September 19, 1996. This extension is granted under the provisions found in 40 CFR 148.4. This extension will allow the Environmental Protection Agency to complete the review of Abbott's No-Migration Petition application. The basis for approval includes the following demonstrations:

40 CFR 268.5(a)(1) Abbott Laboratories has made a good-faith effort on a nationwide basis to locate and contract for adequate alternative treatment, recovery, or disposal capacity, or establish such capacity by the effective date of the applicable restrictions.

40 CFR 268.5(a)(2) Abbott Laboratories has entered into a binding contractual commitment to provide alternative treatment, recovery, or disposal capacity.

40 CFR 268.5(a)(3) Abbott Laboratories has shown the lack of alternative capacity is beyond its control.

40 CFR 268.5(a)(4) Abbott Laboratories has shown that there will be adequate alternative treatment, recovery, or disposal capacity for all waste after the effective date established by the extension.

40 CFR 268.5(a)(5) Abbott Laboratories has provided a detailed schedule for obtaining alternative capacity including dates.

40 CFR 268.5(a)(6) Abbott Laboratories has arranged for adequate capacity to manage waste during the extension period.

40 CFR 268.5(a)(7) No surface impoundments or landfills will be used by Abbott Laboratories to manage the waste during the extension period.

This case-by-case extension is only for the waste code impacted by the September 19, 1994 Land Disposal Restrictions, Phase II and is valid for as long as the basis for granting an extension remains valid, under provisions of 40 CFR Part 124.

FOR FURTHER INFORMATION CONTACT: For information contact Robert L. Morby, Chief Drinking Water/Groundwater Management Branch, EPA-Region 7 or telephone (913) 551–7682.

Dated: December 14, 1995.

Dennis Grams,

Regional Administrator.

[FR Doc. 96–1716 Filed 1–29–96; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection Approved by Office of Management and Budget

January 22, 1996.

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 1995, Pub. L. 96–511. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid control number. For further information contact Dorothy Conway, Federal Communications Commission, (202) 418–0217.

Federal Communications Commission

OMB Control No.: 3060–0689.

Expiration Date: 3/31/96.

Title: Market Entry and Regulations of Foreign-Affiliated Entities.

Estimated Annual Burden: 4,127 total annual hours; average 8 hours per respondent; 431 respondents.

Description: The information required by 47 CFR Part 63 and Sections 214 and 310(b)(4) of the Communications Act of 1934 as amended, is needed to regulate the entry of foreign carriers into the U.S. international service market. In addition, this information is needed in order to regulate carriers in their provision of international service.

OMB Control No.: 3060–0683.

Expiration Date: 1/31/99.

Title: Direct Broadcast Satellite Service 47 CFR Section 100 (Proposed Rule).

Estimated Annual Burden: 3,200 total annual hours; average 400 hours per respondent; 8 respondents.

Description: The Commission proposes to require the DBS auction winners submit (1) ownership information to determine compliance with Parts 1 and 100 of the Commission's rules; (2) a statement describing efforts to comply with the proposed spectrum limitations; (3) an explanation of the terms and conditions and party parties involved with any bidding consortia, joint venture, partnership, other agreement or arrangement they enter into reltating to the competitive bidding process prior to the close of bidding; and (4) any agreements or contracts pertaining to the transfer of the DBS authorization acquired through actions during the six years following the grant of the authorization.

OMB Control No.: 3060–0685.

Expiration Date: 2/29/96.

Title: Annual Updating of Maximum Permitted Rates for Regulated Cable Service FCC Form 1240.

Estimated Annual Burden: 116,438 total annual hours; average 15 hours per respondent; 5,850 respondents.

Description: The Commission has created the FCC Form 1240 Annual

Updating of Maximum Permitted Rates for Regulated Cable Services as a filing alternative to the FCC Form 1210 which is filed quarterly. The Form 1240 like the Form 1210, is filed by cable operators seeking to adjust maximum permitted rates for regulated services to reflect changes in external costs. Cable operators will submit the Form 1240 to their respective local franchising authorities upon certification to regulate basic service tier rates and associated equipment; or with the Commission (in situations where the Commission has assumed jurisdiction). The Form 1240 will also be filed with the Commission when responding to a complied filed with the Commission about cable programming service rates and assocated equipment.

OMB Control No.: 3060–0433.
Expiration Date: 1/31/99.
Title: Basic Signal Leakage.
Estimated Annual Burden: 640,000 total annual hours; average 20 hours per respondent; 32,000 respondents.
Description: Cable television system operators who use frequencies in the bands 108–137 and 225–400 MHz (aeronautical frequencies) are required to file a cumulative signal leakage index (CLI) derived under 47 CFR 76.611(a)(1) or the results of airspace measurements derived under 47 CFR 76.611(a)(2). This yearly filing is done in accordance with 47 CFR 76.615 on FCC Form 320. The data is used by FCC staff to ensure the safe operation of aeronautical an marine radio services and to monitor compliance of cable aeronautical usage which will minimize future interference of these safety of life services.

OMB Control No.: 3060–0475.
Expiration Date: 12/31/98.
Title: Entry Criteria Sections 90.713.
Estimated Annual Burden: 842 total annual hours; average 25.5 hours per respondent; 33 respondents.
Description: Section 90.713 requires applications for nationwide systems in the 220–222 MHz bands to certify that they have an actual presence necessitating internal communications capacity in the 70 or more markets identified in the application. The data will be used to determine the eligibility of the applicant to hold a radio station authorization. Commission licensing personnel will use the data for rule making proceedings and field engineers will use the data for enforcement purposes.

OMB Control No.: 3060–0684.
Expiration Date: 12/31/98.
Title: Amendment to the Commission's rules regarding a plan for sharing the costs of microwave relocation.
Estimated Annual Burden: 540 total annual hours; average 15 minutes for 2,000 respondents to provide information; and 40 hours for an industry clearing house to be created an operated; 2,000 respondents.
Description: The collection is necessary to effectuate burden reimbursement for PCS licenees that incur expenses in relocating existing microwave facilities. Information will be used by PCS licensee to determine reimbursement costs.

OMB Control No.: 3060–0516.
Expiration Date: 11/30/98.
Title: Revision of Radio Rules and Policies, Time Brokerage Ruling.
Estimated Annual Burden: 40 total annual hours; average 40 hours per respondent; 1 respondents.
Description: This information collection requires that parties that are unable to verify that a time brokerage agreement complies with the local ownership rules file a request for ruling with the Commission.

OMB Control No.: 3060–0223.
Expiration Date: 11/30/98.
Title: 90.129(b) Supplemental information to be routinely submitted with applications.
Estimated Annual Burden: 33 total annual hours; average .33 hours per respondent; 100 respondents.
Description: Section 90.129(b) requires applicants using non type-accpeted equipment to provide a description of the equipment. This information is used to evaluate the interference potential of the proposed operation.

Federal Communications Commission.
William F. Caton,
Acting Secretary.
[FR Doc. 96–1603 Filed 1–29–96; 8:45 am]
BILLING CODE 6712–01–F

FEDERAL MARITIME COMMISSION

[Docket No. 96–01]

Low Cost Shipping, Inc., International Student Services, Eugene Rogoway and Marie Arnold Order To Show Cause

This proceeding is instituted pursuant to sections 8, 11, 19 and 23 of the Shipping Act of 1984 ("1984 Act"), 46 U.S.C. app. 1707, 1710, 1718 and 1721, and the Federal Maritime Commission's ("Commission") regulations governing the tariffing and bonding of non-vessel-operating common carriers, 46 C.F.R. part 514 and the licensing of ocean freight forwarders, 46 C.F.R. part 510.

Low Cost Shipping, Inc. ("Low Cost") is a company incorporated under the laws of the State of Washington. It is managed and controlled by Eugene Rogoway, General Manager of Low Cost and his wife, Marie Arnold, President of Low Cost. Low Cost also advertises using the name "International Student Services."

It appears that between June 1, 1994 and September 26, 1995, Low Cost held itself out to the public as a provider and forwarder of ocean transportation for shipments of household goods, furniture and personal effects in the foreign commerce of the United States. For at least thirteen shipments known to the Commission, Low Cost collected ocean freight from shippers. In six of these thirteen shipments, Low Cost, in the capacity of a shipper, contracted with common carriers for the ocean transportation.[1] With respect to the remaining seven shipments, Low Cost dispatched the shipments from the United States by processing the documentation and booking the cargo.[2]

Carrier[1]	Bill of lading No.	Date	Destination
Keymost International Inc	KM 6916	7/16/94	Antwerp.
Yang Ming Line	YMLUDENKARW0002R	8/28/94	Pakistan.
Shipco Transport Inc	SIT1294N3102	1/07/95	Sittard.
Italia Line	ITAUPO502663	4/14/95	South Africa.
Shipco Transport Inc	KAM0495N0907	4/21/95	Kampala.
Shipco Transport Inc	BRE0495N6201	5/08/95	Bremen.

Carrier[2]	Bill of lading No.	Date	Destination
Nantai Line Co., Ltd	NTLU SEAPTE0061	1/31/95	South Africa.
Shipco Transport Inc	MEL0495N1101	4/07/95	Melbourne.

Carrier[2]	Bill of lading No.	Date	Destination
Shipco Transport Inc	KAO0495N1102	4/10/95	Kaohsiung.
Shipco Transport Inc	HAM0495N0903	4/18/95	Hamburg.
Shipco Transport Inc	FRA0495N0901	4/18/95	Frankfurt.
Shipco Transport Inc	ZUR0495N0905	4/19/95	Zurich.
Shipco Transport Inc	LSN0495N0908	4/23/95	London.

Section 8(a) of the 1984 Act, 46 U.S.C. app. 1707(a), provides that no common carrier may provide service in the United States foreign trades unless the carrier first has filed a tariff with the Commission showing all of its rates, charges and practices. Section 23(a) of the 1984 Act, 46 U.S.C. app. 1721(a), further provides that each non-vessel-operating common carrier must furnish to the Commission a bond, proof of insurance or other surety, *inter alia*, to insure the financial responsibility of the carrier to pay any judgment for damages arising from its transportation-related activities. According to the records maintained by the Commission's Bureau of Tariffs, Certification and Licensing, no tariff or bond has been filed with the Commission in the name of Low Cost, International Student Services, Eugene Rogoway or Marie Arnold. Therefore, it would appear that Low Cost, International Student Services, Eugene Rogoway and Marie Arnold, by providing and holding out to the public to provide transportation by water of cargo for compensation and by contracting as a shipper in relation to a common carrier for the carriage of cargo of other persons, have acted as a non-vessel-operating common carrier without a tariff or bond on file with the Commission, in violation of sections 8(a) and 23(a) of the 1984 Act.

Section 19(a) of the 1984 Act, 46 U.S.C. app. 1718(a), provides that no person may act as an ocean freight forwarder unless that person has obtained a license from the Federal Maritime Commission. Section 3(19) of the 1984 Act, 46 U.S.C. app. 1702(19), defines an ocean freight forwarder as a person in the United States that dispatches shipments from the United States to a foreign country via common carriers, books or otherwise arranges space for such shipments on behalf of shippers and processes the documentation or performs related activities incident to those shipments. In order to obtain an ocean freight forwarder license, a forwarder must furnish to the Commission a bond to insure the financial responsibility of the forwarder, and the Commission must determine that the forwarder is qualified by experience and character to render forwarding services. According to a review of records maintained by the Commission's Bureau of Tariffs, Certification and Licensing, no ocean freight forwarder license has been issued in the name of Low Cost, International Student Services, Eugene Rogoway or Marie Arnold. Therefore, it would appear that Low Cost, International Student Services, Eugene Rogoway and Marie Arnold, by booking cargo and processing documentation to dispatch shipments from the United States, have acted as an ocean freight forwarder without a license issued by the Commission, in violation of section 19(a) of the 1984 Act.

Now therefore, it is ordered That pursuant to section 11 of the Shipping Act of 1984, Low Cost Shipping Inc., International Student Services, Eugene Rogoway and Marie Arnold show cause why they should not be found to have violated section 8(a) of the Shipping Act of 1984 by acting as a non-vessel-operating common carrier in six (6) instances, specified above, without a tariff for such services on file with the Commission;

It is further ordered That pursuant to section 11 of the Shipping Act of 1984, Low Cost Shipping Inc., International Student Services, Eugene Rogoway and Marie Arnold show cause why they should not be found to have violated section 23(a) of the Shipping Act of 1984 by acting as a non-vessel-operating common carrier in six (6) instances, specified above, without a bond for such services on file with the Commission;

It is further ordered That pursuant to section 11 of the Shipping Act of 1984, Low Cost Shipping Inc., International Student Services, Eugene Rogoway and Marie Arnold show cause why they should not be found to have violated section 19(a) of the Shipping Act of 1984 by acting as an ocean freight forwarder in seven (7) instances, specified above, without an ocean freight forwarder license issued by the Commission;

It is further ordered That Low Cost Shipping Inc., International Student Services, Eugene Rogoway and Marie Arnold show cause why an order should not be issued directing them to cease and desist from providing or holding themselves out to provide transportation as common carrier(s) and from obtaining from any common carrier transportation by water of cargo of any other person between the United States and a foreign country unless and until such time as Low Cost Shipping, Inc., International Student Services, Eugene Rogoway or Marie Arnold shall have filed a tariff and bond for such service with the Commission;

It is further ordered That Low Cost Shipping Inc., International Student Services, Eugene Rogoway and Marie Arnold show cause why an order should not be issued directing them to cease and desist from dispatching shipments from the United States to a foreign country via common carriers, booking or otherwise arranging space for such shipments and processing the documentation or performing related activities incident to those shipments unless and until such time as Low Cost Shipping, Inc., International Student Services, Eugene Rogoway or Marie Arnold shall have obtained an ocean freight forwarder license from the Commission.

It is further ordered That this proceeding is limited to the submission of affidavits of facts and memoranda of law;

It is further ordered That any person having an interest and desiring to intervene in this proceeding shall file a petition for leave to intervene in accordance with Rule 72 of the Commission's Rules of Practice and Procedure, 46 C.F.R. 502.72. Such petition shall be accompanied by the petitioner's memorandum of law and affidavits of fact, if any, and shall be filed no later than the day fixed below;

It is further ordered That Low Cost Shipping Inc., International Student Services, Eugene Rogoway and Marie Arnold are named Respondents in this proceeding. Affidavits of fact and memoranda of law shall be filed by Respondents and any intervenors in support of Respondents no later than February 12, 1996;

It is further ordered That the Commission's Bureau of Enforcement be made a party to this proceeding;

It is further ordered That reply affidavits and memoranda of law shall be filed by the Bureau of Enforcement and any intervenors in opposition to Respondent no later than March 4, 1996;

It is further ordered That rebuttal affidavits and memoranda of law shall

be filed by Respondents and intervenors in support no later than March 14, 1996;

It is further ordered That:

(a) Should any party believe that an evidentiary hearing is required, that party must submit a request for such hearing together with a statement setting forth in detail the facts to be proved, the relevance of those facts to the issues in this proceeding, a description of the evidence which would be adduced, and why such evidence cannot be submitted by affidavit;

(b) Should any party believe that an oral argument is required, that party must submit a request specifying the reasons therefore and why argument by memorandum is inadequate to present the party's case; and

(c) Any request for evidentiary hearing or oral argument shall be filed no later than March 14, 1996;

It is further ordered That notice of this Order to Show Cause be published in the **Federal Register**, and that a copy thereof be served upon Respondents;

It is further ordered That all documents submitted by any party of record in this proceeding shall be filed in accordance with Rule 118 of the Commission's Rules of Practice and Procedure, 46 C.F.R. 502.118, as well as being mailed directly to all parties of record;

Finally, it is ordered That pursuant to the terms of Rule 61 of the Commission's Rules of Practice and Procedure, 46 C.F.R. 502.61, the final decision of the Commission in this proceeding shall be issued by July 22, 1996.

By the Commission.

Joseph C. Polking,

Secretary.

[FR Doc. 96–1628 Filed 1–29–96; 8:45 am]

BILLING CODE 6730–01–M

FEDERAL RESERVE SYSTEM

Agency Forms Under Review

Background

Notice is hereby given of the final approval of proposed information collection by the Board of Governors of the Federal Reserve System (Board) under OMB delegated authority, as per 5 C.F.R. 1320.16 (OMB Regulations on Controlling Paperwork Burdens on the Public). The Federal Reserve may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

FOR FURTHER INFORMATION CONTACT:

Federal Reserve Board Clearance Officer—Mary M. McLaughlin—Division of Research and Statistics, Board of Governors of the Federal Reserve System, Washington, DC 20551 (202-452-3829)

OMB Desk Officer—Milo Sunderhauf—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 3208, Washington, DC 20503 (202-395-7340)

Final approval under OMB delegated authority of the extension, without revision, of the following report:

1. Information collection title: Recordkeeping and Disclosure Requirements in Connection with Regulation DD (Truth in Savings)
Agency form number: None
OMB Control number: 7100-0271
Frequency: Event-generated
Respondents: State member banks
Annual reporting hours: 1,447,225
Estimated average hours per response: Complete account disclosures: 5 minutes; Subsequent change in terms notice, Subsequent prematurity notice, or Periodic statement: 1 minute; and Advertising: 1 hour.
Number of respondents: 975
Small businesses are affected.

General description of report: This information collection is mandatory (12 U.S.C. § 4308). No issue of confidentiality under the Freedom of Information Act normally arises.

Abstract: Regulation DD implements the Truth in Savings Act (12 U.S.C. § 4301 *et seq*). The act and regulation require depository institutions to disclose information such as fees and rates that apply to deposit accounts so that consumers may more easily compare deposit accounts offered by depository institutions. Depository institutions that provide periodic statements are required to include information about fees imposed, interest earned, and the annual percentage yield (APY) during those statement periods. The substantive requirements of the act and regulation mandate the methods by which institutions determine the balance on which interest is calculated. Rules dealing with advertisements for deposit accounts are also included in the regulation. Model clauses and sample forms are appended to the regulation to provide guidance. Depository institutions are required to retain records as evidence of compliance.

The Board's Regulation DD applies to all depository institutions, not just state member banks. However, under Paperwork Reduction Act regulations, the Federal Reserve accounts for the burden of the paperwork associated with the regulation only for state member banks. Other agencies account for the Regulation DD paperwork burden on their respective constituencies.

This extension of authority under the Paperwork Reduction Act has no bearing on the pending rulemaking related to the method of APY calculation.

Board of Governors of the Federal Reserve System, January 24, 1996.

William W. Wiles,

Secretary of the Board.

[FR Doc. 96–1649 Filed 1–29–96; 8:45 am]

BILLING CODE 6210–01–F

[Docket No. R–0914]

Federal Reserve Payment System Risk Policy

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Policy statement.

SUMMARY: The Board has approved modifications to its Fedwire third-party access policy that establish additional requirements applicable to third-party access arrangements involving a service provider located outside the United States ("foreign service provider"). On August 9, 1995, the Board approved certain interim modifications to its Fedwire third-party access policy to clarify its applicability and to reduce the administrative burden of several provisions. At that time, the Board indicated the Federal Reserve Banks would not approve any new third-party access arrangements involving a foreign service provider, pending a review of the supervisory issues associated with such arrangements. The Board has completed its assessment and has modified its policy to address the conditions under which the Federal Reserve would consider approving foreign service provider arrangements. The revised policy is intended to ensure that the Federal Reserve's oversight of Fedwire is not diminished or inappropriately limited by the conduct of activity outside the United States and that the Federal Reserve's supervisory and examination objectives are met. In addition, the policy provides important safeguards to both depository institutions participating in third-party access arrangements and to the Reserve Banks. Among other things, the policy requires depository institutions to impose prudent controls over Fedwire funds transfers and Fedwire book-entry securities transfers initiated, received, or otherwise processed on their behalf by a third-party service provider.

EFFECTIVE DATE: February 1, 1996.

FOR FURTHER INFORMATION CONTACT: Jeff Stehm, Manager (202/452–2217) or Lisa K. Hoskins, Project Leader (202/452–3437), Fedwire Section, Division of Reserve Bank Operations and Payment Systems; or Howard Amer, Assistant Director (202/452–2958), Division of Banking Supervision and Regulation; for the hearing impaired *only*: Telecommunications Device for the Deaf, Dorothea Thompson (202/452–3544).

SUPPLEMENTARY INFORMATION:

I. Background

Fedwire is the large-value payment and securities settlement mechanism operated by the Federal Reserve Banks. Fedwire provides depository institutions with real-time gross settlement in central bank money of funds transfers and book-entry securities transfers made for their own account or on behalf of their customers. Typically, each depository institution that holds an account at the Federal Reserve processes its own transfers and accesses Fedwire directly. In some cases, however, a depository institution accesses Fedwire through a third-party access arrangement in which a service provider, acting as agent for a depository institution, initiates payments that are posted to the institution's account at the Federal Reserve. Third-party access arrangements are a form of outsourcing.[1]

In July 1987, the Board approved a set of conditions under which Fedwire third-party access arrangements could be established, as part of its payment system risk reduction policy (52 FR 29255, August 6, 1987). The Board approved modifications to the policy in August 1995 that clarified the scope and application of the policy and reduced the administrative burden of several provisions (60 FR 42418, August 15, 1995). The scope of the original policy was silent on whether the service provider could be located outside the United States. Such arrangements raise certain supervisory issues, such as the ability of U.S. examiners to access relevant information, conduct on-site reviews of Fedwire operations, and exercise their enforcement authority. As a result, in August the Board broadened the scope of the policy to include third-party access arrangements involving an office of the participant located outside the United States that acts as a service provider, but indicated that new third-party arrangements involving a foreign service provider would not be approved by the Reserve Banks pending an assessment of the relevant supervisory issues.[2]

II. Provision-by-Provision Analysis

The policy establishes conditions that a sending or receiving institution ("the participant") must meet in order to designate another depository institution or other entity ("the service provider") to initiate, receive, and/or otherwise process Fedwire funds transfers or Fedwire book-entry securities transfers that are posted to the participant's reserve or clearing account held at the Federal Reserve. These conditions include requirements that the participant have the ability to retain operational control of the credit-granting process, monitor transfer activity conducted on its behalf, and remain responsible for managing its Federal Reserve account. In addition, the participant is expected to comply with all requirements related to Fedwire access generally, such as encryption standards, as well as all applicable state and federal laws and regulations. The policy also requires a participant that uses an unaffiliated service provider to maintain adequate termination backup arrangements so that it can continue Fedwire operations if the third-party access arrangement must be terminated.

The policy also addresses certain supervisory concerns, including requirements for the participant to obtain an affirmative written statement from its primary supervisor(s) indicating that it does not object to the arrangement; the existence of an adequate audit program for the participant to review the arrangement and compliance with the Board's policy; and the requirement that the service provider be subject to examination by the appropriate federal depository institution regulatory agency(ies). Finally, the participant and the service provider(s) must execute an agreement with the relevant Reserve Bank(s) incorporating the policy's conditions.

The Board has modified the policy to address the conditions that apply to Fedwire third-party access arrangements involving a service provider that is located outside the United States. In particular, foreign service provider arrangements are expected to comply with the same requirements as domestic service provider arrangements as well as meet some additional conditions with regard to information and examination access. Such arrangements will also be subject to review and concurrence by the Directors of the Board's Division of Reserve Bank Operations and Payment Systems and Division of Banking Supervision and Regulation. Taken together, these requirements are intended to ensure that the Federal Reserve's oversight of Fedwire is not diminished or inappropriately limited by the conduct of Fedwire activity outside the United States and that supervisory objectives can be met.[3] The following discussion identifies those provisions of the Fedwire third-party access policy that have been revised and discusses how and why they differ from the current policy provisions.

A. Scope

Opening Paragraph (Unchanged)

The Board will allow third-party access arrangements whereby a sending or receiving institution ("the participant") designates another depository institution or other entity ("the service provider") to initiate, receive, and/or otherwise process Fedwire funds transfers or book-entry securities transfers that are posted to the participant's reserve or clearing account held at the Federal Reserve, provided the following conditions are met:

Revised Footnote #1 to the Opening Paragraph

This policy also applies to third-party access arrangements in which an organization, including an office of the participant, located outside the United States acts as service provider by initiating, receiving, or otherwise processing Fedwire transfers on behalf of the U.S. participant ("foreign service provider").

Previous Footnote #1 to the Opening Paragraph

This policy applies to third-party access arrangements in which an office of the participant located outside the United States acts as service provider by initiating, receiving, or otherwise processing Fedwire transfers on behalf of the U.S. participant.

The Board, in approving the August 1995 modifications to the policy, stated that no new third-party access

[1] Depository institutions use service providers to perform a number of functions, including customer accounting, check and automated clearing house (ACH) processing, and the processing and/or transmission of large-value funds and securities transfers. Depository institutions have increasingly viewed outsourcing arrangements as one way to reduce operating costs.

[2] The Reserve Banks have not approved any foreign service provider arrangements, although several inquiries have been received during the last few years. In its August 1995 action, the Board required that any existing arrangement involving a foreign office of a Fedwire participant acting as a service provider be reported promptly to the participant's Reserve Bank. No such arrangements have been reported.

[3] The four primary examination objectives with regard to Fedwire are to 1) minimize systemic risk from payment activities, 2) identify weaknesses in payments operations that could jeopardize the condition of the depository institution, 3) ensure that proper records are available to assist law enforcement authorities pursuing illegal payments activities, and 4) minimize risk of loss to the Federal Reserve from a depository institution's payment activities that may result if a depository institution were to fail while in an overdraft position at the Federal Reserve.

arrangements involving a foreign service provider would be approved until an assessment of the supervisory issues associated with such arrangements was completed. As a result of that assessment, the revised policy applies to all arrangements where the service provider is located outside the United States. In applying the policy to arrangements involving foreign service providers, however, the Board recognizes that such arrangements should be subject to consultation and coordination with home country supervisors, on-site examination of foreign service providers, and the availability of and access to Fedwire records. To address these issues the Board expects that such arrangements will comply with the policy conditions applicable to domestic service provider arrangements and, in addition, meet the additional requirements applicable to arrangements involving a foreign service provider.

B. Audit Program

Revised Condition (#10)

The participant must have in place an adequate audit program to review the arrangement at least annually to confirm that these requirements are being met. In addition, in the case of an arrangement involving a foreign service provider, both the participant and the foreign service provider must have in place an adequate audit program that addresses Fedwire operations. Audit reports in English must be made available to the Federal Reserve and the participant's primary supervisor(s) in the United States.

Previous Condition (#10)

The participant must have in place an adequate audit program to review the arrangement at least annually to confirm that these requirements are being met.

The revised condition requires that the Fedwire audit program of both the participant and the foreign service provider be an acceptable means to review and assess effectively, at least on an annual basis, the sufficiency of internal and data security controls, credit-granting processes, operational procedures and contingency arrangements, and compliance with applicable U.S. laws and regulations. This requirement is intended to maintain U.S. examiners' abilities to supervise effectively the Fedwire function and to ensure that it is managed in a safe and sound manner.

C. Examination of the Arrangement

Revised Condition (#11)

In the case of a service provider located within the United States, the service provider must be subject to examination by the appropriate federal depository institution regulatory agency(ies). [*Footnote: The U.S. federal depository institution regulatory agency(ies) must be able to examine any aspects of the service provider as may be necessary to assess the adequacy of the operations and financial condition of the service provider.*]

In the case of a service provider located outside the United States, the service provider must be subject to the supervision of a home country bank supervisor. In its review of a proposed foreign service provider arrangement, the Federal Reserve will consider the extent to which the service provider's home country supervisor 1) oversees banks on a consolidated basis, 2) is familiar with supervising payment systems activities, 3) is willing to examine the Fedwire operations at the service provider, and 4) has demonstrated a willingness to work closely with U.S. banking authorities in addressing supervisory problems. In addition, the home country supervisor, the participant, and the service provider must agree to permit the participant's primary supervisor(s) to conduct on-site reviews of the Fedwire operations at the foreign service provider. [*Footnote: If a participant proposes to conduct its Fedwire processing at a foreign site outside the home country of the service provider, both the home country and host country supervisors would need to permit the participant's primary supervisor(s) to review the Fedwire operations.*] The participant and the service provider must agree to make all policies, procedures, and other documentation relating to Fedwire operations, including those related to internal controls and data security requirements, available to the Federal Reserve and the participant's primary supervisor(s) in English.

Previous Condition (#11)

The service provider must be subject to examination by the appropriate federal depository institution regulatory agency(ies). [*Footnote: The U.S. federal depository institution regulatory agency(ies) must be able to examine any aspects of the service provider as may be necessary to assess the adequacy of the operations and financial condition of the service provider.*]

The revised condition provides the opportunity for the Federal Reserve and the participant's primary supervisor(s) to 1) assess the risks associated with the third-party access arrangement in the context of the service provider's home country's bank supervision program, 2) determine if it would be reasonable for the participant's primary supervisor(s) to depend, to some extent, on the home country supervisor to examine the Fedwire operation at the service provider, and 3) ensure that the participant's primary supervisor(s) has access to relevant Fedwire records. These conditions are intended to maintain U.S. examiners' ability to supervise effectively the Fedwire function and to ensure that it is managed in a safe and sound manner.

In reviewing the arrangement in the context of the foreign service provider's home country supervision program, the Federal Reserve would carefully consider each of the four criteria contained in this portion of the modified policy. The Federal Reserve, however, will not grant approval to outsource Fedwire absent an affirmative implementing agreement with the home country supervisor.

The Federal Reserve may also discuss other supervisory issues, such as home country laws and regulations that may limit examination access, with the particular home country supervisor prior to approving an arrangement involving a foreign service provider. With regard to proposals to outsource Fedwire processing to an unaffiliated foreign service provider, and in particular to an organization that is not a depository institution, the Federal Reserve would discuss with the home country supervisor issues related to the level of supervision and examination of the proposed service provider and other issues that could affect the risks associated with such an arrangement.

D. Review and Approval of Proposed Arrangements

Revised Condition (Closing Paragraph)

The participant's Federal Reserve Bank is responsible for approving each proposed Fedwire third-party access arrangement. The Directors of the Board's Division of Reserve Bank Operations and Payment Systems and Division of Banking Supervision and Regulation must concur with a proposed arrangement (1) in which the participant is not affiliated through at least 80 percent common ownership with the service provider and where the participant is owned by one of the 50 largest bank holding companies (based on consolidated assets), or (2) in which the service provider is located outside the United States. Approval of a foreign service provider arrangement would be contingent on a review of both the participant's and the foreign service provider's Fedwire policies, procedures, and operations, which would be conducted by the Federal Reserve prior to the commencement of operations.

Previous Condition (Closing Paragraph)

The Federal Reserve Bank is responsible for approving each proposed Fedwire third-party access arrangement. In a proposed arrangement in which the participant is not affiliated through at least 80 percent common ownership with the service provider and where the participant is owned by one of the 50 largest bank holding companies (based on consolidated assets), the Directors of the Division of Reserve Bank Operations and Payment Systems and the Division of Banking Supervision and Regulation must concur with the arrangement.

The revised condition recognizes the potential risks associated with

outsourcing Fedwire operations to a foreign service provider and the need for Board staff review and concurrence with such arrangements. Arrangements involving a foreign service provider warrant careful consideration in order to determine whether the proposed arrangement poses any undue risks and whether adequate supervisory oversight can be maintained. An infrastructure review is appropriate to confirm compliance with the Fedwire third-party access policy and other relevant policies and regulations. The infrastructure review also would permit the Federal Reserve to assess the adequacy of system integrity, controls and contingency arrangements, and would allow it to determine first hand whether information access issues pose unacceptable risks.

III. Effective Date

The revised Fedwire third-party access policy becomes effective February 1, 1996.

IV. Competitive Impact Analysis

The Board assesses the competitive impact of changes that may have a substantial effect on payment system participants. In particular, the Board assesses whether a proposed change would have a direct and material adverse effect on the ability of other service providers to compete effectively with the Federal Reserve Banks in providing similar services and whether such effects are due to legal differences or due to a dominant market position deriving from such legal differences.

The Federal Reserve Banks' Fedwire funds transfer and book-entry securities transfer services provide real-time gross settlement in central bank money. While these services cannot be duplicated by private-sector service providers, banks can make large-dollar funds transfers through other systems, such as CHIPS, or through correspondent book transfers, although these transactions have attributes that differ from Fedwire transfers. Similarly, there are private-sector securities clearing and/or settlement systems, such as the Government Securities Clearing Corporation and the Participants Trust Company, that facilitate primary and secondary market trades of U.S. Treasury and agency securities. Other transactions involving U.S. government securities may be cleared and settled on the books of banks to the extent that the counterparties are customers of the same bank.

The Board's third-party access policy places conditions on arrangements in which a Fedwire participant may contract with another organization to initiate, receive, or otherwise process Fedwire transfers. The Board has revised the policy to establish additional conditions applicable to depository institutions wishing to access Fedwire through a foreign service provider to ensure that the Federal Reserve's oversight of Fedwire is not diminished or inappropriately limited by the conduct of activity outside the United States and that the Federal Reserve's supervisory and examination objectives are met. Other large-dollar systems can and do place restrictions on the ability of participants to outsource their operations to foreign service providers. The Board's policy, as revised, does not adversely affect the ability of depository institutions or service providers to compete with the Federal Reserve Banks to provide funds transfer or securities transfer services.

V. Policy Statement

The Board has amended its "Federal Reserve System Policy Statement on Payments System Risk" under the heading "I. Federal Reserve Policy" by replacing "G. Fedwire Third-party Access Policy" with the following:

G. Fedwire Third-Party Access Policy

The Board will allow third-party access arrangements whereby a sending or receiving institution ("the participant") designates another depository institution or other entity ("the service provider") to initiate, receive, and/or otherwise process Fedwire funds transfers or book-entry securities transfers that are posted to the participant's reserve or clearing account held at the Federal Reserve, provided the following conditions are met: [1]

1. The participant retains operational control of the credit-granting process by (1) individually authorizing each funds or securities transfer, or (2) establishing individual customer transfer limits and a transfer limit for the participant's own activity, within which the service provider can act. The transfer limit could be a combination of the account balance and established credit limits. For the purposes of this policy, these arrangements are called "line-of-credit arrangements."

2. In funds transfer line-of-credit arrangements, the service provider must have procedures in place and the operational ability to ensure that a funds transfer that would exceed the established transfer limit is not permitted without first obtaining the participant's approval. In book-entry securities transfer line-of-credit arrangements, the service provider must have procedures in place and the operational ability to provide the participant with timely notification of an incoming transfer that exceeds the applicable limit and must act upon the participant's instructions to accept or reverse the transfer accordingly.

3. Transfers will be posted to the participant's reserve or clearing account held at the Federal Reserve, and the participant will remain responsible for managing its Federal Reserve account, with respect to both its intraday and overnight positions. The participant must be able to monitor transfer activity conducted on its behalf.

4. The participant's board of directors must approve the role and responsibilities of a service provider(s) that is not affiliated with the participant through at least 80 percent common ownership. In line-of-credit arrangements, the participant's board of directors must approve the intraday overdraft limit for the activity to be processed by the service provider and the credit limits for any inter-affiliate funds transfers.[2]

5. The Board expects all participants to ensure that their Fedwire operations could be resumed in a reasonable period of time in the event of an operating outage, consistent with the requirement to maintain adequate contingency backup capabilities as set forth in the interagency policy (FFIEC SP–5, July 1989). A participant is not relieved of such responsibility because it contracts with a service provider.

6. In cases where the service provider is not affiliated with the participant through at least 80 percent common ownership, the participant must be able to continue Fedwire operations if the participant is unable to continue its service provider arrangement (e.g., in the event the Reserve Bank or the participant's primary supervisor terminates the service provider arrangement).

7. The participant must certify that the arrangement is consistent with corporate separateness and does not violate branching restrictions.

[1] This policy also applies to third-party access arrangements in which an organization, including an office of the participant, located outside the United States acts as service provider by initiating, receiving, or otherwise processing Fedwire transfers on behalf of the U.S. participant ("foreign service provider").

[2] In cases where a U.S. branch of a foreign bank wishes to be a participant in an arrangement subject to this policy, and its board of directors has a more limited role in the bank's management than a U.S. board, the role and responsibilities of the service provider should be reviewed by senior management at the foreign bank's head office that exercises authority over the foreign bank equivalent to the authority exercised by a board of directors over a U.S. depository institution.

8. The participant must certify that the specifics of the arrangement will allow the participant to comply with all applicable state and federal laws and regulations governing the participant, including, for example, retaining and making accessible records in accordance with the regulations adopted under the Bank Secrecy Act.

9. The participant's primary supervisor(s) must affirmatively state in writing that it does not object to the arrangement.

10. The participant must have in place an adequate audit program to review the arrangement at least annually to confirm that these requirements are being met. In addition, in the case of an arrangement involving a foreign service provider, both the participant and the foreign service provider must have in place an adequate audit program that addresses Fedwire operations. Audit reports in English must be made available to the Federal Reserve and the participant's primary supervisor(s) in the United States.

11. In the case of a service provider located within the United States, the service provider must be subject to examination by the appropriate federal depository institution regulatory agency(ies).[3]

In the case of a service provider located outside the United States, the service provider must be subject to the supervision of a home country bank supervisor. In its review of a proposed foreign service provider arrangement, the Federal Reserve will consider the extent to which the service provider's home country supervisor (1) oversees banks on a consolidated basis, (2) is familiar with supervising payment systems activities, (3) is willing to examine the Fedwire operations at the service provider, and (4) has demonstrated a willingness to work closely with U.S. banking authorities in addressing supervisory problems. In addition, the home country supervisor, the participant, and the service provider must agree to permit the participant's primary supervisor(s) to conduct on-site reviews of the Fedwire operations at the foreign service provider.[4] The participant and the service provider must agree to make all policies, procedures, and other documentation relating to Fedwire operations, including those related to internal controls and data security requirements, available to the Federal Reserve and the participant's primary supervisor(s) in English.

12. The participant and the service provider(s) must execute an agreement with the relevant Reserve Bank(s) incorporating these conditions.

The participant's Federal Reserve Bank is responsible for approving each proposed Fedwire third-party access arrangement. The Directors of the Board's Division of Reserve Bank Operations and Payment Systems and Division of Banking Supervision and Regulation must concur with a proposed arrangement (1) in which the participant is not affiliated through at least 80 percent common ownership with the service provider and where the participant is owned by one of the 50 largest bank holding companies (based on consolidated assets), or (2) in which the service provider is located outside the United States. Approval of a foreign service provider arrangement would be conditioned on satisfactory findings of a review of both the participant's and the foreign service provider's Fedwire policies, procedures, and operations, which would be conducted by the Federal Reserve prior to the commencement of operations.

By order of the Board of Governors of the Federal Reserve System, January 24, 1996.

William W. Wiles,

Secretary of the Board.

[FR Doc. 96–1652 Filed 1–29–96; 8:45 am]

BILLING CODE 6210–01–P

[3] The U.S. federal depository institution regulatory agency(ies) must be able to examine any aspects of the service provider as may be necessary to assess the adequacy of the operations and financial condition of the service provider.

[4] If a participant proposes to conduct its Fedwire processing at a foreign site outside the home country of the service provider, both the home country and host country supervisors would need to permit the participant's primary supervisor(s) to review the Fedwire operations.

BancTenn Corp. et al.; Formations of; Acquisitions by; and Mergers of Bank Holding Companies

The companies listed in this notice have 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)).

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 to the Reserve Bank 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.

Unless otherwise noted, comments regarding each of these applications must be received not later than February 23, 1996.

A. Federal Reserve Bank of Atlanta (Zane R. Kelley, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:

1. BancTenn Corp., Kingsport, Tennessee; and Carter County Bancorp, Inc., Chattanooga, Tennessee; each to acquire a total of 12.495 percent of the voting shares of Cornerstone Community Bank (in organization), Chattanooga, Tennessee.

2. Community Financial Group, Inc., Nashville, Tennessee; to become a bank holding company by acquiring 80 percent of the voting shares of The Bank of Nashville, Nashville, Tennessee.

Board of Governors of the Federal Reserve System, January 24, 1996.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 96–1647 Filed 1–29–96; 8:45 am]

BILLING CODE 6210–01–F

First Bankshares of Las Animas, Inc.; Notice of Proposal to Engage de novo in Permissible Nonbanking Activities

The company listed in this notice has given notice 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.

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 on the question whether commencement of the activity 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 February 13, 1996.

A. Federal Reserve Bank of Kansas City (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. First Bankshares of Las Animan, Inc., Las Animan, Colorado; to engage *de novo* through its subsidiary, Sunshine Village Apartments of Las Animas, LTD, Las Animas, Colorado, in the construction of 24-unit senior and multi-family housing project, and thereby engage in community deveopment activities, pursuant to § 225.25(b)(6) of the Board's Regulation Y. The geographic scope for these activities is Las Animas, Colorado.

Board of Governors of the Federal Reserve System, January 24, 1996.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 96–1648 Filed 1–29–96; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Agency Forms Submitted to the Office of Management and Budget for Clearance

The Department of Health and Human Services, Office of the Secretary periodically publishes a list of information collections it has submitted to the Office of Management and Budget (OMB) for clearance in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) and 5 CFR 1320.5. The following are those information collections recently submitted to OMB.

1. Application for Correction of Public Health Service Commissioned Corps Records—0937–0095—Reinstatement No Change—An application is submitted by present and former PHS Commissioned Corps officers to request correction of an error or alleged injustice in their personnel records.

The information submitted is used by the Board for Correction to determine if an error or injustice has occurred and to rectify such error or injustice.

Respondents: Individuals; Annual Number of Respondents: 8;

Average Burden per Response: four hours; Frequency of response: single-time; Total Burden: 32 hours.

2. State Medicaid Fraud Control Units Annual Report and Certification Application (42 CFR 1007.15 and 1007.17)—0990–0162—Reinstatement No Change—The program data required of initial applicants to become certified, and the annual reports required for recertification are used by the Office of Inspector General to ensure that Federal matching funds are only expended for allowable costs. In addition, the reports are analyzed to monitor program activities and determine whether technical assistance is required.

Respondents: States; Burden Information for New Applicants—Number of Respondents: 2; Frequency of Response: one-time; Burden per Response: 112 hours; Burden for New Applicants: 224 hours—Burden Information for Recertification—Number of Respondents: 45; Frequency of Response: annually; Burden per Response: 56 hours; Burden for Recertification: 2520 hours—Total Burden: 2744 hours.

OMB Desk Officer: Allison Eydt.

Copies of the information collection packages listed above can be obtained by calling the OS Reports Clearance Officer on (202) 619–1053. Written comments and recommendations for the proposed information collection should be sent directly to the OMB desk officer designated above at the following address: Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW., Washington, D.C. 20503.

Dated: January 18, 1996.

Dennis P. Williams,

Deputy Assistant Secretary, Budget.

[FR Doc. 96–1633 Filed 1–29–96; 8:45 am]

BILLING CODE 4150–04–M

Notice of Interest Rate on Overdue Debts

Section 30.13 of the Department of Health and Human Services' claims collection regulations (45 CFR Part 30) provides that the Secretary shall charge an annual rate of interest as fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date that HHS becomes entitled to recovery. The rate generally cannot be lower than the Department of Treasury's current value of funds rate or the applicable rate determined from the "Schedule of Certified Interest Rates with Range of Maturities." This rate may be revised quarterly by the Secretary of the Treasury and shall be published quarterly by the Department of Health and Human Services in the **Federal Register.**

The Secretary of the Treasury has certified a rate of 13¾% for the quarter ended December 31, 1995. This interest rate will remain in effect until such time as the Secretary of the Treasury notifies HHS of any change.

Dated: January 22, 1996.

George Strader,

Deputy Assistant Secretary, Finance.

[FR Doc. 96–1632 Filed 1–29–96; 8:45 am]

BILLING CODE 4150–04–M

Food and Drug Administration

[Docket No. 95N–0155]

Bio-Components, Inc.; Opportunity for a Hearing on a Proposal to Revoke U.S. License No. 1160

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for a hearing on a proposal to revoke the establishment license (U.S. License No. 1160) and the product licenses issued to Bio-Components Inc. (BCI), for the manufacture of Source Plasma and Source Leukocytes. The proposed revocation is based on the firm's significant and continued noncompliance with Federal biologics regulations and standards included in the firm's license.

DATES: The firm may submit a written request for a hearing to the Dockets Management Branch by February 29, 1996, and any data and information justifying a hearing by April 1, 1996. Other interested persons may submit written comments on the proposed revocation by April 1, 1996

ADDRESSES: Submit written requests for a hearing, any data and information justifying a hearing, and any written comments on the proposed revocation to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Timothy W. 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 proposing to revoke the establishment license (U.S. License No. 1160) and the product licenses issued to Bio-Components, Inc., 440 North Beach St., Daytona Beach, FL 32114, for the manufacture of Source Plasma and Source Leukocytes. The proposed revocation is based on the failure of BCI, and its responsible management to conform to the Federal regulations applicable to the manufacture of biological products.

FDA conducted an inspection of BCI between January 21, 1993, and February 12, 1993. The inspection revealed deviations from the Federal regulations in 21 CFR parts 600 through 640 and from the applicable standards in the firm's license. FDA determined that these deviations constituted a danger to public health. The deviations were listed in a March 19, 1993, letter, from FDA to BCI which suspended the establishment license (U.S. License No. 1160) and the product licenses for the manufacture of Source Plasma and Source Leukocytes. The deviations included, but were not limited to, the failure to assure that: (1) Each donor's clinical post-immunization response to stimulation red blood cells was evaluated by a qualified physician (21 CFR 640.66); (2) serum protein electrophoresis (SPE) and a serologic test for syphilis were performed on each donor at least every 4 months (21 CFR 640.65(b)(1)(i)); (3) a qualified physician approved the plasmapheresis procedures of any donor whose SPE or rapid plasma reagin (RPR) test sample had not been collected at the required 4-month interval (21 CFR 640.65(b)(1)(ii)); (4) SPE results were reviewed by a qualified physician within 21 days after the sample was drawn to determine whether or not the donor may continue in the program (21 CFR 640.65(b)(2)(i)); (5) personnel had the capabilities commensurate with their assigned functions (21 CFR 600.10(b) and 640.66); and (6) adequate records were maintained to document unsuitable donors, and the performance of each significant step in the collection, processing, storage, and distribution of each unit of blood and blood components (21 CFR 606.160(a), 606.160(b), and 606.160(e)).

FDA received corrective action plans from BCI in letters dated March 26, 1993, and September 17, 1993. By letters dated May 19, 1993, August 26, 1993, and December 3, 1993, FDA, among other things, addressed BCI's proposed corrective action plans and provided the firm with explanations of why its proposals were inadequate.

In the December 3, 1993, letter, pursuant to 21 CFR 600.10, FDA informed BCI's responsible head that he had been deemed unsuitable for that position or any position of authority at the firm. Factors contributing to this decision included, but were not limited to: (1) The deviations cited in regard to the January through February 1993 inspection that resulted in license suspension; (2) failure to submit adequate corrective action plans; (3) failure to exercise control of the establishment in all matters relating to compliance; (4) failure to assure that personnel were adequately trained, properly supervised and had a thorough understanding of the procedures that they performed; and (5) a repeated history of license suspensions and revocations while responsible head of two other blood establishments.

In the May 13, 1994, letter, FDA made clear that the nature of the deficiencies at BCI, the firm's past history of noncompliance, the firm's failure to submit an adequate corrective action plan, and the unsuitability of the firm's responsible head demonstrated BCI's careless disregard for the applicable regulations and the applicable standards in its license. Due to this evidence of willfulness, based upon the evidence of careless disregard, and pursuant to 21 CFR 601.6, FDA was not required to provide BCI with further opportunity to correct its deficiencies and achieve compliance with the applicable standards.

In a letter dated May 13, 1994, FDA informed BCI of the agency's intent to revoke the firm's licenses and issue a notice of opportunity for a hearing pursuant to 21 CFR 601.5(b). BCI did not contact FDA within 10 days of receipt of the letter to voluntarily request revocation of its licenses. Pursuant to 21 CFR 12.21(b), FDA is now issuing a notice of opportunity for a hearing on a proposal to revoke U.S. License No. 1160 and the product licenses issued to BCI for the manufacture of Source Plasma and Source Leukocytes.

FDA has placed copies of letters supporting the proposed license revocation on file in the Dockets Management Branch under the docket number found in brackets in the heading of this notice. These documents include the following: FDA letters of March 19, 1993, May 19, 1993, August 26, 1993, December 3, 1993, May 13, 1994, and BCI letters of March 26, 1993, September 17, 1993, December 13, 1993, and February 16, 1994. These documents are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FDA procedures and requirements governing a notice of opportunity for a hearing, notice of appearance and request for a hearing, grant or denial of a hearing, and submission of data and information to justify a hearing on proposed revocation of licenses are contained in 21 CFR parts 12 and 601. A request for a hearing may not rely upon mere allegations or denials but is required to set forth a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses submitted in support of the request for a hearing that there is no genuine and substantial issue of fact for resolution at a hearing, the Commissioner of Food and Drugs will deny the hearing request, making findings and conclusions that justify the denial.

BCI may submit a written request for a hearing to the Dockets Management Branch by February 29, 1996, and any data or information justifying a hearing must be submitted by April 1, 1996. Other interested persons may submit comments on the proposed license revocation to the Dockets Management Branch by February 29, 1996. The failure of a licensee to file a timely written request for a hearing constitutes an election by the licensee not to avail itself of the opportunity for a hearing concerning the proposed license revocation.

Two copies of any submissions are to be provided to FDA, except that individuals may submit one copy. Submissions are to be identified with the docket number found in brackets in the heading of this document. Submissions, except for data and information prohibited from public disclosure under 21 CFR 10.20(j)(2)(i), 21 U.S.C. 331(j), or 18 U.S.C. 1905, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Public Health Service Act (sec. 351 (42 U.S.C. 262)) and the Federal Food, Drug, and Cosmetic Act (secs. 201, 501, 502, 505, 701 (21 U.S.C. 321, 351, 352, 355, 371)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director and Deputy Director, Center for Biologics Evaluation and Research (21 CFR 5.67).

Dated: January 19, 1996.

Michael G. Beatrice,

Deputy Director, Center for Biologics Evaluation and Research.

[FR Doc. 96–1656 Filed 1–29–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95N–0369]

Memorandum on the Recommendations for Donor Screening With a Licensed Test for HIV–1 Antigen; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a memorandum to all registered blood and plasma establishments, dated August 8, 1995. In the memorandum, the Center for Biologics Evaluation and Research (CBER) recommends the implementation of donor screening tests for human immunodeficiency virus, type 1 (HIV–1) antigen(s) using licensed tests that are approved for donor screening. FDA is recommending the implementation of HIV–1 antigen screening because of the benefit that it will provide to a small number of blood product recipients, as a partial preventive measure against the possibility of any increase in HIV–1 "window period" donations and to decrease the virus burden in plasma pools for fractionation. FDA expects HIV–1 antigen testing will reduce, but not eliminate, the residual risk of HIV–1 from transfusion and, therefore, regards such screening as only an interim measure pending the availability of more advanced test methodology.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the memorandum to the Congressional and Consumer Affairs Branch (HFM–12), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, or call FDA's automated information system at 800–835–4709. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the memorandum to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the memorandum and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Persons with access to INTERNET may request the memorandum be sent by return E-mail by sending a message to "HIVANTIGEN@A1.CBER.FDA.GOV". The memorandum may also be obtained through INTERNET via File Transfer Protocol (FTP). Requestors should connect to the Center for Drug Evaluation and Research (CDER) using the FTP. CBER documents are maintained in a subdirectory called CBER on the server, "CDVS2.CDER.FDA.GOV" (150.148.24.202). The "READ.ME" file in that subdirectory describes the available documents which may be available as an ASCII text file (*.TXT), or a WordPerfect 5.1 document (*.w51), or both. A sample dialogue for obtaining the "READ.ME" file with a text-based FTP program would be:

FTP CDVS2.CDER.FDA.GOV
LOGIN: ANONYMOUS
<ANY PASSWORD> <"Your E-mail address">
BINARY
CD CBER
GET READ.ME
EXIT

The memorandum may also be obtained by calling the CBER FAX Information System (FAX—ON—DEMAND) at 301–594–1939 from a touch tone telephone.

FOR FURTHER INFORMATION CONTACT: Paul A. Mied, Center for Biologics Evaluation and Research (HFM–310), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3008.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a memorandum to all registered blood and plasma establishments, dated August 8, 1995, recommending the implementation of donor screening for HIV–1 antigen with a licensed test approved for this use. As of August 8, 1995, there were no tests for HIV–1 antigen(s) approved for donor screening. However, FDA issued these recommendations in advance of the availability of such tests in order to provide blood and plasma establishments with maximum time to prepare for implementation of this testing. These recommendations supersede some of the rationale/recommendations provided in a previous FDA memorandum dated October 4, 1989, following licensure of the first test for HIV–1 antigen(s).

Based on the data available in 1989, FDA did not approve HIV–1 antigen testing for routine donor screening. Recently, however, the role of HIV–1 antigen testing in the donor setting has been reconsidered for several reasons. For instance, there have been four documented instances of HIV–1 transmission by HIV–1 antigen positive blood donations from three HIV–1 antibody negative donors. Also, based on recent estimates of the antibody negative infectious "window period," the residual risk of HIV transmission by screened blood, and the efficacy of antigen testing to detect seronegative, infectious donations, it has been estimated that donor screening by HIV–1 antigen can be expected to prevent up to 25 percent of the current "window period" cases or about 5 to 10 cases of transfusion associated HIV infection per year.

In September 1994, FDA sponsored a "Conference on the Feasibility of Genetic Technology to Close the HIV Window in Donor Screening." Although the majority of participating experts expressed the opinion that genetic techniques were not ready for use in mass screening, the meeting did spark renewed interest in considering other direct viral detection methods for donor screening, such as HIV–1 antigen testing as an interim measure to further reduce current low risk of

HIV–1 transmission through transfusions of blood and blood products. To further address direct viral detection methods, FDA brought the issue of donor screening for HIV–1 antigen to a public meeting of the Blood Products Advisory Committee (BPAC) in June 1995. After hearing the most recent available data on HIV–1 risk in the blood supply, the estimated efficacy of antigen screening, and other issues bearing on a risk/benefit assessment, 9 of the 15 BPAC members present were of the opinion that donor screening for HIV–1 antigen by candidate test kits is not likely to provide a significant public health benefit which outweighs the potential risks. After considering the available information and the opinions of the BPAC members, FDA recommended that blood establishments should implement donor screening for HIV–1 antigen using licensed tests that are approved for this indication. FDA recommended implementation of HIV–1 antigen screening because of the benefit that it will provide to a small number of blood product recipients, as a partial preventive measure against the possibility of any increase in HIV–1 "window period" donations and to decrease the virus burden in plasma pools for fractionation.

FDA recommended that the screening for HIV–1 antigen(s) be implemented within 3 months of the commercial availability of the first such test approved for donor screening for all donations of Whole Blood, blood components, Source Leukocytes and Source Plasma, and all such inventoried units available for release. FDA also recommended that consigned within-date units intended for transfusion and still in the consignee's inventory be either replaced with screened units or tested for HIV–1 antigen(s) as soon as feasible. The memorandum included additional recommendations and information on the following: (1) Disposition and labeling of units; (2) donor deferral; (3) Public Health Service recommendations for donor notification and counseling; (4) exclusion/retrieval of potentially contaminated units from prior collections and notification of consignees; and (5) notification of consignees of neutralization test results.

Because HIV–1 antigen testing will reduce, but not eliminate, the residual risk of HIV–1 from transfusion, FDA regards such screening as an interim measure pending the availability of better technology for this purpose. FDA encourages continued development of new methods to further reduce the risk of HIV transmissions in the "window period."

As with other memoranda, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The memorandum is intended to provide information and does not set forth new requirements. The procedures cited in the memorandum are recommendations. FDA anticipates that blood and plasma establishments may develop alternative procedures and discuss them with FDA. FDA may find those alternative procedures acceptable. FDA recognizes that the scientific technology for controlling the risk of transmission of HIV by blood and blood products may continue to advance and that this document may become outdated as those advances occur. The memorandum does not bind FDA and does not create or confer any rights, privileges, or benefits on or for any private person, but is intended merely for guidance.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the memorandum. 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. A copy of the memorandum and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Received comments will be considered in determining whether further revisions to the memorandum are warranted.

Dated: January 22, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–1657 Filed 1–29–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 93D–0398]

Microbiological Testing for Antimicrobial Food-Animal Drugs; Final Guidance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled "Microbiological Testing of Antimicrobial Drug Residues in Food." The availability of the draft guideline was announced on January 6, 1994; this final guidance document addresses the comments submitted on the draft guideline. The final guidance document, which was prepared by the Center for Veterinary Medicine (CVM), addresses human food safety issues that may be associated with food-animal antimicrobial drug products. This guidance document also provides points to consider when determining which antimicrobials may require supplemental testing and recommends test procedures for establishing that antimicrobial drug residues will not cause intestinal microflora perturbations in the consumer.

DATES: Written comments on the guidance document may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the final guidance document "Microbiological Testing of Antimicrobial Drug Residues in Food," to the Communications and Education Branch (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1755. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the guidance document and received comments may be seen at the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Haydee Fernandez, Center for Veterinary Medicine (HFV–154), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1684.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of the final guidance document entitled "Microbiological Testing of Antimicrobial Drug Residues in Food." In evaluating the safety of new animal drugs, the agency must determine, among other things, their cumulative effect in man or other animal as required by section 512(d)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(d)(2)(B)). The guidance document describes the testing that may be necessary to establish that antimicrobial drug residues in food will be safe and will not cause intestinal microflora perturbations in the consumer.

In the **Federal Register** of January 6, 1994 (59 FR 754), FDA issued a notice of availability of the draft guideline entitled "Microbiological Testing of

Antimicrobial Drug Residues in Food." The draft guideline was made available for public comment to provide the agency with views to be considered in the development of the guideline. Comments were requested specifically on: (1) Recommendations for additional microbiological testing for antimicrobial drug residues that seek a safe concentration higher than 1 part per million (ppm) of microbiologically active residues in the total diet; (2) how the proposed guideline should relate the effect of low doses of antibiotics observed in model systems to potential adverse biological effects in humans; and (3) appropriate endpoints for monitoring the effects of the different classes of antibiotics. Interested persons were given until April 6, 1994, to comment on the draft guideline.

The agency received comments from university faculty members and the animal drug industry. FDA has revised the draft guideline as a result of these comments. In addition, FDA is reviewing its approach to the development of guidance documents. In order to eliminate confusion caused by use of different nomenclature for guidance documents (e.g., "guidelines," "points to consider") and to make it clear that this document is not being issued under current § 10.90(b) (21 CFR 10.90(b)). FDA is issuing this document as "guidance," not as a "guideline."

I. General Comments on the Draft Guideline

1. There was general consensus among the comments that microbiologically inactive metabolites and rapidly absorbed antimicrobials would not produce any adverse effect on the intestinal microflora of humans.

CVM agrees that the compounds that are most likely to raise human food safety concerns are those that are microbiologically active. Microbiologically inactive metabolites and rapidly absorbed antimicrobials are not the focus of this guidance document.

2. Industry commented that the sponsor of a compound should identify the active residues and conduct the appropriate microbiological endpoints in consultation with the agency.

FDA agrees that, under the act, it is the sponsor's responsibility to identify the microbiological activity of its product and to monitor the appropriate microbiological endpoint(s) to establish the antimicrobial no observed effect level (NOEL). As with all studies with animal drugs, the sponsor is encouraged to discuss the protocol with CVM representatives prior to initiating the study.

II. Comments Regarding Model Systems

3. The agency received several comments on the use of model systems to evaluate the effect of active residues on the human intestinal microflora. The model systems proposed in the comments were mainly in vitro systems using continuous flow. According to the comments, continuous flow systems allow the study of the effect of "low levels" of antimicrobials on human intestinal microflora by studying the selection for antibiotic resistance, the change in colonization resistance, the determination of anaerobic population counts, and the detection of virulence enhancement.

The agency agrees that in vitro models may offer a valid test system for assessing the effect of "low levels" of antimicrobials on the human intestinal microflora.

4. A trade association stated that it would be very difficult for the sponsors to undertake de novo development and validation of test procedures. The comment suggested that before requiring testing, CVM should have some experience with the model systems that could be used to study the microbiological endpoints. This could be done by funding research studies to develop and, if possible, validate the test procedures.

CVM is not aware of any validated model system for the testing of all antimicrobial agents. CVM does intend to initiate research which will lead to the development of validated model systems for evaluating the effect of low levels of antimicrobials on the human intestinal microflora.

III. Comments Regarding the Proposed Upper Limit of 1 ppm Antimicrobial Activity

5. Most comments agreed with FDA that 1 ppm was a level of microbiologically active residues that would be unlikely to produce any adverse effect on the human intestinal microflora and would, therefore, be safe. Because there was some confusion about how 1 ppm in the total diet should be interpreted in practice, the guidance document states CVM's belief, based on available data, that for antimicrobial drug residues in edible tissues from food-producing animals the acceptable daily intake (ADI) should be 1.5 milligrams per person per day (mg/person/day). Sponsors may demonstrate through additional specific testing that an ADI for drug residues in excess of 1.5 mg/person/day is safe.

6. One comment expressed concern that 1 ppm might not be a "very low level" for all antibiotics, mainly for new and more active molecules (per unit of weight) than current antimicrobials.

CVM disagrees based on the majority of scientific opinion. CVM has concluded that 1 ppm (or 1.5 mg/person/day) is a conservative level for determining whether or not antibiotic residues will produce an adverse effect on the human intestinal microflora. However, as the guidance makes clear, CVM may request information on microbiological activity of any new animal drug.

7. One comment from industry agreed that studies should be conducted by sponsors to establish microbiological activity, but disagreed with CVM's proposed use of microbiological activity as a valid endpoint for establishing tolerances for antimicrobial drugs. The comment argued that the predictive value of microbiological activity in determining the no effect level for the health and safety of individuals and the public has not been established. Therefore, according to the comment, microbiological activity should not be used to set the safe concentration but should only help to evaluate a NOEL established by classic toxicology. Instead, the comment stated that "if there is a microbiological effect at a safe concentration higher than 1 ppm microbiologically active residue, then the regulated toxicological no adverse effect level for total residue will need to be adjusted downward accordingly, taking into account the percentage of microbiologically active residue in the total residue and the nature of the observed microbiological effect."

CVM disagrees. It is well documented that high levels of antibiotics produce deleterious effects on intestinal microflora (see "Symposium on Microbiological Significance of Drug Residues in Food," *Veterinary and Human Toxicology*, 35 (supplement 1), 1993). Therefore, CVM has concluded that microbiological activity is a valid endpoint for establishing the safe concentration for antimicrobial drugs. Thus, when scientifically appropriate, CVM will determine the no effect level and calculate the safe concentration based on the results of microbiological testing.

IV. Comments Regarding the Proposed Classification of Intestinal Microflora Changes

8. One comment suggested that FDA should classify the changes in the intestinal microflora as follows: (1) Changes in the number of microorganisms and composition of intestinal microflora; (2) changes in metabolic activity of the flora related to metabolism of exogenous and

endogenous compounds; and (3) changes in antimicrobial resistance patterns and resistant genetic elements within the microflora.

CVM generally agrees. CVM has identified the following areas for which microbiological residues represent a potential public health concern: (1) Changes in the metabolic activity of the intestinal microflora; (2) changes in antimicrobial resistance patterns of the intestinal microflora; (3) changes in the colonization resistance properties (barrier effect) of the microflora; and (4) changes in the number of microorganisms and composition of the intestinal microflora.

V. Conclusion

The Center specifically invites comments on how to relate the effect produced in the model systems to the identified public health concerns. In addition, information on the appropriate endpoints for monitoring the effects of the different classes of antibiotics is requested. The public has the opportunity to comment on this guidance document at any time. CVM will consider all comments for future modifications of this guidance document.

Guidelines are generally issued under §§ 10.85(a) (21 CFR 10.85(a)) and 10.90(b). The agency is now in the process of revising §§ 10.85(a) and 10.90(b). This guidance document does not bind the agency, and it does not create or confer any rights, privileges, or benefits for or on any person; however, it represents the agency's current thinking on microbiological testing of antimicrobial drug residues in food. A person may follow the guidance document or may choose to follow alternate procedures or practices. If a person chooses to use alternate procedures or practices, that person may wish to discuss the matter further with the agency to prevent an expenditure of money and effort on activities that may later be determined to be unacceptable to FDA.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the guidance 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. The guidance 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.

Received comments will be considered to determine if further revision of the guidance document is necessary.

Dated: January 22, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–1579 Filed 1–29–96; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Projects

1. Evaluation of the Community Integrated Service System (CISS) Program—New—Data will be collected by mail and in person to assess demonstration effectiveness for program management purposes. Mail surveys will be conducted with four managers in each of 40 CISS grant funded programs: (1) Project director, (2) supervisor of intake/outreach, (3) medical director or closest equivalent, and (4) supervisors of care coordination. The purposes are to describe the organizational structure, service networks, and expected decision-making patterns prior to the more focussed on-site inquiries. Data subsequently will be collected in person from managers, staff, and clients of the 40 CISS grant-funded programs: (1) Project director and director of grant-receiving institution, (2) managers of each service in the program, (3) staff providing health services, (4) staff providing care coordination and services other than health care, and (5) a sample of clients who agree to participate. Numbers (3) and (4) will respond to focus group protocols. The purposes of the in-person data collection are to assess the day-to-day interaction of the service units, decision strategies employed by managers, and the effect on access for targeted clients. The study will provide the only evaluation to date of the effectiveness of the CISS program. The information will also be used to identify models with promise for replication. Because this data collection is targeted to a limited number of respondents, automated collection techniques will not be used. Burden estimates are as follows:

Respondent type	Number of respondents	Responses per respondent	Average burden per response (hours)	Total burden hours
Project Director	40	1	2	80
Intake/Outreach Supervisor	40	1	1.5	60
Medical Director	40	1	1.5	60
Supervisor of Care Coord	40	1	1.5	60
Proj. Dir./Inst. Dir	80	1	2	160
Service Managers	200	1	2	400
Health Service Staff	400	1	2	800
Care Coord./Other Service Staff	400	1	2	800
CISS clients	200	1	.3	60

Total burden is estimated to be 2,480 hours.

Send comments to Patricia Royston, HRSA Reports Clearance Officer, Room 14–36, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: January 24, 1996.

J. Henry Montes,

Associate Administrator for Policy Coordination.

[FR Doc. 96–1585 Filed 1–29–96; 8:45 am]

BILLING CODE 4160–15–P

National Institutes of Health

Amended Notice of Meeting

Due to the partial shutdown of the Federal Government, notice is hereby given of a change in the following meeting, as previously advertised in the **Federal Register.**

National Institutes of Environmental Health Sciences

National Advisory Environmental Health Sciences Council was to have convened at 9:00 a.m., February 5, 1996, Building 101 Conference Room, South Campus, Research Triangle Park, North Carolina, as published in the **Federal Register** on January 22, 1996 (61 FR 1598). The meeting has been changed to convene at 8:30 a.m. The meeting will be open on February 5, from 8:30 a.m. to approximately 3:30 p.m., and will be closed on February 5 from 3:30 p.m. to recess and from 9 a.m. to adjournment on February 6, as previously advertised.

Dated: January 24, 1996.

Susan K. Feldman,

NIH Committee Management Officer.

[FR Doc. 96–1645 Filed 1–29–96; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Public and Indian Housing

[Docket No. FR–2880–N–07]

Notice of Proposed Information Collection for Public Comment

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments due: April 1, 1996.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Mildred M. Hamman, Reports Liaison Officer, Public and Indian Housing, Department of Housing and Urban Development, 451 - 7th Street SW., Room 4240, Washington, D.C. 20410–5000.

FOR FURTHER INFORMATION CONTACT: Mildred M. Hamman, (202)–708–0846, (This is not a toll-free number.) for copies of the proposed forms and other available documents.

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Community Development Block Grants for Indian Tribes and Alaskan Native Villages.

OMB Control Number: 2577–

Description of the need for the information and proposed use: The Community Development Block Grant Program for Indian tribes and Alaska native villages requires eligible applicants to submit information to HUD to select the best projects for funding during annual competitions. Additionally, the requirements are essential for HUD in monitoring grants to insure that grantees are making proper use of Federal dollars, and to show employment of any force account construction.

Agency form numbers, if applicable: HUD–4011, HUD–4121, HUD–4122, HUD–4123, HUD–4125, HUD–4126.

Members of affected public: State or Local Governments (Indian Tribes and Alaska Native Villages).

Estimation of the total number of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: 670 respondents, annually and on occasion, 31.3 average hours per response, 21,760 hours for a total reporting burden.

Status of the proposed information collection: New.

Authority: Section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: January 24, 1996.

Michael B. Janis,

General Deputy Assistant Secretary for Public and Indian Housing.

[FR Doc. 96–1675 Filed 1–29–96; 8:45 am]

BILLING CODE 4210–33–M

Office of the Secretary

[Docket No. FR–3481–O–04]

The Secretary of HUD's Regulation of the Federal National Mortgage Association (Fannie Mae) and the Federal Home Loan Mortgage Corporation (Freddie Mac), Final Rule; Announcement of OMB Approval Number

AGENCY: Office of the Secretary, HUD.

ACTION: Announcement of OMB approval number.

SUMMARY: On December 1, 1995 (60 FR 61846), the Department published in the **Federal Register**, a final rule that implemented the Secretary's regulatory authorities respecting the Federal National Mortgage Association ("Fannie Mae") and the Federal Home Loan Mortgage Corporation ("Freddie Mac") (collectively the "Government-Sponsored Enterprises" or "GSEs") under the Federal Housing Enterprises Financial Safety and Soundness Act of 1992 ("FHEFSSA"). FHEFSSA's purpose is to establish a new regulatory framework for the GSEs that reflects their unique status as shareholder-owned corporations that receive substantial public benefits. The document indicated that information collection requirements contained in the notice had been submitted to the Office of Management and Budget for emergency review and approval under section 3507 of the Paperwork

Reduction Act of 1995 (44 U.S.C. 3501–3520), and that when approved, the OMB control number would be announced by separate notice in the **Federal Register.**

The purpose of this document is to announce the OMB approval number for the December 1, 1995 final rule.

FOR FURTHER INFORMATION CONTACT: Janet Tasker, Director, Office of Government-Sponsored Enterprises, Room 6154, telephone (202) 708–2224; or, for questions on data or methodology, Harold Bunce, Director, Financial Institutions Regulation, Office of Policy Development and Research, Room 8204, telephone (202) 708–2770; or, for legal questions, Kenneth A. Markison, Assistant General Counsel for Government Sponsored Enterprises/RESPA, Office of the General Counsel, Room 9262, telephone (202) 708–3137. The address for all of these persons is: Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410. A telecommunications device for deaf persons (TDD) is available at (202) 708–9300. (The telephone numbers are not toll-free).

SUPPLEMENTARY INFORMATION: Accordingly, the control number approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) for The Secretary of HUD's Regulation of the Federal National Mortgage Association (Fannie Mae) and the Federal Home Loan Mortgage Corporation (Freddie Mac), Final Rule, published in the **Federal Register** on December 1, 1995 (60 FR 61846) is 2502–0514. This approval number expires on January 31, 1999. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection displays a valid control number.

Dated: January 24, 1996.

Camille E. Acevedo,

Assistant General Counsel for Regulations.

[FR Doc. 96–1674 Filed 1–29–96; 8:45 am]

BILLING CODE 4210–32–P

Office of the Assistant Secretary for Community Planning and Development

[Docket No. FR–3959–O–03]

Ounce of Prevention Grant Program; Notice of Funding Availability; Announcement of OMB Approval Number

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Announcement of OMB approval number.

SUMMARY: On October 16, 1995 (60 FR 53686), the Department published in the **Federal Register,** a Notice of Funding Availability (NOFA) that announced the availability of up to $1.2 million of FY 1995 funds for grant assistance under the Ounce of Prevention Council's (the Council) Ounce of Prevention Grant Program. The notice stated that the funds would be awarded competitively, through a selection process conducted by HUD, after consultation with the Council, for projects that are targeted to Federally-designated urban and rural Empowerment Zone and Enterprise Community areas (EZ/EC). The document indicated that information collection requirements contained in the notice had been submitted to the Office of Management and Budget for emergency review and approval under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), and that when approved, the OMB control number would be announced by separate notice in the **Federal Register.**

The purpose of this document is to announce the OMB approval number for the October 16, 1995 notice.

FOR FURTHER INFORMATION CONTACT: All questions should be directed to the Office of Economic Development, Department of Housing and Urban Development, Room 7136, Washington, DC 20410. Telephone: (202) 708–6355; TDD: 1–800–877–8339. (These are not toll free numbers.)

SUPPLEMENTARY INFORMATION: Accordingly, the control number approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) for the Ounce of Prevention Grant Program; Notice of Funding Availability, published in the **Federal Register** on October 16, 1995 (60 FR 53686), is 2506–0155. This approval number expires on December 31, 1998. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection displays a valid control number.

Dated: January 24, 1996.

Camille E. Acevedo,

Assistant General Counsel for Regulations.

[FR Doc. 96–1629 Filed 1–29–96; 8:45 am]

BILLING CODE 4210–29–P

Office of Assistant Secretary for Housing—Federal Housing Commissioner

[Docket No. FR–3995–N–01]

Notice of Impact of Rescissions Act on Section 202 Supportive Housing for the Elderly Program and Section 811 Supportive Housing for Persons With Disabilities Program

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice of Impact of Rescissions Act on the Section 202 Supportive Housing for the Elderly Program and Section 811 Supportive Housing for Persons with Disabilities Program.

SUMMARY: The Fiscal Year (FY) 1995 Rescissions Act rescinded, among other amounts appropriated for HUD in FY 1995, $1.115 billion from the assisted housing account. The Act authorized the Secretary to take several actions to realize the $1.115 billion savings, including waiving provisions of Section 202 of the Housing Act of 1959 and Section 811 of the National Affordable Housing Act, including the provisions governing the terms and conditions of project rental assistance. This notice advises the public of the impact of these rescissions on the Supportive Housing for the Elderly and the Supportive Housing for Persons with Disabilities Programs, including those projects selected in response to the FY 1995 Notices of Fund Availability for these programs.

EFFECTIVE DATE: January 30, 1996.

FOR FURTHER INFORMATION CONTACT: Aretha M. Williams, Office of Elderly and Assisted Housing, Department of Housing and Urban Development, 451 Seventh Street S.W., Room 6120, Washington, DC 20410, telephone (202) 708–2866; (TDD) (202) 708–4594. (These are not toll-free numbers.)

SUPPLEMENTARY INFORMATION: The Emergency Supplemental Appropriations for Additional Disaster Assistance, for Anti-Terrorism Initiatives, for Assistance in the Recovery from the Tragedy that Occurred at Oklahoma City, and Rescissions Act, 1995 (Pub. L. 104–19; approved July 27, 1995) (the FY 1995

Rescissions Act) provides in relevant part that:

"[I]n allocating this $1,115,000,000 rescission, the Secretary may reduce the appropriations needs of the Department by (1) waiving any provision of section 202 of the Housing Act of 1959 and section 811 of the National Affordable Housing Act (including the provisions governing the terms and conditions of project rental assistance) that the Secretary determines is not necessary to achieve the objectives of these programs, or that otherwise impedes the ability to develop, operate or administer projects assisted under these programs, and may make provision for alternative conditions or terms where appropriate * * * ."

The Department has identified the following provisions that affected the procedures for calculating the amount of project rental assistance contract (PRAC) funds reserved for Section 202 and 811 projects funded in FY 1993, 1994, and 1995, as well as to reduce the term for reserving PRAC funds and to waive certain statutory and regulatory provisions for Section 202 and 811 projects funded in FY 1995.

I. Projects Funded in Fiscal Years 1993 and 1994

A Memorandum from Assistant Secretary for Housing—Federal Housing Commissioner Retsinas dated August 28, 1995 notified State and Area Offices that all Section 202 and Section 811 projects funded in FY 1993 and 1994 that had not yet reached initial closing must include an Addendum to the Agreement to Enter into the Project Rental Assistance Contract (Forms HUD–90172–A–CA and HUD–90172–B–CA) at the time of initial closing. The Addendum, which had to be signed by both HUD and the Owner, alerted the Owner of HUD's right to reduce the PRAC reserved for the project at a later time.

By instructions to the HUD offices, the PRAC funds reserved for projects funded in FY 1993 and 1994, which either had not gone to initial closing or had the Addendum described above as an attachment to their Agreement to Enter into the PRAC, were reduced by an amount equivalent to the anticipated tenant contributions. Based on a review of the average tenant contributions to rent and the average project operating expenses, tenants on the average contribute at least 25 percent of the projects' operating expenses. Therefore, the PRAC funds were calculated at 75 percent of the estimated project's total operating expenses, thereby reducing the PRAC reserved funds by 25 percent.

II. Projects Funded in Fiscal Year 1995

A. For projects funded in FY 1995, PRAC funds were reserved at 75 percent of the estimated project's total operating expenses to take into consideration estimated tenant contributions.

B. In addition to the above, based on the authorization in the FY 1995 Rescissions Act, the Secretary is hereby waiving the following statutory and regulatory provisions:

1. Reducing the Term of the PRAC From 20 to 5 Years

Consequently, for all projects selected in FY 1995, project rental assistance funds were only reserved initially for five years. The Department anticipates that at the end of the five-year period, renewals will be approved depending upon the availability of funds.

2. Extending Income Eligibility for Admission to Lower Income Households

Currently, eligible residents' income cannot exceed 50 percent of the median. A waiver of this provision extends the eligibility of elderly persons and persons with disabilities to persons with incomes up to 80 percent of median. These individuals, whether their incomes are up to 50 percent or 80 percent of median, must be admitted to occupancy on a first-come, first-served basis in accordance with fair housing requirements.

3. Waiving the Federal Preferences for Admission

Waiving this provision permits project owners to admit to occupancy eligible residents without regard to Federal preferences. However, local preferences will still be allowed in accordance with HUD regulations. Project owners must still ensure that applicants for housing are selected for occupancy in a fair and equitable manner.

Dated: January 19, 1996.

Stephanie A. Smith,

Acting General Deputy Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 96–1630 Filed 1–29–96; 8:45 am]

BILLING CODE 4210–27–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Notice of Intent To Prepare an Environmental Impact Statement for the Revision of the Forest Management Plan for Trust Forest Lands Within the Flathead Indian Reservation, Montana

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of intent and public scoping meetings.

SUMMARY: This notice advises the public that the Bureau of Indian Affairs (BIA), Flathead Agency, intends to gather information necessary for preparing an Environmental Impact Statement (EIS) for the revision of the Forest Management Plan (Plan) for the trust forest lands of the Flathead Indian Reservation, Montana. A description of the proposed action and possible alternatives to be addressed in the EIS follows as supplemental information.

This notice is published in accordance with the National Environmental Policy Act (NEPA) regulations found in 40 CFR 1501.7. The purpose of this notice is to solicit suggestions and information from other agencies and the public on the scope of the issues to be addressed in the EIS. The BIA encourages all who wish to do so to comment and participate in this scoping process.

DATES: The public comment period closes on March 29, 1996. Public Scoping Meetings will be held on February 20, 1996, at the Arlee Elementary School Lunchroom, Arlee MT; on February 21, 1996, at the Salish Longhouse, St. Ignatius MT; on February 22, 1996, at the Elmo Bingo Hall, Elmo MT; and on February 23, 1996, at the Senior Citizen's Center, Hot Springs, MT. All meetings will begin at 6 p.m. and end at 8 p.m. A Public Meeting will also be held on February 26, 1996, at the BIA East Conference Room, Tribal Complex, Pablo, MT, beginning at 1 p.m. and ending at 3 p.m.

ADDRESSES: Comments may be addressed to Mr. Ernest "Bud" Moran, Superintendent, Flathead Agency, Pablo, MT 59855.

SUPPLEMENTARY INFORMATION: The Confederated Salish and Kootenai Tribes' (Tribes) interdisciplinary team has developed and drafted a proposed action that complies with the Tribes' Purpose and Need Statement for the Plan. This Statement is as follows:

"The purpose of the Flathead Indian Reservation Forest Management Plan is to provide long-term direction for Indian forest resources. The plan describes resource management practices and levels of resource production. It establishes management standards, allocates land, and prescribes management practices to achieve balanced forest ecosystems. The Plan is needed to: (1) satisfy Tribal goals and objectives; (2) ensure that management activities are compatible with sustainable forest ecosystems; (3) balance Tribal cultural, social, economic and environmental values; and (4) establish an adaptive management and monitoring process that incorporates Tribal member values."

There are approximately 451,391 acres of forest trust land on the Flathead

Indian Reservation. The proposed action describes the forest in terms of seral stages and structure. It measures existing conditions against the natural or pre-European contact condition and proposes a Desired Condition that more closely resembles the pre-European contact condition. It also prescribes management activities to manipulate vegetation toward the Desired Condition, and identifies management standards and constraints for cultural protection, for other natural resources, and for social and economic concerns.

The EIS will evaluate alternatives that address the purpose and need for action. These may include: (1) No action, which would continue current operating policies, including those in the 1982–1992 Flathead Forest Management Plan; (2) management activities and strategies to develop, restore or promote sustainable ecosystems while treating forest outputs as by-products of a healthy forest; and (3) other reasonable alternatives identified via public input.

Dated: December 19, 1995.

Ada E. Deer,

Assistant Secretary—Indian Affairs.

[FR Doc. 96–1390 Filed 1–29–96; 8:45 am]

BILLING CODE 4310–02–P

Bureau of Land Management

[NV–060–7122–00–8661; N64–93–001P]

Notice of Availability of the Final Environmental Impact Statement for the Cortez Pipeline Gold Deposit Plan of Operation

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Availability of the Final Environmental Impact Statement for the Cortez Pipeline Gold Deposit Plan of Operation for mining in Lander County, Nevada.

SUMMARY: Pursuant to section 102(2)(c) of the National Environmental Policy Act (NEPA) of 1969 as amended, and to 43 Code of Federal Regulations Part 3809, the Bureau of Land Management (BLM), Battle Mountain District has made available the Final Environmental Impact Statement (Final EIS) for the proposed development of an open pit mine and associated facilities, in Lander County, Nevada.

DATES: The Environmental Protection Agency (EPA) will publish its **Federal Register** Notice of Availability on February 2, 1996. That publication begins the official 30 day period required by the Council on Environmental Quality for Final EISs.

ADDRESSES: Bureau of Land Management, Battle Mountain District Manager, 50 Bastian Rd., P.O. Box 1420, Battle Mountain, NV 89820 ATTN: Dave Davis. Copies of the Final EIS may be made in writing to the preceding address or by calling Dave Davis at (702) 635–4000.

FOR FURTHER INFORMATION CONTACT: Dave Davis, Pipeline Project Manager, at (702) 635–4000.

SUPPLEMENTARY INFORMATION: Cortez Gold Mines filed a Plan of Operations in October, 1992 for the development of the Pipeline Gold deposit open pit mine. The Pipeline proposal calls for the development of an 1827 acre open pit gold mine operation located in the southern end of Crescent Valley, Lander County, Nevada. In addition to the 235 acre open pit, there will be a dewatering program required to keep the pit dry during mining operations. This dewatering program will pump an estimated 30,000 gallons per minute (gpm). Approximately 28,000 gpm of the total 30,000 gpm will be returned to the Crescent Valley aquifer through a series of infiltration ponds. Associated facilities include a new 5,000 ton per day mill, constructing a new combined heap leach/tailings facility, waste dumps and associated support facilities, offices, etc.

The Draft and Final EISs evaluate the impacts of the Pipeline proposal on a number of resources. The focus of both documents include the impacts to ground and surface water resources, pit lake chemistry, social and economic impacts to the region, air quality, cultural resources and Native American religious concerns.

The Final EIS incorporates changes to the findings in the Draft EIS that resulted from the public comment process on the Draft EIS. These changes include an expanded regional ground water modelling study. The regional study supports and expands upon the subregional ground water modelling effort prepared for the Draft EIS. Water quality modelling was expanded for the Final EIS. These expanded water quality modelling results indicate some metal species and other constituents may exceed current Nevada Drinking water standards in the long term (250 years after cessation of mining operations). Precise estimates for such long term predictions are impossible to predict with current technology. In order to better understand the potential future impacts, the BLM also had an ecological risk assessment for the pit lake prepared. This risk assessment identifies some potential to affect avian wildlife in the long term. Mitigation is proposed for those potential avian impacts. Cortez has committed to an irrevocable, long term monetary contingency fund. This funding will be used by the BLM for monitoring all aspects of the project after cessation of mining operations; although the primary focus of the funding will be used to monitor the pit lake water quality. The contingency fund will also be used to mitigate any future long term impacts resulting from pit lake water quality.

Dated: January 22, 1996.

Gerald M. Smith,

District Manager.

[FR Doc. 96–1627 Filed 1–29–96; 8:45 am]

BILLING CODE 4310–HC–M

[NV–050–1020–001]

Mojave-Southern Great Basin Resource Advisory Council; Amendment of Meeting Locations and Times

AGENCY: Bureau of Land Management, Interior.

ACTION: Amendment to meeting location and times.

SUMMARY: In accordance with the Federal Land Policy and Management Act and the Federal Advisory Committee Act of 1972 (FACA), 5 U.S.C., the Department of the Interior, Bureau of Land Management (BLM), council meeting of the Mojave-Southern Great Basin Resource Advisory Council will be held as indicated below. The agenda includes a discussion of laws and regulations that pertain to grazing, and a statewide update of standards and guidelines.

All meetings are open to the public. The public may present written comments to the council. Each formal council meeting will have a time allocated for hearing public comments. The public comment period for the council meeting is listed below. Depending on the number of persons wishing to comment, and time available, the time for individual oral comments may be limited. Individuals who plan to attend and need further information about the meetings, or need special assistance such as sign language interpretation or other reasonable accommodations, should contact Michael Dwyer at the Las Vegas District Office, 4765 Vegas Dr., Las Vegas, NV 89108, telephone, (702) 647–5000.

DATES, TIMES: Dates are February 14 and 15, 1996. The council will meet at the BLM Las Vegas District Office located at 4765 Vegas Drive, Las Vegas, Nevada, at 7:30 a.m. on February 14, 1996, and will depart for a field trip at 8 a.m.

Individuals who want to attend the field trip must provide their own transportation and lunch. A schedule for the field trip will be available prior to departure. The council will return to the District Office approximately 1 p.m. for a business meeting. From 3 p.m. to 5 p.m., the council members and BLM support staff will host an open house for public input on the development of Standards and Guidelines for range reform. On February 15, the council will meet from 8 a.m. to approximately 4 p.m. at the Las Vegas District Office.

SUPPLEMENTAL INFORMATION: The purpose of the council is to advise the Secretary of the Interior, through the BLM, on a variety of planning and management issues associated with the management of the public lands.

FOR FURTHER INFORMATION CONTACT:

Lorraine Buck, Public Affairs Specialist, Las Vegas District, telephone: (702) 647–5000.

Michael F. Dwyer,

District Manager.

[FR Doc. 96–1750 Filed 1–29–96; 8:45 am]

BILLING CODE 4310–HC–M

[UT–912–06–0777–52]

Notice of Meeting of the Utah Resource Advisory Council

AGENCY: Bureau of Land Management, Utah.

SUMMARY: The Utah Resource Advisory Council will meet on Friday, February 16, 1996 at the Airport Hilton Hotel, Lakeview Room, 5151 Wiley Post Way, Salt Lake City, Utah. The first half of the meeting will consist of a training session on rangeland ecology. The training will begin at 9 a.m. and conclude at 12 noon. The Council will reconvene at 1:00 p.m. to discuss various items including the development of standards and guidelines to promote rangeland health and other resource management issues affecting BLM programs within Utah and the West. A public comment period where members of the public may address the Council, is scheduled for 4:30 p.m. The meeting will conclude at approximately 5 p.m. All sessions of the Utah Resource Advisory Council meeting are open to the public.

FOR FURTHER INFORMATION CONTACT: Don Banks, Utah State Office, Bureau of Land Management, 324 S. State St., Suite 300, Salt Lake City, 84111; phone (801) 539–4021.

Dated: January 23, 1996.

G. William Lamb,

Utah BLM State Director.

[FR Doc. 96–1751 Filed 1–29–96; 8:45 am]

BILLING CODE 4310–DQ–M

Fish and Wildlife Service

Notice of Receipt of Applications for Permit

The following applicants have applied for a permit to conduct certain activities with endangered species. This notice is provided pursuant to Section 10(c) of the Endangered Species Act of 1973, *as amended* (16 U.S.C. 1531, *et seq.*):

PRT–810290

Applicant: International Wildlife Museum, Tucson, AZ.

The applicant requests a permit to import one taxidermied cheetah (*Acinonyx jubatus*) mount from the estate of a foreign individual to enhance the survival of the species. The cheetah was originally taken in 1992 as a personal sport-hunted trophy in Zimbabwe.

PRT–810330

Applicant: Mary Katherine Gonder, New York, NY.

The applicant requests a permit to import hair samples of chimpanzee (*Pan troglodytes*) collected from sleeping nests and museum specimens in Nigeria for enhancement of the species through scientific research.

PRT–785441

Applicant: Zoological Society of San Diego, San Diego, CA.

The applicant requests a permit to import an additional captive-born female Persian fallow deer (*Dama dama mesopotamica*) from the Opel Zoo, Kronberg, Germany, to enhance the propagation of survival of the species through captive-breeding.

Written data or comments should be submitted to the Director, U.S. Fish and Wildlife Service, Office of Management Authority, 4401 North Fairfax Drive, Room 420(c), Arlington, Virginia 22203 and must be received by the Director within 30 days of the date of this publication.

Documents and other information submitted with these applications are available for review, *subject to the requirements of the Privacy Act and Freedom of Information Act,* by any party who submits a written request for a copy of such documents to the following office within 30 days of the date of publication of this notice: U.S. Fish and Wildlife Service, Office of Management Authority, 4401 North Fairfax Drive, Room 420(c), Arlington, Virginia 22203. Phone: (703/358–2104); FAX: (703/358–2281).

The Fish and Wildlife Service regrets that due to circumstances beyond its control, the Office of Management Authority's permitting process and other work have been significantly impacted by the recent partial Federal furlough and inclement weather. While the Fish and Wildlife Service is attempting to deal with these circumstances, please be aware that there will be delays in permit processing, response to informational inquiries, returning of phone calls, and other office activities. Your understanding and patience are greatly appreciated during this time.

The furlough of December 18 to January 5, 1996, followed by severe weather conditions the week of January 8, created a significant backlog of unprocessed permit applications, while delaying our ability to complete applications already received. The Service's Office of Management Authority processes more than 5,000 permits annually, or approximately 450 per month. Prior to the furlough, streamlined procedures had cut the processing time in half for certain permits. Due to these events, the time required to process permit applications temporarily has increased significantly.

Six hundred applications were pending at the time of the furlough, slightly more than our monthly average. During the intervening three weeks of Federal closure, 205 new applications and 114 new written requests for information were received. Due to this backlog, applications received after December 16 may require an additional 30 days beyond the normal 60–90 days. Please note that applications are being processed in date order. We anticipate needing the extra time to work through the 600 applications pending before the furlough and complete subsequent applications. Since our goal is to reduce the number of backlogged applications as quickly as possible, this activity is the office's priority until the backlog is reduced and will preclude work on other office commitments.

These circumstances also resulted in an increased volume of phone calls. We are returning calls as quickly as possible. To help us help you, leave a detailed voice mail message if a biologist is unavailable to take your call directly. You may fax specific questions to (703) 358–2281. If requesting an application, include your name, phone and fax numbers, type of activity and species. If inquiring about the status of a permit, include the date you mailed

your application, purpose of the permit, and, if known, permit number and name of the permit biologist processing it.

The Fish and Wildlife Service is operating under a temporary spending authority. Should another Federal shutdown occur, our capability to carry out our responsibilities to the public to process applications expeditiously will be further delayed. Please be assured that we will continue to do everything we can to process applications as quickly and effectively as possible.

Dated: January 25, 1996.

Caroline Anderson,

Acting Chief, Branch of Permits, Office of Management Authority.

[FR Doc. 96–1732 Filed 1–29–96; 8:45 am]

BILLING CODE 4310–55–P

Notice of Availability of "Black-footed Ferret Survey Guidelines for Oil and Gas Activities in Wyoming for Compliance With the Endangered Species Act" for Review and Comment

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of document availability.

SUMMARY: The Fish and Wildlife Service (Service) announces the availability for public review of draft "Black-footed Ferret Survey Guidelines For Oil and Gas Activities In Wyoming For Compliance With The Endangered Species Act". The draft guidelines offer an alternative, only in Wyoming, to the existing survey guidelines found in "Black-footed Ferret Survey Guidelines For Compliance With The Endangered Species Act", which were developed by the Service in 1989. The Service solicits review and comment from the public on these draft guidelines.

DATES: Comments on the draft guidelines must be received on or before February 29, 1996, to ensure they receive consideration by the Service.

ADDRESSES: Persons wishing to review the draft guidelines may obtain a copy by contacting the Field Supervisor, Ecological Services, U.S. Fish and Wildlife Service, 4000 Morrie Avenue, Cheyenne, Wyoming 82001. Written comments and materials regarding the draft guidelines should be sent to the Field Supervisor at the Cheyenne address given above. Comments and materials received are available on request for public inspection, by appointment, during normal business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Chuck Davis (see **ADDRESSES** above), at telephone 307/772–2374.

SUPPLEMENTARY INFORMATION:

Background

The Fish and Wildlife Service (Service) proposes to implement the newly developed "Black-footed Ferret Survey Guidelines for Oil and Gas Activities in Wyoming for Compliance with the Endangered Species Act" (proposed guidelines) as an alternative to the existing ferret survey guidelines found in "Black-footed Ferret Survey Guidelines for Compliance with the Endangered Species Act" (1989 guidelines) which were developed by the Service in April 1989. The failure of ferret surveys to locate new populations, coupled with the minimal impacts arising from oil and gas activities, has prompted the Service to develop the proposed guidelines for use in Wyoming. This alternative to the existing survey recommendations as outlined in the 1989 guidelines is elective, not mandatory, and available only in Wyoming. It deviates from the 1989 guidelines by eliminating the black-ferret survey requirements in white-tailed prairie dog towns/colonies/complexes in Wyoming for all oil and gas exploration, development, and transmission activities except in certain areas, which are identified in Appendix A of the proposed guidelines. Wyoming was selected to be the prototype area for the proposed guidelines because of intensive oil and gas development, particularly in the southwestern part of the State. If a project proponent opts not to choose this alternative, the provisions of the 1989 guidelines will continue to apply.

The Service believes this alternative approach will increase the potential for black-footed ferret survival and recovery by improving the manner in which funds are used, particularly regarding fruitless ferret survey efforts in white-tailed prairie dog towns as well as repeated ferret surveys in black-tailed prairie dog towns. Furthermore, the Service believes this alternative to the 1989 guidelines will add to the flexibility and options for the recovery of this species. Instead of surveys, the project proponent contributes to ferret recovery through voluntary participation in the Ferret Recovery Enhancement Program (FREP), a strategy the Service believes offers a better black-footed ferret conservation approach than the current strategy. The money generated by FREP will fund ferret recovery efforts that have a higher potential for success than ferret surveys in areas of limited habitat value and low probability of impacts to ferrets from the oil and gas activities.

Participation in the FREP requires the project proponent to coordinate with the Cheyenne Field Office of the Service, provide documentation that the project and project site qualify (including identification of specific proposed oil and gas activities, description of anticipated disturbance, and a map of the white-tailed prairie dog town showing location of the disturbance), and agree to provide to the FREP Fund a one-time fee of $30/acre of prairie dog town disturbance. Disturbance will be defined to include all rights-of-way, well sites, and other areas of ground disturbance. Funds generated by the contributions into FREP will be used for actions that benefit the recovery of the black-footed ferret. Such actions might include, but would not be limited to: activities such as development of improved survey methodologies; identification, mapping, digitizing of maps; conducting ferret surveys of prairie dog complexes greater than 5,000 acres or areas where physical evidence has been found; and, identification of potential reintroduction sites.

Applicability of the proposed guidelines to black-tailed prairie dog towns will be addressed on a case-by-case basis by the Cheyenne Field Office of the Service. The determination will be based on the size of the town/colony/complex, quality of habitat, extent and results of previous black-footed ferret surveys in the vicinity, historical presence of ferrets, and the importance of the complex to the overall recovery and survival of the black-footed ferret.

Other values of maintaining the biological integrity of the prairie dog ecosystem are still important and should not be overlooked. The prairie dog, as a keystone species, plays an important role in maintaining specific habitat conditions or providing forage for many species, including several candidate and sensitive species such as the mountain plover, ferruginous hawk, and burrowing owl. Severe impacts to or loss of prairie dog colonies threaten all species associated with that community. This document addresses only requirements for surveys and for potential impacts to black-footed ferrets. Other listed and candidate species potentially impacted by proposed actions must be addressed separately to ensure compliance with applicable laws and regulations.

Public Comments Solicited

The Service solicits written comments on the draft guidelines described above. All comments received by the date specified in the **DATES** section above will be considered prior to approval of the guidelines.

Authority: The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: January 24, 1996.

Terry T. Terrell,

Deputy Regional Director, Denver, CO.

[FR Doc. 96–1666 Filed 1–29–96; 8:45 am]

BILLING CODE 4310–55–M

Geological Survey

Federal Geographic Data Committee (FGDC); Public Meeting of the FGDC Facilities Working Group

AGENCY: U.S. Geological Survey, Interior.

ACTION: Notice of meeting.

SUMMARY: This notice is to invite public participation in a meeting of the FGDC Facilities Working Group. The major topic for this meeting is the development of a Facility/Installation ID standard.

TIME AND PLACE: 14 February 1996, from 1:00 p.m. until 4:00 p.m. The meeting will be held at Headquarters U.S. Army Corps of Engineers, in Room 8222D of the Pulaski Building, 20 Massachusetts Avenue, NW, Washington, DC. The Pulaski building is located just a few blocks west of Union Station.

FOR FURTHER INFORMATION CONTACT: Jennifer Fox, FGDC Secretariat, U.S. Geological Survey, 590 National Center, 12201 Sunrise Valley Drive, Reston, Virginia 22092; telephone (703) 648–5514; facsimile (703) 648–5755; Internet "gdc@usgs.gov".

SUPPLEMENTARY INFORMATION: The FGDC is a committee of Federal Agencies engaged in geospatial activities. The FGDC Facilities Working Group specifically focuses on geospatial data issues related to facilities and facility management. A facility is an entity with location, deliberately established as a site for designated activities. A facility database might describe a factory, a military base, a college, a hospital, a power plant, a fishery, a national park, an office building, a space command center, or a prison. The database for a complex facility may describe multiple functions or missions, multiple buildings, or even a county, town, or city. The objectives of the Working Group are to: promote standards of accuracy and currentness in facilities data that are financed in whole or in part by Federal funds; exchange information on technological improvements for collecting facilities data; encourage the Federal and non-Federal communities to identify and adopt standards and specifications for facilities data; and promote the sharing of facilities data among Federal and non-Federal organizations.

Dated: January 19, 1996.

Richard E. Witmer,

Acting Chief, National Mapping Division.

[FR Doc. 96–1635 Filed 1–29–96; 8:45 am]

BILLING CODE 4310–31–M

Minerals Management Service

Outer Continental Shelf, Alaska Region, Proposed Cook Inlet Lease Sale 149

AGENCY: Minerals Management Service, Interior.

ACTION: Notice of Availability of the Final Environmental Impact Statement.

The Minerals Management Service (MMS) has prepared a final Environmental Impact Statement (EIS) relating to the proposed 1996 Outer Continental Shelf oil and gas lease sale of available unleased blocks in Cook Inlet. The proposed Cook Inlet Sale 149 will offer for lease approximately 2.0 million acres. Single copies of the EIS can be obtained from the Regional Director, Minerals Management Service, Alaska Region, 949 East 36th Avenue, Anchorage, Alaska 99503–4302, Attention: Public Information. Copies can be requested by telephone, (907) 271–6070.

Copies of the final EIS will also be available for inspection in the following public libraries:

A. Holmes Johnson Memorial Library, 319 Lower Mill Bay Road, Kodiak, AK 99615
Alaska Pacific University, Academic Support Center Library, 4101 University Drive, Room 310, Anchorage, AK 99508–4672
Alaska Resources Library, U.S. Department of the Interior, Anchorage, AK
Alaska State Library, Government Publications, PO Box 110571, Juneau, AK 99811
Anchor Point Public Library, PO Box 129, Anchor Point, AK 99556
ARCO Alaska, Inc. Library, PO Box 100360, Anchorage, AK 99510–0360
Arctic Environmental Information and Data Center, University of Alaska, 707 A Street, Anchorage, AK
BP Exploration, Information Resource Center, PO Box 196612, Anchorage, AK 99519
Chiniak Public Library, PO Box 5610, Chiniak, AK 99615
Cordova Public Library, PO Box 1170, Cordova, AK 99574
Dillingham Public Library, PO Box 870, Dillingham, AK 99576
Fairbanks North Star Borough Public Library (Noel Wien Library) 1215 Cowles Street, Fairbanks, AK
U.S. Fish & Wildlife Service Library, 1011 E. Tudor Road, Anchorage, AK 99503
Halibut Cove Public Library, PO Box 6413, Halibut Cove, AK 99603
ENRI Information Services, 707 A Street, Anchorage, AK 99501
Jesse Wakefield Memorial Library, PO Box 49, Port Lions, AK 99550
Juneau Memorial Library, 114 4th Street, Anchorage, AK
Juneau Public Library, 292 Marine Way, Juneau, AK 99801
Kasilof Public Library, PO Box 176, Kasilof, AK 99610
Kenai Community Library, 163 Main Street Loop, Kenai, AK 99611
Kenai Peninsula College, 34820 College Drive, Soldotna, AK 99669
Kenai Peninsula College, 533 E. Pioneer Avenue, Homer, AK 99603
Ketchikan Public Library, 629 Dock Street, Ketchikan, AK 99901
Kettleson Memorial Library, 320 Harbor Road, Sitka, AK 99835
King Cove Community School Library, PO Box 6, King Cove, AK 99612
Kodiak College, 117 Benny Benson Drive, Kodiak, AK 99615
Martin Monson Library, PO Box 147, Naknek, AK 99633–0147
Nanwalek Elementary/High School Library, PO Box 8007, Nanwalek, AK 99603–6007
Northern Alaska Environmental Center Library, 218 Driveway, Fairbanks, AK
Oil Spill Information Center, 645 G Street, Anchorage, AK 99510–0600
Old Harbor Library, PO Box 109, Old Harbor, AK 99643
Palmer Public Library, 655 Soputh Valley Way, Palmer, AK 99645
Sand Point School Library, PO Box 269, Sand Point, AK 99661
Seldovia Public Library, Drawer D, Seldovia, AK 99663
Seward Community Library, PO Box 537, Seward, AK 99664
Soldotna Public Library, 235 Brinkley Street, Soldotna, AK 99669
State of Alaska, DEC Library, 410 Willoughby Avenue, Juneau, AK 99801–1795
State of Alaska Department of Fish and Game Library, 333 Rasberry Road, Anchorage, AK 99518–1599
U.S. Army Corps of Engineers Library, PO Box 898, Anchorage, AK 99506–0898
University of Alaska-Fairbanks, Elmer E. Rasmuson Library, 310 Tanana Drive, Fairbanks, AK 99775–1007
University of Alaska-Fairbanks, Institute of Arctic Biology, 311 Irving Building, Fairbanks, AK
University of Alaska-Anchorage, Government Documents Library, 3211

Providence Drive, Anchorage, AK 99508
University of Alaska-Anchorage, Consortium Library, 3211 Providence Drive, Anchorage, AK 99508
University of Alaska-Juneau Library, 11120 Glacier Highway, Juneau, AK
University of Alaska, Seward Marine Center Library, PO Box 730, Seward, AK 99664
Valdez Public Library, PO Box 609, Valdez, AK 99686
Whittier Public Library, PO Box 749, Whittier, AK 99693
Z.J. Loussac Public Library, 3600 Denali Street, Anchorage, AK 99503

Dated: January 18, 1996.

Thomas Gernhofer,

Associate Director for Offshore Minerals Management.

[FR Doc. 96–1676 Filed 1–29–96; 8:45 am]

BILLING CODE 4310–MR–P

National Park Service

Voyageurs National Park, MN; Historic Resort Hotel and Villas Operations

AGENCY: National Park Service, Interior.

ACTION: Public notice.

SUMMARY: Public notice is hereby given that the National Park Service proposes to award a concession contract authorizing continued operation of historic resort hotel and villas, with food service, boat portaging, and water-related services for the public at Voyageurs National Park, Minnesota, for a period of approximately ten (10) years from January 1, 1996, through December 31, 2005.

EFFECTIVE DATE: April 1, 1996.

ADDRESSES: Interested parties should contact the Superintendent, Voyageurs National Park, 3131 Highway 53 South, International Falls, Minnesota 56649, to obtain a copy of the prospectus describing the requirements of the proposed contract.

SUPPLEMENARY INFORMATION: This contract renewal has been determined to be categorically excluded from the procedural provisions of the National Environmental Policy Act and no environmental document will be prepared. There was an existing concessioner for this operation under a previous contract which expired on October 8, 1995, but that concessioner is not entitled to a right of preference in the negotiation of the new contract. This means that the contract will be awarded to the party submitting the best offer.

The Secretary will consider and evaluate all proposals received as a result of this notice. All proposals must be received by the Superintendent not later than the sixtieth (60) day following publication of this notice to be considered and evaluated.

Dated: December 12, 1995.

William W. Schenk,

Field Director, Midwest Region.

[FR Doc. 96–1605 Filed 1–29–96; 8:45 am]

BILLING CODE 4310–70–M

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

[INS No. 1740E–95]

RIN 1115–AC30

Further Extension of Work Authorization for Salvadorans Under Deferred Enforced Departure (DED)

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Notice.

SUMMARY: The Immigration and Naturalization Service ("the Service" or "INS") is granting a further automatic extension until April 30, 1996, of the validity of any Employment Authorization Document (EAD or work permit) bearing an expiration date of December 31, 1994, previously issued to a Salvadoran on the basis of Deferred Enforced Departure (DED). The Service is taking this action in order to ensure an ample opportunity for Salvadoran beneficiaries of DED to apply for a new EAD based on a pending asylum application.

Salvadoran nationals currently eligible for benefits under the *American Baptist Churches* (*ABC*) settlement agreement must mail an asylum application to the appropriate INS Service Center by January 31, 1996, if they do not already have one on file, in order to remain eligible for settlement benefits. Asylum applications will be considered timely filed if postmarked on or before January 31, 1996. This notice does not constitute an extension of the *ABC* asylum application filing deadline.

EFFECTIVE DATE: January 30, 1996.

FOR FURTHER INFORMATION CONTACT: Ronald Chirlin, Adjudications Officer, Immigration and Naturalization Service, Examinations Division, 425 I Street, NW, Room 3214, Washington, DC 20536, Telephone (202) 514–5014.

SUPPLEMENTARY INFORMATION:

Background

The Service announced on December 6, 1994, that it was automatically extending work authorization until September 30, 1995, for Salvadorans covered by the DED program. 59 FR 62751. This extension allowed Salvadorans covered by DED a transitional period to apply for work authorization under other immigration law provisions. Almost all Salvadorans covered by DED are class members of the "*ABC*" lawsuit, which was settled in 1991. *American Baptist Churches* v. *Thornburgh*, 760 F.Supp. 796 (N.D. Cal. 1991). Under the *ABC* settlement, Salvadoran class members are entitled to apply for asylum under the old asylum regulations (promulgated in 1990) and may apply for work authorization based upon a previously or concurrently filed asylum application.

On July 7, 1995, the Service published in the Federal Register Special Filing Instructions for *ABC* Class Members, Form M–426, which provided instructions to class members regarding the filing of asylum and employment authorization applications. 60 FR 35424. On July 31, 1995, the Service mailed *ABC* Notice 5 advising Salvadoran *ABC* class members who have never filed an asylum application to do so by January 31, 1996, in order to remain eligible for *ABC* benefits. In a notice published September 27, 1995, the Service clarified the *ABC* Special Filing Instructions, extended the validity of DED-based work permits until January 31, 1996, and published the text of Notice 5. 60 FR 49921.

Salvadoran *ABC* class members who apply for asylum and employment authorization in the period ending on January 31, 1996, may face a lapse in their employment authorization, since the processing time for EAD applications at the Service Centers is approximately 60 to 90 days. In order to avoid possible interruption of employment authorization for class members, this Notice extends the validity of Salvadoran DED-based work permits until April 30, 1996, and reminds Salvadorans with DED work authorization to file their requests for a new work permit as soon as possible.

Automatic Extension of Employment Authorization

In order to ensure an ample opportunity for Salvadorans covered by DED to apply for a new employment authorization document (EAD), the Service is granting an automatic extension of the validity of their EADs until April 30, 1996. This automatic extension is limited to EAD cards which expire on December 31, 1994, and were previously issued to DED Salvadorans pursuant to 8 CFR 274a.12(a)(11). Salvadorans who need work

authorization after April 30, 1996, should file applications for their new EADs as soon as possible in order to ensure continuous employment authorization.

Employers of DED Salvadorans

For purposes of verifying or reverifying employment eligibility until *April 30 1996*, employers of DED Salvadorans whose employment authorization is automatically extended may not refuse to accept an EAD card, Form I–688B, which:

(1) Bears an expiration date of December 31, 1994 (or bears on its reverse an extension sticker punched for December 1994), and

(2) Contains the notation "274A.12(A)(11)" or "274A.12(A)(12)" on the face of the card under "Provision of Law."

EAD cards or extension stickers showing the automatic April 1996 expiration date will not be issued. Employers should *not* request proof of Salvadoran citizenship or any other document, if an automatically extended EAD card appears genuine and relates to the individual. Employers are reminded that this action does not affect the right of a worker to present any other legally acceptable document as proof of eligibility for employment. Employers are reminded that the law prohibiting unfair immigration-relate employment practices remain in full force.

To complete or update the Form I–9, Employment eligibility Verification, for an employee who presents an automatically extended EAD card, the employer should include or add the following information under Section 2 (List A) or Section 3C, as appropriate:

(1) The expiration date of "12/31/94" from the EAD card;

(2) The last part of the provision of law, "(A)(11)" or "(A)(12)", from the face of the EAD card; and

(3) "Automatic expiration date 4/30/96".

Obtaining Subsequent Employment Authorization

In order to be eligible for asylum-based work authorization under the *ABC* settlement, Salvadoran class members must have an asylum application on file or must mail a complete Form I–589, Request for Asylum in the United States, to the appropriate INS Service Center on or before January 31, 1996. *ABC* class members should refer to the Form M–426, Special Filing Instructions for *ABC* Class Members, for important information on the procedures for filing their asylum and work authorization applications. The Special Filing Instructions and the Form I–855, *ABC* Change of Address Form, can be obtained at local district offices or by calling 1–800–755–0777 or 1–800–870–3676 and requesting an "*ABC* packet."

Although Salvadorans do not have a deadline for filing employment authorization applications, the Service emphasizes that the adjudication of the application and issuance of the EAD may take 60 to 90 days not including delays caused by incomplete applications. Therefore, Salvadoran class members should file their work authorization applications early enough to allow for issuance and return of their new work permits before their old ones expire.

ABC Notice 5 and the Asylum Application Filing Deadline for Salvadoran Class Members

Salvadoran *ABC* class members who have never filed an asylum application, including those who did not receive Notice 5, must mail a complete asylum application by January 31, 1996, in order to remain eligible for *ABC* benefits. This asylum filing deadline remains unchanged. Salvadorans may file an initial asylum application after January 31, 1996, but they will not be eligible for *ABC* benefits.

Change of Address Reporting Requirement for ABC Class Members

ABC class members must notify the Service of any change of address by filing the Form I–855, *ABC* change of Address Form. Class members must mail the *ABC* Change of Address Form, but no other materials, to the Washington, DC address shown on the form. Class members who have filed an asylum application with the Service are encouraged also to send a copy of the *ABC* Change of Address Form to their local asylum office.

Dated: January 23, 1996.

Doris Meissner,

Commissioner, Immigration and Naturalization Service.

[FR Doc. 96–1634 Filed 1–29–96; 8:45 am]

BILLING CODE 4410–10–M

Office of Justice Programs

Office of the Controller

Information Collection Under Review

The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for "sixty days" from the date listed at the top of this page in the **Federal Register**.

Request written comments and suggestions from the public and affected agencies concerning the proposed collection of information. Your comments should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Maureen Smythe, 202–616–3505, Office of the Controller, Office of Justice Programs, U.S. Department of Justice, Room 942, 633 Indiana Avenue, NW., Washington, DC 20531. Additionally, comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time should be directed to Cynthia J. Schwimer, 202–307–3186, Director, Financial Management Division, Office of Justice Programs, U.S. Department of Justice, 633 Indiana Avenue, NW., Washington, DC 20531.

Overview of this information collection:

(1) Type of Information Collection: *Revision of a currently approved collection.*

(2) Title of the Form/Collection: Simplified Request for Advance of Reimbursement.

(3) Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection: Form: H–3. Office of the Controller, Office of Justice Programs, United States Department of Justice.

(4) Affected public who will be asked or required to respond, as well as a brief abstract: Primary: State and Local governments, private non-profit organizations, individuals, education institutions, hospitals, and private

commercial organizations (if legislation allows). Other: None. The information collected is used to process request for payments to recipients of agency funds, either through advance or reimbursement. Upon receipt, review, and approval of the H–3, the agency will notify Treasury either to electronically send funds to the grantee's bank account or to issue and mail a Treasury check.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: 10,000 responses at 0.25 hours, or 15 minutes per response.

(6) An estimate of the total public burden (in hours) associated with the collection: 30,000 annual burden hours.

If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 850, Washington center, 1001 G Street, NW., Washington, DC 20530.

Dated: January 25, 1996.

Robert B. Briggs,

Department Clearance Office, United States Department of Justice.

[FR Doc. 96–1678 Filed 1–29–96; 8:45 am]

BILLING CODE 4410–18–M

DEPARTMENT OF LABOR

Office of the Secretary

Agency Recordkeeping/Reporting Requirements Under Review by the Office of Management and Budget (OMB)

January 25, 1996.

The Department of Labor has submitted the following public information collection requests (ICRs) to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). Copies of these individual ICRs, with applicable supporting documentation, may be obtained by calling the Department of Labor Acting Departmental Clearance Office, Theresa M. O'Malley ((202) 219–5095). Comments and questions about the ICRs listed below should be directed to Ms. O'Malley, Office of Information Resources Management Policy, U.S. Department of Labor, 200 Constitution Avenue, NW., Room N–1301, Washington, DC 20210 within 30 days from the date of this publication in the **Federal Register**. Comments should also be sent to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for (BLS/DM/ESA/ETA/OAW/MSHA/OSHA/PWBA/VETS), Office of Management and Budget, Room 10325, Washington, DC 20503 ((202) 395–7316).

Individuals who use a telecommunications device for the deaf (TTY/TDD) may call (202) 219–4720 between 1 p.m. and 4 p.m. Eastern time, Monday through Friday.

Agency: Bureau of Labor Statistics.

Title: Producer Price Indexes, by Industry.

OMB Number: 1220–0008.

Agency Number: BLS 473P, BLS 1810A, A1, B, C, C1 C2, C3, E, and A–F.

Affected Public: Business or other for-profit; Not-for-profit institutions; Federal Government; State, Local or Tribal Government.

Form No.	Respondents	Frequency	Average time per response	Total annual responses
BLS 1810A	4,648	One-time	2 hours	4,648
A1, B, C, C1, C3, E, and A–F				
BLS 473P	24,052	Monthly	18 minutes	1,128,845

Total Burden Hours: 347,949.

Description: The Producer Price Index, which is one of the nation's leading economic indicators, is used as a measure of price movements, indicator of inflationary trends in the economy, inventory valuation measure for some organizations, and measure of purchasing power of the dollar at the primary market level. It is also used in market research and as a basis for escalation in long-term contracts.

Agency: Employment Standards Administration.

Title: Survivor's Claim for Benefits Under the Black Lung Benefits Act.

OMB Number: 1215–0069.

Agency Number: CM–912.

Frequency: On occasion.

Affected Public: Individuals or households.

Number of Respondents: 1,200.

Estimated Time Per Respondent: 25 minutes.

Total Burden Hours: 500.

Description: A survivor of a coal miner must file a claim for benefits under the Black Lung Benefits Act, as amended, in order to receive benefits. The claim and supporting documentation are reviewed by a Division of Coal Mine Workers' Compensation claims examiner to determine the survivor's eligibility for benefits.

Agency: Employment Standards Administration.

Title: Report of Ventilatory Study; Roentgenographic Interpretation; Medical History and Examination for Coal Mine Workers' Pneumoconiosis; Report of Arterial Block Gas Study.

OMB Number: 1215–0090.

Agency Number: CM–907, CM–933; CM–933b; CM–988; CM–1159.

Frequency: On occasion.

Affected Public: Business or other for-profit; Non-for-profit institutions.

Form	Respondents	Estimated time per response (minutes)	Total annual hours
CM–907	7,425	20	2,475
CM–933	14,850	5	1,238
CM–933b	675	5	56
CM–988	7,425	30	3,713
CM–1159	7,425	15	2,856

Total Burden Hours: 9,338.

Description: 20 CFR part 718 specifies that certain information relative to the medical condition of a claimant who is alleging the presence of pneumoconiosis be obtained as a route function of the claim adjudication process. The medical specifications in the regulations have been formatted in a variety of forms to promote efficiency and accuracy in gathering the required data. These forms were designed to meet the need to establish medical evidence.

Theresa M. O'Malley,

Acting Departmental Clearance Officer.

[FR Doc. 96–1686 Filed 1–29–96; 8:45 am]

BILLING CODE 4510–27–M

Secretary's Task Force on Excellence in State and Local Government Through Labor-Management Cooperation: Meeting

AGENCY: Office of the Secretary, Labor.

ACTION: Notice of public meeting.

SUMMARY: The Secretary's Task Force on Excellence in State and Local Government Through Labor-Management Cooperation was established in accordance with the Federal Advisory Committee Act (FACA) (Pub. L. 82–463)). Pursuant to Section 10(a) of FACA, this is to announce that the Task Force will meet at the time and place shown below.

TIME AND PLACE: The meeting will be held on Monday, February 12, 1996, from approximately 9 a.m. to 10 a.m. in Conference Room N–3437 B–D in the Department of Labor, 200 Constitution Avenue, NW., Washington, DC.

AGENDA: At the meeting, the Task Force will review final issues and any submitted comments.

PUBLIC PARTICIPATION: The meeting will be open to the public. Seating will be available on a first-come, first-served basis. Individuals with disabilities wishing to attend should contact the Task Force if special accommodations are necessary. Individuals or organizations wishing to submit written statements should send 20 copies on or before February 5 to Mr. Charles A. Richards, Designated Federal Official, Secretary of Labor's Task Force on Excellence in State and Local Government through Labor-Management Cooperation, U.S. Department of labor, 200 Constitution Avenue, NW., Room S–2203, Washington, DC 20210. These statements will be thoroughly reviewed and become part of the record.

For the purposes of this meeting, the Task Force is primarily interested in statements that address the topics mentioned above under the heading "Agenda." However, the Task Force continues to welcome submissions that address the questions in the mission statement and the following eight general areas: (1) Finding Models, Ingredients, and Barriers to Service Excellence and Labor-Management Cooperation and, as the following relate to promoting workplace cooperation and excellence; (2) Bargaining and Related Institutions and Practices; (3) Conflict Resolution Skills, Practices, and Institutions; (4) Legal and Regulatory Issues; (5) Effects of Civil Service; (6) Ensuring a High-Performance Work Environment; (7) Political and Electoral Considerations and Relationships; and (8) Financial Background, Financial Security, and Budget Systems.

FOR FURTHER INFORMATION CONTACT: Mr. Charles A. Richards, Designated Federal Official, Secretary of Labor's Task Force on Excellence in State and Local Government through Labor-Management Cooperation, U.S. Department of Labor, Room S–2203, Washington, DC 20210, (202) 219–6045.

Signed at Washington, DC this 24th day of January 1996.

Robert B. Reich,

Secretary of Labor.

[FR Doc. 96–1606 Filed 1–29–96; 8:45 am]

BILLING CODE 4510–23–M

Labor Advisory Committee for Trade Negotiations and Trade Policy; Meeting Notice

Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92–463 as amended), notice is hereby given of a meeting of the Labor Advisory Committee for Trade Negotiations and Trade Policy.

DATE TIME AND PLACE: February 15, 1996, 10 pm–12 noon, U.S. Department of Labor, Room S–1011, 200 Constitution Ave., NW., Washington, DC 20210.

PURPOSE: The meeting will include a review and discussion of current issues which influence U.S. trade policy. Potential U.S. negotiating objectives and bargaining positions in current and anticipated trade negotiations will be discussed. Pursuant to section 9(B) of the Government in the Sunshine Act, 5 U.S.C. 552b(c)(9)(B) it has been determined that the meeting will be concerned with matters the disclosure of which would seriously compromise the Government's negotiating objectives or bargaining positions. Accordingly, the meeting will be closed to the public.

FOR FURTHER INFORMATION, CONTACT: Fernand Lavallee, Director, Trade Advisory Group, Phone: (202) 219–4752.

Signed at Washington, DC this 24th day of January, 1996.

Andrew Samet,

Acting Deputy Under Secretary, International Affairs.

[FR Doc. 96–1684 Filed 1–29–96; 8:45 am]

BILLING CODE 4510–28–M

Occupational Safety and Health Administration

Maritime Committee; Renewal

AGENCY: Occupational Safety and Health Administration (OSHA), Department of Labor.

ACTION: Notice of renewal of the Maritime Advisory Committee for Occupational Safety and Health (MACOSH).

SUMMARY: The Secretary of Labor has determined that it is in the public interest to renew the Maritime Advisory Committee for Occupational Safety and Health (MACOSH); an advisory committee to advise the Assistant Secretary for the Occupational Safety and Health Administration (OSHA) on issues relating to the delivery of occupational safety and health programs, policies, and standards in the maritime industries of the United States. The committee will continue to provide a collective expertise not otherwise available to the Secretary to address the complex and sensitive issues involved. The committee is being renewed for two years, beginning January 1, 1996.

DATES: Comments must be received on or before February 14, 1996.

ADDRESSES: Any written comments in response to this notice should be sent to the following address: OSHA, Office of Maritime Standards, Room N–3621, 200 Constitution Avenue, NW., Washington, DC 20210. Phone (202) 219–7234, fax (202) 219–7477.

FOR FURTHER INFORMATION CONTACT: Mr. Larry Liberatore, Office of Maritime Standards, OSHA (202) 219–7234.

SUPPLEMENTARY INFORMATION: MACOSH addresses the concerns of the entire maritime community, focusing on the shipyard and marine cargo (longshoring) handling industries. The specific objectives of this committee continue to be to make recommendations on issues related to: (1) Reducing injuries and illnesses in the maritime industries, (2) expanding OSHA's outreach and training programs through the use of innovative partnerships, and (3) expediting the development and promulgation of OSHA standards.

Background

Renewal of the Maritime Advisory Committee for Occupational Safety and Health (MACOSH) will enable OSHA to continue to be responsive to the uniqueness of industries that have suffered economically as a result of changes in the global market. This committee will continue a focused forum for ongoing discussions with the marine cargo handling community. This action is consistent with the President's initiative to make the U.S. shipyard industry competitive in the worldwide community. This committee addresses the maritime community's concerns, and its efforts will result in streamlined standards promulgation, better focused

enforcement efforts, and extended and improved outreach and training initiatives. Furthermore, this committee focuses on the resolution of controversial issues, particularly those with international implications, that have an impact on the shipyard and marine cargo handling communities.

In accordance with the provisions of the Occupational Safety and Health Act of 1970 (OSH Act) and the Federal Advisory Committee Act (FACA), and after consultation with the General Services Administration, the Secretary of Labor has determined that the renewal of MACOSH to address the complexities of the maritime community is essential to the conduct of Agency business and in the public interest.

The committee will continue to be composed of approximately 20 members who have been selected to represent the divergent interests of the maritime community. The makeup of the membership complies with section 7(b) of the OSH Act, which requires the following: at least one member who is a designee of the Secretary of Health and Human Services; at least one member who is designee of a State safety and health agency; and equal numbers of representatives of employees and employers, respectively. Other members have been selected based on their knowledge and experience to include representatives from professional and other governmental organizations with specific maritime responsibilities. In accordance with section 2(c) of FACA, the committee is "balanced in membership and in terms of point of view and functions * * *" The Agency intends that this committee continue to provide a comprehensive representation of the maritime community and have the opportunity to offer recommendations on safety and health initiatives that would be considered as part of an integrated U.S. maritime policy.

MACOSH functions solely as an advisory body and in compliance with the provisions of the FACA. This notice will be filed with the appropriate committees of Congress.

Meetings of this committee will be announced in the **Federal Register** and are open to the public.

Interested parties are invited to submit comments regarding the renewal of the committee to Larry Liberatore, Office of Maritime Standards, OSHA, U.S. Department of Labor, Room N–3621, 200 Constitution Avenue, NW., Washington, DC 20210. Telephone (202) 219–7234, fax (202) 219–7477.

With this notice, I am renewing for two years the Maritime Advisory Committee for Occupational Safety and Health under section 7(b) of the OSH Act and the FACA to address occupational safety and health issues unique to maritime employment.

Signed at Washington, DC, this 24th day of January 1996.

Robert B. Reich,

Secretary of Labor.

[FR Doc. 96–1685 Filed 1–29–96; 8:45 am]

BILLING CODE 4510–26–M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 96–003]

Fiscal Year 1995 Report of Closed Meeting Activities of Advisory Committees

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of availability of reports.

SUMMARY: Pursuant to the Federal Advisory Committee Act, Public Law 92–463, as amended, the NASA advisory committees that held closed or partially closed meetings in Fiscal Year 1995, consistent with the policy of 5 U.S.C. 552b(c), have prepared reports on activities of these meetings. Copies of the reports have been filed and are available for public inspection at the Library of Congress, Federal Advisory Committee Desk, Washington, DC 20540, and the National Aeronautics and Space Administration, Headquarters, Code Z, Washington, DC 20546. The names of the committees are: NAC NASA/NIH Advisory Committee on Biomedical and Behavioral Research, and the NAC Life and Microgravity Sciences and Applications Advisory Committee.

FOR FURTHER INFORMATION CONTACT: Mechthild E. Peterson, Code JMC, National Aeronautics and Space Administration, Washington, DC 20546 (202–358–1306).

Dated: January 24, 1996.

Timothy M. Sullivan,

Advisory Committee Management Officer.

[FR Doc. 96–1752 Filed 1–29–96; 8:45 am]

BILLING CODE 7510–01–M

[Notice 96–002]

Aerospace Safety Advisory Panel; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Pub. L. 92–463, as amended, the National Aeronautics and Space Administration announces a forthcoming meeting of the Aerospace Safety Advisory Panel.

DATES: February 29, 1996, 2 p.m. to 3:30 p.m.

ADDRESSES: National Aeronautics and Space Administration, 300 E Street, SW, Room 9H40, Washington, DC 20546.

FOR FURTHER INFORMATION CONTACT: Mr. Frank L. Manning, Code Q–1, National Aeronautics and Space Administration, Washington, DC 20546 (202/358–0914).

SUPPLEMENTARY INFORMATION: The Aerospace Safety Advisory Panel will present its annual report to the NASA Administrator. This is pursuant to carrying out its statutory duties for which the Panel reviews, identifies, evaluates, and advises on those program activities, systems, procedures, and management activities that can contribute to program risk. Priority is given to those programs that involve the safety of human flight. The major subjects covered will be the Space Shuttle, Space Station, and Aeronautical Operations. The Aerospace Safety Advisory Panel is chaired by Paul M. Johnstone and is composed of 8 members and 6 consultants. The meeting will be open to the public up to the capacity of the room (approximately 50 persons including members of the Panel).

Type of Meeting

Open.

Agenda

Thursday, February 29

2 p.m.—Presentation of the findings and recommendations of the Aerospace Safety Advisory Panel.

3:30—Adjourn.

All attendees will be requested to sign an attendance register.

Dated: January 23, 1996.

Timothy M. Sullivan,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 96–1604 Filed 1–29–96; 8:45 am]

BILLING CODE 7510–01–M

[Notice 96–005]

Notice of Prospective Patent License

AGENCY: National Aeronautics and Space Administration.

SUMMARY: NASA hereby gives notice that 3M Company of St. Paul, Minnesota 55144–1000, has requested an exclusive

license to practice the invention protected by U.S. Patent Application entitled "Environmentally-Friendly Anti-Icing and Deicing Fluid," NASA Case No. ARC–12,069–1, which was filed on January 23, 1995, and assigned to the United States of America as represented by the Administrator of the National Aeronautics and Space Administration. Written objections to the prospective grant of a license should be sent to Mr. Ken Warsh, Patent Counsel, Ames Research Center.

DATES: Responses to this Notice must be received by April 1, 1996.

FOR FURTHER INFORMATION CONTACT: Mr. Ken Warsh, Patent Counsel, Ames Research Center, Mail Code 202A–3, Moffett Field, CA 94035; telephone (415) 604–1592.

Dated: January 22, 1996.

Edward A. Frankle,

General Counsel.

[FR Doc. 96–1754 Filed 1–29–96; 8:45 am]

BILLING CODE 7510–01–M

[Notice 96–007]

Notice of Prospective Patent License

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of prospective patent license.

SUMMARY: NASA hereby gives notice that Laser Technology, Inc. of Norristown, Pennsylvania, has applied for an exclusive license to practice the invention described and claim in a pending U.S. Patent Application entitled "Apparatus and Method for High Speed Characterization of Surfaces," which is assigned to the United States of America as represented by the Administrator of the National Aeronautics and Space Administration. Written objections to the prospective grant of the license to Laser Technology should be sent to Beth Vrioni, John F. Kennedy Space Center, Mail Code DE–TPO, Kennedy Space Center, FL 32899.

DATES: Responses to this Notice must be received within 60 days from date of publication in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT:

Beth Vrioni at (407) 867–2780.

Dated: January 22, 1996.

Edward A. Frankle,

General Counsel.

[FR Doc. 96–1756 Filed 1–29–96; 8:45 am]

BILLING CODE 7510–01–M

[Notice 96–006]

Notice of Prospective Patent License

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of Prospective Patent License.

SUMMARY: NASA hereby gives notice that UE Systems Inc. of Elmsford, New York, has applied for an exclusive license to practice the invention described and claimed in a pending U.S. Patent Application, entitled "Ultrasonic Leak Detection System", which is assigned to the United States of America as represented by the Administrator of the National Aeronautics and Space Administration. Written objections to the prospective grant of a license to UE Systems Inc. should be sent to Beth Vrioni, John F. Kennedy Space Center, Mail Code DE–TPO, Kennedy Space Center, FL 32899.

DATES: Responses to this Notice must be received by April 1, 1996.

FOR FURTHER INFORMATION CONTACT: Beth Vrioni at (407) 867–2780.

Dated: January 22, 1996.

Edward A. Frankle,

General Counsel.

[FR Doc. 96–1755 Filed 1–29–96; 8:45 am]

BILLING CODE 7510–01–M

[Notice (96–004)]

Notice of Prospective Patent License

AGENCY: National Aeronautics and Space Administration.

SUMMARY: NASA hereby gives notice that VISTA Automation Systems, Inc., of Frederick, Maryland 21702 has requested an exclusive license to practice the inventions protected by U.S. Patent Application Numbers 08/416,598, entitled "THIN-LAYER COMPOSITE-UNIMORPH PIEZOELECTRIC DRIVER AND SENSOR, "THUNDER," for which a U.S. Patent was applied for on April 4, 1995; 60/003,633 entitled "METHODS OF FORMING A COMPOSITE COATING WITH PARTICLE MATERIALS/READILY DISPERSED IN A SPRAYABLE POLYMIDE SOLUTION," which was applied for on September 12, 1995; 08/359,752 entitled TOUGH, SOLUBLE, AROMATIC, THERMOPLASTIC COPOLYIMIDES," which was applied for on December 16, 1994; and 08/444,185 entitled "PROCESS FOR PREPARING TOUGH, SOLUBLE, THERMOPLASTIC COPOLYMIDES" which was applied for on May 18, 1995, all by the United States of America as represented by the Administrator of the National Aeronautics and Space Administration. Written objections to the prospective grant of a license should be sent to Mr. George F. Helfrich, Patent Counsel, Langley Research Center.

DATES: Responses to this Notice must be received by April 1, 1996.

FOR FURTHER INFORMATION CONTACT: Mr. George F. Helfrich, Patent Counsel, Langley Research Center, Mail Code 212, Hampton, VA 23681–0001; telephone (804) 864–3521.

Dated: January 22, 1996.

Edward A. Frankle,

General Counsel.

[FR Doc. 96–1753 Filed 1–29–96; 8:45 am]

BILLING CODE 7510–01–M

NUCLEAR REGULATORY COMMISSION

[Docket No. 40–3453]

Atlas Corporation; Draft Environmental Impact Statement

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of availability.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC), in cooperation with the National Park Service (NPS), U.S. Department of Interior, has published a Draft Environmental Impact Statement (DEIS) regarding the proposed reclamation by Atlas Corporation (Atlas) of an existing uranium mill tailings pile near Moab, Utah. This DEIS describes and evaluates the potential environmental impacts of approving Atlas' request to amend its existing NRC License No. SUA–917 to reclaim the tailings pile in place. Based on the evaluations in this DEIS, the NRC staff's preliminary conclusion is that the Atlas proposal is acceptable with respect to environmental costs and benefits.

The NRC has also published a Draft Technical Evaluation Report (DTER) evaluating the proposed reclamation with respect to appropriate NRC safety regulations, primarily Appendix A of 10 CFR, Part 40. Until and unless open issues identified in geology, seismology, geotechnical engineering, erosion protection, water resources protection, and radon attenuation are adequately resolved, NRC will not approve the proposed reclamation plan.

DATES: A public meeting on the DEIS and DTER will be held at Star Hall in Moab, Utah, on Wednesday, February 28, 1996, at 6:30 in the evening. Written comments on either document should be received at the address listed below

within 60 days from the date of this notice.

ADDRESSES: A free single copy of the DEIS (NUREG–1531) and DTER (NUREG–1532) may be requested by those considering public comment by writing to the NRC Publications Section, ATTN: Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20013–7082. A copy of each document is also available for inspection and/or copying in the NRC Public Document Room, 2120 L St. NW, Washington, DC.

Any interested party may submit comments on these documents for consideration by the staff. Consistent with its past commitments, NRC is extending the comment period 15 days beyond the required minimum of 45 days. To be certain of consideration, comments on these reports must be received within 60 days from the date of this notice. Comments received after the due date will be considered to the extent practical. Comments on either document should be sent to Chief, High-Level Waste and Uranium Recovery Projects Branch, Mail Stop TWFN 7–J9, Division of Waste Management, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

FOR FURTHER INFORMATION CONTACT: Dr. Myron Fliegel, High-Level Waste and Uranium Recovery Projects Branch, Mail Stop TWFN 7–J9, Division of Waste Management, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Telephone 301/415–6629.

SUPPLEMENTARY INFORMATION: The NRC, in cooperation with the NPS, has prepared a DEIS regarding the administrative action of approving an amendment to Atlas' NRC license authorizing reclamation of uranium mill tailings at the existing site near Moab, Utah. The uranium mill no longer operates and is currently being dismantled. The nearby 9.52-million-metric-ton (10.5-million-ton), 52.6–ha (130-acre), uranium mill tailings pile needs to be stabilized for long-term disposal. The DEIS describes the evaluation concerning (1) the purpose of and need for the proposed action, evaluated under NEPA and the agencies' implementing regulations, (2) alternatives considered, (3) existing environmental conditions, and (4) environmental consequences of the proposed action and proposed mitigating measures.

Three alternatives were evaluated. Atlas' proposal (Alternative 1) is to reclaim the tailings pile for permanent disposal and long-term custodial care by a government agency in its current location near Moab, prepare the 162-ha (400-acre) site for closure, and depart the site after having its NRC license terminated.

Under Alternative 2, Atlas would transport all of the tailings and other contaminated material to an alternate site. The DEIS considers the Plateau site, located approximately 29 km (18 mi) northwest of Moab, as the primary alternate site. The DEIS considers several alternatives for transporting the tailings to the alternate site.

Under the no-action alternative (Alternative 3), the NRC would make no licensing decision, and Atlas would cease operations involving management of the tailings. Because this alternative would not comply with regulations and is not environmentally acceptable, it is not evaluated in detail in this DEIS.

As documented in the DEIS, the NRC's preliminary conclusion is that Atlas' proposal (reclamation on site) is acceptable with respect to environmental costs and benefits. Alternative 2 (transport to and stabilization at an alternate site) would result in some advantages (primarily by freeing the current site near the Colorado River for other uses and eliminating the potential for impacts to the Colorado River) and disadvantages (primarily related to the transport of tailings to a new site and the longer period of construction) compared to Alternative 1. Alternative 2 would be considerably more expensive than Alternative 1.

The NRC has also prepared a DTER that evaluates Atlas' proposed reclamation of the uranium mill tailings with respect to NRC safety regulations. NRC regulations applicable to reclamation of uranium tailings are primarily in Part 40 of 10 CFR, with specific technical criteria appearing in Appendix A. The DTER is organized by the technical disciplines involved in the assessment of the proposed reclamation, but also provides a criterion by criterion evaluation of Atlas' proposed reclamation with respect to Appendix A. The NRC review identified 20 issues in geology, seismology, geotechnical engineering, erosion protection, water resources protection, and radon attenuation that preclude the NRC from concluding that the applicable regulations would be met under Atlas' proposed reclamation. Atlas can provide further information to try to resolve these issues.

Dated at Rockville, Maryland, this 24th day of January 1996.

For the Nuclear Regulatory Commission.

Joseph J. Holonich,

Chief, High-Level Waste and Uranium Recovery Projects Branch, Division of Waste Management, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 96–1679 Filed 1–29–96; 8:45 am]

BILLING CODE 7590–01–P

Consideration of Valve Mispositioning in Pressurized-Water Reactors; Issued

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of issuance.

SUMMARY: The Nuclear Regulatory Commission (NRC) has issued Generic Letter 89–10, Supplement 7 to notify licensees of nuclear power reactors that the NRC is removing the recommendation that motor operated valve (MOV) mispositioning be considered by pressurized-water reactor licensees in responding to Generic Letter 89–10, "Safety-Related Motor-Operated Valve Testing and Surveillance," as was done for boiling-water reactor licensees in Supplement 4. Although this generic letter supplement forwards a new NRC position, no specific action or written response is required. This generic letter is available in the Public Document Rooms under accession number 9601190442.

DATES: The generic letter was issued on January 24, 1996.

ADDRESSEES: Not applicable.

FOR FURTHER INFORMATION CONTACT: David C. Fischer at (301) 415–2728.

SUPPLEMENTARY INFORMATION: None.

Dated at Rockville, Maryland, this 24th day of January, 1996.

For the Nuclear Regulatory Commission.

Dennis M. Crutchfield,

Director, Division of Reactor Program Management, Office of Nuclear Reactor Regulation.

[FR Doc. 96–1682 Filed 1–29–96; 8:45 am]

BILLING CODE 7590–01–P

[Docket No. 50–322]

Long Island Power Authority—Shoreham Nuclear Power Station; Closing of Local Public Document Room

Notice is hereby given that the Nuclear Regulatory Commission (NRC) is closing the local public document room (LPDR) for records pertaining to the Long Island Power Authority (LIPA) Shoreham Nuclear Power Station located at the Shoreham-Wading River Public Library, Shoreham, New York.

This LPDR is no longer needed and will close effective March 16, 1996.

The Shoreham Public Library has been the LPDR for the Shoreham Nuclear Power Station since January 1979. Since that time the LPDR has continued to maintain documents on the construction through decommissioning stages of the facility. On April 11, 1995, NRC issued an order terminating License Number NPF–82, releasing the facility and site for unrestricted use. Therefore, effective March 16, 1996, the LPDR will be closed.

Dated at Rockville, Maryland, this 24th day of January 1996.

For the Nuclear Regulatory Commission.

Carlton Kammerer,

Director, Division of Freedom of Information and Publications Services, Office of Administration.

[FR Doc. 96–1680 Filed 1–29–96; 8:45 am]

BILLING CODE 7590–01–P

[Docket Nos. 72–14, 50–346, 72–1004 (License No. NPF–3)]

Davis-Besse Nuclear Power Station; Toledo Edison Company; Receipt of Petition for Director's Decision Under 10 C.F.R. § 2.206

Notice is hereby given that by a Petition dated December 5, 1995, filed on behalf of the Toledo Coalition for Safe Energy, Alice Hirt, Charlene Johnston, Dini Schut, and William Hoops (Petitioners), the Nuclear Regulatory Commission was requested to immediately issue orders to prevent the loading of spent nuclear fuel into the VECTRA Technologies Inc., NUHOMS–24P dry shielded canisters (DSCs) at the Davis-Besse nuclear power station until an NRC rulemaking and/or license modification hearing is conducted on all safety-related changes which have been made to the canisters, as described in the Safety Analysis Report. Also, the NRC was requested not to authorize any loading of the canisters until a written procedure for unloading in both urgent and nonurgent circumstances is written, approved, and field-tested.

Petitioners contend that the safety of the canisters has been compromised because of reduction in the thickness of the canister welds. In addition, they claim that the NRC administrative process by which permission was granted for VECTRA to deliver the canisters to the Davis-Besse station and for the canisters to be used on site are legally suspect, expressing the belief that agency rulemaking or some other public proceeding is necessary for permission for such a transfer and use to be granted.

The Petition is being treated pursuant to 10 C.F.R. § 2.206 of the Commission's regulations. The Petition has been referred to the Director of the Office of Nuclear Material Safety and Safeguards. As provided by Section 2.206, appropriate action will be taken on this Petition within a reasonable time. By letter dated December 18, 1995, the Director denied the Petitioners' request for immediate action on the Petition.

A copy of the Petition is available for inspection at the Commission's Public Document Room at 2120 L Street, NW, Washington, DC 20555.

Dated at Rockville, Maryland this 23rd day of January 1996.

For the Nuclear Regulatory Commission.

Carl J. Paperiello,

Director Office of Nuclear Material Safety and Safeguards.

[FR Doc. 96–1681 Filed 1–29–96; 8:45 am]

BILLING CODE 7590–01–p

SECURITIES AND EXCHANGE COMMISSION

Agency Information Collection Activities; Request For Public Comment

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549.

Extension: Form 40–F, SEC File No. 270–335, OMB Control No. 3235–0381.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), the Securities and Exchange Commission ("Commission") is publishing the following summary of collection for public comment.

Form 40–F is used by certain Canadian issuers to register securities pursuant to Section 12 of the Securities Exchange Act of 1934 ("Exchange Act") or as an annual report pursuant to Section 13(a) or 15(d) of the Exchange Act. An estimated 320 submissions are made pursuant to Form 40–F, resulting in an estimated annual total burden of 640 hours.

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Direct your written comments to Michael E. Bartell, Associate Executive Director, Office of Information Technology, Securities and Exchange Commission, 450 5th Street, N.W. Washington, DC 20549.

Dated January 23, 1996.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–1671 Filed 1–29–96; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–36763; File No. SR–Philadep–95–11]

Self-Regulatory Organizations; Philadelphia Depository Trust Company; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Restate, and Amend Schedule of Fees and Charges

January 24, 1996.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] notice is hereby given that on December 26, 1995, the Philadelphia Depository Trust Company ("Philadep") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which items have been prepared primarily by Philadep. 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 proposed rule change will restate Philadep's schedule of fees and charges with certain amendments.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Philadep included statements concerning the purpose of and statutory basis for the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. Philadep has prepared summaries, set forth in sections (A), (B),

[1] 15 U.S.C. 78s(b)(1) (1988)

and (C) below, of the most significant aspects of such statements.[2]

(A) Self-Regulatory Organization's Statements of the Purpose of, and Statutory Basis for, the Proposed Rule Change

Philadep last filed amendments to its fee schedule in July 1995.[3] Philadep hereby increases certain fees in the areas of account charges, certificate withdrawals, post-corporate actions (reorganizations), and eligibility book. Philadep also is instituting new fees for rush transfers, cancelled transfers, and customer transmittal messages.

Additionally, Philadep seeks to consolidate and restate all existing fees and charges in its schedule. This reflects Philadep's policy to file annually a comprehensive schedule of all existing fees, charges, and any amendments. The amendments to the fee schedule shall become effective January 1, 1996.

CONSOLIDATED RESTATEMENT OF FEES[4]

Service	Fee
1. ACCOUNT FEES	
a. General Maintenance Fee	[$360.00] *$400.00* per month with account activity. [$150.00] *$200.00* per month for accounts with less than $10.00 of depository activity.
b. Pledge Bank Fee	$100.00 per month.
c. Manual Interface Fee	$150.00 per month in addition to the general maintenance fee.
d. Bearer Municipal Bonds	$200.00 per month in addition to the general maintenance fee. $260.00 per month for bearer bond account only.
2. CUSTODY FEES	
a. Registered Securities	Base fee of $0.50 per issue, per month. Plus for each 100 shares or $4,000.00 in bonds: 0–1 Million Shares—$0.01. 1–5 Million Shares—$0.005. Over 5 Million Shares—$0.0025 Additional $0.50 fee per issue if Philadep eligible only, per month.
b. Bearer Municipal Bonds	Base fee of $1.45 per issue, per month. Plus for each $1,000 of par value: $0–$0.5 Billion—$0.010. $0.5–$1.0 Billion—$0.007. More than $1 Billion—$0.005.
3. DEPOSIT FEES	
a. Registered Securities	$1.60 per deposit.*
b. Bearer Municipal Bonds	$8.00 per deposit.
4. DEPOSIT REJECT FEES	
a. Registered Securities	No charge if total deposit rejects are less than 1% of total deposits for the month. Charge of $10.00 per reject if more than 1%.
b. Bearer Municipal Bonds	$10.00 per reject.
5. LEGAL DEPOSITS	
Processing fees are based on monthly deposit volume:	
Volume Level	Per Deposit.
0–100	$8.50.
101–500	$6.00.
501–1,000	$5.50.
1,001–1,700	$5.00.
1,701–2,500	$4.50.
2,501–3,000	$3.50 flat fee for all legal deposits.
3,001 and over	$2.75 flat fee for all legal deposits.
	No charge for deposit rejects. Transfer agent charges will be passed through to the participant on an item for item basis.
6. WITHDRAWALS	
a. Registered Securities	$2.60 per manual (paper) transfer.* $1.65 per computer to computer transfer.* $2.60 per terminal originated transfer.* *$25.00 per rush transfer.* *$2.00 per cancelled transfer.*
b. By Certificate	[$17.95] *$22.95* per urgent certificate withdrawal (same-day or next-day).*
7. CUSTOMER NAME MAILINGS	
a. Full Service	$0.65 per transfer, plus appropriate transfer withdrawal charge (fee does not include postage and delivery valuation charges).
b. Interdepository	$0.75 per transfer, for securities delivered interdepository plus appropriate transfer withdrawal charge (fee does not include postage and delivery valuation charges).
c. Transmittal Messages	*$.10 per transmittal.*
8. CERTIFICATE FEES	$5.75 deposits. $7.50 transfers.
9. ACCOMMODATION TRANSFERS AND IRONCLADS.	$5.00 per request, plus applicable transfer agent fees.
10. MDO MOVEMENTS	
a. Automated Bookentry Delivery/Receive	$0.75 per movement.
b. Manual Bookentry Delivery/Receive	$1.50 per movement.

[2] The Commission has modified parts of these statements.

[3] Securities Exchange Act Release No. 36013 (July 24, 1995), 60 FR 39037.

CONSOLIDATED RESTATEMENT OF FEES[4]—Continued

Service	Fee
c. Automatic Bookentry Interdepository Deliveries.	$0.50 per CUSIP (daily deliveries). $0.55 per CUSIP (weekly deliveries). $0.60 per CUSIP (biweekly deliveries). $0.65 per CUSIP (monthly deliveries).
d. Bearer Municipal Bonds Automated or Manual.	$0.94 per movement.
11. CNS/PHILADEP MOVEMENTS	$0.20 per movement.
12. UNDERWRITINGS	$400.00 plus $3.00 per million (plus applicable activity charges).
13. PLEDGE FEES	
a. Bank loan pledge or release	$0.35 each per line item to broker and bank.
b. OCC pledge or release	$0.35 per line item.
c. SCCP margin pledge (no charge for release).	$0.10 per line item.
14. DIVIDEND AND INTEREST PAYMENTS	$1.50 per cash line item. $10.00 per stock dividend payment.
15. REORGANIZATION FEES	
a. Mandatory Exchanges	$23.00 per position.
b. Voluntary Offers	$30.00 per instruction received before cut-off. $50.00 per instruction received after cut-off, with authorization.
c. Redemptions: Stocks, Corporate Bonds, Registered Municipal Bonds, others.	$25.00 per position.
d. Post Corporate Actions	[$17.50] *$20.00* per item (plus costs).
16. COMBINED LEGAL DEPOSITS AND LETTERS OF CORRECTION (IRONCLADS).	$6.25 per item (one legal deposit and one letter of correction is defined as one item).
17. RESEARCH FEES	
a. Per photocopy of records	$4.00.
b. Per microfiche copy	$4.00.
c. Items less than 90 days old	No charge.
d. Items 1 year old or less	$15.00 per hour.
e. Items over 1 year old	$15.00 per hour, $25.00 minimum, plus archive retrieval costs.
18. REPORTS ON MICROFICHE	$1.25 per page.
19. ELIGIBILITY BOOK	[$8.00] *$35.00* per book.
20. STOCK LOAN PROGRAM	
Interest charge to lender	Percentage of bank broker call rate.
21. NATIONAL INSTITUTIONAL DELIVERY SYSTEM (NIDS)	
a. Confirms	$0.40 per confirm.
b. For each unaffirmed trade reported	$0.09 to broker.
c. For each eligible trade reported	$0.09 to broker and clearing agent.
d. For each ineligible trade reported	$0.09 to broker and clearing agent.
e. Automated Settlement	$0.26 per receive and per delivery to broker and clearing agent.
22. PHILADEP DISCOUNTS	
Participants may select one of the following discount plans (the greater discount will apply):	
a. Volume	5% off Philadep charges for participants with 10,001 to 15,000 trades per month. An additional 5% off Philadep charges for participants with 15,001 to 30,000 trades per month. An additional 5% off Philadep charges for participants with 30,001 to 45,000 trades per month. An additional 5% off Philadep charges for participants with 45,001 or more trades per month.
b. Automated Deposit Service (ADS)	$0.40 per deposit for participants utilizing Philadep ADS and CNM services.
23. COMPUTER TRANSMISSION/TAPES	
a. Eligibility Files:	
1. Daily Update	$50.00 per month.
2. Weekly Full File	$200.00 per month.
3. Monthly or on Request	$75.00 each request.
b. Bookkeeping Positions:	
1. Daily	$150.00 per month.
2. Weekly	$100.00 per month.
3. Monthly or on Request	$50.00 each request.
c. Activity:	
1. Daily	$150.00 per month.
d. Bookkeeping plus Activity:	
1. Daily	$250.00 per month.
2. Weekly	$200.00 per month.
e. Cash Settlement (fee includes both dividends and reorganizations; transmissions are separate):	
1. Daily	$100.00 per month.
f. Record Date Positions:	
1. Daily	$100.00 per month.

CONSOLIDATED RESTATEMENT OF FEES[4]—Continued

Service	Fee
g. Status of Withdrawals by Transfer:	
1. Daily	$100.00 per month.
24. PHILANET TERMINAL	
a. Dedicated Line	$250.00 per month.
b. Dial-up Line	$150.00 per month.
c. Installation	$600.00
d. Usage	No Charge.
25. POSITION-LISTINGS	$45.00—per individual request (per date, per CUSIP) (plus costs). $360.00 annually—monthly basis (plus costs). $1,300.00 annually—weekly basis (plus costs).

[4] Deleted text is bracketed. New text is italicized.
*Transfer and deposit activity subject to pass-through costs.

The aforementioned fee revisions are intended to align fees with costs incurred to provide particular services. The proposed rule change is consistent with section 17A(b)(3)(D) of the Act[5] in that it provides for equitable allocations of reasonable dues, fees, and other charges among participants.

(B) Self-Regulatory Organization's Statement on Burden on Competition

Philadep does not perceive any burdens on competition as a result of the proposed rule change.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

A Philadep participant bulletin will notify participants of changes to the fee schedule and advise them to whom they may direct questions upon receipt of the new fee schedule.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to section 19(b)(3)(A)(ii)[6] and Rule 19b–4(e)(2)[7] promulgated thereunder because the proposed rule change establishes or changes a due, fee, or other charge imposed by Philadep. At any time within sixty days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

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 also will be available for inspection and copying at Philadep. All submissions should refer to File No. SR–Philadep–95–11 and should be submitted by February 20, 1996.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[8]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–1672 Filed 1–29–96; 8:45 am]

BILLING CODE 8010–01–M

[5] 15 U.S.C. 78q–1(b)(3)(D) (1988).
[6] 15 U.S.C. 78s(b)(3)(A)(ii) (1988).
[7] 17 CFR 240.19b–4(e)(2) (1994).

[Rel. No. IC–21695; International Series Rel. No. 921; 812–9904]

Banque Paribas (Deutschland) OHG et al.; Notice of Application

January 23, 1996.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of Application for an Order under the Investment Company Act of 1940 (the "Act").

[8] 17 CFR 200.30–3(a)(12) (1994).

APPLICANTS: Banque Paribas (Deutschland) OHG ("BPD") and Banque Paribas ("Banque Paribas").

RELEVANT ACT SECTIONS: Order requested under section 6(c) of the Act from section 17(f).

SUMMARY OF APPLICATION: Applicants request an order that would permit registered management investment companies for which BPD acts as foreign custodian or subcustodian (other than investment companies registered under section 7(d)) ("Investment Companies") to maintain their foreign securities and other assets in the custody of BPD.

FILING DATES: The application was filed on December 15, 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 February 20, 1996, 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 may request notification of a hearing by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street, N.W., Washington, D.C. 20549. Applicants, Banque Paribas (Deutschland) OHG, Grüneburgweg 14. 60322 Frankfurt A.M., Germany, and Banque Paribas, 3 rue d'Antin, 75002 Paris, France.

FOR FURTHER INFORMATION CONTACT: James M. Curtis, Senior Counsel, at (202) 942–0563, or Robert A. Robertson, Branch Chief, at (202) 942–0564 (Office of Investment Company Regulation, Division of Investment Management).

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. BPD, a general partnership organized under German law, is licensed and regulated as a banking institution under the laws of Germany. Banque Paribas, organized under the laws of France as a stock corporation, is one of the three general partners of BPD. The other general partners of BPD are Paribas Deutschland B.V., organized under the laws of The Netherlands as a limited liability corporation, and Paribas Verwaltungs-und Beteiligungesellschaft mbH, organized under the laws of Germany as a limited liability corporation. Both are subsidiaries of Banque Paribas. Under German law, each partner of BPD is jointly and severally liable to the creditors of BPD.

2. According to its partnership agreement (the "Partnership Agreement"), the scope of BPD's permissible business covers all segments of the banking business permitted for banking institutions by the *Bundesaufscichtsamt für das Kreditwesen* (the "BAK"). BAK has specifically authorized BPD to engage in all banking activities contemplated by the German Federal Banking Act, including, among others, deposit taking, lending, securities activities, guarantee, and custodianship activities. BPD currently maintains sizable activities in all such areas, including the custody of securities. As of December 31, 1994, BPD had assets in excess of U.S. $1.1 billion and partners' equity of approximately U.S. $69.4 million.

3. One hundred percent of Banque Paribas's voting rights and 98.5% of its equity is owned, directly and indirectly, by Compagnie Financiere de Paribas ("Paribas"), a leading French and international financial institution. At December 31, 1994, Banque Paribas had total consoldiated assets of approximately U.S.$175.7 billion, and consolidated shareholders' equity of approximately U.S.$3.4 billion (excluding minority interests). At December 31, 1994, Paribas had total consolidated assets of approximately U.S.$242.2 billion, and consolidated shareholders' equity of approximately U.S.$8.1 billion (excluding minority interests).

4. Banque Paribas recently acquired the custodial services business of J.P. Morgan in several European countries, including Germany. As a result of this transaction, BPD acquired the systems, the computer hardware and software, and the personnel dedicated to J.P. Morgan's German custodial services operations.

5. Applicants request an order under section 6(c) of the Act exempting BPD, Banque Paribas, and any Investment Company for which BPD acts as custodian or subcustodian, from section 17(f) of the Act. The order would permit BPD, as custodian of the securities and other assets of an Investment Company (the "Securities")[1] or as subcustodian of such Securities, to accept deposits of such Securities in Germany, but only under an agreement in which Banque Paribas assumes responsibility for certain losses of Securities held by BPD as custodian or subcustodian.

Applicants' Legal Analysis

1. Section 17(f) of the Act provides that an Investment Company may place and maintain its securities and similar assets in the custody of (a) a bank or banks meeting the requirements of section 26(a) of the Act, (b) a member firm of a national securities exchange, (c) the Investment Company itself, or (d) a system for the central handling of securities established by a national securities exchange or national securities association registered with the SEC. BPD does not fall within the definition of "bank" as that term is defined in the Act.[2]

2. Rule 17f–5 permits an Investment Company to deposit Securities with an "eligible foreign custodian," as defined therein. Such custodian, includes among other institutions, a banking institution or trust company incorporated or organized under the laws of a country other than the United States that is regulated as such by that country's government and that has shareholders' equity in excess of U.S. $200,000,000 (or equivalent). Banque Paribas qualifies as an "eligible foreign custodian" under rule 17f–5. BPD, however, does not currently quality as an "eligible foreign custodian" because it does not meet the minimum shareholders' equity requirement.

3. Section 6(c) of the Act provides that the SEC may exempt any person from the provisions of the Act or any rules thereunder if and to the extent such exemption is necessary or appropriate in the public interest, consistent with the protection of investors, and consistent with the purposes fairly intended by the policy and provisions of the Act.

4. Applicants believe that the proposed arrangements meet the section 6(c) standard. BPD and Banque Paribas believe that the Paribas Agreement would provide Investment Companies which deposit Securities with BPD in Germany with the safety and security of an eligible foreign custodian under section 17(f) and rule 17f–5.

Applicants' Conditions

The requested exemption would be subject to the following conditions:

1. The foreign custody arrangements with BPD will comply with the provisions of rule 17f–5 in all respects, except those relating to the minimum shareholders' equity requirements of eligible foreign custodians.

2. Banque Paribas currently satisfies and will continue to satisfy the minimum shareholders' equity requirement set forth in rule 17f–5(c)(2)(i).

3. An Investment Company or a custodian for an Investment Company will deposit Securities with BPD only in accordance with a three-party contractual agreement that will remain in effect at all times during which BPD fails to meet the requirement of rule 17f–5 relating to minimum shareholders' equity. Each agreement will be a three-party agreement among (a) Banque Paribas, (b) BPD, and (c) the Investment Company or custodian of the Securities of the Investment Company. Under the agreement, BPD will undertake to provide specified custodial or subcustodial services. The agreement will further provide that Banque Paribas will be liable for any loss, damage, cost, expense, liability, or claim arising out of or in connection with the performance by BPD of its responsibilities under the agreement to the same extent as if Banque Paribas had been required to provide custody services under such agreement.

[1] As used herein, the term "Securities" shall not include securities issued by the government of the United States or by any State or any political subdivision thereof or by any agency thereof or any securities issued by any entity organized under the laws of the United States or any State thereof (other than certificates of deposit, evidence of indebtedness and other securities, issued or guaranteed by an entity so organized which have been issued and sold outside the United States).

[2] Section 2(a)(5) of the Act defines a "bank" to include a banking institution organized under the laws of the United States, a member bank of the Federal Reserve System, and any other banking institution or trust company, whether incorporated or not, doing business under the laws of any State of the United States, a substantial portion of the business of which consists of receiving deposits or exercising fiduciary powers similar to those permitted for national banks under the authority of the Comptroller of the Currency, and which is supervised and examined by State or Federal authority having supervision over banks, and which is not operated for purposes of evading the provisions of the Act.

For the SEC, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–1638 Filed 1–29–96; 8:45 am]

BILLING CODE 8010–01–M

[Rel. No. IC–21697; 812–9824]

IDEX Fund, et al.; Notice of Application

January 23, 1996.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of Application for Exemption under the Investment Company Act of 1940 (the "Act").

APPLICANTS: IDEX Fund ("IDEX"), IDEX II Series Fund ("IDEX II"), IDEX Fund 3 ("IDEX 3"), WRL Series Fund, Inc. ("WRL"), (collectively, the "Existing Funds"), any future registered open-end management investment company, or series thereof, for which IDEX Management, Inc ("IMI"), InterSecurities. Inc ("ISI"), or Western Reserve Life Assurance Co. of Ohio ("Western Reserve," and together with IMI and ISI the "Investment Advisers") or any entity controlling, controlled by, or under common control with the Investment Advisors, acts as investment adviser (the "Future Funds," and together with the Existing Funds, the "Funds"), and the Investment Advisers.

RELEVANT ACT SECTIONS: Order requested under section 6(c) of the Act for an exemption from sections 13(a)(2), 18(f)(1), 22(f), and 22(g), and rule 2a–7 thereunder, under sections 6(c) and 17(b) of the Act for an exemption from section 17(a)(1), and under section 17(d) of the Act and rule 17d–1 thereunder to permit certain joint arrangements.

SUMMARY OF APPLICATION: Applicants request an order that would permit the Funds to enter into deferred compensation arrangements with their independent trustees.

FILING DATES: The application was filed on October 16, 1995 and amended on January 18, 1996.

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 February 20, 1996, 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 NW., Washington, DC 20549. Applicants, 201 Highland Avenue, Largo, Florida 34640.

FOR FURTHER INFORMATION CONTACT: Marianne H. Khawly, Staff Attorney, at (202) 942–0562, 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 at the SEC's Reference Branch.

Applicants' Representations

1. IDEX, IDEX II, and IDEX 3 are Massachusetts business trusts registered under the Act as open-end management investment companies. IDEX and IDEX II currently offer one series and eleven series of shares, respectively, that are continuously offered for sale to the general investing public. IDEX 3 currently consists of one series of shares but discontinued its sale to new investors effective June 15, 1990. WRL is a Maryland Corporation registered under the Act as an open-end management investment company. WRL currently offers eighteen series of shares, one of which is a money-market series, that are continuously offered for sale to insurance company separate accounts that fund variable annuity contracts.

2. Each of the Investment Advisers is registered under the Investment Advisers Act of 1940. IMI is the investment adviser of IDEX, IDEX 3, and the following five IDEX II portfolios: Growth Portfolio, Global Portfolio, Flexible Income Portfolio, Balanced Portfolio, and Capital Appreciation Portfolio. ISI is the investment adviser to the remaining six IDEX II portfolios: Tax-Exempt Portfolio, Income Plus Portfolio, Aggressive Growth Portfolio, Equity Income Portfolio, Tactical Asset Allocation Portfolio, and C.A.S.E. Portfolio. Western Reserve is the investment adviser to each of the WRL portfolios.

3. Each Existing Fund has a board of trustees/directors (collectively, the "boards"), a majority of the members of which are not "interested persons" (the "Independent Trustees") of such Existing Fund within the meaning of section 2(a)(19) of the Act. The boards of IDEX, IDEX II, and IDEX 3 currently consist of the same seven persons, five of whom are Independent Trustees. Each of the five Independent Trustees currently is entitled to receive a total annual retainer of $13,000 of which IDEX, IDEX II, and IDEX 3 each pay a pro rata share based on its relative net assets. In addition, each of the five Independent Trustees receives $1,250 plus reimbursement for incidental expenses for each IDEX II board meeting attended and $500 plus reimbursement for incidental expenses for each IDEX or IDEX 3 board meeting attended.[1] The board of WRL currently consists of five persons, three of whom are Independent Trustees. Each WRL Independent Trustee is entitled to receive an annual fee of $6,000, and $500 for each board meeting attended plus reimbursement for incidental expenses.

4. Applicants request an order to permit the Independent Trustees to elect to defer receipt of all or a portion of their trustees' fees pursuant to a deferred compensation plan (the "Plan") and related election agreement (the "Agreement") entered into between each Independent Trustee and the appropriate Fund. Under the Plan, the Independent Trustee could defer payment of trustees' fees (the "Deferred Compensation") in order to defer payment of income taxes, or for other reasons.

5. Under the Plan, the deferred fees payable by a Fund to a participating Independent Trustee (a "Participant") will be credited to a book reserve account established by the Fund (an "Account"), as of the date such fees would have been paid to such Independent Trustee. The value of the Account as of any date will be determined by reference to a hypothetical investment in Class A shares of one or more portfolios of IDEX II ("Underlying Securities"), as selected by a Participant.

6. The election to participate in the Plan must be made on or before September 30 preceding the calendar year during which the amounts to be deferred, absent deferral, would be paid to the Participant. The Plan's effective date is January 1, 1996. In order to facilitate implementation of the Plan, a

[1] The boards of IDEX, IDEX II, and IDEX 3 have adopted a policy whereby any Independent Trustee in office on September 1, 1990 who has served at least three years may, subject to certain limitations, elect upon his or her resignation to serve as a trustee emeritus. A trustee emeritus has no authority, power, or responsibility with respect to any IDEX, IDEX II, or IDEX 3 matter. A trustee emeritus, however, is entitled to receive an annual fee equal to one-half the fee then payable per annum to the Independent Trustees of the Fund or Funds from which he or she resigned, plus reimbursement of expenses incurred for attendance at board meetings.

Participant may elect to defer fees payable during 1996 no later than January 30, 1996. An individual who becomes a Participant after the effective date of the Plan may make a deferral election with respect to fees that, absent deferral, would be paid to him or her during the remainder of the calendar year in which he or she becomes a Participant on or before the date that is 30 days after the date on which he or she becomes a Participant.[2]

7. The initial value of Deferred Compensation credited to an Account will be effected at the respective current net asset value of each Fund. Thereafter, the value of such Account will fluctuate as the net asset value of the shares of each Fund fluctuates and also will reflect the value of assumed reinvestment of dividends and capital gains distributions from each Fund in additional shares of such Fund.

8. The Funds' respective obligations to make payments of amounts accrued under the Plan will be general unsecured obligations, payable solely from their respective general assets and property. The Plan provides that the Funds will be under no obligation to purchase, hold or dispose of any investments under the Plan, but, if one or more of the Funds choose to purchase investments to cover their obligations under the Plan, then any and all such investments will continue to be a part of the respective general assets and property of such Funds.

9. As a matter of prudent risk management, to the extent a Participant selects Underlying Securities of a Fund other than the Fund for which the Participant is deferring his or her trustee's fees, each Fund intends in all cases to, and with respect to any money market Fund or portfolio that values its assets by the amortized cost method will, purchase and maintain Underlying Securities in amounts equal in value to the deemed investments of the Account of its Participants. Thus, in cases where the Funds purchase shares of the Underlying Securities, liabilities created by the credits to the Accounts under the Plan are expected to be matched by an equal amount of assets (i.e., a direct investment in Underlying Securities), which assets would not be held by the Fund if trustees' fees were paid on a current basis.

[2] Until such time as an order is granted with respect to the application, Deferred Compensation will be credited to an Account in the form of cash, and each Account shall be deemed to earn interest at an annual rate, effective on each January 1, determined by the committee established by the boards to administer the Plan. The initial interest rate shall be a rate equal to the yield on 90-day U.S. Treasury Bills.

10. Payments under the Plan will be made in one lump sum or in quarterly installments (not to exceed 40) as the Independent Trustee elects. Upon application by an Independent Trustee and a determination by the board or such person(s) as the board may designate from time to time (the "Plan Administrator") that the Independent Trustee has suffered a severe financial hardship resulting from an unanticipated emergency caused by an event beyond the control of the Independent Trustee, the Plan Administrator shall distribute to the Trustee, in a single lump sum, an amount equal to the lesser of the amount needed by the Independent Trustee to meet the hardship, or the balance of the Trustee's Account.

11. In the event of a Participant's death, amounts payable under the Plan will thereafter be payable to the Participant's designated beneficiaries. In all other events, a Participant's right to receive payments will be nontransferable. In the event of the liquidation, dissolution, or winding up of a Fund or the distribution of all or substantially all of a Fund's assets and property to its shareholders (unless the Fund's obligations under the Plan have been assumed by a financially responsible party purchasing such assets) or in the event of a merger or reorganization of a Fund (unless prior to such merger or reorganization, the Fund's Board determines that the Plan shall survive the merger or reorganization), all unpaid amounts in the Accounts maintained by such Fund shall be paid in a lump sum to the Participants on the effective date thereof.[3] The Plan will not obligate any participating Fund to retain a trustee in such a capacity, nor will it obligate any Fund to pay any (or any particular level of) trustees' fees to any trustee.

Applicants' Legal Analysis

1. Applicants request an order which would exempt the Funds: (a) under section 6(c) of the Act from sections 13(a)(2), 18(f)(1), 22(f), and 22(g), and rule 2a–7 thereunder, to the extent necessary to permit the Funds to adopt and implement the Plan; (b) under sections 6(c) and 17(b) of the Act from section 17(a)(1) to permit the Funds to sell securities for which they are the issuer to participating Funds in connection with the Plan; and (c) under section 17(d) of the Act and rule 17d–1 thereunder to permit the Funds to effect certain joint transactions incident to the Plan.

2. Section 18(f)(1) generally prohibits a registered open-end investment company from issuing senior securities. Section 13(a)(2) requires that a registered investment company obtain shareholder authorization before issuing any senior security not contemplated by the recitals of policy in its registration statement. Applicants state that the Plan possesses none of the characteristics of senior securities that led Congress to enact these sections. The Plan would not: (a) induce speculative investments or provide opportunities for manipulative allocation of any Fund's expenses or profits; (b) affect control of any Fund; or (c) confuse investors or convey a false impression as to the safety of their investments. All liabilities created under the Plan would be offset by equal amounts of assets that would not otherwise exist if the fees were paid on a current basis.

3. Section 22(f) prohibits undisclosed restrictions on transferability or negotiability of redeemable securities issued by open-end investment companies. The Plan would set forth all such restrictions, which would be included primarily to benefit the Participants and would not adversely affect the interests of the trustees or of any shareholder.

4. Section 22(g) prohibits registered open-end investment companies from issuing any of their securities for services or for property other than cash or securities. This provision prevents the dilution of equity and voting power that may result when securities are issued for consideration that is not readily valued. Applicants believe that the Plan would merely provide for deferral of payment of such fees and thus should be viewed as being issued not in return for services but in return for a Fund not being required to pay such fees on a current basis.

5. Rule 2a–7 imposes certain restrictions on the investments of "money market funds," as defined under the rule, that would prohibit a Fund that is a money market Fund from investing in the shares of any other Fund. Applicants believe that the requested exemption would permit the Funds to achieve an exact matching of Underlying Securities with the deemed investments of the Accounts, thereby ensuring that the deferred fees would not affect net asset value.

6. Section 6(c) provides, in relevant part, that the SEC may, conditionally or unconditionally, by order, exempt any person or class of persons from any provision of the Act or from any rule thereunder, if such exemption is

[3] Applicants acknowledge that the requested order would not permit a party acquiring a Fund's assets to assume a Fund's obligations under the Plan if such obligations would constitute a violation of the Act by the assuming party.

necessary or appropriate in the public interest, consistent with the protection of investors, and consistent with the purposes fairly intended by the policy and provisions of the Act. Applicants submit that the relief requested from the above provisions satisfies this standard.

7. Section 17(a)(1) generally prohibits an affiliated person of a registered investment company from selling any security to such registered investment company. Funds that are advised by the same entity are "affiliated persons" under section 2(a)(3)(C) of the Act by reason of being under common control. Applicants assert that section 17(a)(1) was designed to prevent, among other things, sponsors of investment companies from using investment company assets as capital for enterprises with which they were associated or to acquire controlling interest in such enterprises. Applicants submit that the sale of securities issued by the Funds pursuant to the Agreement does not implicate the concerns of Congress in enacting this section, but merely would facilitate the matching of each Fund's liability for deferred trustees' fees with the Underlying Securities that would determine the amount of such Fund's liability.

8. Section 17(b) authorizes the SEC to exempt a proposed transaction from section 17(a) if evidence establishes that the terms of the transaction, including the consideration to be paid or received, are reasonable and fair and do not involve overreaching on the part of any persons concerned, and the transaction is consistent with the policies of the registered investment company and the general purposes of the Act. Applicants assert that the proposed transaction satisfies the criteria of section 17(b). Applicants also request relief from section 17(a)(1) under section 6(c) to the extent necessary to implement the Deferred Compensation under the Plan and Agreement on an ongoing basis.

9. Section 17(d) and rule 17d–1 generally prohibit a registered investment company's joint or joint and several participation with an affiliated person in a transaction in connection with any joint enterprise or other joint arrangement or profit-sharing plan "on a basis different from or less advantageous than that of" the affiliated person. Participants will not receive a benefit, directly or indirectly, that would otherwise inure to a Fund or its shareholders. Participants will receive tax deferral but the Plan otherwise will maintain the parties, viewed both separately and in their relationship to one another, in the same position as if the deferred fees were paid on a current basis. When all payments have been made to a participant, the Participant will be no better off (apart from the effect of tax deferral) than if he or she had received trustees fees on a current basis and invested them in Underlying Securities.

Applicants' Conditions

Applicants agree that the order granting the requested relief shall be subject to the following conditions:

1. With respect to the requested relief from rule 2a–7, any money market Fund or any money market portfolio thereof that values its assets by the amortized cost method will buy and hold Underlying Securities that determine the value of the Accounts to achieve an exact match between the liability of any such Fund's or portfolio's liability to pay deferred fees and the assets that offset that liability.

2. If a Fund purchases Underlying Securities issued by an affiliated Fund, the Fund will vote such shares in proportion to the votes of all other shareholders of such affiliated Fund.

For the Commission, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–1637 Filed 1–29–96; 8:45 am]

BILLING CODE 8010–01–M

[Rel. No. IC–21700; 812–9928]

Van Kampen American Capital Global Managed Assets Fund, et al.; Notice of Application

January 24, 1996.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of application for exemption under the Investment Company Act of 1940 (the "Act").

APPLICANTS: Van Kampen American Capital Global Managed Assets Fund, Van Kampen American Capital Life Investment Trust, Van Kampen American Capital World Portfolio Series Trust (collectively, the "Funds"), Van Kampen American Capital Asset Management, Inc. (the "Adviser"), John Govett & Co. Limited ("Govett"), and John Govett Holdings Limited ("Govett Holdings").

RELEVANT ACT SECTIONS: Order requested under section 6(c) of the Act for an exemption from sections 15 (a) and (c) of the Act.

SUMMARY OF APPLICATION: Applicants request an order that would permit the implementation, without shareholder approval, of new sub-advisory agreements (each a "New Sub-Advisory Agreement") for a period of up to 120 days following the termination of the former sub-advisory contracts on December 29, 1995 (each a "Former Sub-Advisory Contract") (the "Interim Period"). The order also would permit the sub-adviser to receive from the Funds fees earned during the Interim Period after shareholders have approved the New Sub-Advisory Agreements. The order further would allow the implementation, without board of trustee approval, of the New Sub-Advisory Agreements, for a limited period of time.

FILING DATES: The application was filed on December 28, 1995, and amended on January 23, 1996.

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 February 19, 1996, 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 NW., Washington, DC 20549. Applicants, Transco Tower, 2800 Post Oak Boulevard, Houston, TX 77056.

FOR FURTHER INFORMATION CONTACT: Elaine M. Boggs, Staff Attorney, at (202) 942–0572, or Alison E. Baur, 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 at the SEC's Public Reference Branch.

Applicant's Representations

1. Each Fund is an open-end management investment company registered under the Act. The Adviser serves as investment adviser to each Fund and has engaged Govett to serve as subadviser in connection with non-U.S. securities held by the Funds pursuant to the Former Sub-Advisory Contracts. Govett is a United Kingdom corporation that is registered under the Investment Advisers Act of 1940 as an investment adviser.

2. On December 7, 1995, the former ultimate parent of Govett, London

Pacific Group Limited, entered into a sale and purchase agreement (the "Sale Agreement") with Govett Holdings. Under the Sale Agreement, Govett Holdings, an indirect newly-formed majority owned subsidiary of Allied Irish Banks p.l.c., acquired all of the outstanding capital shares of Govett. Govett Holdings has represented to the Adviser and the Funds' board of trustees that it does not intend to make any significant changes in the way Govett conducts its business.

3. The Sale Agreement was consummated on December 29, 1995, immediately after which the Former Sub-Advisory Contracts terminated. It is anticipated that proxy materials soliciting shareholder votes approving the New Sub-Advisory Agreements will be mailed to shareholders on or about February 5, 1996. Shareholder meetings are scheduled to take place on or about March 14, 1996. The terms and conditions of each New Sub-Advisory Agreement are identical in all respects to those of the Former Sub-Advisory Contracts, except for the effective and termination dates and a fee escrow provision. The New Sub-Advisory Agreements do not contemplate any changes in the nature of the service provided by Govett or the compensation to be paid by the Adviser to Govett.

4. On December 19, 1995, the board of trustees of each Fund approved the New Sub-Advisory Agreements between Govett and the Adviser. However, due to weather conditions, one of the non-interested trustees was unable to be present at the meeting and could only participate by telephone. Because a sufficient number of non-interested trustees was not present at this meeting, the New Sub-Advisory Agreements remain subject to approval by the non-interested trustees at in-person meetings. These meetings have been scheduled for January 25, 1996. At these meetings, it is anticipated that the trustees will confirm their approvals of the New Sub-Advisory Agreements on the basis that they are in the best interests of the Funds' shareholders and the interests of the Funds and their shareholders will not be diminished as a result of the transactions. Thus, the New Sub-Advisory Agreements should be recommended for approval by the Funds' shareholders.

5. The portion of the advisory fees received by the Adviser from each Fund and payable to Govett for services rendered during the Interim Period will be maintained in an interest-bearing escrow account. Amounts in the account will be paid to Govett only after approval by the non-interested trustees at the January meetings and by the shareholders of the New Sub-Advisory Agreements and receipt of the requested exemptive relief. The escrow agent would release the monies in each account as provided above, only upon receipt of a certificate of an officer of the Fund (none of who is an affiliate of Govett) stating, in the case where the monies are to be delivered to Govett, that the New Sub-Advisory Agreements have received the requisite non-interested trustee and shareholder votes or, in the case where the monies are to be returned to the Funds, that the Interim Period has ended. Before any such certificates were sent, the board of trustees of the relevant Fund would be notified.

Applicants' Legal Analysis

1. Applicants seek an exemption pursuant to section 6(c) from section 15(a) of the Act to permit the implementation, without shareholder approval, of the New Sub-Advisory Agreements during the Interim Period. Applicants also request relief so that Govett may receive all fees earned under the New Sub-Advisory Agreements during the Interim Period if and to the extent they are approved by the shareholders of a Fund. Applicants also seek relief from section 15(c) of the Act to permit the implementation of the New Sub-Advisory Agreements before approval by the board of trustees, which is expected to be given on January 25, 1996.

2. Section 15(a) prohibits an investment adviser from providing investment advisory services to a registered investment company except under a written contract that has been approved by a majority of the voting securities of such investment company.

Section 15(a) further requires that such written contract provide for its automatic termination in the event of an assignment. Section 2(a)(4) defines "assignment" to include any direct or indirect transfer of a contract by the assignor. The consummation of the Sale Agreement resulted in an "assignment," within the meaning of section 2(a)(4), of the Former Sub-Advisory Contracts, thereby resulting in the termination of each Former Sub-Advisory Contract, according to its terms.

3. Section 15(c) requires that all investment advisory contracts be approved by a majority of an investment company's trustees who are not interested persons of the investment adviser at an in-person meeting called for the purpose of voting on the approval of the advisory contract.

4. Section 6(c) provides, in relevant part, that the SEC may, conditionally or unconditionally, by order, exempt any person or class of persons from any provision of the Act or from any rule thereunder, if such exemption is necessary or appropriate in the public interest, consistent with the protection of investors, and consistent with the purposes fairly intended by the policy and provisions of the Act. Applicants submit that the requested relief meets this standard.

5. Applicants believe that the requested relief is necessary, as it would permit continuity of management notwithstanding the sale of Govett and the resulting assignment of the Former Sub-Advisory Contracts. Applicants state that obtaining shareholder approval prior to the consummation of the Sale Agreement was not possible due to the short period of time between the execution of the Sale Agreement and the anticipated closing date of the transaction. In addition, applicants believe that the Funds made a good faith effort to comply with section 15(c) by holding board of trustees meetings on December 19, 1995, which did not have the required number of non-interested trustees present due to factors beyond the Funds' control, namely the weather. Further, applicants state that the scope and quality of services provided by Govett to the Funds during the Interim Period will not be diminished, and each Fund will operate under its new Sub-Advisory Agreement, which is substantially the same as its Former Sub-Advisory Contract. Applicants believe that depriving Govett of fees for the Interim Period would be a harsh result and would serve no useful purpose.

Applicants' Conditions

Applicants expressly consent to the following conditions in connection with the request for exemptive relief:

1. The New Sub-Advisory Agreements will have the same terms and conditions as the Former Sub-Advisory Contracts, except for their effective and termination dates and fee escrow provisions.

2. The portion of the Adviser's fee payable by the Adviser to Govett under the New Sub-Advisory Agreements will be placed into interest-bearing escrow accounts by the Adviser immediately after receipt. The escrow arrangements will be established and maintained as follows: (a) Fees payable to Govett during the Interim Period under the New Sub-Advisory Agreements would be paid into interest-bearing escrow accounts maintained by the escrow agent; and (b) the amounts in the escrow accounts (including interest earned on fees paid) would be paid to Govett on behalf of a Fund only upon approval by

the non-interested members of the boards of trustees at in-person meetings and the Funds' shareholders of the New Sub-Advisory Agreements or, in the absence of such approval, returned to such Fund.

3. The Funds will hold in-person trustees' meetings in January, 1996 to confirm their December approval of the New Sub-Advisory Agreements. In addition, shareholder meetings will be held in March, 1996 to vote on the approval of the New Sub-Advisory Agreements, and such approvals will be obtained on or before the 120th day following the termination of the Former Sub-Advisory Contracts.

4. Govett Holdings will bear the costs of preparing and filing this request for exemptive relief and the costs related to the solicitation of shareholder approval of the Funds' shareholders necessitated by consummation of the Sales Agreement.

5. The Adviser will take all appropriate steps to ensure that the scope and quality of sub-advisory services provided to the Funds by Govett during the Interim Period will be at least equivalent, in the judgment of the respective boards of trustees, to the scope and quality of services previously provided by Govett. If there is a material change in the personnel providing material services to the Funds during the Interim Period, Govett and the Adviser will notify the respective Boards of Trustees of the affected Funds to ensure that they, including a majority of the non-interested trustees, are satisfied that the services provided will not be materially diminished in scope and quality.

For the Commission, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–1673 Filed 1–29–96; 8:45 am]

BILLING CODE 8010–01–M

[Rel. No. IC–21698; 812–9912]

Walnut Properties Limited Partnership, et al.; Notice of Application

January 23, 1996.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of application for an order under the Investment Company Act of 1940 (the "Act").

APPLICANTS: Walnut Properties Limited Partnership (the "Partnership"), and John J. Hansman ("Hansman") and Summit Investment Services, Inc. ("Summit") (collectively, the "General Partners").

RELEVANT ACT SECTIONS: Order requested under section 6(c) for an exemption from all provisions of the Act.

SUMMARY OF APPLICATION: Applicants request an order to permit the Partnership to invest in limited partnerships that engage in the ownership and operation of apartment complexes for low and moderate income persons.

FILING DATE: The application was filed on December 15, 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 February 20, 1996, 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 may request notification of a hearing by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street NW., Washington, D.C. 20549. Applicants, 600 Stewart Street, Suite 1704, Seattle, Washington 98101.

FOR FURTHER INFORMATION CONTACT: Marianne H. Khawly, Staff Attorney, at (202) 942–0654, 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 at the SEC's Public Reference Branch.

Applicants' Representations

1. The Partnership was formed as a Washington limited partnership on August 11, 1995. The Partnership will operate as a "two-tier" partnership, *i.e.*, the Partnership, as a limited partner, will invest in other limited partnerships (the "Property Partnerships"). The Property Partnerships will be managed by general partners (the "Developer General Partners") that are not affiliated with the Partnership or the General Partners. The Property Partnerships, in turn, will engage in the ownership and operation of apartment complexes ("Properties") expected to qualify for low income housing tax credits ("Credits") under the Internal Revenue Code of 1986 (the "Code").

2. The objectives of the Partnership are to: (a) provide tax benefits, including Credits and passive activity losses, which investors may use to offset their Federal income tax liabilities; (b) distribute proceeds from liquidation, sale, or refinancing transactions; and (c) to the extent permitted by the terms of applicable local, state, and/or federal government assistance, distribute cash from operating the Properties.

3. Units of limited partnership interest in the Partnership (the "Units") will be offered and sold without registration under the Securities Act of 1933 (the "Securities Act") in reliance on section 4(2) of the Securities Act and Regulation D thereunder. No Units will be sold unless subscriptions to purchase at least six Units (the "Minimum Offering") are received and accepted by the General Partners prior to September 30, 1996. If the Minimum Offering has not been sold by such date, no Units will be sold and all funds received from subscribers will be refunded with interest.

4. Until the Minimum Offering has been sold, offering proceeds will be deposited and held in trust for the benefit of purchasers in an escrow account with Seattle-First National Bank in Seattle, Washington, to be used only for the specific purposes set forth in the Confidential Private Placement Memorandum dated November 21, 1995 (the "Memorandum"). The Partnership intends to apply offering proceeds to the acquisition of limited partnership interests in the Property Partnerships as promptly as possible (although such proceeds may be invested temporarily in bank time deposits, certificates of deposit, money market accounts, and government certificates). The Partnership will not trade or speculate in temporary investment.

5. The Partnership will require that each purchaser of Units represent in writing that such purchase meets the applicable suitability standards. Each individual subscriber must represent that he or she has: (a) a net worth (exclusive of home, home furnishings, and automobiles) of at least $200,000 per Unit; or (b) a net worth (exclusive of home, home furnishings and automobiles) of not less than $125,000 per Unit and annual income of at least $100,000 ($75,000 in the case of a purchase of one-half of a Unit). Units will be sold in certain states only to persons who meet different standards, as set forth in the Memorandum. The Partnership will also allow certain corporate subscribers to purchase Units.

6. Although the Partnership will not have responsibility for the day-to-day management of the Properties, the Partnership's ownership of limited partnership interests in the Property Partnerships will, in an economic sense, be tantamount to direct ownership of each Property. Typically, the Partnership will acquire at least a 98% interest in the profits, losses, Credits, and cash flow of each Property Partnership. In addition, the General Partners anticipate that the Partnership will receive approximately 49.99% of any gain and residual proceeds generated by the Property Partnerships. A small percentage interest in these items will be allocated to Summit as the special limited partner, and the remaining interest in such items will be allocated to the Developer General Partner.

7. In some cases, however, the Partnership and Summit may acquire smaller aggregate percentage interests in a particular Property Partnership. In those cases where the Partnership acquires less than a 98% interest in the profits, losses, Credits, and cash flow of a Property Partnership: (a) the Partnership will own a minimum of 49.49% of such Property Partnership items; and (b) the balance of the limited partnership interest in such Property Partnership, after the allocation of a .01% interest to Summit, will be owned by a single affiliated "upper-tier" limited partnership of which Hansman and Summit will also be the general partners. Moreover, the Partnership's investment in any Property Partnership in which it owns less than 50% (but more than 49.49%) of the profits, losses, Credits, and cash flow will not constitute more than 15% of its aggregate investment in all Property Partnerships.

8. The Partnership and Summit will have rights under the terms of the limited partnership agreements for the Property Partnerships to consent to certain fundamental decisions, which will generally include: (a) the right to approve or disapprove any sale or refinancing of a Property; (b) the right to replace the Developer General Partner on the basis of the Developer General Partner's performance and discharge of its obligations; (c) any borrowing of money or encumbering of Property Partnership assets; (d) any change in identity of the Developer General Partner; (e) any tax elections; and (f) any admission of additional partners.

9. The Partnership will be managed by the General Partners pursuant to a partnership agreement (the "Partnership Agreement"). Holders of Units in the Partnership ("Investor Limited Partners"), consistent with their limited liability status, will not be entitled to participate in the control of the Partnership's business. However, a majority-in-interest of the Investor Limited Partners will have rights: (a) to amend the Partnership Agreement (subject to certain limitations; (b) to remove any General Partner and elect a replacement; (c) to dissolve the Partnership; (d) to consent to the sale or refinancing of a Property; and (e) to designate a replacement for Summit as the special limited partner of each Property Partnership. In addition, under the Partnership Agreement, each Investor Limited Partner is entitled to review all books and records of the Partnership.

10. The Partnership Agreement and Memorandum contain numerous provisions designed to ensure fair dealing by the General Partners with the Investor Limited Partners. All fees and compensation to be paid to the General Partners and their affiliates are specified in the Partnership Agreement and Memorandum. While the fees and other forms of compensation that will be paid to the General Partners and their affiliates will not have been negotiated at arm's length, applicants believe that the compensation and fees are reasonable and comparable to those that would be charged by third parties for the services provided by the General Partners and their affiliates.

11. The Partnership Agreement also contains various provisions designed to significantly reduce conflicts of interest between the Partnership and the General Partners and their affiliates. For example, in the event an investment in a Property Partnership becomes available which would satisfy the investment criteria of the Partnership and any other partnership in which the General Partners and/or their affiliates have an interest, the General Partners will analyze each opportunity in relation to the investment objectives of each partnership and will consider such factors as cash available for investment, maximum investment limit per acquisition, estimated income tax effects, leverage policies, any regulatory restrictions on investment policies, and the length of time funds have been available for investment. The General Partners will then determine which partnership should have the opportunity to make the particular investment and, if a particular investment is suitable for more than one partnership, the General Partners will recommend such investment to the partnership which has had the most funds available for investment for the longest period of time.

Applicants' Legal Analysis

1. Applicants believe that the Partnership is not an investment company under sections 3(a)(1) or 3(a)(3) of the Act. If the Partnership is deemed to be an investment company, however, applicants request an exemption under section 6(c) from all provisions of the Act.

2. Section 3(a)(1) of the Act provides that an issuer is an investment company if it is, or holds itself out as being, engaged primarily, or proposes to engage primarily, in the business of investing, reinvesting, or trading in securities. Applicants believe that the Partnership is not an investment company under section 3(a)(1) because the Partnership will be in the business of investing in, and being beneficial owner of, the Properties, not securities.

3. Section 3(a)(3) of the Act provides that an issuer is an investment company if it is engaged or proposes to engage in the business of investing, reinvesting, owning, holding, or trading in securities. and owns or proposes to acquire investment securities having a value exceeding 40% of the value of such issuer's total assets (exclusive of Government securities and cash items). Applicants believe that the Partnership's interests in the Property Partnerships should not be considered investment securities because such interests are not readily marketable, have no value apart from the value of the Properties owned by the Property Partnerships, and cannot be sold without severe adverse tax consequences.

4. Applicants believe that the two-tier structure is consistent with the purposes and criteria set forth in the SEC's release concerning two-tier real estate partnerships (the "Release").[1] The Release states that two-tier real estate partnerships that invest in limited partnerships engaged in the development and operation of housing for low and moderate income persons may qualify for an exemption from the Act under section 6(c). Section 6(c) provides that the SEC may exempt any person from any provision of the Act and any rule thereunder 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.

5. The Release lists two requirements, designed for the protection of investors, which must be satisfied by two-tier partnerships to qualify for an exemption

[1] Investment Company Act Release No. 8456 (Aug. 9, 1974).

under section 6(c). First, interests in the issuer should be sold only to persons for whom investments in limited profit, essentially tax-shelter, investments would not be unsuitable. Second, requirements for fair dealing by the general partner of the issuer with the limited partners of the issuer should be included in the basic organizational documents of the company.

6. Applicants state, among other considerations, that the suitability standards set forth in the Memorandum, the requirements for fair dealing provided by the Partnership Agreement, and pertinent governmental regulations imposed on each Property Partnership by various Federal, state, and local agencies provide protection to Unitholders comparable to that provided by the Act. In addition, applicants assert that the requested exemption is both necessary and appropriate in the public interest.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–1639 Filed 1–29–96; 8:45 am]

BILLING CODE 8010–01–M

DEPARTMENT OF TRANSPORTATION

Aviation Proceedings; Agreements Filed During the Week Ending January 19, 1996

The following Agreements were filed with the Department of Transportation under the provisions of 49 U.S.C 412 and 414. Answers may be filed within 21 days of date of filing.

Docket Number: OST–96–1004.

Date filed: January 18, 1996.

Parties: Members of the International Air Transport Association.

Subject: Application of IATA for Renewal of DOT Approval of Procedures Permitting Third Parties to Participate as Technical Advisers in Working Group Sessions of the Billing and Settlement Plan.

Paulette V. Twine,

Chief Documentary Services Division.

[FR Doc. 96–1619 Filed 1–29–96; 8:45 am]

BILLING CODE 4910–62–P

Notice of Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits Filed Under Subpart Q During the Week Ending January 19, 1996

The following Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits were filed under Subpart Q of the Department of Transportation's Procedural Regulations (See 14 CFR 302.1701 *et seq.*). The due date for Answers Conforming Applications or Motions to modify Scope are set forth below for each application. Following the Answer period DOT may process the application by expedited procedures. Such procedures may consist of the adoption of a show-cause order a tentative order or in appropriate cases a final order without further proceedings.

Docket Number: OST–96–1011.

Date filed: January 19, 1996.

Due Date for Answers Conforming Applications or Motions to Modify Scope: February 16, 1996.

Description: Application of Excalibur Airways Limited pursuant to 49 U.S.C. 41301, applies for a foreign air carrier permit to engage in the foreign charter air transportation of persons property and mail as follows:

—Between any point or points in the United Kingdom and any point or points in the United States either directly or via intermediate or beyond points in other countries with or without stopovers;

—Between any point or points in the United States and any point or points not in the United Kingdom or the United States; and

—Any other charter flights authorized pursuant to Part 212 of the Department's regulations.

Paulette V. Twine,

Chief, Documentary Services Division.

[FR Doc. 96–1620 Filed 1–29–96; 8:45 am]

BILLING CODE 4910–62–M

Operations by Canadian and Mexican Specialty Air Service Operators

AGENCY: Office of the Secretary, Department of Transportation.

ACTION: Order to Show Cause, Docket OST–96–1021, Order 96–1–28.

SUMMARY: The Department is inviting comments on its tentative decision to grant Canadian and Mexican "specialty air service" operators a blanket foreign aircraft permit under 14 CFR Part 375 to conduct such operations in the United States, to the extent the operations covered under the North American Free Trade Agreement (NAFTA). The specific specialty air services involved are: aerial mapping, aerial surveying, aerial photography, forest fire management, fire fighting, aerial advertising, glider towing, parachute jumping, aerial construction, heli-logging, aerial sightseeing, flight training, aerial inspection and surveillance, and aerial spraying services. NAFTA provides for the operation of these services on a phase-in basis, with coverage for some services already effective, and coverage for others becoming effective at various times through January 1, 2000. The blanket foreign aircraft permit the Department proposes would remove the present requirement that operators obtain prior Department approval, on a contract-by-contract basis, before conducting those specialty air services that are provided for and for which coverage has become effective under NAFTA. The authority would be subject to each operator's compliance with applicable regulations and procedures of the Federal Aviation Administration, and would be effective until further order of the Department.

DATES: Objections to the issuance of a final order in this proceeding are due: February 7, 1996. If objections are filed, answers to objections are due: February 14, 1996. Persons filing pleadings should contact the Department's Foreign Air Carrier Licensing Division at the telephone number listed below for a list of persons to be served with objections and answers to objections.

ADDRESSES: All documents in this proceeding, with appropriate filing copies, should be filed in Docket OST–96–1021, addressed to Central Docket Management Facility, U.S. Department of Transportation, Room PL401, 400 Seventh Street SW., Washington, D.C. 20590.

FOR FURTHER INFORMATION CONTACT: George Wellington, Foreign Air Carrier Licensing Division, U.S. Department of Transportation, Room 6412, 400 Seventh Street, SW., Washington, DC. 20590. Telephone (202) 366–2391.

Dated: January 24, 1996.

Mark L. Gerchick,

Acting Assistant Secretary for Aviation and International Affairs.

[FR Doc. 96–1655 Filed 1–29–96; 8:45 am]

BILLING CODE 4910–62–P

Coast Guard

[CGD 95–074]

Oil Spill Removal Organization Classification Guidelines

AGENCY: Coast Guard, DOT.

ACTION: Notice of availability.

SUMMARY: The Coast Guard has developed revised Oil Spill Removal Organization (OSRO) guidelines to facilitate the preparation and approval of facility or vessel response plans required under the Oil Pollution Act. The revised OSRO guidelines make

fundamental changes in the Coast Guard's OSRO classification process.

The OSRO guidelines replace Navigation and Vessel Circular (NVIC) 12–92, Guidelines for the Classification and Inspection of Oil Spill Removal Organizations. This notice announces the availability of the revised OSRO guidelines.

EFFECTIVE DATE: The revised OSRO guidelines are effective December 28, 1995.

ADDRESSES: Copies of the revised OSRO guidelines may be obtained by contacting the National Maritime Center at (703) 235–0018. Facsimile requests should be sent to (703) 235–1062 and written requests should be addressed to: Publications, National Maritime Center, 4200 Wilson Blvd., Suite 510, Arlington, VA 22203–1804. The document is also available through the World Wide Web at: http://www.starsoftware.com/uscgnmc/nmc/

FOR FURTHER INFORMATION CONTACT: Specific questions regarding the revised OSRO guidelines should be directed to LT Terry Hoover, Response Division (G–MRO), U.S. Coast Guard, 2100 Second Street SW., Washington, DC, 20593–0001, telephone (202) 267–0448.

Dated: January 24, 1996.

J. C. Card,

Rear Admiral, U.S. Coast Guard, Chief, Office of Marine Safety, Security and Environmental Protection.

[FR Doc. 96–1758 Filed 1–29–96; 8:45 am]

BILLING CODE 4910–14–M

Federal Aviation Administration

Approval of the Noise Compatibility Program for Glendale Municipal Airport, Glendale, Arizona

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces its findings on the Noise Compatibility Program for the Glendale Municipal Airport, submitted by the city of Glendale, Arizona, under the provisions of Title I of the Aviation Safety and Noise Abatement Act of 1979 (Public Law 96–193) (hereinafter referred to as "the Act") and 14 CFR Part 150. These findings are made in recognition of the description of Federal and nonfederal responsibilities in Senate Report No. 96–52 (1980). On July 5, 1994, the FAA determined that the Noise Exposure Maps, submitted by the city under 14 CFR Part 150, were in compliance with applicable requirements. On December 27, 1995, the Associate Administrator for Airports approved the Noise Compatibility Program for Glendale Municipal Airport. All sixteen (16) proposed noise abatement, land use management and program management measures were approved.

EFFECTIVE DATE: The effective date of the FAA's approval of the Noise Compatibility Program for Glendale Municipal Airport is December 27, 1995.

FOR FURTHER INFORMATION CONTACT: David B. Kessler, Environmental Protection Specialist, Airport Division, AWP–611.2, Federal Aviation Administration, Western-Pacific Region. Mailing address: P.O. Box 92007, Worldway Postal Center, Los Angeles, California 90009–2007. Telephone number: (310) 725–3615. Street address: 15000 Aviation Boulevard, Hawthorne, California 90261. Documents reflecting this FAA action may be reviewed at this same location.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA has given its overall approval of the Noise Compatibility Program for Glendale Municipal Airport, effective December 27, 1995. Under Section 104(a) of the Aviation Safety and the Noise Abatement Act of 1979 (hereinafter referred to as the "Act"), an airport operator who has previously submitted a Noise Exposure Map may submit to the FAA a Noise Compatibility Program which sets forth the measures taken or proposed by the airport operator for the reduction of existing noncompatible land uses and prevention of additional noncompatible land uses within the area covered by the Noise Exposure Maps. The Act requires such programs to be developed in consultation with interested and affected parties including local communities, government agencies, airport users, and FAA personnel.

Each airport Noise Compatibility Program developed in accordance with Federal Aviation Regulations (FAR) Part 150 is a local program, not a Federal Program. The FAA does not substitute its judgment for that of the airport proprietor with respect to which measures should be recommended for action. The FAA's approval or disapproval of FAR Part 150 program recommendations is measured according to the standards expressed in Part 150 and the Act, and is limited to the following determinations:

a. The Noise Compatibility Program was developed in accordance with the provisions and procedures of FAR Part 150;

b. Program measures are reasonably consistent with achieving the goals of reducing existing noncompatible land uses around the airport and preventing the introduction of additional non compatible land uses;

c. Program measures would not create an undue burden on interstate or foreign commerce, unjustly discriminate against types or classes of aeronautical uses, violate the terms of airport grant agreements, or intrude into areas preempted by the Federal government and;

d. Program measures relating to the use of flight procedures can be implemented within the period covered by the program without derogating safety, adversely affecting the efficient use and management of navigable airspace and air traffic control responsibilities of the Administrator prescribed by law.

Specific limitations with respect to FAA's approval of an Airport Noise Compatibility Program are delineated in FAR Part 150, Section 150.5. Approval is not a determination concerning the acceptability of land uses under Federal, State or local law. Approval does not, by itself, constitute an FAA implementation action. A request for Federal action or approval to implement specific Noise Compatibility Measures may be required and an FAA decision on the request may require an environmental assessment of the proposed action. Approval does not constitute a commitment by the FAA to financially assist in the implementation of the program nor a determination that all measures covered by the program are eligible for grant-in-aid funding from the FAA under the Airport and Airway Improvement Act of 1982, as amended. Where Federal funding is sought, requests for project grants must be submitted to the FAA Airports Division Office in Hawthorne, California.

The city of Glendale submitted to the FAA on May 12, 1994, the noise exposure maps, descriptions, and other documentation produced during the noise compatibility planning study conducted from October 5, 1993 through January 12, 1995. The Glendale Municipal Airport noise exposure maps were determined by FAA to be in compliance with applicable requirements on July 5, 1994. Notice of this determination was published in the Federal Register on July 26, 1994.

The Glendale Municipal Airport study contained a proposed Noise Compatibility Program comprised of actions designed for phased implementation by airport management and adjacent jurisdictions from the date of study completion to the year 1999. It

was requested that the FAA evaluated and approve this material as a Noise Compatibility Program as described in section 104(b) of the Act. The FAA began its review of the program on June 30, 1995 and was required by a provision of the Act to approve or disapprove the program within 180-days (other than the use of new flight procedures for noise control). Failure to approve or disapprove such program within the 180-day period shall be deemed an approval of such program.

The submitted program contained sixteen (16) proposed actions for noise mitigation on and off the airport. The FAA completed its review and determined that the procedural and substantive requirements of the Act and FAR Part 150 have been satisfied. The overall program, therefore, was approved by the Associate Administrator for Airports effective December 27, 1995.

Outright approval was granted for all sixteen (16) specific program measures. The approved measures included such items as encouraging right turns on the upwind leg of Runway 1 local traffic pattern; Encourage use of straight-out VFR departures from Runway 19; Right turns for VFR departures from Runway 1; establishment of an informal runway use program; Encourage use of AOPA and NBAA noise abatement and departure/arrival procedures; adoption of noise-sensitive marketing policies; maintain existing general plan designations for compatible land uses in the airport influence area; retain existing compatible use zoning in the airport influence area; Encourage the Flood Control District to include airport noise impacts in priority setting system for flood control projects; Discourage rezoning to higher density residential zones in unincorporated areas of the airport influence area; encourage fair disclosure to future property owners; through rezoning process, prohibit homes in the 65 DNL and "runway approach areas"; acquisition of homes and undeveloped land within the 65 DNL noise contour; maintain a complaint response system, and review and update Noise Exposure Maps and the Noise Compatibility Program as necessary.

These determinations are set forth in detail in the Record of Approval endorsed by the Associate Administrator for Airports on December 27, 1995. The Record of Approval, as well as other evaluation materials, and the documents comprising the submittal are available for review at the FAA office listed above and at the administrative offices of the Glendale Municipal Airport, Glendale, Arizona.

Issued in Hawthorne, California on January 5, 1996.

Herman C. Bliss,

Manager, Airports Division, AWP–600, Western-Pacific Region.

[FR Doc. 96–1626 Filed 1–29–96; 8:45 am]

BILLING CODE 4910–13–M

Aviation Rulemaking Advisory Committee Meeting

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of public meeting.

SUMMARY: This notice announces a public meeting of the FAA's Aviation Rulemaking Advisory Committee to discuss rotorcraft issues, current rulemaking actions, and future activities and plans.

DATES: The meeting will be held on February 21, 1996, 9 a.m.–12 noon. Arrange for oral presentations by February 6, 1996.

ADDRESSES: The meeting will be held at the Dallas Convention Center, Room C254, 650 S. Griffin St., Dallas, TX 75202.

FOR FURTHER INFORMATION CONTACT: Ms. Barbara Herber, Office of Rulemaking, Aircraft & Airport Rules Division, ARM–200, 800 Independence Avenue SW., Washington, DC 20591, telephone (202) 267–3498.

SUPPLEMENTARY INFORMATION: The referenced meeting is announced pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463; 5 U.S.C. App. II). The agenda will include:

1. Presentation of the status reports on the final rules resulting from the ARAC recommendations on "Occupant Protection" Notice of Proposed Rulemaking (NPRM) 94–8 (59 FR 17156) and "Rotorcraft Regulatory Changes Based on European Joint Airworthiness Requirements" NPRM 94–36 (59 FR 67068).

2. Presentation of the "Work Plan" and the "Concept Brief" for Normal Category Gross Weight and Passenger Issues.

3. Presentation of the status reports on each of the tasks listed below:

a. Harmonization of Miscellaneous Rotorcraft Regulations.

b. Critical parts.

c. Performance and Handling Qualities Requirements.

d. Class D External Loads.

Attendance is open to the public but will be limited to the space available. The public must make arrangements by February 6, 1996, to present oral statements at the meeting. Written statements may be presented to the committee at any time by providing 16 copies to the Assistant Chair or by providing the copies to him at the meeting. In addition, sign and oral interpretation, as well as a listening device, can be made available at the meeting if requested 10 calendar days before the meeting. Arrangements may be made by contacting the person listed under the heading **FOR FURTHER INFORMATION CONTACT.**

Issued in Washington, DC, on January 24, 1996.

Chris A. Christie,

Executive Director, Aviation Rulemaking Advisory Committee.

[FR Doc. 96–1736 Filed 1–29–96; 8:45 am]

BILLING CODE 4910–13–M

RTCA, Inc., Special Committee 185; Aeronautical Spectrum Planning Issues

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 185 meeting to be held on February 28–29, 1996, starting at 9:00 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 Remarks; (2) Introductions; (3) Review and Approval of the Agenda; (4) Review and Approval of the Summary of the Previous Meeting; (5) Review Draft Version 6 of SC–185 Report; (6) Develop Conclusions and Recommendations; (7) Other Business; (8) 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 January 23, 1996.

Janice L. Peters,

Designated Official.

[FR Doc. 96–1621 Filed 1–29–96; 8:45 am]

BILLING CODE 4810–13–M

RTCA, Inc., Joint RTCA Special Committee 180 and EUROCAE Working Group 46 Meeting; Design Assurance Guidance for Airborne Electronic Hardware

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 joint RTCA Special Committee 180 and EUROCAE Working Group 46 meeting to be held March 19–21, 1996, starting at 8:30 a.m. on March 19. (On subsequent days, meeting begins at 8 a.m.) The meeting will be held at EUROCAE, rue Hamelin 17, Paris, France.

The agenda will be as follows: (1) Chairman's Introductory Remarks; (2) Review and Approval of Meeting Agenda; (3) Review and Approval of Minutes of Previous Joint Meeting; (4) Leadership Team Meeting Report; (5) Consensus Items; (6) Review Action Items; (7) Review Issue Logs; (8) Review Document by Section in Plenary; (9) Other Business; (10) Agenda for Next Meeting; (10) 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 January 23, 1996.

Janice L. Peters,

Designated Official.

[FR Doc. 96–1622 Filed 1–29–96; 8:45 am]

BILLING CODE 4810–13–M

RTCA, Inc.; Aviation Systems Design Guidelines for Open Systems Interconnection (OSI)

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 the Special Committee 162 meeting to be held February 27–29, 1996, starting at 9:00 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) Chairman's Introductory Remarks; (2) Approval of Proposed Meeting Agenda; (3) Approval of the Minutes of the Previous Meeting; (4) Reports of Related Activities Being Conducted by Other Organizations; (5) Review of "ATN Avionics MOPS"; (6) Other Business; (7) 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, N.W., 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 January 23, 1996.

Janice L. Peters,

Designated Official.

[FR Doc. 96–1623 Filed 1–29–96; 8:45 am]

BILLING CODE 4810–13–M

Passenger Facility Charge (PFC) Approvals and Disapprovals

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Monthly Notice of PFC Approvals and Disapprovals. In December 1995, there were 12 applications approved. Additionally, three approved amendments to previously approved applications are listed.

SUMMARY: The FAA publishes a monthly notice, as appropriate, of PFC approvals and disapprovals under the provisions of 49 U.S.C. 40117 (Pub. L. 103–272) and Part 158 of the Federal Aviation Regulations (14 CFR Part 158). This notice is published pursuant to paragraph d of § 158.29.

PFC Applications Approved

Public Agency: City of Pensacola, Florida.

Application Number: 95–03–C–00–PNS.

Application Type: Impose and use a PFC.

PFC Level: $3.00.

Total Net PFC Revenue Approved in This Application: $2,536,000.

Charge Effective Date: December 1, 1995.

Estimated Charge Expiration Date: August 1, 1999.

Class of Air Carriers Not Required to Collect PFC's: Air taxi operators.

Determination: Approved. Based on information submitted in the public agency's application, the FAA has determined that the approved class accounts for less than 1 percent of the total annual enplanements at Pensacola Regional Airport.

Brief Description of Project Approved for Collection and Use: Expand terminal apron.

Brief Description of Project Partially Approved for Use: Expand passenger terminal building.

Determination: The FAA has analyzed all pertinent data submitted by the public agency and, based on the criteria in Advisory Circular 150/5360–13, *Planning and Design Guidelines for Airport Terminal Facilities,* it has determined that only two additional major airline gates or seven additional commuter gates, instead of the five major airline or eight commuter gates requested, are justified and Pensacola Regional Airport. This corresponds to a 12,225 square foot expansion instead of the 47,000 square feet proposed. Therefore, the FAA's approval is limited to the costs associated with a 12,225 square foot expansion.

Decision Date: December 1, 1995.

For Further Information Contact: Sandra A. Nazar, Orlando Airports District Office, (407) 648–6586.

Public Agency: Metropolitan Airports Commission, Minneapolis, Minnesota.

Application Number: 95–03–C–00–MSP.

Application Type: Impose and use a PFC.

PFC Level: $3.00.

Total Net PFC Revenue Approved in This Application: $32,700,000.

Charge Effective Date: June 1, 1998.

Estimated Charge Expiration Date: May 1, 1999.

Class of Air Carriers Not Required to Collect PFC's: Air Taxi/commercial operators filing FAA Form 1800–31.

Determination: Approved. Based on information submitted in the public agency's application, the FAA has determined that the approved class accounts for less than 1 percent of the total annual enplanements at Minneapolis-St. Paul International Airport.

Brief Description of Project Partially Approved for Collection And Use: Federal Inspection Service (FIS) facility.

Determination: Several elements of this project have been partially approved or disapproved. The relocation of the World Club, concessions, and the parts storage/air cargo building elements have been disapproved as ineligible terminal areas in accordance with paragraph 551(d)(1) of FAA Order 5100.38A, *Airport Improvement Program (AIP) Handbook.* Only those nonrevenue producing public-use areas that are directly related to the movement of passengers and baggage in air carrier and commuter service terminal facilities within the

boundaries of the airport are eligible. The cost of extinguishing the lease with Northwest Airlines is also eligible. However, the FAA's approval of the negotiated lease purchase with Northwest Airlines is limited to the extent that the amount requested does not exceed the appraised value of the lease hold, as supplied to the FAA by the Metropolitan Airports Commission and accepted by the FAA.

Decision Date: December 8, 1995.

For Further Information Contact: Gordon Nelson, Minneapolis Airports District Office, (612) 725–4358.

Public Agency: Niagara Frontier Transportation Authority, Buffalo, New York.

Application Number: 95–02–C–00–BUF.

Application Type: Impose and use a PFC.

PFC Level: $3.00.

Total Net PFC Revenue Approved in This Application: $5,942,858.

Charge Effective Date: December 1, 2004.

Estimated Charge Expiration Date: March 1, 2006.

Class of Air Carriers Not Required To Collect PFC's: Air taxi/commercial operators exclusively filing FAA Form 1800–31.

Determination: Approved. Based on information submitted in the public agency's application, the FAA has determined that the approved class accounts for less than 1 percent of the total annual enplanements at Greater Buffalo International Airport (BUF).

Brief Description of Projects Approved for Use at BUF: Acquisition and demolition of Airways Hotel and associated buildings, Demolition of American Airlines hangar and cargo building, New passenger terminal facility, Circulatory roadway system improvements.

Brief Description of Projects Approved for Collection and Use at BUF: Schematic design for overall airport development, Concept design for overall airport development, Value engineering for overall airport development, Environmental assessment for overall airport development, Rehabilitate north concourse ramps and apron, Purchase two snow blowers and purchase one roadway salter, Replace six-foot security fence, New passenger terminal facility utilities corridor, Purchase one dump truck, Radio system expansion, Purchase one rubber-blade snowplow.

Brief Description of Projects Approved for Collection at BUF and Use at Niagara Falls International Airport: Replace runway 28R/10L high intensity runway lights, Bucket loader with blade, Snow removal truck and blade, Airport runway broom, Snow and ice control equipment building.

Brief Description of Projects Approved for Collection at BUF: Purchase one front end loader, Pavement strengthening/taxiway C and perimeter road, Pavement overlay/taxiways D and F, Pavement study, Rehabilitation/ overlay runway 14/32.

Brief Description of Disapproved Projects: Pavement reconstruction/ aprons and taxiways.

Determination: Disapproved. The project schedule shown in the Attachment B for this project shows that the project will not meet the requirements of section 158.33 which requires implementation within 5 years of approval.

Airfield replacement vehicles.

Determination: Disapproved. The types of vehicles listed are not included in the types of vehicles considered AIP-eligible in Advisory Circular 150/5200–23, *Snow and Ice Control Equipment,* which limits eligibility to vehicles such as snowblowers, snowplows, spreaders, sweepers, and front end loaders. Therefore, this project does not meet the requriements of section 158.15(b)(1) and, thus, is not PFC eligible.

Decision Date: December 8, 1995.

For Further Information Contact: Philip Brito, New York Airports, District Office, (516) 295–9340.

Public Agency: City of Kansas City—Aviation Department, Kansas City, Missouri.

Application Number: 95–01–C–00–MCI.

Application Type: Impose and use a PFC.

PFC Level: $3.00.

Total Approved Net PFC Revenue: $64,043,000.

Estimated Charge Effective Date: March 1, 1996.

Estimated Charge Expiration Date: May 1, 2001.

Class of Air Carriers Not Required To Collect PFC's: Part 135 air taxis.

Determination: Approved. Based on information contained in the public agency's application, the FAA has determined that the approved class accounts for less than 1 percent of the total annual enplanements at Kansas City International Airport.

Brief Description of Projects Approved for Collection and Use: Paving of runway 1R/19L; taxiways E and F; and all connecting taxiways, Terminal remodel design phase, Taxiway D rehabilitation, Aircraft rescue and firefighting (ARFF) vehicles, Overlay runway 1L/19R, taxiway A, A1–A9, Terminal apron rehabilitation, Land acquisition, Terminal apron lights.

Brief Description of Projects Approved for Collection: Overlay runway 9/27 and taxiway C, C1–C9, Expand general aviation apron, Construct FIS facility, Overlay taxiway B, Terminal remodel—construction phase.

Decision Date: December 21, 1995.

For Further Information Contact: Lorna Sandrige, Central Region Airports Division, (816) 426–4730.

Public Agency: Broome County, Binghamton, New York.

Application Number: 95–02–C–00–BGM.

Application Type: Impose and use a PFC.

PFC Level: $3.00.

Total Net PFC Revenue Approved in This Application: $1,124,619.

Charge Effective Date: February 1, 1996.

Estimated Charge Expiration Date: September 1, 1998.

Class of Air Carriers Not Required To Collect PFC'S: No change from previous decision.

Brief Description of Projects Approved For Use: Land acquisition, Equipment replacement, Emergency access road construction.

Brief Description of Project Approved for Collection: Passenger terminal refurbishment, phase II.

Decision Date: December 21, 1995.

For Further Information Contact: Philip Brito, New York Airports District Office, (516) 227–3803.

Public Agency: Westmoreland County Airport Authority, Latrobe, Pennsylvania.

Application Number: 94–01–C–00–LBE.

Application Type: Impose and use a PFC.

PFC Level: $3.00.

Total Approved Net PFC Revenue: $187,266.

Estimated Charge Effective Date: March 1, 1996.

Estimated Charge Expiration Date: October 1, 1998.

Class of Air Carriers Not Required To Collect PFC'S: None.

Brief Description of Projects Approved for Collection and Use: Passenger facility charge application, Airline terminal building rehabilitation and expansion (phase I), Runway 3–21 overlay, ARFF vehicle/apron expansion, Airport signage; access road; snow removal equipment; and pipe replacement, Airport maintenance building expansion.

Decision Date: December 21, 1995.

For Further Information Contact: L. W. Walsh, Harrisburg Airports District Office, (717) 975–3423.

Public Agency: Milwaukee County Airports Division, Milwaukee, Wisconsin.

Application Number: 95–03–C–00–MKE.

Application Type: Impose and use a PFC.

PFC Level: $3.00.

Total Net PFC Revenue Approved in This Application: $32,037,000.

Charge Effective Date: April 1, 1999.

Estimated Charge Expiration Date: April 1, 2002.

Class of Air Carriers Not Required To Collect PFC'S: Air taxi/commercial operators.

Determination: Approved. Based on information submitted in the public agency's application, the FAA has determined that the approved class accounts for less than 1 percent of the total annual enplanements at General Mitchell International Airport (MKE).

Brief Description of Projects Approved for Collection and Use at MKE: Environmental impact statement, West perimeter fencing replacement, Noise mitigation program—phase 1, Sound insulation of schools and churches, West perimeter road repair, Hutsteiner Service Road repairs, Pave taxiway B shoulder, PFC administrative cost.

Brief Description of Project Approved for Collection at MKE and Use at Lawrence J. Timmerman Airport: Master plan update.

Brief Description of Projects Approved for Collection at MKE: Runway 7L/25R extension, Surface movement guidance control system, School/church sound insulation—phase II.

Decision Date: December 21, 1995.

For Further Information Contact: Franklin D. Benson, Minneapolis Airports District Office, (612) 725–4221.

Public Agency: County of Sheridan, Sheridan, Wyoming.

Application Number: 95–01–C–00–SHR.

Application Type: Impose and use a PFC.

PFC Level: $3.00.

Total Net PFC Revenue Approved in This Application: $211,299.

Charge Effective Date: March 1, 1996.

Estimated Charge Expiration Date: September 1, 2001.

Class of Air Carriers Not Required To Collect PFC'S: None.

Brief Description of Projects Approved for Collection and Use: Airport planning studies, ARFF improvements,

Construct new runway 14/32 including parallel taxiway B.

Decision Date: December 21, 1995.

For Further Information Contact: Chris Schaffer, Denver Airports District Office, (303) 286–5525.

Public Agency: Parish of East Baton Rouge and City of Baton Rouge, Baton Rouge, Louisiana.

Application Number: 96–03–C–00–BTR.

Application Type: Impose and use a PFC.

PFC Level: $3.00.

Total Approved Net PFC Revenue: $840,899.

Earliest Charge Effective Date: May 1, 1998.

Estimated Charge Expiration Date: December 1, 1998.

Class of Air Carriers Not Required To Collect PFC'S: No change to previous approvals.

Brief Description of Project Approved for Collection and Use: Terminal building plans and specifications.

Brief Description of Project Approved for Use: Terminal concept study.

Decision Date: December 27, 1995.

For Further Information Contact: Ben Guttery, Southwest Region Airports Division, (817) 222–5614.

Public Agency: County of Eagle, Colorado.

Application Number: 95–02–C–00–EGE.

Application Type: Impose and use a PFC.

PFC Level: $3.00.

Total Approved Net PFC Revenue: $381,276.

Earliest Charge Effective Date: March 1, 1996.

Estimated Charge Expiration Date: March 1, 2000.

Class of Air Carriers Not Required To Collect PFC'S: None.

Brief Description of Projects Approved for Collection and Use: Terminal project, Land acquisition for runway protection zone, Install approach light system to runway 25.

Decision Date: December 28, 1995.

For Further Information Contact: Chris Schaffer, Denver Airports District Office, (303) 286–5525.

Public Agency: Sacramento County Department of Airports, Sacramento, California.

Application Number: 95–02–C–00–SMF.

Application Type: Impose and use a PFC.

PFC Level: $3.00.

Total Approved Net PFC Revenue: $7,327,560.

Earliest Charge Effective Date: January 1, 1996.

Estimated Charge Expiration Date: March 1, 1997.

Class of Air Carriers Not Required To Collect PFC'S: None.

Brief Description of Projects Approved for Collection and Use: Terminals and concourse 1 and 2 rehabilitation phase 2, Taxiway Y completion, Taxiway guidance signs, Runway pavement evaluation, Taxiway C5, Airfield lighting computerized control system replacement, Airfield pavement sweeper replacement, ARFF fire truck replacement, Runway 34L holding apron, Cargo apron expansion, Commuter terminal addition, ARFF station building seismic upgrade, 800 MHz radio system phase 2, West electrical vault seismic upgade, ARFF station building expansion.

Brief Description of Projects Partially Approved for Collection and Use: Terminals 1, 2, and 3 and administration building electrical system reconstruction/upgrade.

Determination: In accordance with paragraph 551(d) of FAA Order 5100.38A, revenue producing and non public-use space such as concessions in the terminals and the administration building in its entirety are not AIP eligible, thus making utilities which serve those areas ineligible. The public agency has determined, and the FAA concurs, that approximately 48 percent of the proposed project serves ineligible areas.

Reconstruct electrical vault.

Determination: In accordance with paragraph 551(d) of FAA Order 5100.38A, revenue producing and non public-use space such as concessions in the terminals, rental car facilities, as well as airport and airline administrative spaces are not AIP eligible, thus making utilities which service those areas ineligible. Only that portion of this project which relates to eligible facilities is eligible. The public agency has determined, and the FAA concurs that approximately 52 percent of the proposed project serves ineligible areas.

Brief Description of Disapproved Projects: Airfield jet rodder vactor replacement.

Determination: Program Guidance Letter 91–8.1, which provides eligibility criteria for payment sweepers, limits the eligibility of pavement sweepers at airports such as Sacramento Metropolitan Airport to two. This project, given previous PFC approvals, exceed the maximum number of pavement sweepers which are eligible under AIP criteria. Therefore, this project is not AIP or PFC eligible.

Refueler parking ramp.

Determination: This project is not AIP eligible in accordance with Appendix 2 of FAA Order 5100.38A. Therefore, this project does not meet the requirements of section 158.15(b) and is disapproved.

Decision Date: December 29, 1995.

For Further Information Contact: Joseph R. Rodriguez, San Francisco Airports District Office, (415) 876–2805.

Public Agency: Port of Seattle, Seattle, Washington.

Application Number: 95–03–C–00–SEA.

Application Type: Impose and use a PFC.

PFC Level: $3.00.

Total Approved Net PFC Revenue: $147,026,000.

Earliest Charge Effective Date: January 1, 1996.

Estimated Charge Expiration Date: July 1, 2000.

Class of Air Carriers Not Required To Collect PFC'S: None.

Brief Description of Projects Approved for Collection and Use: Terminal apron improvements, Runway 16R rehabilitation, Noise programs, Emergency power generators, Electrical system power upgrade.

Brief Description of Projects Approved for Collection: ARFF training facility, Safety area improvements—16L/16R, Passenger conveyance system.

Brief Description of Disapproved Projects: Skybridge elevators, Land acquisition for south aviation support area development.

Determination: The public agency's financial plans and other project documentation for both of these projects state that the projects were financed with the proceeds of 1992 revenue bonds. The public agency then retired the bonds using Airport Development Funds (ADF). The public agency proposes that the PFC revenues be used to reimburse the ADF for the cost of the projects so that the ADF can be used to finance other revenue generating projects in the airport capital improvement plan. The FAA has determined that the source of the ADF is the rates and charges assessed to airlines. Because of this, the public agency cannot comply with Assurance 8(b) of the PFC assurances, which prohibits a public agency from including in its rate base any portion of the capital cost paid for with PFC revenue, for these projects. Furthermore, based on the projects proposed to be funded by the public agency from the reimbursed ADF, the PFC revenue would in effect be used to fund ineligible projects. Therefore, the FAA has determined that the financing plans for these projects do not meet the requirements of Part 158 and is disapproving both projects.

Decision Date: December 29, 1995.

For Further Information Contact: Paul Johnson, Seattle Airports District Office, (206) 227–2655.

AMENDMENTS TO PFC APPROVALS

Amendment No., City, State	Amendment approved date	Amended approved net PFC revenue	Original approved net PFC revenue	Original estimated charge exp. date	Amended estimated charge exp. date
92–01–C–02–RSW, Fort Myers, FL.	10/12/95	$258,450,359	$258,920,512	08/01/18	05/01/17
91–01–C–01–SAV, Savannah, GA.	11/07/95	49,908,639	39,501,502	03/01/04	12/01/15
92–01–I–02–ABE/94–03–U–01–ABE, Allentown PA.	12/05/95	8,700,000	4,350,000	07/01/96	03/01/00

Issued in Washington, DC on January 23, 1996.

Donna P. Taylor,

Manager, Passenger Facility Charge Branch.

[FR Doc. 96–1624 Filed 1–29–96; 8:45 am]

BILLING CODE 4910–13–M

Notice of Intent To Rule on Application (#96–04–C–00–YKM) To Impose and Use the Revenue From a Passenger Facility Charge (PFC) at Yakima Air Terminal, Submitted by Yakima Air Terminal Board, Yakima, WA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of intent to rule on application.

SUMMARY: The FAA proposes to rule and invites public comment on the application to impose and use PFC revenue at Yakima Air Terminal under the provisions of 49 U.S.C. 40117 and Part 158 of the Federal Aviation Regulations (14 CFR 158).

DATES: Comments must be received on or before February 29, 1996.

ADDRESSES: Comments on this application may be mailed or delivered in triplicate to the FAA at the following address: J. Wade Bryant, Manager; Seattle Airports District Office, SEA–ADO; Federal Aviation Administration; 1601 Lind Avenue SW, Suite 250; Seattle, WA 98055–4056.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Mr. Bob Clem, Airport Manager at the following address: Yakima Air Terminal, 2400 West Washington Avenue, Yakima, WA 98903.

Air Carriers and foreign air carriers may submit copies of written comments previously provided to Yakima Air Terminal, under section 158.23 of Part 158.

FOR FURTHER INFORMATION CONTACT: Ms. Cayla Morgan, (206) 227–2653; Seattle Airports District Office, SEA–ADO; Federal Aviation Administration; 1601 Lind Avenue SW, Suite 250; Seattle, WA 98055–4056. 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 (#96–04–C–00–YKM) to impose and use PFC revenue at Yakima Air Terminal, under the provisions of 49 U.S.C. 40117 and Part 158 of the Federal Aviation Regulations (14 CFR Part 158).

On January 22, 1995, the FAA determined that the application to impose and use the revenue from a PFC submitted by Yakima Air Terminal Board, Yakima, Washington, 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 April 26, 1996.

The following is a brief overview of the application.

Level of the proposed PFC: $3.00.

Proposed charge effective date: March 1, 1996.

Proposed charge expiration date: February 28, 1998.

Total estimated PFC revenues: $432,000.00.

Brief description of proposed project: Snow removal equipment—purchase two snow plows; Expand snow removal equipment (SRE) storage facility; Terminal building renovation project—Phase 2.

Class or classes of air carriers which the public agency has requested not be required to collect PFC's: Air taxi/commercial operators filing FAA Form 1800–31.

Any person may inspect the application in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT** and at the FAA Regional Airports Office located at: Federal Aviation Administration, Northwest Mountain Region, Airports Division, ANM–600, 1601 Lind Avenue

S.W., Suite 540, Renton, WA 98055–4056.

In addition, any person may, upon request, inspect the application, notice and other documents germane to the application in person at the Yakima Air Terminal.

Issued in Renton, Washington on January 22, 1996.

David A. Field,

Manager, Planning, Programming and Capacity Branch, Northwest Mountain Region.

[FR Doc. 96–1737 Filed 1–29–96; 8:45 am]

BILLING CODE 4910–13–M

Maritime Administration

[Docket S–930]

Chestnut Shipping Company, Keystone Shipping Co.; Application for Amendment of a Previous Section 804 Waiver Which Authorized Keystone Shipping Co. To Acquire an Interest In or Charter Nine Foreign-Flag Liquid Bulk Vessels

Chestnut Shipping Company (Chestnut) requests amendment of Docket A–180, served by the Maritime Administrator (Administrator) on November 15, 1990, in which the Administrator with respect to Operating-Differential Subsidy Agreement (ODSA), Contract MA/MSB–299, with Chestnut, waived until November 11, 1996, the provisions of section 804(a) of the Merchant Marine Act, 1936, as amended (Act), so as to permit Chestnut's affiliate, Keystone Shipping Co. (Keystone), to acquire an interest in or charter up to nine foreign-flag liquid bulk vessels to be operated in U.S. foreign commerce, none to exceed 200,000 DWT.

Chestnut requests amendment of the section 804 waiver as previously granted to Chestnut in Docket A–180, in order to allow Keystone until February 28, 1997, and any applicable extension thereto, to own, charter, manage, act as agent or broker for, or to have an interest in up to twenty (20) dry, liquid or combination liquid/dry bulk foreign-flag vessels without restrictions as to the size of the vessels or amount of cargo such vessels can load. Chestnut advises that Keystone agrees to be bound by the conditions of earlier waivers imposed by the Administrator which were designed to assure against the diversion of subsidy monies.

On December 22, 1993, the Maritime Administration authorized separate ODSAs for the two original vessels of Chestnut, as follows:

(1) MA/MSB–299(a) on the CHESTNUT HILL, to expire November 30, 1996, and

(2) MA/MSB–299(b) on the KITTANNING, to expire February 28, 1997.

Under either of these ODSAs, Chestnut is authorized to operate the CORONADO, CHERRY VALLEY, CHELSEA, CHILBAR or FREDERICKSBURG, provided that the annual amount of operating-differential subsidy (ODS) accrued under each ODSA can not exceed the amount of ODS that would accrue for one-ship year of operation of the vessel named in the ODSA.

This application may be inspected in the Office of the Secretary, Maritime Administration. Any person, firm or corporation having any interest in such request within the meaning of section 804 of the Act and desiring to submit comments concerning the application must file written comments in triplicate with the Secretary, Maritime Administration, Room 7210, Nassif Building, 400 Seventh Street SW., Washington DC 20590. Comments must be received no later than 5:00 p.m. on February 12, 1996. This notice is published as a matter of discretion. The Maritime Administrator will consider any comments submitted and take such action with respect thereto as may be deemed appropriate.

(Catalog of Federal Domestic Assistance Program No. 2.804 Operating-Differential Subsidies).

By Order of the Maritime Administrator.

Dated: January 25, 1996.

Joel C. Richard,

Secretary.

[FR Doc. 96–1735 Filed 1–29–96; 8:45 am]

BILLING CODE 4910–81–P

National Highway Traffic Safety Administration

[NHTSA Docket No. 94–021; Notice 3]

Highway Safety Programs; Model Specifications for Devices To Measure Breath Alcohol

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Notice.

SUMMARY: This notice amends the Conforming Products List for instruments that conform to the Model Specifications for Evidential Breath Testing Devices (58 FR 48705).

EFFECTIVE DATE: January 30, 1996.

FOR FURTHER INFORMATION CONTACT: Dr. James F. Frank, Office of Alcohol and State Programs, NTS–21, National Highway Traffic Safety Administration, 400 Seventh Street, S.W., Washington, D.C. 20590; Telephone: (202) 366–5593.

SUPPLEMENTAL INFORMATION: On November 5, 1973, the National Highway Traffic Safety Administration (NHTSA) published the Standards for Devices to Measure Breath Alcohol (38 FR 30459). A Qualified Products List of Evidential Breath Measurement Devices comprised of instruments that met this standard was first issued on November 21, 1974 (39 FR 41399).

On December 14, 1984 (49 FR 48854), NHTSA converted this standard to Model Specifications for Evidential Breath Testing Devices, and published a Conforming Products List (CPL) of instruments that were found to conform to the Model Specifications as Appendix D to that notice (49 FR 48864).

On September 17, 1993, NHTSA published a notice (58 FR 48705) to amend the Model Specifications. The notice changed the alcohol concentration levels at which instruments are evaluated, from 0.000, 0.050, 0.101, and 0.151 BAC, to 0.000, 0.020, 0.040, 0.080, and 0.160 BAC; added a test for the presence of acetone; and expanded the definition of alcohol to include other low molecular weight alcohols including methyl or isopropyl. On March 16, 1995, the most recent amendment to the Conforming Products List (CPL) was published (60 FR 14320), identifying those instruments found to conform with the Model Specifications.

Since the last publication of the CPL, three (3) instruments have been evaluated and found to meet the model specifications, as amended on September 17, 1993, for mobile and non-mobile use. They are: CMI, Inc.'s "Intoxilyzer 300" (which is the same as Lion Laboratories' "Alcolmeter 300" that will also be listed); National Patent Analytical Systems, Inc.'s "BAC Verifier Datamaster" (which is the same as Verax Systems' "BAC Verifier Datamaster" that will also be listed); and National Draeger's "Alcotest 7110 MKIII". Additionally, four devices currently listed under the CMI brand name (Intoxilyzer 200, Intoxilyzer 200D, Intoxilyzer 1400 and Intoxilyzer 5000 CD/FG5) will also be listed under the Lion Laboratories brand name. Lion Laboratories and CMI, Inc. are both wholely-owned subsidiaries of the same parent company (MPD, Inc.) and the devices are the same whether they are sold by CMI or Lion Laboratories.

In accordance with the foregoing, the CPL is therefore amended, as set forth below.

CONFORMING PRODUCTS LIST OF EVIDENTIAL BREATH MEASUREMENT DEVICES

Manufacturer and model	Mobile	Nonmobile
Alcohol Countermeasures System, Inc., Port Huron, MI:		
Alert J3AD*	X	X
BAC Systems, Inc., Ontario, Canada:		
Breath Analysis Computer*	X	
CAMEC Ltd., North Shields, Tyne and Ware, England:		
IR Breath Analyzer*	X	X
CMI, Inc., Owensboro, KY:		
Intoxilyzer Model:		
200	X	X
200D	X	X
300	X	X
400	X	X
1400	X	X
4011*	X	X
4011A*	X	X
4011AS*	X	X
4011AS–A*	X	X
4011AS–AQ*	X	X
4011 AW*	X	X
4011A27–10100*	X	X
4011A27–10100 with filter*	X	X
5000	X	X
5000 (w/Cal. Vapor Re-Circ.)	X	X
5000 (w/3/8" ID Hose option)	X	X
5000CD	X	X
5000CD/FG5	X	X
5000 (CAL DOJ)	X	X
5000VA	X	X
PAC 1200*	X	X
S–D2	X	X
Decator Electronics, Decator, IL:		
Alco-Tector model 500*		X
Gall's Inc., Lexington, KY:		
Alcohol Detection System-A.D.S. 500	X	X
Intoximeters, Inc., St. Louis, MO:		
Photo Electric Intoximeter*		X
GC Intoximeter MK II*	X	X
GC Intoximeter MK IV*	X	X
Auto Intoximeter*	X	X
Intoximeter Model:.		
3000*	X	X
3000 (rev B1)*	X	X
3000 (rev B2)*	X	X
3000 (rev B2A)*	X	X
3000 (rev B2A) w/FM option*	X	X
3000 (Fuel Cell)*	X	X
3000 D*	X	X
3000 DFC*	X	X
Alcomonitor		X
Alcomonitor CC	X	X
Alco-Sensor III	X	X
Alco-Sensor IV	X	X
RBT III	X	X
RBT III–A	X	X
RBT IV	X	X
Intox EC–IR	X	X
Portable Intox EC–IR	X	X
Komyo Kitagawa, Kogyo, K.K.:		
Alcolyzer DPA–2*	X	X
Breath Alcohol Meter PAM 101B*	X	X
Life-Loc, Inc., Wheat Ridge, CO:		
PBA 3000B	X	X
PBA 3000–P*	X	X
Lion Laboratories, Ltd., Cardiff, Wales, UK:		
Alcolmeter Model:		
300	X	X
400	X	X
AE–D1*	X	X
SD–2*	X	X
EBA*	X	X
Auto-Alcolmeter*		X
Intoxilyzer Model:		
200	X	X

CONFORMING PRODUCTS LIST OF EVIDENTIAL BREATH MEASUREMENT DEVICES—Continued

Manufacturer and model	Mobile	Nonmobile
200D	X	X
1400	X	X
5000 CD/FG5	X	X
Luckey Laboratories, San Bernadino, CA:		
Alco-Analyzer Model:		
1000*		X
2000*		X
National Draeger, Inc., Durango, CO:		
Alcotest Model:		
7010*	X	X
7110*	X	X
7110 MKIII	X	X
7410	X	X
Breathalyzer Model:		
900*	X	X
900A*	X	X
900BG*	X	X
7410	X	X
7410–II	X	X
National Patent Analytical Systems, Inc., Mansfield, OH:		
BAC DataMaster	X	X
BAC Verifier Datamaster	X	X
Omicron Systems, Palo Alto, CA:		
Intoxilyzer Model:		
4011*	X	X
4011AW*	X	X
Plus 4 Engineering, Mintum, CO:		
5000 Plus4*	X	X
Siemans-Allis, Cherry Hill, NJ:		
Alcomat*	X	X
Alcomat F*	X	X
Smith and Wesson Electronics, Springfield, MA:		
Breathalyzer Model:		
900*	X	X
900A*	X	X
1000*	X	X
2000*	X	X
2000 (non-Humidity Sensor)*	X	X
Sound-Off, Inc., Hudsonville, MI:		
AlcoData	X	X
Stephenson Corp.:		
Breathalyzer 900*	X	X
U.S. Alcohol Testing, Inc./Protection Devices, Inc., Rancho Cucamonga, CA:		
Alco-Analyzer 1000		X
Alco-Analyzer 2000		X
Alco-Analyzer 2100	X	X
Verax Systems, Inc., Fairport, NY:		
BAC Verifier*	X	X
BAC Verifier Datamaster	X	X
BAC Verifier Datamaster II*	X	X

* Instruments marked with an asterisk (*) meet the Model Specifications detailed in 49 FR 48854 (December 14, 1984) (i.e., instruments tested at 0.000, 0.050, 0.101, and 0.151 BAC.) Instruments not marked with an asterisk meet the Model Specifications detailed in 58 FR 48705 (September 17, 1993), and were tested at BACs=0.000, 0.020, 0.040, 0.080, and 0.160.

(23 U.S.C. 402; delegations of authority at 49 CFR 1.50 and 501.1)

Issued on: January 24, 1996.

James Hedlund,

Associate Administrator for Traffic Safety Programs.

[FR Doc. 96–1734 Filed 1–29–96; 8:45 am]

BILLING CODE 4910–59–P

Surface Transportation Board [1]

[STB Dockets No. AB–33 (Sub-No. 95X) and Idaho Northern & Pacific Railroad Company]

Union Pacific Railroad Company; Abandonment Exemption Maddens-Emmett Line in Canyon and Gem Counties, ID; AB–433 (Sub-No. 3X] Discontinuance Service Exemption—Maddens-Emmett Line in Canyon and Gem Counties, ID

Union Pacific Railroad Company (UPRR) and Idaho Northern & Pacific Railroad Company (INPR) have filed a verified notice under 49 CFR Part 1152 Subpart F—*Exempt Abandonments and Discontinuances* for UPRR to abandon and INPR to discontinue service over 17.5 miles of rail line [2] (a portion of the Idaho Northern Branch), between milepost 7.0 at or near Maddens and milepost 24.5 at or near Emmett, in Canyon and Gem Counties, ID.[3]

UPRR and INPR certify that: (1) No local traffic has moved over the line for at least 2 years; (2) any overhead traffic on the line can be rerouted; (3) no formal complaint filed by a user of rail service on the line (or by a State or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Board or with any U.S. District Court or has been decided in complainant's favor within the last 2 years; and (4) the requirements at 49 CFR 1105.7 (environmental reports), 49 CFR 1105.8 (historic reports), 49 CFR 1105.11 (transmittal letter), 49 CFR 1105.12 (newspaper publication) and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met. As a condition to use of this exemption, any employee adversely affected by the abandonment or discontinuance shall be protected under *Oregon Short Line R. Co.—Abandonment—Goshen,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on February 29, 1996, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[4] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),[5] and trail use/rail banking requests under 49 CFR 1152.29 [6] must be filed by February 9, 1996. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by February 20, 1996, with: Office of the Secretary, Case Control Branch, Surface Transportation Board, 1201 Constitution Avenue, N.W., Washington, DC 20423.

A copy of any petition filed with the Board should be sent to applicants' representatives: Joseph D. Anthofer, General Attorney, Union Pacific Railroad Company, 1416 Dodge St., Room 830, Omaha, NE 68179; and Gilbert A. Gillette, President, Idaho Northern & Pacific Railroad Company, 119 N. Commercial Ave., Emmett, ID 83117.

If the verified notice contains false or misleading information, the exemption is void ab initio.

UPRR and INPR have filed an environmental report which addresses the effects, if any, of the abandonment and the discontinuance on environmental and historic resources. The Section of Environmental Analysis (SEA) will issue an environmental assessment (EA) by February 2, 1996. Interested persons may obtain a copy of the EA by writing to SEA (Room 3219, Surface Transportation Board, 1201 Constitution Avenue, NW., Washington, DC 20423) or by calling Elaine Kaiser, Chief of SEA, at (202) 927–6248. Comments on environmental and historic preservation matters must be filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Decided: January 24, 1996.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 96–1688 Filed 1–29–96; 8:45 am]

BILLING CODE 4915–00–P

[1] The ICC Termination Act of 1995, Pub. L. 104–88, 109 Stat. 803 (the Act), was signed into law by President Clinton on December 29, 1995. The Act, which took effect on January 1, 1996, abolished the Interstate Commerce Commission (Commission) and transferred certain functions to the Surface Transportation Board (Board). As a result, the Board is issuing the instant notice in this proceeding, which concerns a function that is subject to the Board's jurisdiction pursuant to 49 U.S.C. 10903.

[2] This was a lease agreement approved by the Commission in Finance Docket No. 32370 issued December 7, 1993.

[3] Under 49 CFR 1152.50(d)(2), the railroad must file a verified notice with the Board at least 50 days before the abandonment or discontinuance is to be consummated. The applicant, in its verified notice, indicated a proposed consummation date of February 18, 1996. Because the verified notice was not filed until January 2, 1996, the earliest date consummation could have occurred would have been February 21, 1996. Applicant's representative has confirmed that the appropriate proposed consummation date is on or after February 21, 1996. As provided in this notice, however, the exemption is not scheduled to take effect until February 29, 1996.

[4] A stay will be issued routinely by the Board in those proceedings where an informed decision on environmental issues (whether raised by a party or by the Board's Section of Environmental Analysis in its independent investigation) cannot be made prior to the effective date of this notice of exemption. See *Exemption of Out-of-Service Rail Lines,* 5 I.C.C.2d 377 (1989). Any entity seeking a stay on environmental concerns is encouraged to file its request as soon as possible in order to permit the Board to review and act on the request before the effective date of this exemption.

[5] See *Exempt. of Rail Abandonment—Offers of Finan. Assist.,* 4 I.C.C.2d 164 (1987).

[6] The Board will accept a late-filed trail use request as long as it retains jurisdiction to do so.

DEPARTMENT OF THE TREASURY

Customs Service

Public Information Collection Requirements; Request for Public Input; U.S. In-Transit Manifest

AGENCY: Customs Service, Department of the Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, Customs invites the general public and other Federal agencies to comment on an information collection requirement concerning the U.S. In-Transit Manifest. This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Public Law 104–13; 44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments should be received on or before April 1, 1996, to be assured of consideration.

ADDRESSES: Direct all written comments to U.S. Customs Service, Printing and Records Services Group, Room 6216, 1301 Constitution Ave., NW., Washington, DC 20229.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to U.S. Customs Service, Attn.: Norman Waits, Room 6216, 1301 Constitution Avenue NW., Washington, DC 20229, Tel. (202) 927–1551.

SUPPLEMENTARY INFORMATION: Customs invites the general public and other

Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Public Law 104–13; 44 U.S.C. 3506(c)(2)(A)). The comments should address the accuracy of the burden estimates and ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology, as well as other relevant aspects of the information collection. The comments that are submitted will be summarized and included in the Customs request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document Customs is soliciting comments concerning the following information collection:

Title: U.S. In-Transit Manifest.

OMB Number: 1515–0045.

Form Number: CF–7533C.

Abstract: This collection of information is required by Customs from railroads to transport merchandise (products and manufactures of the U.S.) from one port to another in the United States through Canada. Customs form 7533C serves as an in-transit manifest for merchandise being laden on trains at one point in the United States, usually with a Customs seal affixed thereon, which will then be transferred through Canada to a port of unloading in the United States.

Current Actions: There are no changes to the information collection. This submission is being submitted to extend the expiration date.

Type of Review: Extension (without change).

Affected Public: Business or other for-profit institutions.

Estimated Number of Respondents: 300.

Estimated Time Per Respondent: 3 minutes.

Estimated Total Annual Burden Hours: 15.

Dated: January 18, 1996.

V. Carol Barr,

Leader, Printing and Records Services Group.

[FR Doc. 96–1594 Filed 1–29–96; 8:45 am]

BILLING CODE 4820–02–P

Public Information Collection Requirements; Request for Public Input; Ship's Stores Declaration

AGENCY: Customs Service, Department of the Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, Customs invites the general public and other Federal agencies to comment on an information collection requirement concerning the Ship's Stores Declaration. This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Public Law 104–13; 44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments should be received on or before April 1, 1996, to be assured of consideration.

ADDRESSES: Direct all written comments to U.S. Customs Service, Printing and Records Services Group, Room 6216, 1301 Constitution Ave., NW., Washington, DC 20229.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to U.S. Customs Service, Attn.: Norman Waits, Room 6216, 1301 Constitution Avenue NW., Washington, DC 20229, Tel. (202) 927–1551.

SUPPLEMENTARY INFORMATION: Customs invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Public Law 104–13; 44 U.S.C. 3506(c)(2)(A)). The comments should address the accuracy of the burden estimates and ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology, as well as other relevant aspects of the information collection. The comments that are submitted will be summarized and included in the Customs request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document Customs is soliciting comments concerning the following information collection:

Title: Ship's Stores Declaration.

OMB Number: 1515–0059.

Form Number: CF–1303.

Abstract: This collection of information is required by Customs from the importing carriers to declare ship's stores to be retained on board the vessel, such as sea stores, ship's stores, or bunker coal, or bunker oil in a format that can be readily audited and checked by Customs.

Current Actions: There are no changes to the information collection. This submission is being submitted to extend the expiration date.

Type of Review: Extension (without change).

Affected Public: Business or other for-profit institutions.

Estimated Number of Respondents: 104,000.

Estimated Time Per Respondent: 15 minutes.

Estimated Total Annual Burden Hours: 26,000.

Dated: January 18, 1996.

V. Carol Barr,

Leader, Printing and Records Services Group.

[FR Doc. 96–1595 Filed 1–29–96; 8:45 am]

BILLING CODE 4820–02–P

Public Information Collection Requirements; Request for Public Input; General Declaration

AGENCY: Customs Service, Department of the Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, Customs invites the general public and other Federal agencies to comment on an information collection requirement concerning the General Declaration. This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Public Law 104–13; 44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments should be received on or before April 1, 1996, to be assured of consideration.

ADDRESSES: Direct all written comments to U.S. Customs Service, Printing and Records Services Group, Room 6216, 1301 Constitution Ave., N.W., Washington, D.C. 20229.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to U.S. Customs Service, Attn.: Norman Waits, Room 6216, 1301 Constitution Avenue N.W., Washington, D.C. 20229, Tel. (202) 927–1551.

SUPPLEMENTARY INFORMATION: Customs invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Public Law 104–13; 44 U.S.C. 3506(c)(2)(A)). The comments should address the accuracy of the burden estimates and ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology, as well as other relevant aspects of the information collection. The comments that are submitted will be summarized and included in the Customs request for Office of Management and Budget (OMB) approval. All comments will become a

matter of public record. In this document Customs is soliciting comments concerning the following information collection:

Title: General Declaration.

OMB Number: 1515–0062.

Form Number: CF–1301.

Abstract: This collection of information is required from the master of a vessel to provide various items of information to Customs as to the location of the vessel in port, and itinerary after leaving (clearing the United States). Customs Form 1301 is used by the importing carrier to request privileges for changes in the itinerary of the vessel and/or its cargo between different United States ports.

Current Actions: There are no changes to the information collection. This submission is being submitted to extend the expiration date.

Type of Review: Extension (without change).

Affected Public: Business or other for-profit institutions.

Estimated Number of Respondents: 208,000.

Estimated Time Per Respondent: 5 minutes.

Estimated Total Annual Burden Hours: 17,326.

Dated: January 18, 1996.

V. Carol Barr,

Leader, Printing and Records Services Group.

[FR Doc. 96–1596 Filed 1–29–96; 8:45 am]

BILLING CODE 4820–02–P

Public Information Collection Requirements; Request for Public Input; Application for Customshouse Broker's License

AGENCY: Customs Service, Department of the Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, Customs invites the general public and other Federal agencies to comment on an information collection requirement concerning the Application for Customhouse Broker's License. This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Public Law 104–13; 44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments should be received on or before April 1, 1996, to be assured of consideration.

ADDRESSES: Direct all written comments to U.S. Customs Service, Printing and Records Services Group, Room 6216, 1301 Constitution Ave., N.W., Washington, D.C. 20229.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to U.S. Customs Service, Attn.: Norman Waits, Room 6216, 1301 Constitution Avenue N.W., Washington, D.C. 20229, Tel. (202) 927–1551.

SUPPLEMENTARY INFORMATION: Customs invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Public Law 104–13; 44 U.S.C. 3506(c)(2)(A)). The comments should address the accuracy of the burden estimates and ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology, as well as other relevant aspects of the information collection. The comments that are submitted will be summarized and included in the Customs request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document Customs is soliciting comments concerning the following information collection:

Title: Application for Customshouse Broker's License.

OMB Number: 1515–0076.

Form Number: CF–3124.

Abstract: This collection of information is required for each individual or entity applying for a Customhouse broker's license. Section 641(b), (c) and (f) of the Tariff Act of 1930, as amended, provide the statutory and regulatory authority for the issuance of Customshouse broker's licenses and permits. Section 111.12 of the Customs Regulations (19 CFR 111.12) implements the statute by setting the procedure for the use of CF 3124 as an application for a Customhouse broker's license. The licensing/permitting of brokers is to ensure that the public is serviced by reputable agents who must account to the Customs Service in handling revenues generated in the duty collection process.

Current Actions: There are no changes to the information collection. This submission is being submitted to extend the expiration date.

Type of Review: Extension (without change).

Affected Public: Business or other for-profit institutions and individuals or households.

Estimated Number of Respondents: 1,800.

Estimated Time Per Respondent: 1 hour.

Estimated Total Annual Burden Hours: 1,800.

Dated: January 18, 1996.

V. Carol Barr,

Leader, Printing and Records Services Group.

[FR Doc. 96–1597 Filed 1–29–96; 8:45 am]

BILLING CODE 4820–02–P

Public Information Collection Requirements; Request for Public Input; Record of Vessel Foreign Repair or Equipment Purchase

AGENCY: Customs Service, Department of the Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, Customs invites the general public and other Federal agencies to comment on an information collection requirement concerning the Record of Vessel Foreign Repair or Equipment Purchase. This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Public Law 104–13; 44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments should be received on or before April 1, 1996, to be assured of consideration.

ADDRESSES: Direct all written comments to U.S. Customs Service, Printing and Records Services Group, Room 6216, 1301 Constitution Ave., N.W., Washington, D.C. 20229.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to U.S. Customs Service, Attn.: Norman Waits, Room 6216, 1301 Constitution Avenue N.W., Washington, D.C. 20229, Tel. (202) 927–1551.

SUPPLEMENTARY INFORMATION: Customs invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Public Law 104–13; 44 U.S.C. 3506(c)(2)(A)). The comments should address the accuracy of the burden estimates and ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology, as well as other relevant aspects of the information collection. The comments that are submitted will be summarized and included in the Customs request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document Customs is soliciting comments concerning the following information collection:

Title: Record of Vessel Foreign Repair or Equipment Purchase.

OMB Number: 1515–0082.

Form Number: CF–226.

Abstract: This collection of information is a requirement under Section 4.14(b) of the Customs Regulations that requires the master of a vessel, who upon first arrival of the vessel in the United States to declare on Customs Form 226 all equipment, parts or materials purchased outside the United States so that appropriate duties may be imposed. Duties are collected on equipment, vessel repairs, parts or materials.

Current Actions: There are no changes to the information collection. This submission is being submitted to extend the expiration date.

Type of Review: Extension (without change).

Affected Public: Business or other for-profit institutions.

Estimated Number of Respondents: 8,000.

Estimated Time Per Respondent: 30 minutes.

Estimated Total Annual Burden Hours: 4,000.

Dated: January 18, 1996.

V. Carol Barr,

Leader, Printing and Records Services Group.

[FR Doc. 96–1598 Filed 1–29–96; 8:45 am]

BILLING CODE 4820–02–P

Public Information Collection Requirements; Request for Public Input; Declaration for Unaccompanied Articles

AGENCY: Customs Service, Department of the Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, Customs invites the general public and other Federal agencies to comment on an information collection requirement concerning the Declaration for Unaccompanied Articles. This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Public Law 104–13; 44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments should be received on or before April 1, 1996, to be assured of consideration.

ADDRESSES: Direct all written comments to U.S. Customs Service, Printing and Records Services Group, Room 6216, 1301 Constitution Ave., N.W., Washington, D.C. 20229.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to U.S. Customs Service, Attn.: Norman Waits, Room 6216, 1301 Constitution Avenue N.W., Washington, D.C. 20229, Tel. (202) 927–1551.

SUPPLEMENTARY INFORMATION: Customs invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Public Law 104–13; 44 U.S.C. 3506(c)(2)(A)). The comments should address the accuracy of the burden estimates and ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology, as well as other relevant aspects of the information collection. The comments that are submitted will be summarized and included in the Customs request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document Customs is soliciting comments concerning the following information collection:

Title: Declaration for Unaccompanied Articles.

OMB Number: 1515–0087.

Form Number: CF–255.

Abstract: This collection of information is required for each parcel or container that is to be sent at a later date. Customs Form 255, "Declaration of Unaccompanied Articles", is completed by the arriving person to determine the traveler's allowable exemption, including accompanying articles as well as those sent by mail and to expedite possible refunds of duties improperly collected.

Current Actions: There are no changes to the information collection. This submission is being submitted to extend the expiration date.

Type of Review: Extension (without change).

Affected Public: Business or other for-profit institutions and individuals or households.

Estimated Number of Respondents: 7,500.

Estimated Time Per Respondent: 5 minutes.

Estimated Total Annual Burden Hours: 1,250.

Dated: January 18, 1996.

V. Carol Barr,

Leader, Printing and Records Services Group.

[FR Doc. 96–1599 Filed 1–29–96; 8:45 am]

BILLING CODE 4820–02–P

Public Information Collection Requirements; Request for Public Input; Application To Receive Free Materials in a Bonded Manufacturing Warehouse

AGENCY: Customs Service, Department of the Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, Customs invites the general public and other Federal agencies to comment on an information collection requirement concerning the Application to Receive Free Materials in a Bonded Manufacturing Warehouse. This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Public Law 104–13; 44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments should be received on or before April 1, 1996, to be assured of consideration.

ADDRESSES: Direct all written comments to U.S. Customs Service, Printing and Records Services Group, Room 6216, 1301 Constitution Ave., N.W., Washington, D.C. 20229.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to U.S. Customs Service, Attn.: Norman Waits, Room 6216, 1301 Constitution Avenue N.W., Washington, D.C. 20229, Tel. (202) 927–1551.

SUPPLEMENTARY INFORMATION: Customs invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Public Law 104–13; 44 U.S.C. 3506(c)(2)(A)). The comments should address the accuracy of the burden estimates and ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology, as well as other relevant aspects of the information collection. The comments that are submitted will be summarized and included in the Customs request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document Customs is soliciting comments concerning the following information collection:

Title: Application for Bonding of Smelting and Refining Warehouses.

OMB Number: 1515–0133.

Form Number: N/A.

Abstract: This collection of information is required from a

proprietor of a bonded manufacturing warehouse making application to Customs to receive therein any domestic merchandise, except merchandise subject to Internal Revenue Tax, which is to be used in connection with the manufacture of articles permitted to be manufactured in such a warehouse. Domestic merchandise for which such application is required includes packages, coverings, vessels and labels used in putting up such articles.

Current Actions: There are no changes to the information collection. This submission is being submitted to extend the expiration date.

Type of Review: Extension (without change).

Affected Public: Business or other for-profit institutions.

Estimated Number of Respondents: 6,000.

Estimated Time Per Respondent: 30 minutes.

Estimated Total Annual Burden Hours: 3,000.

Dated: January 18, 1996.

V. Carol Barr,

Leader, Printing and Records Services Group.

[FR Doc. 96–1600 Filed 1–29–96; 8:45 am]

BILLING CODE 4820–02–P

Public Information Collection Requirements; Request for Public Input; Application for Bonding of Smelting and Refining Warehouses

AGENCY: Customs Service, Department of the Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, Customs invites the general public and other Federal agencies to comment on an information collection requirement concerning the Application for Bonding of Smelting and Refining Warehouses. This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Public Law 104–13; 44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments should be received on or before April 1, 1996, to be assured of consideration.

ADDRESSES: Direct all written comments to U.S. Customs Service, Printing and Records Services Group, Room 6216, 1301 Constitution Ave., N.W., Washington, D.C. 20229.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to U.S. Customs Service, Attn.: Norman Waits, Room 6216, 1301 Constitution Avenue N.W., Washington, D.C. 20229, Tel. (202) 927–1551.

SUPPLEMENTARY INFORMATION: Customs invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Public Law 104–13; 44 U.S.C. 3506(c)(2)(A)). The comments should address the accuracy of the burden estimates and ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology, as well as other relevant aspects of the information collection. The comments that are submitted will be summarized and included in the Customs request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document Customs is soliciting comments concerning the following information collection:

Title: Application for Bonding of Smelting and Refining Warehouses.

OMB Number: 1515–0127.

Form Number: N/A.

Abstract: This collection of information is required from a manufacturer engaged in smelting metal-bearing materials, refining metal-bearing or both, who submits an application to Customs requesting approval for the bonding of the plant.

Current Actions: There are no changes to the information collection. This submission is being submitted to extend the expiration date.

Type of Review: Extension (without change).

Affected Public: Business or other for-profit institutions.

Estimated Number of Respondents: 72.

Estimated Time Per Respondent: 8 hours.

Estimated Total Annual Burden Hours: 576.

Dated: January 18, 1996.

V. Carol Barr,

Leader, Printing and Records Services Group.

[FR Doc. 96–1601 Filed 1–29–96; 8:45 am]

BILLING CODE 4820–02–P

Public Information Collection Requirements; Request for Public Input; Establishment of Container Station

AGENCY: Customs Service, Department of the Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, Customs invites the general public and other Federal agencies to comment on an information collection requirement concerning the Establishment of Container Station. This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Public Law 104–13; 44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments should be received on or before April 1, 1996, to be assured of consideration.

ADDRESSES: Direct all written comments to U.S. Customs Service, Printing and Records Services Group, Room 6216, 1301 Constitution Ave., N.W., Washington, D.C. 20229.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to U.S. Customs Service, Attn.: Norman Waits, Room 6216, 1301 Constitution Avenue N.W., Washington, D.C. 20229, Tel. (202) 927–1551.

SUPPLEMENTARY INFORMATION: Customs invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Public Law 104–13; 44 U.S.C. 3506(c)(2)(A)). The comments should address the accuracy of the burden estimates and ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology, as well as other relevant aspects of the information collection. The comments that are submitted will be summarized and included in the Customs request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document Customs is soliciting comments concerning the following information collection:

Title: Establishment of Container Station.

OMB Number: 1515–0117.

Form Number: N/A.

Abstract: This collection of information is required by Customs from the container station operator applicant to establish a container station that is independent of either an importing carrier or a bonded carrier that may be established at any port or portion thereof where under the jurisdiction of the district director.

Current Actions: There are no changes to the information collection. This submission is being submitted to extend the expiration date.

Type of Review: Extension (without change).

Affected Public: Business or other for-profit institutions.

Estimated Number of Respondents: 177.

Estimated Time Per Respondent: 2 hours.

Estimated Total Annual Burden Hours: 354.

Dated: January 18, 1996.

V. Carol Barr,

Leader, Printing and Records Services Group.

[FR Doc. 96–1602 Filed 1–29–96; 8:45 am]

BILLING CODE 4820–02–P

Announcement of National Customs Automation Test Regarding Electronic Protest Filing

AGENCY: Customs Service, Department of the Treasury.

ACTION: General notice.

SUMMARY: This notice announces Customs plan to conduct a test regarding the electronic filing of protests. This notice invites public comments concerning any aspect of the test, informs interested members of the public of the eligibility requirements for voluntary participation in the test, and describes the basis on which Customs will select participants.

EFFECTIVE DATE: The test will commence no earlier than May 1, 1996, and will run for approximately six months. Comments must be received on or before February 29, 1996. Anyone interested in participating in the test should contact Customs on or before February 29, 1996.

ADDRESSES: Written comments regarding this notice and information submitted to be considered for voluntary participation in the test, should be addressed to the Chief, Commercial Compliance Branch, U.S. Customs Service, 1301 Constitution Avenue, N.W. Room 1313, Washington D.C. 20229–0001.

FOR FURTHER INFORMATION CONTACT:

For protest systems or automation issues: Steve Linnemann (202) 927–0436.

For information on how to become ABI operational: Kris Crane (202) 927–0452.

For operational or policy issues: Jim Casler (713) 313–2876.

SUPPLEMENTARY INFORMATION:

Background

Title VI of the North American Free Trade Agreement Implementation Act (the Act), Public Law 103–182, 107 Stat. 2057 (December 8, 1993), contains provisions pertaining to Customs Modernization (107 Stat. 2170). Subtitle B of title VI establishes the National Customs Automation Program (NCAP)—an automated and electronic system for the processing of commercial importations. Section 631 in Subtitle B of the Act creates sections 411 through 414 of the Tariff Act of 1930 (19 U.S.C. 1411–1414), which define and list the existing and planned components of the NCAP (section 411), promulgate program goals (section 412), and provide for the implementation and evaluation of the program (section 413). In addition section 645 of the Act provides for the electronic filing of protests. Section 411 (2) (A) defines the "electronic filing and status of protests" as a "Planned Component" of the NCAP. Section 101.9(b) of the Customs Regulations (19 CFR 101.9(b)), implements the testing of NCAP components. See T.D. 95–21 (60 FR 14211, March 16,1995).

I. Description of the Test

The Concept of Electronic Protest Filing

The Customs Service has developed transaction sets for the Automated Broker Interface (ABI) system which will allow the following to be filed electronically and their status tracked electronically:

(1) Protests against decisions of the Customs Service under 19 U.S.C. 1514;

(2) Claims for refunds of Customs duties or corrections of errors requiring reliquidation pursuant to 19 U.S.C. 1520(c) and (d); and

(3) Interventions in an importer's protest by an exporter or producer of merchandise from a country that is a party to the North American Free Trade Agreement under § 181.115 of the Customs Regulations.

Customs Regulations regarding who has the right to file a protest and the port having jurisdiction over the protest remain the same. For the purposes of the test, the date of filing for a protest will be determined by the date of ABI input of the protest based on midnight eastern standard time. A customhouse broker will be able to input the protest from any computer processing location, but will still have to be licensed to transact business at the port where the protest is filed.

The test will be implemented at selected ports. Ports selected will depend in part upon the number of volunteers who transact Customs business at those ports and the anticipated volume of protests filed at those ports.

II. Eligibility Criteria

In order to qualify for the electronic protest test, volunteers must be currently ABI operational, or become ABI operational, and willing to develop or acquire the software necessary to input protests into and interact with the electronic protest programming which has been established within Customs Automated Commercial System (ACS).

Note that participation in this testing will not constitute confidential information and lists of participants will be made available to the public upon written request.

Test Participation Application

This notice requests volunteers for the test. Protest filers who wish to volunteer for the test should contact the Trade Compliance Branch, U.S. Customs Service, 1301 Constitution Avenue, N.W., Room 1322, Washington D.C. 20229–0001 on or after the date set forth in the effective date paragraph at the beginning of this notice.

Basis for Participation Selection

Eligible filers will be considered for participation in the test. Those not selected for participation will be invited to comment on the design, conduct, and evaluation of the test. Selections will be based on anticipated volume of protests, ports identified as having jurisdiction over those protests, and the selectee's electronic abilities to interface with Customs ABI electronic protest programming. Participants selected will be notified by means of the Customs Electronic Bulletin Board and the Customs Administrative Message System and by letter of notification.

III. Test Evaluation Criteria

Once participants are selected, Customs and the participants will meet to review all public comments received concerning any aspect of the test program or procedures, finalize procedures in light of those comments, form problem solving teams, and establish baseline measures and evaluation methods and criteria. At 90 days and 180 days after commencement, evaluations of the test will be conducted with the final results published in the **Federal Register** as required by § 101.9(b) of the Customs Regulations.

Dated: January 22, 1996.

Samuel H. Banks,

Assistant Commissioner, Office of Field Operations.

[FR Doc. 96–1593 Filed 1–29–96; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF VETERANS AFFAIRS

Proposed Information Collection Activity; Public Comment Request: Persian Gulf Registry Questionnaire; VA Form 10–20988 (NR)

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: As part of its continuing effort to reduce paperwork and respondent burden, Veterans Benefits Administration (VBA) invites the general public and other Federal agencies to comment on this information collection. This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13; 44 U.S.C. 3506(c)(2)(A)). Comments should address the accuracy of the burden estimates and ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology, as well as other relevant aspects of the information collection.

DATES: Written comments and recommendations on the proposal for the collection of information should be received on or before April 1, 1996.

ADDRESSES: Direct all written comments to Nancy J. Kessinger, Veterans Benefits Administration (20M30), Department of Veterans Affairs, 810 Vermont Avenue, NW, Washington, DC 20420. All comments will become a matter of public record and will be summarized in the VBA request for Office of Management and Budget (OMB) approval. In this document VBA is soliciting comments concerning the following information collection:

OMB Control Number: None assigned.

Title and Form Number: Persian Gulf Registry Questionnaire, VA Form 10–20988 (NR).

Type of Review: Existing collection in use without an OMB control number.

Need and Uses: Participants in the VA Persian Gulf Registry Health Examination Program are given the opportunity to report information on potential exposures during Persian Gulf Service and their reproductive health since serving in Desert Shield and Desert Storm.

Current Actions: VA created the Persian Gulf Registry Health Examination Program in 1992. U.S. troops returning from Operations Desert Shield and Desert Storm began reporting a variety of illnesses which they initially attributed to inhalation of fumes and smoke from burning Kuwaiti oil-well fires. The products of oil-well fires (carbon monoxide, sulfur oxides, hydrocarbons, particulate matter, and nitrogen oxides), may singly or in combination, cause both chronic and acute adverse health conditions. These adverse health conditions include chronic bronchitis, pulmonary emphysema, chronic obstructive pulmonary disease, lung cancer and bronchial asthma.

The Persian Gulf Registry Examination Program was designed to assist VA in identifying possible adverse health conditions in military personnel who served in the Persian Gulf War. The health examination program offers a free, complete physical examination with basic laboratory studies to every Persian Gulf veteran who has health concerns.

Affected Public: Individuals or households.

Estimated Annual Burden: 12,500 hours.

Estimated Average Burden Per Respondent: 15 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 50,000.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form should be directed to Department of Veterans Affairs, Attn: Jacquie McCray, Information Management Service (045A4), Department of Veterans Affairs, 810 Vermont Avenue, NW, Washington, DC 20420, Telephone (202) 565–8266 or FAX (202) 565–8267.

Dated: January 22, 1996.

By direction of the Secretary.

Donald L. Neilson,

Director, Information Management Service.

[FR Doc. 96–1641 Filed 1–29–96; 8:45 am]

BILLING CODE 8320–01–P

Sunshine Act Meetings

Federal Register
Vol. 61, No. 20
Tuesday, January 30, 1996

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).

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

DATE AND TIME: Thursday, February 8, 1996–2:00 p.m.

PLACE: Conference Room on the Ninth Floor of the EEOC Office Building, 1801 "L" Street, N.W., Washington, D.C. 20507.

STATUS: The Meeting will be open to the public.

MATTERS TO BE CONSIDERED:

1. Announcement of Notation Votes.
2. Implementation of Priority Charge Handling Procedures.
3. Proposed National Enforcemnent Plan.

Note: Any matter not discussed or concluded may be carried over to a later meeting. (In addition to publishing notices on EEOC Commission meetings in the **Federal Register**, the Commission also provides a recorded announcement a full week in advance on future Commission sessions.) Please telephone (202) 663–7100 (voice) and (202) 663–4074 (TTD) at any time for information on these meetings.

CONTACT PERSON FOR MORE INFORMATION: Frances M. Hart, Executive Officer on (202) 663–4070.

This Notice Issued January 26, 1996.

Frances M. Hart,

Executive Officer, Executive Secretariat.

[FR Doc. 96–1970 Filed 1–26–96; 3:08 pm]

BILLING CODE 6750–06–M

MERIT SYSTEMS PROTECTION BOARD

DATE & TIME: 3:00 p.m., Monday, February 5, 1996.

PLACE: Hearing Room, Eighth Floor, 1120 Vermont Avenue, N.W., Washington, D.C., 20419.

STATUS: The meeting will be open to the public.

MATTERS TO BE CONSIDERED: Discussion of the report of the MSPB Task Force pursuant to the National Performance Review Number 2 ("REGOII").

CONTACT PERSON FOR ADDITIONAL INFORMATION: Robert E. Taylor, Clerk of the Board, (202) 653–7200.

Dated: January 26, 1996.

Robert E. Taylor,

Clerk of the Board.

[FR Doc. 96–1966 Filed 1–26–96; 3:07 pm]

BILLING CODE 7400–01–M

NATIONAL TRANSPORTATION SAFETY BOARD

TIME AND DATE: 9:30 a.m., Tuesday, February 6, 1996.

PLACE: The Board Room, 5th Floor, 490 L'Enfant Plaza, S.W., Washington, D.C. 20594.

STATUS: Open.

MATTERS TO BE CONSIDERED:

6652—Pipeline Accident Report: UGI Utilities, Inc., Natural Gas Distribution Pipeline Explosion and Fire, Allentown, Pennsylvania, June 9, 1994.

NEWS MEDIA CONTACT: Telephone: (202) 382–0660.

FOR MORE INFORMATION CONTACT: Bea Hardesty, (202) 382–6525.

Dated: January 26, 1996.

Bea Hardesty,

Federal Register Liaison Officer.

[FR Doc. 96–1879 Filed 1–26–96; 3:05 pm]

BILLING CODE 7533–01–P

NUCLEAR REGULATORY COMMISSION

DATE: Weeks of January 29, February 5, 12, and 19, 1996.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public.

MATTERS TO BE CONSIDERED:

Week of January 29

Tuesday, January 30

10:00 a.m.
Briefing by DOE on Status of High Level Waste Program (Public Meeting)

Wednesday, January 31

10:00 a.m.
Periodic Briefing on Operating Reactors and Fuel Facilities (Public Meeting)
(Contact: Victor McCree, 301–415–1711)
2:00 p.m.
Discussion of Full Power Operating License for Watts Bar (Public Meeting)
(Contact: Fred Hebdon, 301–415–2024)

Week of February 5—Tentative

Wednesday, February 7

10:00 a.m.
Briefing on System Reliability Studies (Public Meeting)
(Contact: Patrick Baranowsky, 301–415–7493)

Week of February 12—Tentative

There are no meetings scheduled for the Week of February 12.

Week of February 19—Tentative

There are no meetings scheduled for the Week of February 19.

Note: The Nuclear Regulatory Commission is operating under a delegation of authority to Chairman Shirley Ann Jackson, because with three vacancies on the Commission, it is temporarily without a quorum. As a legal matter, therefore, the Sunshine Act does not apply; but in the interests of openness and public accountability, the Commission will conduct business as though the Sunshine Act were applicable.

The schedule for commission meetings is subject to change on short notice. To verify the status of meetings call (Recording)—(301) 415–1292.

CONTACT PERSON FOR MORE INFORMATION: Bill Hill (301) 415–1661.

This notice is distributed by mail to several hundred subscribers; if you no longer wish to receive it, or would like to be added to it, please contact the Office of the Secretary, ATTN: Operations Branch, Washington, D.C. 20555 (301–415–1963).

In addition, distribution of this meeting notice over the internet system is available. If you are interested in receiving this Commission meeting schedule electronically, please send an electronic message to alb@nrc.gov or gkt@nrc.gov.

* * * * *

Dated: January 26, 1996.

William M. Hill, Jr.,

SECY Tracking Officer, Office of the Secretary.

[FR Doc. 96–1943 Filed 1–26–96; 3:06 pm]

BILLING CODE 7590–01–M

UNITED STATES POSTAL SERVICE BOARD OF GOVERNORS

Notice of Vote To Close Meeting

By telephone vote on January 26, 1996, a majority of the members contacted and voting, the Board of Governors of the United States Postal Service voted to add to the agenda of its meeting closed to public observation on February 5, 1996, in Houston, Texas (see 61 FR 2581, January 26, 1996). The members will consider: (1) the Postal Rate Commission Decision in Docket No. MC95–1, Mail Classification Reform; (2) a funding request for a small parcel and bundle sorter feed system;

and (3) an additional funding request for the Chicago, IL, Processing & Distributing Center, Modification IV/ Sugar House.

The meeting is expected to be attended by the following persons: Governors Alvarado, Daniels, del Junco, Dyhrkopp, Fineman, Mackie, McWherter, Rider and Winters; Postmaster General Runyon, Deputy Postmaster General Coughlin, Secretary to the Board Koerber, and General Counsel Elcanco.

As to the first item, the Board determined that pursuant to section 552b(c)(3) of Title 5, United States Code, and section 7.3(c) of Title 39, Code of Federal Regulations, this portion of the meeting is exempt from the open meeting requirement of the Government in the Sunshine Act [5 U.S.C. 552b(b)] because it is likely to disclose information in connection with proceedings under Chapter 36 of Title 39, United States Code (having to do with postal ratemaking, mail classification and changes in postal services), which is specifically exempted from disclosure by section 410(c)(4) of Title 39, United States Code.

The Board has determined further that pursuant to section 552b(c)(10) of Title 5, United States Code, and section7.3(j) of Title 39, Code of Federal Regulations, the discussion is exempt because it is likely to specifically concern participation of the Postal Service in a civil action or proceeding involving a determination on the record after opportunity for a hearing.

As to the second and third items, the Board determined that pursuant to section 552b(c)(9)(B) of Title 5, United States Code, and section 7.3(i) of Title 39, Code of Federal Regulations, the discussion of this matter is exempt from the open meeting requirement of the Government in the Sunshine Act [5 U.S.C. 552b(b)] because it is likely to disclose information, the premature disclosure of which would significantly frustrate proposed procurement actions.

The Board further determined that the public interest does not require that the Board's discussion of these matters be open to the public.

In accordance with section 552b(f)(1) of Title 5, United States Code, and section 7.6(a) of title 39, Code of Federal Regulations, the General Counsel of the United States Postal Service has certified that in her opinion the meeting may properly be closed to public observation pursuant to section 552b(c)(3), (9)(B) and (10) of Title 5, United States Code; section 410(c)(4) of Title 39, United States Code; and section 7.3(c) (i) and (j) of Title 39, Code of Federal Regulations.

Requests for information about the meeting should be addressed to the Secretary of the Board, Thomas J. Koerber, at (202) 268–4800.

Thomas J. Koerber,

Secretary.

[FR Doc. 96–1971 Filed 1–26–96; 3:09 pm]

BILLING CODE 7710–12–M

federal register

Tuesday
January 30, 1996

Part II

Department of Labor

Occupational Safety and Health Administration

29 CFR Part 1910, et al.

Powered Industrial Truck Operator Training; Proposed Rules

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1910, 1915, 1917, 1918

[Docket No. S–008]

Powered Industrial Truck Operator Training

AGENCY: Occupational Safety and Health Administration, Labor.

ACTION: Proposed rule; reopening of comment period, public hearing.

SUMMARY: The Occupational Safety and Health Administration (OSHA) proposed to revise the standards that provide for the training of powered industrial truck operators in general industry and the maritime industries to reduce injuries and deaths that result from inadequate training. That document was published on March 14, 1995 (60 FR 13782). In a companion document in today's **Federal Register**, OSHA is proposing to improve such training in the construction industry and is scheduling a public hearing.

In order to permit consideration of these overlapping matters in the most efficient manner, OSHA is combining these rulemakings, reopening the comment period for general industry and maritime, and scheduling a hearing for all sectors.

DATES: Written comments on the proposed standard and notices of intention to appear at the informal public hearing on the proposed standard must be postmarked by April 1, 1996. Parties who request more than 10 minutes for their presentations at the informal public hearing and parties who will submit documentary evidence at the hearing must submit the full text of their testimony and all documentary evidence postmarked no later than April 15, 1996. The hearing will take place in Washington, DC and is scheduled to begin on April 30, 1996.

ADDRESSES: Comments should be sent in quadruplicate to: Docket Office, Docket No. S–008; Room N2624; U.S. Department of Labor, Occupational Safety and Health Administration, 200 Constitution Avenue NW., Washington, DC 20210 (202–523–7894).

Notices of intention to appear at the informal rulemaking hearing, testimony, and documentary evidence are to be submitted in quadruplicate to: Mr. Thomas Hall, OSHA Division of Consumer Affairs, Occupational Safety and Health Administration, 200 Constitution Avenue NW,, Room N3647, Washington, DC 20210; (202–219–8615). Written comments received, notices of intention to appear, testimony, and all other material related to the development of this proposed standard will be available for inspection and copying in the public record in the Docket Office, Room N2624, at the above address.

The hearing will be held in the auditorium of the U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Ms. Anne Cyr, Office of Information and Consumer Affairs, U.S. Department of Labor, Occupational Safety and Health Administration, Room N3647; 200 Constitution Avenue NW., Washington, DC 20210 (202–219–8148, FAX 202–219–5986).

SUPPLEMENTARY INFORMATION: On March 14, 1995 (60 FR 13782), OSHA proposed standards to improve training of powered industrial truck operators in general industry (29 CFR part 1910) and the maritime industries (29 CFR parts 1915, 1917 and 1918). After consulting with the Advisory Committee on Construction Safety and Health (ACCSH), OSHA is proposing improved training for those operators in the construction industry in today's **Federal Register**. OSHA believes the most efficient way to consider these matters is to combine the rulemaking into one proceeding that shares the same record. If the evidence indicates different requirements are needed for different sectors, this can be accommodated in the final standard. Also, some commenters to the March proposal requested a public hearing. (See Ex. 2–47.)

Accordingly, OSHA is reopening the comment period for the general and maritime industries to April 1, 1996 to coincide with the comment period for construction. In addition, OSHA is scheduling a public hearing for all sectors commencing April 30, 1996. In light of budget stringency, OSHA is only scheduling a hearing in Washington, DC. Regional hearings create substantial expense.

The Advisory Committee on Construction Safety and Health made several recommendations for powered industrial truck training in the construction industry that may have merit for other sectors as well. Accordingly, OSHA is requesting comment on these issues for all sectors, in addition to the other issues arising from the proposal. The four specific issues raised by the ACCSH are as follows:

1. Should an employer be allowed to accept the certification of training by a third party such as a union, training institute, manufacturer, consultant, or other private or public organization? Since OSHA does not accredit certifiers, what criteria should be used to establish their credibility?

Employees sometimes work only briefly for an employer and it might be inefficient for an employer with high turnover to have to specifically review the performance of each new employee. There would need to be some mechanism to ensure that the operator would be trained in the conditions comparable to those found at the work site and that the employer would know that the operator had been adequately trained.

2. What type of testing should be conducted during initial training to judge the competency of the trainee (performance testing and oral and/or written tests)?

A. If tests are administered, what subjects should be tested, and what methods, if any, should be used to judge that the tests are reliable and address the subject matter adequately?

B. What, if any, should be the acceptable pass/fail requirement for the tests?

ACCSH recommended that the employer or other organization training operators should give both performance tests and oral/written tests to ensure the skill and knowledge of the operator. The committee also recommended that there should be pass/fail criteria for those tests and that records be kept of the results of the tests. They asserted that the requirement would assist in lowering accident rates. They also suggested that if this turned out not to be effective, that OSHA consider accreditation of training programs. OSHA did not propose a written or oral test requirement for general industry or maritime and in its experience, this issue has proven to be very controversial.

3. Are some of the training areas listed not needed? ACCSH believes that most of the areas for training were necessary but they felt a few might not be. Specifically, they felt that the recommended topic on the differences between driving an auto and a powered industrial truck might be unnecessary. OSHA is concerned that the stability differences and the effects of rear wheel steering are significant matters.

4. Should an employee receive refresher or remedial training only if operating a vehicle unsafely or if involved in an accident? Is a one year interval too frequent for retraining or recertification?

The ACCSH asserted that a periodic retraining provision for construction was inappropriate because most construction employees are only on a particular job a short period. However, they recommended reevaluation and possible retraining after an incident, accident or expiration of a certificate. (See question 1.)

OSHA has also made a few minor stylistic changes to improve the clarity of the regulatory text for construction. Interested parties may wish to comment on these.

Collection of Information Under the Paperwork Reduction Act

In addition to the issues raised above, OSHA seeks specific comment on the collection of information requirement proposed in §§ 1910.178(l)(5), 1915.120(a)(5), 1917.43(i)(5), and

1918.77(a)(5) [60 FR 13782; March 14, 1995]. Those sections contain a collection of information requirement as defined by the new OMB regulations at 60 FR 44978, August 29, 1995. OSHA is asking for comment on a similar collection of information in § 1926.602(d)(5) as part of the NPRM covering the construction industry. These paragraphs require employers to prepare and maintain a record to certify that employees have been trained and evaluated as required by the powered industrial truck operator training proposed standard. The proposed rule requires employers to certify compliance with the standard by preparing a certification record that contains the name of the employee trained, the date of training, and the signature of the person performing the training and evaluation.

This certification record is needed to verify that powered industrial truck operators are trained to perform their duties competently and safely. To comply with the training requirement, employers must keep a record certifying that their employees have successfully completed powered industrial truck operator training. Safe operation can decrease the number of fatalities and injuries associated with powered industrial trucks.

It has been estimated that there are approximately 1.2 million powered industrial truck operators, and which each firm averaging four powered industrial trucks in operation, the total number of responses to this standard should be 360,000. Initial training should occur one time per operator and refresher training when necessary. The refresher training is to be done when working conditions change for any reason, for example, when an operator leaves a job working in general industry (a warehouse) to a job working on a construction site. The working conditions are different, therefore, the operator should be retrained about the new hazards that may exist in the new work environment.

OSHA estimates that it will take employers about 1 hour to prepare and 8 hours to deliver the training and another 15 minutes to prepare a certification record, make it available during compliance inspections, retain current training materials and course outlines, and document the types of trucks that an operator is authorized to operate. It will cost employers on average about $53 to initially train and certify each employee. The total first year burden for all workplaces is 641,125 burden hours at an annual cost of $4,570,881. It should be noted that the $4,570,881 cost is included in the regulatory analysis cost and, by OMB definition, includes training costs, not just the cost of preparing written documents.

OSHA requests comment from the public on all aspects of this collection of information. Specifically OSHA requests comment or whether this proposed collection of information does:

- Ensure that the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

Comments on the collection of information (certification record) should be sent to the OMB Desk Officer for OSHA at Room 10235, 726 Jackson Place, NW, Washington, DC 20503. Commenters are encouraged to send a copy of their comment on the collection of information to OSHA along with their other comments. The supporting statement for this collection of information requirement is available in both OMB and the OSHA Docket Offices.

OMB is currently reviewing OSHA proposed collection of information to determine its consistency with the Paperwork Reduction Act of 1995. At this time OMB has not approved this collection of information.

Public Participation

Interested persons are requested to submit written data, views and arguments concerning the proposal of March 14, 1995 and the additional issues raised in this document. These comments must be postmarked by April 1, 1996, and submitted in quadruplicate to the Docket Office, Docket No. S–008, Room N2624, U.S. Department of Labor, Occupational Safety and Health Administration, 200 Constitution Avenue NW., Washington, DC 20210.

All written comments received within the specified comment period will be made a part of the record and will be available for public inspection and copying at the above Docket Office address. The comments submitted as part of the proposal for general industry and maritime will be considered part of the record for construction and those submitted for construction will be considered part of the record for general industry and maritime.

Notice of Intention to Appear at the Informal Hearing

Pursuant to section 6(b)(3) of the Occupational Safety and Health Act, an opportunity to submit oral testimony concerning the issues raised by the proposed standard including economic and environmental impacts, will be provided at an informal public hearing to be held in Washington, DC on April 30, 1996. If OSHA receives sufficient requests to participate in the hearing, the hearing period may be extended. Conversely, the hearing may be shortened if there are few requests.

The hearing will commence at 9:30 a.m. on April 30, 1996, in the Auditorium, Frances Perkins Building, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210.

All persons desiring to participate in the hearing must file in quadruplicate a notice of intention to appear, postmarked on or before April 1, 1996. The notice of intention to appear, which will be available for inspection and copying at the OSHA Technical Data Center Docket Office (Room N2624), telephone (202) 219–7894, must contain the following information:

1. The name, address, and telephone number of each person to appear;
2. The capacity in which the person will appear;
3. The approximate amount of time required for the presentation;
4. The issues that will be addressed;
5. A brief statement of the position that will be taken with respect to each issue; and
6. Whether the party intends to submit documentary evidence and, if so, a brief summary of it.

The notice of intention to appear shall be mailed to Mr. Thomas Hall, OSHA Division of Consumer Affairs, Docket S–008, Room N3647, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 219–8615.

A notice of intention to appear also may be transmitted by facsimile to (202) 219–5986 (Attention: Thomas Hall), by the same date, provided the original and 3 copies are sent to the same address and postmarked no more than 3 days later.

Filing of Testimony and Evidence Before the Hearing

Any party requesting more than 10 minutes for a presentation at the hearing, or who will submit documentary evidence, must provide in quadruplicate, the complete text of the testimony, including any documentary evidence to be presented at the hearing. One copy shall not be stapled or bound and be suitable for copying. These materials must be provided to Mr. Thomas Hall, OSHA Division of Consumer Affairs at the address above and be postmarked no later than April 15, 1996.

Each such submission will be reviewed in light of the amount of time requested in the notice of intention to appear. In those instances when the information contained in the submission does not justify the amount of time requested, a more appropriate amount of time will be allocated and the participant will be notified of that fact prior to the informal public hearing.

Any party who has not substantially complied with this requirement may be limited to a 10-minute presentation, and may be requested to return for questioning at a later time.

Any party who has not filed a notice of intention to appear may be allowed to testify for no more than 10 minutes as time permits, at the discretion of the Administrative Law Judge, but will not be allowed to question witnesses.

Notice of intention to appear, testimony and evidence will be available for copying at the Docket Office at the address above.

Conduct and Nature of the Hearing

The hearing will commence at 9:30 a.m. on April 30, 1996. At that time, any procedural matters relating to the proceeding will be resolved.

The nature of an informal rulemaking hearing is established in the legislative history of section 6 of the Occupational Safety and Health Act and is reflected by OSHA's rules of procedure for hearings (29 CFR 1911.15(a)). Although the presiding officer is an Administrative Law Judge and limited questioning by persons who have filed notices of intention to appear is allowed on crucial issues, the proceeding is informal and legislative in type. The Agency's intent, in essence, is to provide interested persons with an opportunity to make effective oral presentations that can proceed expeditiously in the absence of procedural restraints that impede or protract the rulemaking process.

Additionally, since the hearing is primarily for information gathering and clarification, it is an informal administrative proceeding rather than an adjudicative one.

The technical rules of evidence, for example, do not apply. The regulations that govern hearings and the pre-hearing guidelines to be issued for this hearing will ensure fairness and due process and also facilitate the development of a clear, accurate and complete record. Those rules and guidelines will be interpreted in a manner that furthers that development. Thus, questions of relevance, procedure and participation generally will be decided so as to favor development of the record.

The hearing will be conducted in accordance with 29 CFR part 1911. It should be noted that § 1911.4 specifies that the Assistant Secretary may, upon reasonable notice, issue alternative procedures to expedite proceedings or for other good cause.

The hearing will be presided over by an Administrative Law Judge who makes no decision or recommendation on the merits of OSHA's proposal. The responsibility of the Administrative Law Judge is to ensure that the hearing proceeds at a reasonable pace and in an orderly manner. The Administrative Law Judge, therefore, will have all the powers necessary and appropriate to conduct a full and fair informal hearing as provided in 29 CFR 1911, including the powers:

1. To regulate the course of the proceedings;
2. To dispose of procedural requests, objections and comparable matters;
3. To confine the presentations to the matters pertinent to the issues raised;
4. To regulate the conduct of those present at the hearing by appropriate means;
5. At the Judge's discretion, to question and permit the questioning of any witness and to limit the time for questioning; and
6. At the Judge's discretion, to keep the record open for a reasonable, stated time (known as the post-hearing comment period) to receive written information and additional data, views and arguments from any person who has participated in the oral proceedings.

OSHA recognizes that there may be interested persons who, through their knowledge of safety or their experience in the operations involved, would wish to endorse or support certain provisions in the standard. OSHA welcomes such supportive comments, including any pertinent accident data or cost information that may be available, in order that the record of this rulemaking will present a balanced picture of the public response on the issues involved.

Signed at Washington, DC, this 22nd day of January, 1996.

Joseph A. Dear,

Assistant Secretary of Labor.

[FR Doc. 96–1215 Filed 1–29–96; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1926

[Docket No. S–008]

Powered Industrial Truck Operator Training

AGENCY: Occupational Safety and Health Administration, Labor.

ACTION: Proposed rule.

SUMMARY: The Occupational Safety and Health Administration (OSHA) is proposing to revise the Agency's construction safety standard that mandates the training of powered industrial truck operators. These revisions are being proposed to reduce the number of injuries and deaths that have continued to occur as a result of inadequate truck operator training. The proposal is a follow-up to a parallel proposal to improve truck operator training in the general and maritime industries that was published in the **Federal Register** on March 14, 1995.

The proposed operator training requirements would mandate the development of a training program that bases the amount and type of training on the prior knowledge of the trainee and the ability of that trainee to acquire, retain, and use the knowledge and skills that are necessary to safely operate a powered industrial truck. A periodic evaluation of each operator's performance would also be required. Refresher or remedial training would be required, if unsafe vehicle operation, an accident or near miss, or other deficiencies were identified in this periodic evaluation.

Today, OSHA also is publishing a **Federal Register** notice reopening the comment period for the general industry and maritime industry truck operator training proposal. OSHA is scheduling a joint informal hearing to revise comments and testimony on both proposals, i.e., the proposal published in March and the one being published today.

DATES: Written comments on the proposed standards and notices of intention to appear at the informal public hearings on the proposed standards must be postmarked by April

1, 1996. Parties who request more than 10 minutes for their presentations at the informal public hearing and parties who will submit documentary evidence at the hearing must submit the full text of their testimony and all documentary evidence postmarked no later than April 15, 1996. The hearing will take place in Washington, DC and is scheduled to begin on April 30, 1996. OSHA also is reopening the comment period for the proposed revision of the training requirements for powered industrial truck operators in general industry and the maritime industries to April 1, 1996 as announced in a separate document published today and is scheduling a joint hearing for those sectors along with the construction industry hearing.

ADDRESSES: Comments and information should be sent in quadruplicate to: Docket Office, Docket No. S–008; Room N2624; U.S. Department of Labor, Occupational Safety and Health Administration; 200 Constitution Ave., NW., Washington, DC 20210 (202–219–7894).

Notices of intention to appear at the informal rulemaking hearing, testimony, and documentary evidence are to be submitted in quadruplicate to: Mr. Thomas Hall, OSHA Division of Consumer Affairs, Occupational Safety and Health Administration, 200 Constitution Ave., NW., Room N3647, Washington, DC 20210 (202–219–8615). Written comments received, notices of intention to appear, and all other material related to the development of these proposed standards will be available for inspection and copying in the public record in the Docket Office, Room N2624, at the above address.

The hearing will be held in the auditorium of the U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Ms. Ann Cyr, Office of Information and Consumer Affairs, U.S. Department of Labor, Occupational Safety and Health Administration, Room N3647; 200 Constitution Ave., NW., Washington, DC 20210 (202–219–8148, FAX 202–219–5986).

SUPPLEMENTARY INFORMATION:

I. Background

a. The Construction Safety Standard

Congress amended the Contract Work Hours and Safety Standards Act (CWHSA) (40 U.S.C. 327 *et seq.*) in 1969 by adding a new section 107 (40 U.S.C. 333) to provide employees in the construction industry with a safer work environment and to reduce the frequency and severity of construction accidents and injuries. The amendment, commonly known as the Construction Safety Act (CSA) (Pub. L. 91–54, August 9, 1969), significantly strengthened employee protection by providing for the adoption of occupational safety and health standards for employees of the building trades and construction industry working on federally financed or federally assisted construction projects. Accordingly, the Secretary of Labor issued Safety and Health Regulations for Construction at 29 CFR part 1518 (36 FR 7340, April 17, 1971) pursuant to section 107 of the Contract Work Hours and Safety Standards Act.

The Occupational Safety and Health Act allowed the Secretary of Labor to adopt established Federal standards issued under other statutes as occupational safety and health standards that are enforceable under the OSH Act. Accordingly, the Secretary of Labor adopted the Construction Standards that had been issued under the CSA at 29 CFR part 1518 as OSHA standards. These standards were redesignated as part 1926 later in 1971 (36 FR 25232, Dec. 30, 1971). The provisions pertaining to powered industrial trucks are contained at § 1926.602(c). Section 1926.602(c)(1)(vi) states:

> (vi) All industrial trucks in use shall meet the applicable requirements of design, construction, stability, inspection, testing, maintenance, and operation, as defined in American National Standards Institute B56.1–1969, Safety Standards for Powered Industrial Trucks.

Thus, the construction standard relating to the training of industrial truck operators is an adoption by reference of the training provision of the consensus standard which is identical to the corresponding general industry standard, which contains the full text of the American National Standards Institute (ANSI) standard.

The present training provision that is applicable to construction through cross reference to the ANSI B56.1–1969 (and is directly incorporated into general industry as § 1910.178(l)) reads, "Only trained and authorized operators shall be permitted to operate a powered industrial truck. Methods of training shall be devised to train operators in the safe operation of powered industrial trucks."

b. Action on Other Powered Industrial Truck Operator Training Requirements

In the **Federal Register** of March 14, 1995 (60 FR 13782), OSHA published a proposal to revise the general industry standard for training powered industrial truck operators (§ 1910.178(l)) and to adopt the same requirements for the maritime industries (§§ 1915.120(a), 1917.43(I), and 1918.77(a)). Copies of a draft of that **Federal Register** document had been provided to OSHA's Advisory Committee on Construction Safety and Health (ACCSH) at the Committee's meeting on Feb. 28 and March 1, 1995. The Committee advised OSHA that it would like additional time to study the proposal and would finalize its recommendations by its next meeting on May 25–26, 1995. Because OSHA had received no recommendations or other information from the ACCSH, the Agency decided to delay proposing the adoption of training requirements for powered industrial truck operators in the construction industry until the Committee had concluded its deliberations.

ACCSH met on May 25–26, at which time the Committee prepared its comments and recommendations. The Committee recommended that OSHA propose improved powered industrial truck training for construction employees. The Committee also suggested some changes from the general industry proposed standard that OSHA is considering incorporating in the construction standard. Some of these suggestions may be of value to employees in the general and maritime industries as well.

OSHA has decided that the most effective way to fully consider the Committee's suggestions in the proposal is to raise them in the preamble discussion as a series of issues and to invite public comment on them. OSHA also is asking in a companion **Federal Register** document published today whether some of these changes also should be made to the general and maritime industries' powered industrial truck operator training regulations. In the final rule, OSHA will consider the suggestions of the committee and changes for the construction, general and maritime industries based on the comments and evidence received.

In Section VIII below, OSHA discusses the specific recommendations of the ACCSH. It also poses to the public various questions to focus comments on these recommendations.

c. Updated Consensus Standard

Since promulgation of the OSHA safety and health standards for construction in 1971, the consensus standard on which the powered industrial truck standard was based (ANSI B56.1) has undergone four complete revisions (dated 1975, 1983, 1988 and 1993). The current consensus standard (Ex. 3–1) addresses retraining of truck operators as follows:

4.18 Operator qualifications.

Only trained and authorized persons shall be permitted to operate a powered industrial truck. Operators of powered industrial trucks shall be qualified as to visual, auditory, physical, and mental ability to operate the equipment safely according to 4.19 and all other applicable parts of Section 4.

4.19 Operator training.

4.19.1 Personnel who have not been trained to operate powered industrial trucks may operate a truck for the purposes of training only, and only under the direct supervision of the trainer. This training should be conducted in an area away from other trucks, obstacles, and pedestrians.

4.19.2 The operator training program should include the user's policies for the site where the trainee will operate the truck, the operating conditions for that location, and the specific truck the trainee will operate. The training program shall be presented to all new operators regardless of previous experience.

4.19.3 The training program shall inform the trainee that:

(a) The primary responsibility of the operator is to use the powered industrial truck safely following the instructions given in the training program.

(b) Unsafe or improper operation of a powered industrial truck can result in: Death or serious injury to the operator or others; damage to the powered industrial truck or other property.

4.19.4 The training program shall emphasize safe and proper operation to avoid injury to the operator and others and prevent property damage, and shall cover the following areas:

(a) Fundamentals of the powered industrial truck(s) the trainee will operate, including:

(1) Characteristics of the powered industrial truck(s), including variations between trucks in the workplace;

(2) Similarities to and differences from automobiles:

(3) Significance of nameplate data, including rated capacity, warnings, and instructions affixed to the truck;

(4) Operating instructions and warnings in the operating manual for the truck, and instructions for inspection and maintenance to be performed by the operator;

(5) Type of motive power and its characteristics;

(6) Method of steering;

(7) Braking method and characteristics, with and without load;

(8) Visibility, with and without load, forward and reverse;

(9) Load handling capacity, weight and load center.

(10) Stability characteristics with and without load, with and without attachments;

(11) Controls—location, function, method of operation, identification of symbols;

(12) Load handling capabilities; forks, attachments;

(13) Fueling and battery charging;

(14) Guards and protective devices for the specific type of truck;

(15) Other characteristics of the specific industrial truck.

(b) Operating environment and its effect on truck operation, including:

(1) Floor or ground conditions including temporary conditions;

(2) Ramps and inclines, with and without load;

(3) Trailers, railcars, and dockboards (including the use of wheel chocks, jacks, and other securing devices);

(4) Fueling and battery charging facilities;

(5) The use of "classified" trucks in areas classified as hazardous due to risk of fire or explosion, as defined in ANSI/NFPA 505;

(6) Narrow aisles, doorways, overhead wires and piping, and other areas of limited clearance;

(7) Areas where the truck may be operated near other powered industrial trucks, other vehicles, or pedestrians;

(8) Use and capacity of elevators;

(9) Operation near edge of dock or edge of improved surface;

(10) Other special operating conditions and hazards which may be encountered.

(c) Operation of the powered industrial truck, including:

(1) Proper preshift inspection and approved method for removing from service a truck which is in need of repair;

(2) Load handling techniques, lifting, lowering, picking up, placing, tilting;

(3) Traveling, with and without loads; turning corners;

(4) Parking and shutdown procedures;

(5) Other special operating conditions for the specific application.

(d) Operating safety rules and practices, including:

(1) Provisions of this Standard in Sections 5.1 to 5.4 addressing operating safety rules and practices;

(2) Provisions of this Standard in Section 5.5 addressing care of the truck;

(3) Other rules, regulations, or practices specified by the employer at the location where the powered industrial truck will be used.

(e) Operational training practice, including;

(1) If feasible, practice in the operation of powered industrial trucks shall be conducted in an area separate from other workplace activities and personnel;

(2) Training practice shall be conducted under the supervision of the trainer;

(3) Training practice shall include the actual operation or simulated performance of all operating tasks such as load handling, maneuvering, traveling, stopping, starting, and other activities under the conditions which will be encountered in the use of the truck.

4.19.5 Testing, Retraining, and Enforcement

(a) During training, performance and oral and/or written tests shall be given by the employer to measure the skill and knowledge of the operator in meeting the requirements of the Standard. Employers shall establish a pass/fail requirement for such tests. Employers may delegate such testing to others but shall remain responsible for the testing. Appropriate records shall be kept.

(b) Operators shall be retrained when new equipment is introduced, existing equipment is modified, operating conditions change, or an operator's performance is unsatisfactory.

(c) The user shall be responsible for enforcing the safe use of the powered industrial truck according to the provisions of this Standard.

Note: Information on operator training is available from such sources as powered industrial truck manufacturers, government agencies dealing with employee safety, trade organizations of users of powered industrial trucks, public and private organizations, and safety consultants.

(For an explanation of why OSHA decided to propose a standard that is somewhat different from the consensus standard, see section entitled Summary and Explanation of the Proposed Standard, below.)

Since 1971, the ANSI consensus committee has adopted other volumes [1] for additional types of vehicles that fall within the broad definition of a powered industrial truck. Specifically, volumes have been developed and adopted for guided industrial vehicles, rough terrain forklift trucks, industrial crane trucks, personnel and burden carriers, operator controlled industrial tow tractors, and manually propelled high lift industrial trucks. The training provisions OSHA is proposing are performance oriented and are applicable to all types of industrial trucks. Accordingly, OSHA is proposing the same training standards language for all types of industrial trucks. Comments are requested on this issue.

d. Petitions and Requests

Since the promulgation of the OSHA standard in 1971, interested persons have requested that OSHA improve its training requirements for powered industrial truck operators. ANSI (now the American Society of Mechanical Engineers (ASME)) has substantially upgraded its training provisions for powered industrial truck operators.

On March 15, 1988, the Industrial Truck Association (ITA) petitioned OSHA to revise its standard requiring the training of powered industrial truck operators (Ex. 3–2). The petition contained suggested language for a proposed requirement along with a model operator training program by which compliance with the recommended requirement could be met. OSHA responded to the petition on April 8, 1988, stating that work on the revision of the OSHA powered industrial truck operator training requirement would begin as soon as other priority projects were completed.

Congress, in particular, has expressed a special interest in this standard. A resolution urging OSHA to revise its regulations on forklift operator safety

[1] The consensus committees call the standards for different pieces of equipment "volumes" and all of the volumes produced by the committee the "standard". OSHA has decided to use the same nomenclature.

training was passed by the Senate in the 103rd Congress. Senate Concurrent Resolution 17 was approved by voice vote with 55 cosponsors and broad bipartisan support. Its companion measure in the House of Representatives, H. Con. Res. 92, had 236 cosponsors from both parties, although no formal vote was taken.

OSHA preliminarily concludes that upgrading the training requirements for powered industrial truck operators will substantially reduce a significant risk of death and injury caused by the unsafe operation of powered industrial trucks driven by untrained or inadequately trained operators.

II. The Powered Industrial Truck

The term "powered industrial truck" is defined in the ASME B56.1 (formerly the ANSI B56.1) standard as a "mobile, power propelled truck used to carry, push, pull, lift, stack, or tier material." Powered industrial trucks are particularly useful when handling palletized materials.

There are presently approximately 855,900 powered industrial trucks in use in American industry. Of this number, OSHA estimates that there are about 8300 powered industrial trucks in use in the construction industry.

Powered industrial trucks are classified by manufacturers according to their individual characteristics. There are seven classes of powered industrial trucks:

Class 1—Electric Motor, Sit-down Rider, Counter-Balanced Trucks (Solid and Pneumatic Tires).

Class 2—Electric Motor Narrow Aisle Trucks (Solid Tires).

Class 3—Electric Motor Hand Trucks or Hand/Rider Trucks (Solid Tires).

Class 4—Internal Combustion Engine Trucks (Solid Tires).

Class 5—Internal Combustion Engine Trucks (Pneumatic Tires).

Class 6—Electric and Internal Combustion Engine Tractors (Solid and Pneumatic Tires).

Class 7—Rough Terrain Forklift Trucks (Pneumatic Tires).

Each of the different types of powered industrial trucks has its own unique characteristics and inherent hazards. To maximize effectiveness, training must address the unique characteristics of the type vehicle(s) the employee is being trained to operate.

These trucks may operate on almost any type surface, from smooth and level floors to rocky, uneven ground, provided they were manufactured to operate on that type floor or ground and the surface does not have an excessive slope. Construction forklift trucks are more frequently operated on rough terrain than trucks used in other industry sectors.

Trucks of different types are designed and manufactured to operate in various work environments. Powered industrial trucks can be used for moving material about the workplace. High lift trucks can be used to raise loads up to 30 or 40 feet above the ground, to deposit the material on a roof under construction, a mezzanine or another elevated location, and subsequently to retrieve and lower the material.

Powered industrial trucks also may be equipped with, or can be modified to accept, attachments that allow movement of odd-shaped materials or permit the truck to carry out tasks that may not have been envisioned when the truck was designed and manufactured. Many of these attachments may be added to or installed on the vehicle by the dealer or by the employer. For example, there are powered industrial truck attachments for grasping barrels or drums of material. Some of these attachments not only grasp a barrel or drum but allow the vehicle operator to rotate the barrel or drum to empty the vessel or lay it on its side. OSHA recognizes that certain attachments may limit the safe use of the vehicle. To ensure that modifications or additions do not adversely affect the safe use of the vehicle, OSHA requires at § 1926.602(c)(1)(ii) that:

> (ii) No modifications and additions which affect capacity and safe operation of the equipment shall be made without the manufacturer's written approval. If such modifications or changes are made, the capacity, operation, and maintenance instruction plates, tags, or decals shall be changed accordingly. In no case shall the original safety factor of the equipment be reduced.

When the use of specialized attachments restricts the use of the powered industrial truck or when the truck is used to lift people, it is essential that operator training include instruction on the safe use of the vehicle so that the operator knows and understands the restrictions or limitations that are imposed upon the operation of the vehicle by the use of those attachments or the conduct of those operations.

III. Powered Industrial Truck Hazards

Powered industrial trucks are used in many construction activities. Their principal utility lies in the fact that either a large number of objects on a pallet or confined in a large box, crate or other container or large objects may be moved about the workplace and raised and placed on elevated surfaces with relative ease. Since powered industrial truck movement is controlled by the operator and is not restricted by the frame of the machine or other impediments, virtually unrestricted movement of the vehicle about the workplace is possible.

The hazards that are commonly associated with powered industrial trucks may not exist or be as pronounced for every type, make or model of vehicle. Each type of truck presents different operating hazards. For example, the chance of a falling load accident occurring when the truck is a sitdown, counterbalanced high lift rider truck is much greater than when the vehicle is a motorized hand truck, because the height to which the load can be raised by a sitdown rider truck is much greater than that for the hand truck.

Correspondingly, the method or means to prevent an accident or to protect employees from injury may be different with different types of trucks. For example, when a rider truck is involved in a tipover accident, the operator has the opportunity to remain in the operator's position in the vehicle during the tipover, thereby minimizing the potential for injury. In most cases, the operator of a rider truck is injured in a tipover accident when he or she attempts to jump clear of the vehicle when it begins to tip over. Because the natural tendency of the operator is to jump downward, he or she lands on the floor or ground and is then crushed by the overhead guard of the vehicle. Consequently, the operator of a rider truck should be trained to stay with the vehicle during a lateral tipover. On the other hand, when an order picker tips over with the platform in a raised position, the operator usually should attempt to jump clear of the vehicle, and should be trained accordingly.

Because a powered industrial truck is a motor vehicle, its operation is similar in some respects to that of an automobile, and some of its hazards are the same as those experienced during the operation of an automobile. Automobile and powered industrial truck are both subject to a number of common hazards, such as contacting fixed or movable objects (including employees) and tipping over.

Additionally, operating a car or an industrial truck at excessive speed or skidding on a wet or otherwise slippery ground or floor can be dangerous to the operator or nearby employees. Driving a powered industrial truck at excessive speed may result in loss of control, causing the vehicle to skid, tip over, or fall off a loading dock or other elevated walking or working surface. Failure to maintain control of the vehicle also may

cause the vehicle to strike an employee or to strike stored material, causing the material to topple and possibly injure an employee. Driver training is necessary so that the operator will act properly to minimize the hazard to himself or herself and to other employees.

Although there are many similarities between the automobile and the powered industrial truck, there are also many differences. Another reason for training industrial truck operators is to make operators aware of these differences. Some of the characteristics of a powered industrial truck that have a pronounced effect upon truck operation and safety that are outside auto driving experience are the truck's ability to change its stability, to raise, lower and tilt loads, and to steer with the rear wheels while being powered by the front wheels. In addition, vision is sometimes partially obscured by the load. Moving loads upwards, downwards, forwards and backwards causes a shift of the center of gravity and can adversely affect the overall stability of the vehicle. When a load is raised or moved away from the vehicle, the vehicle's longitudinal stability is decreased. When the load is lowered or moved closer to the vehicle, its longitudinal stability is increased.

To mitigate the hazards posed to the stability of the truck by the movement of the material being handled, the ANSI B56.1–1969 has seven provisions that address proper operation of a powered industrial truck. These provisions specify:

604 Q. While negotiating turns, speed shall be reduced to a safe level by means of turning the hand steering wheel in a smooth, sweeping motion. Except when maneuvering at a very low speed, the hand steering wheel shall be turned at a moderate, even rate.

605 A. Only stable or safely arranged loads shall be handled. Caution shall be exercised when handling off-center loads which cannot be centered.

605 B. Only loads within the rated capacity of the truck shall be handled.

605 C. The long or high (including multiple-tiered) loads which may affect capacity shall be adjusted.

605 D. Trucks equipped with attachments shall be operated as partially loaded trucks when not handling a load.

605 E. A load engaging means shall be placed under the load as far as possible; the mast shall be carefully tilted backward to stabilize the load.

605 F. Extreme care shall be used when tilting the load forward or backward, particularly when high tiering. Tilting forward with load engaging means elevated shall be prohibited except to pick up a load. An elevated load shall not be tilted forward except when the load is in a deposit position over a rack or stack. When stacking or tiering, only enough backward tilt to stabilize the load shall be used.

Knowledge of and adherence to these principles, as well as the other requirements of the OSHA standard, are essential for safe load handling and vehicle operation. Operators of vehicles used in construction need to be trained about the requirements of the consensus standard because failure to adhere to the techniques emphasized in these provisions are major causes of accidents.

The hazards addressed in this proposed rule are those associated with industrial trucks in general, as well as those posed by specific makes or models of trucks. Each powered industrial truck has a different feel that makes its operation slightly different from the operation of other trucks, and operators must therefore be aware of the effects of these differences on safe truck operation. The workplaces where these trucks are being used may also present particular hazards. For these reasons, a uniform and all-inclusive set of hazards that applies to all industrial trucks and workplaces cannot be delineated. For the same reason, the development of a single "generic" training program that fits all powered industrial trucks and all workplaces is impractical. In developing an effective powered industrial truck training program, there are however three major areas of concern that should be kept in mind. These are the hazards associated with the particular make and model of truck, the hazards of the workplace (which are particularly important on construction sites), and the general hazards that apply to the operation of all or most powered industrial trucks.

In addition, some hazards are related to the improper operation of a powered industrial truck. Among these hazards are: Falling loads caused by overloading, unbalanced loading or other improper loading; the vehicle falling from a platform, curb, trailer or other surface on which the vehicle is operating; the vehicle being driven while the operator has an obstructed view in the direction of travel; and the vehicle being operated at an excessive rate of speed.

OSHA has identified several accidents that have occurred when an employee other than the operator is "given a ride" on a powered industrial truck. Most trucks were designed and are intended to allow only the operator to ride on the vehicle. The carrying of other persons may result in an accident when that other person either falls from the vehicle or hits an obstruction when the vehicle comes too close to that obstruction. Finally, powered industrial truck accidents occur because the vehicle is not properly maintained (These accidents most commonly involve employees being overcome by excessive carbon monoxide emissions or vehicle component failure).

The seriousness of the consequences associated with these accidents depends on such factors as the method of operation of the powered industrial truck, the load being carried, and the characteristics of the workplace in which the vehicle is being operated. Accordingly, truck operators must be trained to recognize unsafe conditions and how to react to them when they occur.

Several features of powered industrial trucks contribute either directly or indirectly to the hazards posed by these vehicles. Some of the factors that influence the extent of the hazards presented by a particular truck are the placement of the critical components of the vehicle, the age of the vehicle, and the manner in which the vehicle is operated and maintained.

There are other hazards related to the use of powered industrial trucks that are caused or enhanced by the characteristics of the workplace. These hazards include the following: Operating powered industrial trucks on rough, uneven or sloped surfaces; operating powered industrial trucks with unusual loads; operating in hazardous (classified) areas; operating in areas where there are narrow aisles; and operating where there is pedestrian traffic or where employees are working in or adjacent to the path of travel of the powered industrial truck. The first hazard is particularly pronounced on construction sites.

The operation of a powered industrial truck presents hazards not only to the operator, but also to other employees working with or around the vehicle. As explained in the section entitled "Studies and Accident, Injury and Other Data," below, employees other than operators have been injured or killed in accidents involving powered industrial trucks. Proper training can reduce accidents resulting from the causes described above.

IV. Studies and Accident, Injury and Other Data

A detailed analysis of powered industrial truck studies and accident and injury data appears in the NPRM for truck training for general industry and the maritime industry, which was published in the **Federal Register** on March 14, 1995 (60 FR 13787). The section presented here briefly summarizes the data relevant to the construction industry.

a. Studies Measuring the Effectiveness of an Industrial Lift Truck Safety Training Program

In 1984, H. Harvey Cohen and Roger C. Jensen, working under contract with the National Institute for Occupational Safety and Health (NIOSH), published an article in the Journal of Safety Research (Fall 1984, Vol. 15, No. 3, pp. 125–135) entitled "*Measuring the Effectiveness of an Industrial Lift Truck Safety Training Program*" (Ex. 4). The article contained an analysis of two studies that were undertaken to measure objectively the effects of safety training on the driving performance and safety practices of powered industrial truck operators.

This article detailed the results of an experiment that was conducted to evaluate training of powered industrial truck operators using a behavioral (work) sampling procedure to obtain objective data about work practices that correlate with injury risk. There were two separate studies conducted in this experiment, one at each of two similar warehouses. The studies that comprised the experiment were conducted to assess the value of training and the influence of post- training actions on the safety performance of workers. These studies demonstrate that training powered industrial truck operators reduced the operators' error rates (number of unsuccessful operations divided by the total number of operations) and that training combined with feedback reduced error rates even more.

The studies were conducted at different warehouses using similar training techniques. The training was conducted to emphasize those operator behaviors that were measurable, frequently observed, capable of being reliably observed, related to frequent accident occurrence and amenable to corrective action through training. There were 14 behaviors evaluated in these studies. Positive reinforcement of the training was used with some trainees to measure its effectiveness. The experiment was conducted in four phases:

(1) The pre-training phase, during which none of the operators had been trained;

(2) The post-training 1 phase, during which the control group remained untrained, the treatment group had received training, and the treatment-plus-feedback group had received training and also was receiving performance feedback;

(3) The post-training 2 phase, during which all three groups had received training but only the training-plus-feedback group received performance feedback; and

(4) The retention phase, which started 3 months after the end of the post-training 2 phase (and the end of the feedback program).

Following the initial training (post-training 1), all three groups showed a decrease in their mean error rates with the training-plus-feedback group showing the largest decrease (from .35 to .27, a 23 percent decrease) followed by the training-only (from .33 to .27, an 18 percent decrease) and the control group (from .34 to .32, a 6 percent decrease). The reduction in the error rate of the control group from the pre-training to the post-training 1 phase of the study was attributed to the influence of peer modeling, i.e., the untrained control group operators were copying the behavior of their trained counterparts. Toward the end of the post-training 1 phase, the error rates of the three groups converged, suggesting that the effects of the training program had begun to wear off. Observers also noted that some behaviors were being compromised when employees of different knowledge levels were required to interact, particularly in conflict avoidance situations such as signaling and yielding at blind intersections.

During the post-training 2 phase of the study, all groups improved in performance. The control group's performance improved by 28 percent (from a mean error rate of .32 to .23) while the training group experienced a 4 percent improvement (from a mean error rate of .27 to .26) and the training-plus-feedback group had a 7 percent improvement (from .27 to .25). The authors concluded that there was further evidence of the effect of peer modeling because the performance of all three groups continued to improve although no additional instruction was given.

The retention phase of the study was conducted three months following the completion of the post-training 2 phase of the study. It was intended to determine the longer term effects of the training. During this phase of the study, mean error rates were checked, as was done during the other phases of the study. The results of this phase of the study indicate an additional improvement in the performance of the operators, with the mean error rate decreasing from .25 to .19, a 24 percent improvement in their performance. The total performance gain achieved during this study was a 44 percent improvement from the pre-training (baseline) phase through the retention phase (from a mean error rate of .34 to a final error rate of .19). The data indicate that there were significantly fewer errors at each successive phase of the study.

The second study was conducted to verify and extend the findings of the first study. A modified experimental design was used to eliminate the mitigating influence of the untrained control group. In the second study, all operators were trained at the same time and all received performance feedback. Comparisons were made only before and after training. The study was divided into three phases: Pre-training, post-training and retention. The retention phase of the study was again conducted three months after the conclusion of the prior phase.

Following the training of the vehicle operators, there was a 61 percent improvement in performance scores (from an error rate of .23 to .09). Observation in the retention phase of this study showed an additional reduction of 22 percent in mean error rates (from .09 to .07 mean error rate). The overall improvement in mean error rates between the pre-training error rate (.23) to that achieved during the retention phase (.07) was a reduction of 70 percent.

b. The OSHA Fatality/Catastrophe Reports

OSHA records a summary of the results of investigations of all accidents resulting in fatalities, catastrophes, amputations and hospitalizations of two or more days, and those accidents that have received significant publicity or caused extensive property damage. These summaries are recorded on an OSHA Form 170 and include an abstract describing the activities taking place at the time of the accident and the causes of the accident. These reports are stored in a computerized database system.

A substantial percentage of the serious powered industrial truck accidents that were investigated occurred in the construction industry. Specifically, 29 out of the 200 accidents investigated took place in the construction industry.

c. Bureau of Labor Statistics (BLS) Data

In April, 1994, BLS published a booklet entitled "*Fatal Workplace Injuries in 1992: A Collection of Data and Analysis*" (Ex. 3–4). In this booklet, there was an article written by Gary A. Helmer entitled "*Fatalities Involving Forklifts and Other Powered Industrial Carriers, 1991–1992.*" This report contains information contained in the Census of Fatal Occupational Injuries (CFOI) on 170 fatal powered industrial truck accidents. Table 1 lists the

classifications of those powered industrial truck accidents.

TABLE 1.—CLASSIFICATION OF FORKLIFT FATALITIES, CFOI, 1991–1992

How accident occurred	Number	Percent
Forklift overturned	41	24
Forklift struck something, or ran off dock	13	8
Worker pinned between objects	19	11
Worker struck by material	29	17
Worker struck by forklift	24	14
Worker fell from forklift	24	14
Worker died during forklift repair	10	6
Other accident	10	6
Total	170	100

Source: Bureau of Labor Statistics, *"Fatal Workplace Injuries in 1992, A Collection of Data and Analysis"*, Report 870, April 1994.

d. Fatality and Injury Data

As discussed in the Preliminary Economic Analysis, there are on average 15 deaths and 1440 serious injuries from powered industrial truck operations in the construction industry each year. It is estimated that this standard would prevent 3 or 4 deaths and 463 to 601 of these serious injuries per year.

V. Basis for Agency Action

OSHA believes that, as the above discussion indicates, there is a sufficient body of data and information on which to base a revision of the existing standard for powered industrial truck operator training in the construction industry. The data indicate that there are a substantial number of fatalities and injuries from industrial truck accidents in the construction industry. Studies indicate that better training would substantially reduce the number of such fatalities and serious injuries. Consequently, these requirements would reduce the number of fatalities and injuries resulting from accidents involving powered industrial trucks operated by untrained or insufficiently trained employees.

In addition, as discussed above, there are other reasons to update the standard. For example, there now exist substantially updated consensus standards on this subject. In addition, OSHA has been petitioned to improve the requirements for industrial truck training. Further, the Advisory Committee on Construction Safety and Health has recommended improving the standard. Finally, the Senate recently passed a resolution urging OSHA to revise its outdated powered industrial truck operator standards.

VI. The Need for Training

Training is generally defined as making a person proficient through the use of specialized instruction and practice. Training is the means by which an employer ensures that employees have the knowledge, skills, and abilities that are necessary for the employees to do their jobs correctly.

Once an employee acquires the basic knowledge, skills, and abilities, refresher or remedial training may be used to reinforce or improve those attributes, to provide new material, to provide material that was previously discussed in a new manner, or to simply maintain an awareness of the material that has previously been taught. Refresher or remedial training is normally conducted on a predetermined periodic basis, that is, on a monthly, semi-annual, or annual basis.

Training may be as simple and informal as a supervisor pointing out an error in the manner in which an employee is doing a job (making an on-the-spot correction) or showing an employee how to do a particular task (demonstrating the proper method to do the job). On the other end of the spectrum is the detailed, structured instruction that uses formal methods of training (lectures, conferences, formal demonstrations, practical exercises, examinations, etc.). Formal training is usually used to impart more, or more complicated information to a trainee.

For the most part, employees do not start out with the knowledge, skills, and abilities to perform the tasks necessary for safe lift truck operation. Although many employees who are selected or assigned to drive powered industrial trucks are licensed to drive automobiles, there are enough dissimilarities between these two types of vehicles and their operation to require additional knowledge, skills, and abilities to operate a powered industrial truck safely. Operational characteristics of powered industrial trucks, such as vehicles equipped with rear-wheel steering and front-wheel drive and the capability to hoist-move-lower loads, require operator training and practice to master the different driving skills that must be used when an employee operates powered industrial trucks.

Many accidents can be prevented, or the seriousness of the injury to the employee can be mitigated, by training employees. Effective training and supervision also can prevent the occurrence of unsafe acts such as speeding, failing to look in the direction of travel, and failing to slow down or stop and sound the vehicle's horn at blind intersections and other areas where pedestrian traffic may not be observable. Another example in which training can prevent or lessen the severity of an accident of this kind is directly related to the stability of powered industrial trucks when traveling with an elevated load. Effective operator training should emphasize that the vehicle can only be moved when the load is at its lowest point. However, even if an operator fails to follow this practice and the vehicle tips over, the injury to the operator is usually minimal if he or she stays with the vehicle. As previously discussed, the usual injury in a powered industrial truck tipover occurs when the operator attempts to jump off the vehicle while it is tipping over. In these cases, since the normal tendency is for a person to jump downward, the operator lands on the floor or ground in the path of the overhead guard, leading to a crushing injury of the head, neck or back. Training an employee to stay with the vehicle will reduce the severity of some of these injuries.

The studies conducted by Cohen and Jensen, discussed under *Studies, Accident, Injury and Other Data* earlier in this preamble, found a reduction in operator errors rate of up to 70 percent from training. Although a 70 percent error rate reduction cannot be directly equated to a corresponding reduction in the number of accidents that this or any other group of operators will experience, improper or unsafe operation of powered industrial trucks is the major cause of accidents and their resultant fatalities and injuries. Therefore, a reduction in the unsafe operation of these trucks will reduce the number of accidents, and the resultant fatalities and injuries.

Although not all powered industrial truck accident reports spell out lack of training as a causal factor in the accident, each accident can, in part, be attributed to the actions or inactions of the operator. For example, when a powered industrial truck tips over, the accident is caused by one or more of several factors, including speeding, traveling with the load in an elevated position, or improperly negotiating a turn. Training can minimize the number of times that these events occur.

Proper training of an employee must take into account the fact that different operating conditions (including the type and size of the load, the type and condition of the surface on which the vehicle is being operated, and other factors) can adversely affect vehicle operation. Construction sites usually include many of these factors, such as rough terrain. Operator training must emphasize two points regarding any

potential accident scenario. These two factors are: (1) The employee should not engage in activities that may cause an accident, and (2) the employee should minimize the potential for injury (either to himself or herself or to other employees) by taking appropriate actions.

VII. Summary and Explanation of the Proposed Rule

a. Specific Provisions Included in the Proposed Standard

OSHA is proposing to improve the training of powered industrial truck operators in construction by adding a new 29 CFR 1926.602(d) that would supersede the current cross- reference to the 1969 ANSI standard insofar as that standard specifies that only trained operators be permitted to operate powered industrial trucks. This proposal is intended to enhance the safe operation of powered industrial trucks in the construction workplace.

In developing this proposal, OSHA looked at the training requirements of the existing national consensus standard for powered industrial trucks, ANSI B56.1–1993, as well as training requirements from other standards (both industry and government). The non-training related requirements of those standards are beyond the scope of this proposal.

The proposed standard includes six elements. First, the employer is only to use powered industrial truck operators who are trained for and capable of performing the job. Operator training is to include both formal training and practical experience. Various relevant topics are to be covered in the training unless they are not relevant to the employer's vehicles or workplace. Refresher training is to be provided, and if there is an accident or unsafe operation of the vehicle, remedial training must be given. Employers are to certify that employees are trained. Prior training and experience may count toward the required training.

At paragraph (d)(1)(i), OSHA specifies that each employee who will be required to operate a powered industrial truck must be capable of performing the duties that are required of the job after training and appropriate accommodation. This means that the employee must have to climb onto and off a truck, to sit on the vehicle for extended periods of time, to turn his or her body to be able to drive in reverse, and to have the physical and mental abilities to perform the job. Information obtained during the initial employee evaluation can be used to, among other things, determine how best to train the employee. For example, if the employee cannot read and comprehend the operator's manuals for the type of trucks that the employee will operate, this information would have to taught by means other than assigning the employee to read the truck manuals. The initial evaluation can also be useful in avoiding duplicative training.

Paragraph (d)(1)(ii) provides that the employer shall ensure that the employee has received required training, that the employee has been evaluated and that the operator can perform the job competently. After the training, the evaluation must be carried out by a designated person so that the employer can ensure that the trainee can perform the duties required of an operator in a competent manner. Conducting evaluations during training is known as a practical exercise or a performance test. OSHA believes that only through evaluation by a knowledgeable person after training can an employer know that the employee has been adequately trained and can safely perform the job.

The designated person may be the employer, if qualified. A small business person who has employees may decide to send the employees to an outside training organization. Alternately, the employer may be sufficiently trained to enable the employer to be qualified as a designated person.

At paragraph (d)(2), OSHA is proposing to require that the employer implement a training program for all powered industrial truck operators. This program would ensure that only trained drivers who have successfully completed the training program would be allowed to operate these vehicles. An exception to the rule would allow trainees to operate powered industrial trucks provided the operation is under the direct supervision of a designated person and the operation is conducted where there is minimum danger to the trainee or other employees.

OSHA is proposing at paragraph (d)(2)(ii) that the training consist of a combination of classroom instruction and practical training. The Agency believes that only a combination of training methods will ensure adequate employee training. Although classroom training is invaluable for the teaching of the principles of vehicle operation, it is the hands-on training and the evaluation of the operation of the vehicle that finally proves the adequacy of the training and the ability of the employee to use that training to operate a powered industrial truck successfully.

At paragraph (d)(2)(iii), OSHA is proposing to require that all training be conducted by a designated person. OSHA defines a designated person as one who has the requisite knowledge, training and experience to train powered industrial truck operators and judge their competence. As discussed elsewhere in this preamble, the employer may have the necessary prerequisites to qualify as a designated person, or he or she may assign the training responsibility to another person (either a knowledgeable employee or an trainer from outside the company).

To ensure that the training contains the appropriate information for the operator, OSHA has provided a list of subjects at paragraph (d)(3). Under this rule, it is the responsibility of the employer to select the particular items that are pertinent to the types of truck that the employee will be allowed to operate and the work environment in which the vehicle will be operated. For example, if the employee will be allowed to operate an order picker, it is essential that he or she understand the location and function of the controls, the location and operation of the powerplant, steering and maneuvering, visibility, inspection and maintenance, and other general operating functions of the vehicle. Additionally, it is essential that the employee know and understand that he or she must be restrained from falling when the platform of the truck is in an elevated position and that the truck must never be driven when the platform is elevated. Under this proposed requirement, it is the responsibility of the employer to select those elements of the training that are necessary for the type of vehicle to be used and the workplace in which that vehicle will be operated. The employer may leave out elements if the employer can demonstrate that they are not relevant to safe operation in the employer's workplace.

An additional component of the training program is a continuing evaluation of the operator. At paragraph (d)(4), OSHA specifies that this evaluation be conducted on a periodic basis so that the employee retains and uses the knowledge, skills and abilities that are necessary for the safe operation of the vehicle. This evaluation need only be conducted at the intervals necessary to ensure that the operators have not forgotten or chosen to disregard their training. OSHA is proposing that such evaluations be carried out at least annually. The evaluation does not have to be formal; for example, it could be something as simple as having the designated person observe an operation to ensure that the powered industrial truck is being operated safely.

OSHA is requiring at paragraph (d)(5) that the employer certify that the

required training and evaluations have been conducted. To minimize paperwork burden on the employer, OSHA is specifying that the certification consist only of the name of the employee, the date of the training or evaluation, and the signature of the person conducting the training or evaluation. In light of the Paperwork Reduction Act of 1995, OSHA is requesting comment on ways it can determine whether employees have been properly trained without using even the minimal requirement of certification. In this paragraph, OSHA also specifies that all of the current training materials used in the conduct of training or the name and address of the outside trainer, if one is used, be maintained.

At paragraph (d)(6), OSHA is proposing to allow the employers to forego those portions of the required training that employees have previously received. The intent of these provisions is to prevent duplicative training. For example if an employee is already trained in powered industrial truck operation, knows the necessary information, has been evaluated, and has proven to be competent to perform the duties of an operator, there is no reason to require an employer to repeat the training.

As previously discussed, three major areas must be emphasized when conducting a powered industrial truck training program. These three areas are: (1) The characteristics, operation and limitations of the vehicles that the trainee will be authorized to operate, (2) the hazards associated with the workplace in which these vehicles will operate, and (3) the general safety rules that apply to these vehicles and their operation.

This proposed rule has been drafted in performance language to allow the employer a reasonable degree of flexibility in developing the training program and conducting the training. OSHA recognizes that there are inherent differences in the capabilities and limitations of employees, both in their ability to assimilate the training and then to use the knowledge that has been gained. Therefore, the proposed regulation does not limit the employer by specifying the manner in which the training must be conducted. Similarly, the specific content of the training course has not been prescribed because different topics must be taught to address the variations associated with different makes and models of vehicles and cover hazards specific to each workplace. However, the proposal does identify the topics that should be covered unless the employer determines that one or more of them are not relevant to the employer's situation.

OSHA believes that the training needs to be administered before the employee begins to operate a vehicle. To this end, OSHA has required initial training of employees so that they will acquire the knowledge and skills that are necessary for the safe operation of the powered industrial truck before being allowed to operate the vehicle without close supervision.

OSHA has generally left the particulars of the type of training (lecture, conference, demonstration, practical exercise, test or examination, etc.) to the employer. However, the training must include some formal instruction and some practical experience. The length of the training must be based on the employee's experience and other qualifications and the nature of the work environment. The training must be based upon the type of vehicles the employee will be allowed to operate, the conditions that exist in the workplace, the general safety rules included in this OSHA standard, the trainer's skills and knowledge, and the trainee's skill level. Consequently, OSHA believes that one standardized training course will not suffice for all employees.

The employer may choose the training provider. This could include contracting with an outside professional training company to come into the company and train the powered industrial truck operators or the employer developing and conducting the training program. In either case, the employer can choose the method or methods by which the employees will be trained and when the training is conducted.

The standard requires at paragraph (d)(4) that a designated person evaluate the trainee's understanding of the training and his/her competency to operate a powered industrial truck. This is the best method of proving that the operator has been adequately trained and that the training has been, and continues to be, effective. By observing how the trainee operates the vehicle, the evaluator can assess how well the trainee has absorbed the necessary information.

When a new employee claims prior experience in operating a powered industrial truck, the employer must ensure that the employee knows how to operate the vehicle safely. This can be ascertained by questioning the employee on various aspects of the operation of the truck and by requiring the operator to demonstrate his or her ability to operate the vehicle safely through the conduct of a practical exercise.

In evaluating the applicability and adequacy of an employee's prior experience, the employer must consider the type of equipment the employee has operated, how long ago this experience was gained, and the type of work environment in which the employee worked. Some written documentation of the earlier training is also necessary to determine that proper training has been given. In addition, the competency of the employee must be evaluated. Based on an evaluation of this information, the employer can determine whether the experience is recent and thorough enough, the documentation sufficient, and the competency adequate to forego some or much of the initial training. Some training on the specific factors of the new employee's workplace will always be necessary. Again, the major criterion for evaluating an employee is: Does the person know how to do the job and does the vehicle operator have and use the knowledge that is needed to do the job safely?

The proposed regulatory text for construction includes some minor changes to improve the clarity from the language proposed for other sectors. OSHA also is proposing to add two non-mandatory appendices to the standard. These appendices are intended to provide guidance to employers in establishing a training program (Appendix A) and in understanding the basic principles of stability (Appendix B). In neither case is the information contained in these appendices intended to provide an exhaustive explanation of the techniques of conducting training or of understanding the principles of stability, but each appendix is intended to introduce the basic concepts so that the employer can use the material to provide basic training.

b. Specific Provisions of the ASME Standard Not Included in This Proposal

OSHA has not included some of the suggested language contained in the ASME B56.1–1993 standard. Specifically, paragraph 4.19.2 of the consensus standard has not been included because other enforceable language in the proposed standard covers the issue. This paragraph states:

> The operator training program should include the user's policies for the site where the trainee will operate the truck, the operating conditions for that location, and the specific truck the trainee will operate. The training program shall be presented to all new operators regardless of previous experience.

The Agency also has not adopted the language contained in 4.19.3(a) of the consensus standard because the responsibility for providing a safe

workplace (including the use of a powered industrial truck) is vested with the employer under the OSH Act. Paragraph 4.19.3(a) specifies, "The primary responsibility of the operator is to use the powered industrial truck safely following the instructions given in the training program."

The consensus standard, at 4.19.4(e) and 4.19.5, specifies the type of training and the testing that should be conducted, whereas the OSHA standard leaves the methods of training up to the employer. As explained above, the employer is responsible for selecting the methods that are employed to train the operators. For example, in some circumstances, the employee may be able to gain valuable information from reading the operator's manual for the vehicle. In other circumstances, reading the manual may be less effective than practical lessons in how to operate the truck safely.

Many OSHA standards and consensus standards specify that some means be used to verify that training has been conducted. Examples of such verification include: (1) Documentation of training, (2) retention of lesson plans and attendance rosters and, (3) issuance of training certificates. When refresher or remedial training is specified, these other rules usually require that a set amount of training be conducted at a regular interval (for example, a certain number of hours of refresher training be conducted annually). The proposed rule would require evaluation by a designated person and certification that the employee has taken the training and can competently operate the truck. Course materials also must be kept. OSHA believes that this is a sufficient method of verification. The ASME provision would require additional paperwork that is discouraged by the Paperwork Reduction Act of 1995.

VIII. The Comments and Recommendations of the Advisory Committee on Construction Safety and Health

The Advisory Committee on Construction Safety and Health (ACCSH) was advised at its meeting of February 28 and March 1, 1995, of the effort being undertaken by OSHA to promulgate like training requirements for all powered industrial truck operators regardless of where the powered industrial truck is being used. At that time, the ACCSH recommended to the Agency that the issuance of an NPRM for construction be delayed until the Committee had more time to study the draft of the proposal and to submit its formal comments and recommendations to OSHA. At that meeting, the Committee also set up a task force to consider the matter.

At its meeting of May 25 and 26, ACCSH received the recommendations from the task force. ACCSH voted unanimously that OSHA should publish a proposal for improving the training requirement for powered industrial truck operators in the construction industry. The Committee also suggested that OSHA consider the changes recommended and get feedback from the public on the proposal and then proceed from there (Tr. pp. 202–223)(Ex. 9).

OSHA has carefully considered the comments and recommendations received from the ACCSH. OSHA has decided that the best approach at this time is to raise the suggested ACCSH changes as issues for public comment in this preamble rather than to incorporate them into the proposed regulatory text. OSHA believes this is the best approach to highlight these issues for public comment. After considering the public comments, OSHA will consider the best approach for handling the suggested changes in the final powered industrial truck operator training standard for construction. OSHA also is publishing these recommendations for consideration for inclusion in the final general industry and maritime rules to see whether the ACCSH recommendations may be appropriate in these industries as well. Therefore, OSHA is not making specific word changes in the proposed regulatory text and will examine the comments received in response to this document before it does so. This also may prevent possible confusion, because ACCSH used the specific language and paragraph numbering of the ASME standard rather than the proposed general industry regulatory text and paragraphic numeration when referencing its discussion.

The following issues were submitted by ACCSH. Also included is a short discussion of the reasons for the ACCSH recommendations:

1. In the construction industry, should an employer be allowed to accept the certification of training by a third party such as a union, manufacturer, consultant, or other private or public organization? Since OSHA does not accredit certifiers, what criteria should be used to establish their credibility?

ACCSH recommended that construction employers be permitted to accept such accreditation. In the construction industry, it is common that such training would be presented by the union, an apprenticeship program, or by a local employer organization. In addition, employees often work for an employer only briefly and it would be inefficient for the new employer to have to review the performance of each new employee. If this approach were adopted, there would need to be some mechanism to ensure that the operator would be trained in conditions comparable to those found at the present site and to enable the employer to know that the operator had been trained.

2. What type of testing should be conducted during initial training to judge the competency of the trainee (performance testing and oral and/or written tests)?

A. If tests are administered, what subjects should be tested, and what methods, if any, should be used to judge that the tests are reliable and address the subject matter adequately?

B. What, if any, should be the acceptable pass/fail requirement for the tests?

ACCSH recommended that the employer or other organization training operators give both performance tests and oral/written tests to ensure the skill and knowledge of the operator. The committee also recommended that there should be pass/fail requirements for those tests and that records be kept of the results of the tests. ACCSH believed that this requirement would assist in lowering accident rates. The Committee also suggested that, if this turned out not to be effective, OSHA consider accreditation of training programs.

3. Are some of the listed training subjects not needed?

ACCSH believes that most of the training topics in the proposed standard are necessary but that a few might not be. Specifically, they felt that the recommended topic of the differences between driving an auto and a powered industrial truck might be unnecessary.

4. Should an employee receive refresher or remedial training only if operating a vehicle unsafely or if involved in an accident? Is there any fixed operator retraining frequency suitable for the construction industry?

The Advisory Committee believed that a periodic retraining provision for construction was inappropriate because most construction employees are only on a particular job a short period. However, the Committee recommended reevaluation and possible retraining after an incident, accident or expiration of a certificate. (See question 1.)

IX. Statutory Considerations

Section 2(b)(3) of the Occupational Safety and Health (OSH) Act authorizes

"the Secretary of Labor to set *mandatory occupational safety and health standards* applicable to businesses affecting interstate commerce", and section 5(a)(2) provides that "(each employer shall comply with *occupational safety and health standards* promulgated under this Act" (emphasis added). Section 3(8) of the OSH Act (29 U.S.C. 652(8)) provides that "the term 'occupational safety and health standard' means a standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment."

OSHA considers a standard to be "reasonably necessary or appropriate" within the meaning of section 3(8) if it meets the following criteria: (1) The standard will substantially reduce a significant risk of material harm; (2) compliance is technologically feasible in the sense that the protective measures being required already exist, can be brought into existence with available technology, or can be created with technology that can reasonably be developed; (3) compliance is economically feasible in the sense that industry can absorb or pass on the costs without major dislocation or threat of instability; and (4) the standard is cost effective in that it employs the least expensive protective measures capable of reducing or eliminating significant risk. Additionally, safety standards must better effectuate the Act's protective purpose than the corresponding national consensus standards, must be compatible with prior agency action, must be responsive to significant comment in the record, and, to the extent allowed by statute, must be consistent with applicable Executive Orders. OSHA believes that application of these criteria results in standards that provide a high degree of worker protection without imposing an undue burden on employers. (See the discussion of 60 FR 13796–13799, March 14, 1995, for a detailed analysis of the case law.)

As discussed in various places in the preamble of the March 14 notice, OSHA has determined that the operation of powered industrial trucks by untrained or inadequately trained operators generally poses significant risks to employees. It is also OSHA's view that operation of powered industrial trucks by untrained or inadequately trained operators poses a significant risk to employees in the construction industry. There have been on average 15 fatalities and 1441 serious injuries in the construction industry annually due to unsafe powered industrial truck operation. OSHA estimates that compliance with the revised training requirement for powered industrial truck operators will reduce the risk of these injuries and deaths to those operators and other employees by between 20 and 45 percent (preventing 3 to 4 fatalities and 463 to 600 serious injuries annually). This constitutes a substantial reduction of significant risk of material harm.

The Agency believes that compliance is technologically feasible because there exists a current rule for the training of powered industrial truck operators and the revised regulation merely specifies in more detail what is to be taught to those operators and requires the employer to institute effective supervisory measures to ensure continued safe operation of those vehicles. In many companies, the training of vehicle operators and the subsequent supervisory measures required by the standard have already been implemented.

Additionally, OSHA believes that compliance is economically feasible, because, as documented by the Preliminary Economic Analysis, all regulated sectors can readily absorb or pass on compliance costs. OSHA estimates total costs of $250,000, a negligible percent of the industry's $500 billion in sales and $35 billion in pretax profits.

The standard's costs, benefits, and compliance requirements are reasonable, amounting to approximately $250,000 per year while preventing 3–4 fatalities and 463–600 serious injuries per year.

In some subsectors of the construction industry there are relatively few lift trucks and in any given year, there may be no fatalities and few injuries in these subsectors. Nevertheless, OSHA believes the risks to individual drivers in these environments are significant and that the costs of compliance in these subsectors will be negligible.

For these reasons and those further spelled out in the **Federal Register** document of March 14, 1995 (60 FR 13795), OSHA has determined that it is inappropriate to exclude any construction subsectors merely because they have not recently reported documented powered industrial truck injuries or fatalities, insofar as these subsectors contain workplaces where powered industrial trucks are operated.

As discussed above in sector VII(b) of this preamble; many of the provisions of this proposed standard are based on the current ASME consensus standard. Pursuant to section 6(b)(8) of the OSH Act, OSHA explains above why the proposed provisions that differ from the ASME standard better effectuate the purpose of the Act.

Conclusion

OSHA has preliminarily determined that the proposed powered industrial truck standard for construction, like other safety standards, is subject to the constraints of section 3(8) of the OSH Act, and that the standard is "reasonably necessary or appropriate to provide safe or healthful employment and places of employment."

The Agency believes that the use of powered industrial trucks in the construction workplace by untrained or poorly trained employees poses significant risks and that the need to require that only properly trained employees operate these vehicles is reasonably necessary to protect affected employees from those risks. OSHA also has determined that compliance with the standard for the training of these operators is technologically feasible because many companies offer the type of training that the standard would require. In addition, OSHA believes that compliance is economically feasible, because, as documented by the Preliminary Economic Analysis (Ex. 2), all regulated sectors can readily absorb or pass on initial compliance costs and the benefits are substantial. In particular, the Agency believes that compliance with the proposed powered industrial truck training requirements will result in substantial cost savings and productivity gains at facilities that utilize powered industrial trucks whose operations might otherwise be disrupted by accidents and injuries.

As detailed in OSHA's March 14, 1995, document (60 FR 13799) and in the Preliminary Economic Analysis, the standard's costs, benefits, and compliance requirements are consistent with those of other OSHA safety standards.

X. Summary of the Preliminary Economic Feasibility and Regulatory Flexibility Analyses and Environmental Impact Assessment

Introduction

Executive Order 12866 and the Regulatory Flexibility Act require Federal Agencies to analyze the costs, benefits and other consequences and impacts of proposed standards and final rules. Consistent with these requirements, OSHA has prepared this preliminary economic analysis to accompany the revised proposal being published, which would extend requirements for the training of powered

industrial truck operators to the construction industry. OSHA's initial proposal, which proposed such training for truck operators in general industry and the maritime industries, was published in the Federal Register on March 14, 1995 (60 FR 13782). These proposed construction industry training requirements will supplement and extend the minimal powered industrial truck operator training requirements currently codified at 29 CFR 1926.602 (c)(1)(vi). This preliminary economic analysis of the potential impacts of the proposal on firms in the construction industry will be incorporated into the Preliminary Economic Analysis developed by OSHA to support the proposed powered industrial truck operator training requirements for the general industry and maritime sectors published on March 14, 1995.

This preliminary economic analysis of the potential impacts of the proposed rule on the construction industry includes a description of the industry, an assessment of the benefits attributable to the proposal, a preliminary determination of the technological feasibility of the proposed requirements, an estimation of the costs of compliance, an analysis of the economic feasibility of the proposed provisions, and an evaluation of the economic and other impacts of the proposed rule on establishments in this sector. This preamble discussion summarizes the more detailed analysis that is available in the docket (Ex. 2).

Affected Industries

Using powered industrial truck sales data provided by the Industrial Truck Association (ITA), OSHA estimates that, of the 822,831 industrial trucks in use in industries covered by OSHA, the construction sector (SICs 15–17) uses about 8,300. This proposed rule will cover construction workers who operate powered industrial trucks, including workers who are employed as dedicated (i.e., full time) truck operators and those whose operation of powered industrial trucks is incidental to the performance of another job. These incidental users of powered industrial trucks include maintenance personnel and general laborers. Non-driving workers such as materials handlers, laborers, and pedestrians who work on or are present in the vicinity of powered industrial truck operations may also be injured or killed in powered industrial truck accidents.

OSHA estimates that approximately 1.2 million workers are employed as industrial truck operators in industries regulated by OSHA. OSHA estimates that 12,400 of these operators are employed by the construction sector.

Technological Feasibility

OSHA did not identify any proposed requirement that raises technological feasibility problems for construction establishments that use industrial trucks. On the contrary, there is substantial evidence that establishments can achieve compliance with all of the proposed requirements using existing methods and equipment. In addition, the proposed standard introduces no technological requirements of any type. Therefore, OSHA has preliminarily concluded that technological feasibility is not an issue in relation to the proposed construction industry training standard for powered industrial truck operators.

Costs of Compliance

The proposed industrial truck operator training requirements would expand the training required by OSHA's existing industrial truck training standard (29 CFR 1926.602 (c)(1)) to include training information on the operating instructions and warnings appropriate to the type of truck used, the specific hazards found in the workplace where the truck will be operated, and the requirements of this standard. Additionally, the proposed provisions require construction employers to monitor the performance of industrial truck operators through an annual evaluation and to provide remedial training when this evaluation suggests that such training is needed.

The annual costs construction employers will incur to comply with the proposed revisions are estimated to be $254,420. Table 2 presents estimated annual costs, by provision, at the three-digit SIC level. OSHA developed these industry compliance cost estimates based on per- operator costs, the number of operators affected, and employee turnover rates. Costs are annualized based on a 7 percent discount rate, as directed by the Office of Management and Budget, and are projected over 10-years.

Current industry practice was also taken into consideration when calculating costs, i.e., where employers have already voluntarily implemented practices that would be required by the proposed standard, no cost is attributed to the new standard. OSHA estimated that it is current practice for 80 percent of employers in this industry to conduct an initial evaluation of each powered industrial truck operator's skill, as would be required by the proposal. In addition, specific equipment training is often a component of initial training in this industry. Many operators are also currently trained in both classroom and hands-on settings, and on the specific type of truck they will use. OSHA estimates that about 75 percent of employers currently are in compliance with these proposed requirements. Across all OSHA-regulated sectors, including construction, 65 percent of employers are assumed to be providing truck operators with training in the hazards of the industrial truck environment they will operate in. This requirement is often overlooked in generic or off-the-shelf training programs and may be inadequately covered in programs provided by external trainers.

TABLE 2.—ANNUALIZED COMPLIANCE COSTS

[For the Proposed Industrial Truck Operator Training Standard in the Construction Sector, by Provision and by Three-Digit SIC]

SIC/Industry	Initial evaluation	Initial training		Monitoring		Remedial training	Annual cost
		Specific equipment	Operating environment	Annual monitoring	Record-keeping		
152 Residential building construction	$905	$2,962	$7,592	$8,297	$6,223	$830	$26,810
153 Operative builders	74	242	620	677	508	68	2,189
154 Nonresidential building construction	1,423	4,655	11,931	13,039	9,779	1,304	42,130
161 Highway and street construction	259	846	2,169	2,371	1,778	237	7,660
162 Heavy construction, except highway	499	1,632	4,184	4,572	3,429	457	14,773
171 Plumbing, heating, air-conditioning .	1,167	3,819	9,788	10,697	8,023	1,070	34,564
172 Painting and paper hanging	322	1,054	2,701	2,952	2,214	295	9,539
173 Electrical work	952	3,115	7,983	8,724	6,543	872	28,190

TABLE 2.—ANNUALIZED COMPLIANCE COSTS—Continued

[For the Proposed Industrial Truck Operator Training Standard in the Construction Sector, by Provision and by Three-Digit SIC]

SIC/Industry	Initial evaluation	Initial training		Monitoring		Remedial training	Annual cost
		Specific equipment	Operating environment	Annual monitoring	Record-keeping		
174 Masonry, stonework and plastering	833	2,727	6,989	7,638	5,728	764	24,679
175 Carpentry and floor work	363	1,187	3,042	3,425	2,493	332	10,742
176 Roofing, siding and sheet metal work	366	1,198	3,071	3,356	2,517	336	10,844
177 Concrete work	427	1,397	3,581	3,914	2,935	391	12,646
178 Water well drilling	36	118	302	330	247	33	1,065
179 Miscellaneous special trade contractors	966	3,159	8,096	8,848	6,636	885	28,590
Total Construction Sector	8,592	28,109	72,051	78,739	59,054	7,874	254,420

Source: US Department of Labor, OSHA, Office of Regulatory Analysis, 1995.
[a] Costs are annualized over 10 years at a 7 percent discount rate (annualization factor 0.1424).
Note: Totals may not add due to rounding.

OSHA estimated per-operator compliance costs for each component of the proposed standard. These compliance costs include the wages of trainees and trainers[2], as well as monitoring and recordkeeping costs. Auxiliary costs (e.g., costs for course development and travel) will remain unchanged from those required by the existing standard, and were not included when computing compliance costs for the proposed revisions. The cost associated with the 30-minute initial truck operator evaluation required to categorize operators either as experienced or inexperienced is estimated to be $11.01; this figure includes the expense of the supervisor's time. The cost per trainee for each of the proposed two and one-half hour training sessions on specific equipment to be used and the hazards in the operating environment is estimated to be $52.74 per session, or $105.48 for both types of training. The per-operator cost for annual monitoring and recordkeeping is estimated to be $16.51. Therefore, the cost of compliance for each untrained newly hired truck operator in construction is estimated to be $133.01 ($11.01 + $105.49 +$16.51).

A more detailed analysis of costs is presented in Chapter III of the full Preliminary Economic Analysis. OSHA welcomes comments on the preliminary costs and the underlying assumptions presented in this Preliminary Economic Analysis.

Benefits

The number of truck-related fatalities and injuries that will be prevented by the proposed training standard in all OSHA-regulated sectors is estimated by first determining the number of powered industrial truck fatalities and injuries attributable to hazards addressed by OSHA's existing powered industrial truck training standards as well as the number of fatalities and injuries determined not to be preventable by OSHA's existing requirements or by the proposed standard. The number of fatalities and injuries likely to be prevented by compliance with the standard is based on the Agency's analysis of powered industrial truck accidents as reported in the narratives and citation data from OSHA's fatality catastrophe reports gathered through the OSHA Integrated Management Information System (IMIS).

OSHA used results from the Cohen and Jensen study (Ex. 4) to derive an estimate of the beneficial effect of enhanced training on powered industrial truck accidents. This study, which was conducted in two warehouses where powered industrial trucks were widely used, provides a quantitative estimate of the effectiveness of an operators' training program similar to the one required by the proposed standard. The training program described in the study included a series of short training sessions, post-training feedback, and supervision and monitoring of driver behavior. The study estimated the effect of increased training and operator monitoring on operator driving practices, and showed that the mean error rates before and after training[3], as well as three months after training, declined by 44 and 70 percent after training, respectively.

As presented in Table 3, an estimated 15 fatalities and 1,441 lost workday injuries occur annually as a result of industrial truck-related accidents in the construction industry. OSHA estimates that compliance with the proposed standard in the construction sector will prevent 3 or 4 of these fatalities and between 463 and 600 lost workday injuries per year. These preventable fatalities and injuries are attributable directly to the proposed training requirements, i.e., they are in addition to the lives already being saved and the injuries already being prevented by OSHA's existing powered industrial truck training requirements for construction (29 CFR 1926.602(c)(1)). A discussion of the methodology used to calculate these estimates is presented in Chapter IV of the Preliminary Economic Analysis.

[2] The construction operator wage rate, with compensation estimated at 30 percent of the wage rate, is estimated to be $18.34 per hour. The supervisor wage rate of $22.01 used in the analysis is calculated by increasing the operator's wage rate by 20 percent.

[3] Mean error rate = operator errors divided by total number of driving behaviors observed.

TABLE 3.—NUMBER OF FATALITIES AND LOST WORKDAY INJURIES POTENTIALLY PREVENTED ANNUALLY BY COMPLIANCE WITH THE PROPOSED POWERED INDUSTRIAL TRUCK TRAINING STANDARD IN THE CONSTRUCTION SECTOR

Sector	Total number of powered industrial truck fatalities	Preventable fatalities under proposed standard		Total number of industrial truck lost workday injuries	Preventable injuries under proposed standard	
		Low estimate	High estimate		Low estimate	High estimate
Construction	15	3.0	3.8	1,441	463	600

Source: U.S. Department of Labor, OSHA, Office of Regulatory Analysis, 1995.

Economic Impacts and Regulatory Flexibility Analysis

OSHA assessed the potential economic impacts of compliance with the proposed standard and has preliminarily determined that the standard is economically feasible for all covered industry groups. Detailed information at the three-digit SIC level is presented in Chapter V of the full Preliminary Economic Analysis.

When an industry enjoys an inelastic demand for its products, any increase in operating costs can ordinarily be passed on to consumers. In this case, the maximum expected price increase is calculated by dividing the average estimated annualized compliance cost in each industry by the average revenue for that industry. As shown in Table 4, OSHA estimates that the average price increase for the construction sector would be negligible, i.e., less than 0.0001 percent. These estimates indicate that, even if all costs were passed on to consumers through price increases, the proposed standard would have a negligible impact on prices overall. Given the minimal price increases necessary to cover the cost of the proposed training requirements, employers should be able to pass along compliance costs to their customers. However, even if all costs were absorbed by the affected firms, the highest reduction in profits in the construction sector would be 0.001 percent for the construction special trades industry (SIC 17). Because most firms will not find it necessary to absorb all of the costs from profits and should be able to pass most if not all of the standard's costs on to consumers, average profits are not expected to decline to the extent calculated here. OSHA, therefore, does not expect the proposed standard to have a significant economic impact on affected firms.

TABLE 4.—ECONOMIC IMPACT OF THE PROPOSED POWERED INDUSTRIAL TRUCKS OPERATOR TRAINING STANDARD IN THE CONSTRUCTION SECTOR

SIC/Industry sector	Value of industry shipments, receipts or sales ($ millions)	Annualized compliance costs	Compliance costs as a percent of sales	Pre-tax income ($ millions)	Compliance costs as a percent of pre-tax income
15 Building Construction	$223,007	$71,128	Negligible	$16,149	0.0004
16 Heavy Construction	77,746	22,433	Negligible	6,496	0.0003
17 Construction (Special Trades)	204,154	160,859	Negligible	13,522	0.0012

Source: U.S. Department of Labor, OSHA, Office of Regulatory Analysis, 1995. Negligible denotes less than 0.0001 percent.

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*), OSHA has also analyzed the economic impact of the proposed standard on small establishments (19 or fewer employees), looking particularly for evidence that the rule would have a significant impact on a substantial number of small entities. Small businesses will incur lower compliance costs than larger businesses because the compliance costs depend directly on the number of industrial truck operators requiring training in a given facility. OSHA has preliminarily concluded that the proposed standard would not have a significant impact on a substantial number of small entities.

It has already been shown that the revenue and price increases for all businesses are negligible. To test the possibility that the proposed standard might have significant impacts on some small businesses, OSHA developed a worst case-analysis of small firms in the construction sector by assuming that the establishment is currently not in compliance with any of the requirements of the proposed standard and that all truck operators in the establishment would need specific equipment and operating environment training, i.e., that none of the operators currently employed have any training. The representative establishment was assumed to have 14 employees, the average for establishments with 10 to 19 employees. OSHA estimates that 60 percent of employees, or a total of 8 employees, would operate powered industrial truck either full-time or as part of another job. Using a turnover rate of 15 percent, the small establishment is expected to spend $449 annually to achieve full compliance with the proposed standard. Under this worst case scenario, the impacts of compliance costs as a percent of revenues are approximately 0.06 percent, an insignificant impact even in the worst case. Similarly, OSHA estimates that, if the average small construction establishment could not pass any of the compliance costs through to its customers (a highly unlikely scenario), the costs would impact average profits by less than 1.2 percent. These impacts are judged to be relatively minor; therefore, the proposed standard is preliminarily determined to be economically feasible even for very small construction industry establishments.

Environmental Impact

The proposed standard has been reviewed in accordance with the requirements of the National Environmental Policy Act of 1969 (42

U.S.C. 4321, et seq.), the regulation of the Council on Environmental Quality (40 CFR part 1500 through 1517), and the Department of Labor's NEPA procedures (29 CFR part 11). As a result of this review, OSHA has determined that the proposed standard will have no significant environmental impact.

XIII. Federalism

This proposed regulation has been reviewed in accordance with Executive Order 12612 (52 FR 41685, Oct. 30, 1987), regarding Federalism. This Order requires that agencies, to the extent possible, refrain from limiting state policy options, consult with states prior to taking any actions which would restrict state policy options, and take such actions only when there is clear constitutional authority and the presence of a problem of national scope. The Order provides for preemption of state law only if there is a clear Congressional intent for the Agency to do so. Any such preemption is to be limited to the extent possible.

Section 18 of the Occupational Safety and Health Act (OSH Act) expresses Congress' intent to preempt state laws relating to issues on which Federal OSHA has promulgated occupational safety and health standards. Under the OSH Act, a state can avoid preemption in issues covered by Federal standards only if it submits, and obtains Federal approval of, a plan for the development of such standards and their enforcement. Occupational safety and health standards developed by such Plan states must, among other things, be at least as effective in providing safe and healthful employment and places of employment as the Federal standards. When such standards are applicable to products distributed or used in interstate commerce they may not unduly burden commerce and must be justified by compelling local conditions.

The Federal proposed standard on powered industrial truck operator training addresses hazards that are not unique to any one state or region of the country. Nonetheless, states with occupational safety and health plans approved under section 18 of the OSH Act will be able to develop their own state standards to deal with any special problems which might be encountered in a particular state. Moreover, because this standard is written in general, performance-oriented terms, there is considerable flexibility for state plans to require, and for affected employers to use, methods of compliance which are appropriate to the working conditions covered by the standard.

In brief, this proposed rule addresses a clear national problem related to occupational safety and health in general industry. Those states which have elected to participate under section 18 of the OSH Act are not preempted by this standard, and will be able to address any special conditions within the framework of the Federal Act while ensuring that the state standards are at least as effective as their standard. State comments are invited on this proposal and will be fully considered prior to promulgation of a final rule.

XIV. OMB Review Under the Paperwork Reduction Act

This paragraph contains a collection of information as defined in OMB's new regulations at 60 FR 44978 (August 29, 1995) in § 1926.602(d)(5). This provision requires employers to prepare and maintain a certification record. Specifically, the employer must prepare a record to certify that employees have been trained and evaluated as required by the standard. The record includes the name of the employee who was trained, the date of the training and the signature of the person who performed the training and evaluation.

Under the Paperwork Reduction Act of 1995, agencies are required to seek OMB approval for all collections of information. As part of the approval process, agencies are required to solicit comment from affected parties with regard to the collection of information, including the financial and time burdens estimated by the agencies for the collection of information. OSHA believes it is necessary for employers to prepare the certification record to verify that powered industrial truck operators are trained to perform their duties competently and safely. To comply with the training requirement, employers must keep a record certifying that their employees have successfully completed powered industrial truck operator training. Safe operation can decrease the number of fatalities and injuries associated with powered industrial trucks.

OSHA estimates that it will take employers about 1 hour to prepare and 8 hours to deliver the training; and another 15 minutes to prepare a certification record, make it available during compliance inspections, retain current training materials and course outlines, and document the types of trucks that an operator is authorized to operate. It will cost employers on average about $53 to initially train and certify each employee. The total respondent burden for construction workplaces in the first year is $45,709 and 6,411 burden hours. In subsequent years cost is $6,000 and the hourly burden is 3,543. The number of operators in construction is 1% of the total number.

OSHA requests comment from the public on all aspects of this collection of information. Specifically, OSHA requests comment on whether this proposed collection of information does:

- Ensure that the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

Comments on the collection of information proposed provision should be sent to the OMB Desk Officer for OSHA at Room 10235, 726 Jackson Place, NW, Washington, DC 20503. Commenters are encouraged to send a copy of their comment on the collection of information to OSHA along with their other comments. The supporting statement for this collection of information requirement is available in both OSHA and OMB Docket Offices.

OMB is currently reviewing OSHA proposed collection of information to determine its consistency with the Paperwork Reduction Act of 1995. At this time OMB has not approved this collection of information.

XV. Public Participation

Interested persons are requested to submit written data, views and arguments concerning this proposal. These comments must be postmarked by April 1, 1996, and submitted in quadruplicate to the Docket Office; Docket No. S–008, Room N2624; U.S. Department of Labor, Occupational Safety and Health Administration; 200 Constitution Ave., NW; Washington, DC 20210.

All written comments received within the specified comment period will be made a part of the record and will be available for public inspection and copying at the above Docket Office address. The comments submitted as part of this proposal for construction also will be considered part of the record for general industry and maritime and the comments for general industry and maritime will be considered part of the record for this

rulemaking. In addition, OSHA is reopening the record for additional comment on the proposed requirements for general industry and maritime to coincide with the comment period for construction.

This rulemaking is for procedural purposes combined with the rulemaking that was proposed for general industry and maritime industries on March 14, 1995. The docket will be combined, comments and evidence submitted in response to one notice, need not be repeated for the other notice and will be considered for all sectors. The hearing will be conducted for all sectors. Of course, to the extent that the record supports different provisions for different sectors, these differences will be incorporated into the final rule.

Notice of Intention to Appear at the Informal Hearing

Pursuant to section 6(b)(3) of the Act, an opportunity to submit oral testimony concerning the issues raised by the proposed standard including economic and environmental impacts, will be provided at an informal public hearing to be held in Washington, DC on April 30, 1996. If OSHA receives sufficient requests to participate in the hearing, the hearing period may be extended. Conversely, the hearing may be shortened if there are few requests.

The hearing will commence at 9:30 a.m. on April 30, 1996, in the Auditorium, Frances Perkins Building, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210.

All persons desiring to participate at the hearing must file in quadruplicate a notice of intention to appear, postmarked on or before April 1, 1996. The notice of intention to appear, which will be available for inspection and copying at the OSHA Technical Data Center Docket Office (Room N2624), telephone (202) 219–7894, must contain the following information:

1. The name, address, and telephone number of each person to appear;
2. The capacity in which the person will appear;
3. The approximate amount of time required for the presentation;
4. The issues that will be addressed;
5. A brief statement of the position that will be taken with respect to each issue; and
6. Whether the party intends to submit documentary evidence and, if so, a brief summary of it.

The notice of intention to appear shall be mailed to Mr. Thomas Hall, OSHA Division of Consumer Affairs, Docket S–008, Room N3647, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210; telephone (202) 219–8615.

A notice of intention to appear also may be transmitted by facsimile to (202) 219–5986 (Attention: Thomas Hall), by the same date, provided the original and 3 copies are sent to the same address and postmarked no more than 3 days later.

Filing of Testimony and Evidence Before the Hearing

Any party requesting more than 10 minutes for a presentation at the hearing, or who will submit documentary evidence, must provide in quadruplicate, the complete text of the testimony, including any documentary evidence to be presented at the hearing. One copy shall not be stapled or bound and be suitable for copying. These materials must be provided to Mr. Thomas Hall, OSHA Division of Consumer Affairs at the address above and be postmarked no later than April 15, 1996.

Each such submission will be reviewed in light of the amount of time requested in the notice of intention to appear. In those instances when the information contained in the submission does not justify the amount of time requested, a more appropriate amount of time will be allocated and the participant will be notified of that fact prior to the informal public hearing.

Any party who has not substantially complied with this requirement may be limited to a 10-minute presentation, and may be requested to return for questioning at a later time.

Any party who has not filed a notice of intention to appear may be allowed to testify for no more than 10 minutes as time permits, at the discretion of the Administrative Law Judge, but will not be allowed to question witnesses.

Notice of intention to appear, testimony and evidence will be available for copying at the Docket Office at the address above.

Conduct and Nature of the Hearing

The hearing will commence at 9:30 a.m. on April 30, 1996. At that time, any procedural matters relating to the proceeding will be resolved.

The nature of an informal rulemaking hearing is established in the legislative history of section 6 of the OSH Act and is reflected by OSHA's rules of procedure for hearings (29 CFR 1911.15(a)). Although the presiding officer is an Administrative Law Judge and limited questioning by persons who have filed notices of intention to appear is allowed on crucial issues, the proceeding is informal and legislative in type. The Agency's intent, in essence, is to provide interested persons with an opportunity to make effective oral presentations that can proceed expeditiously in the absence of procedural restraints that impede or protract the rulemaking process.

Additionally, since the hearing is primarily for information gathering and clarification, it is an informal administrative proceeding rather than an adjudicative one. The technical rules of evidence, for example, do not apply. The regulations that govern hearings and the pre-hearing guidelines to be issued for this hearing will ensure fairness and due process and also facilitate the development of a clear, accurate and complete record. Those rules and guidelines will be interpreted in a manner that furthers that development. Thus, questions of relevance, procedure and participation generally will be decided so as to favor development of the record.

The hearing will be conducted in accordance with 29 CFR part 1911. It should be noted that § 1911.4 specifies that the Assistant Secretary may, upon reasonable notice, issue alternative procedures to expedite proceedings or for other good cause.

The hearing will be presided over by an Administrative Law Judge who makes no decision or recommendation on the merits of OSHA's proposal. The responsibility of the Administrative Law Judge is to ensure that the hearing proceeds at a reasonable pace and in an orderly manner. The Administrative Law Judge, therefore, will have all the powers necessary and appropriate to conduct a full and fair informal hearing as provided in 29 CFR part 1911, including the powers:

1. To regulate the course of the proceedings;
2. To dispose of procedural requests, objections and comparable matters;
3. To confine the presentations to the matters pertinent to the issues raised;
4. To regulate the conduct of those present at the hearing by appropriate means;
5. At the Judge's discretion, to question and permit the questioning of any witness and to limit the time for questioning; and
6. At the Judge's discretion, to keep the record open for a reasonable, stated time (known as the post-hearing comment period) to receive written information and additional data, views and arguments from any person who has participated in the oral proceedings.

OSHA recognizes that there may be interested persons who, through their knowledge of safety or their experience in the operations involved, would wish to endorse or support certain provisions

in the standard. OSHA welcomes such supportive comments, including any pertinent accident data or cost information that may be available, so that the record of this rulemaking will present a balanced picture of the public response on the issues involved.

XVI. State Plan Standards

The 25 States with their own OSHA approved occupational safety and health plans must adopt a comparable standard within six months of the publication date of the final standard. These States are: Alaska, Arizona, California, Connecticut (for State and local government employees only), Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, New York (for State and local government employees only), North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Virgin Islands, Washington, and Wyoming. Until such time as a State standard is promulgated, Federal OSHA will provide interim enforcement assistance, as appropriate, in those States.

List of Subjects in 29 CFR part 1926

Construction industry, Motor vehicle safety, Occupational safety and health, Transportation.

XVII. Authority

This document was prepared under the direction of Joseph A. Dear, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

Accordingly, pursuant to section 4, 6(b), 8(c) and 8(g) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657), the Construction Safety Act (40 U.S.C. 333), Secretary of Labor's Order No. 1–90 (55 FR 9033), and 29 CFR part 1911, it is proposed to amend 29 CFR part 1926 as set forth below.

Signed at Washington, DC, this 22nd day of January, 1996.

Joseph A. Dear,

Assistant Secretary of Labor.

PART 1926—CONSTRUCTION SAFETY AND HEALTH STANDARDS

1. The authority citation for subpart O of part 1926 would be revised to read as follows:

Authority: Section 107, Construction Work Hours and Safety Standards Act (Construction Safety Act) (40 U.S.C. 333); secs. 4, 6, 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), or 1–90 (55 FR 9033), as applicable. Section 1926.602 also issued under 29 CFR part 1911.

2. Section 1926.602 is proposed to be amended by adding a new paragraph (d) and by adding appendices A and B to read as follows:

§ 1926.602 Material handling equipment.

* * * * *

(d) Powered industrial, truck Operator training.—(1) *Operator qualifications.* (i) The employer shall ensure that each powered industrial truck operator is capable of performing the duties that are required to operate the truck safely.

(ii) Prior to permitting an operator to drive except for training purposes, the employer shall ensure that each operator has received the training required by this paragraph, that each operator has been evaluated by a designated person while performing the required duties, and that each operator performs the required duties competently.

(2) *Training program implementation.* (i) The employer shall implement a training program and ensure that only trained operators who have successfully completed the training program are allowed to operate powered industrial trucks. Exception: Trainees under the direct supervision of a designated person shall be allowed to operate a powered industrial truck provided the operation of the vehicle is conducted in an area where other employees are not near and where the conditions are such that the trainee can safely operate the truck.

(ii) Training shall consist of a combination of classroom instruction (Lecture, discussion, video tapes, and/or conference) and practical training (demonstrations and practical exercises by the trainee).

(iii) All training and evaluation shall be conducted by a designated person who has the requisite knowledge, training and experience to train powered industrial truck operators and judge their competency.

(3) *Training program content.* Powered industrial truck operator trainees shall be trained in the following topics unless the employer can demonstrate that some of the topics are not needed for safe operation.

(i) Truck related topics.

(A) All necessary operating instructions, warnings and precautions for the types of trucks the operator will be authorized to operate;

(B) Similarities to and differences from the automobile;

(C) Controls and instrumentation: location, what they do and how they work;

(D) Power plant operation and maintenance;

(E) Steering and maneuvering;

(F) Visibility (including restrictions due to loading);

(G) Fork and attachment adaption, operation and use limitations;

(H) Vehicle capacity;

(I) Vehicle stability;

(J) Vehicle inspection and maintenance;

(K) Refueling or charging and recharging batteries;

(L) Operating limitations; and

(M) Any other operating instruction, warning, or precaution listed in the operator's manual for the type vehicle that the employee is being trained to operate.

(ii) Workplace related topics.

(A) Surface conditions where the vehicle will be operated;

(B) Composition of probable loads and load stability;

(C) Load manipulation, stacking, unstacking;

(D) Pedestrian traffic;

(E) Narrow aisles and other restricted places of operation;

(F) Operating in hazardous classified locations;

(G) Operating the truck on ramps and other sloped surfaces that could affect the stability of the vehicle;

(H) Other unique or potentially hazardous environmental conditions that exist or may exist in the workplace; and

(I) Operating the vehicle in closed environments and other areas where insufficient ventilation could cause a buildup of carbon monoxide or diesel exhaust.

(iii) The requirements of this section.

(4) *Evaluation and refresher or remedial training.* (i) Sufficient evaluation and remedial training shall be conducted so that the employee retains and uses the knowledge, skills and ability needed to operate the powered industrial truck safely.

(ii) An evaluation of the performance of each powered industrial truck operator shall be conducted at least annually by a designated person.

(iii) Refresher or remedial training shall be provided when there is reason to believe that there has been unsafe operation, when an accident or a near-miss occurs or when an evaluation indicates that the operator is not capable of performing the assigned duties.

(5) *Certification.* (i) The employer shall certify that each operator has received the training, has been evaluated as required by this paragraph, and has demonstrated competency in the performance of the operator's duties. The certification shall include the name

of the trainee, the date of training, and the signature of the person performing the training and evaluation.

(ii) The employer shall retain the current training materials and course outline or the name and address of the person who conducted the training if it was conducted by an outside trainer.

(6) *Avoidance of duplicative training.* (i) Each current truck operator who has received training in any of the elements specified in paragraph (d)(3) of this section for the types of truck the employee is authorized to operate and the type of workplace that the trucks are being operated in need not be retrained in those elements if the employer certifies in accordance with paragraph (d)(5)(i) of this section that the operator has been evaluated and found to be competent to perform those duties.

(ii) Each new truck operator who has received training in any of the elements specified in paragraph (d)(3) of this section for the types of truck the employee will be authorized to operate and the type of workplace in which the trucks will be operated need not be retrained in those elements before initial assignment in the workplace if the employer has a record of the training and if the employee is evaluated pursuant to paragraph (d)(1)(ii) of this section and is found to be competent.

Appendix A—Training of Powered Industrial Truck Operators

(Non-mandatory appendix to paragraph (d) of this section)

A–1. Operator Selection

A–1.1. Prospective operators of powered industrial trucks should be identified based upon their ability to be trained and permitted to perform job functions that are essential to the operation of a powered industrial truck. Determination of the capabilities of a prospective operator to fulfill the demands of the job should be based upon the tasks that the job demands.

A–1.2. The employer should identify all the aspects of the job that the employee must meet/perform when doing his or her job. These aspects could include the level at which the employee must see and hear, the physical demands of the job, and the environmental extremes of the job.

A–1.3. One factor to be considered is the ability of the candidate to see and hear within reasonably acceptable limits. Included in the vision requirements are the ability to see at distance and peripherally. In certain instances, there also is a requirement for the candidate to discern different colors, primarily red, yellow and green.

A–1.4. The environmental extremes that might be demanded of a potential powered industrial truck operator include the ability of the person to work in areas of excessive cold or heat.

A–1.5. After an employee has been trained and appropriate accommodations have been made, the employer needs to determine whether the employee can safely perform the job.

A–2. The Method(s) of Training

A–2.1. Among the many methods of training are the lecture, conference, demonstration, test (written and/or oral) and the practical exercise. In most instances, a combination of these methods has been successfully used to train employees in the knowledge, skills and abilities that are essential to perform the job function that the employee is being trained to perform. To enhance the training and to make the training more understandable to the employee, employers and other trainers have used movies, slides, video tapes and other visual presentations. Making the presentation more understandable has several advantages including:

(1) The employees being trained remain more attentive during the presentation if graphical presentation is used, thereby increasing the effectiveness of the training;

(2) The use of visual presentations allows the trainer to ensure that the necessary information is covered during the training;

(3) The use of graphics makes better utilization of the training time by decreasing the need for the instructor to carry on long discussions about the instructional material; and

(4) The use of graphics during instruction provides greater retention by the trainees.

A–3. Training Program Content

A–3.1. Because each type (make and model) of powered industrial truck has different operating characteristics, limitations and other unique features, an optimum employee training program for powered industrial truck operators must be based upon the type vehicles that the employee will be trained and authorized to operate. The training must also emphasize the features of the workplace that will affect the manner in which the vehicle must be operated. Finally, the training must include the general safety rules applicable to the operation of all powered industrial trucks.

A–3.2. Selection of the methods of training the operators has been left to the reasonable determination of the employer. Whereas some employees can assimilate instructional material while seated in a classroom, other employees may learn best by observing the conduct of operations (demonstration) and/or by having to personally conduct the operations (practical exercise). In some instances, an employee can receive valuable instruction through the use of electronic mediums, such as the use of video tapes and movies. In most instances, a combination of the different training methods may provide the mechanism for providing the best training in the least amount of time. OSHA has specified at paragraph (d)(2)(ii) that the training must consist of a combination of classroom instruction and practical exercise. The use of both of these modes of instruction is the only way of ensuring that the trainee has received and comprehended the instruction and can use the information to safely operate a powered industrial truck.

A–4. Initial Training

A–4.1. The following is an outline of a generalized forklift operator training program:

(1) Characteristics of the powered industrial truck(s) the employee will be allowed to operate:

(a) Similarities to and differences from the automobile;

(b) Controls and instrumentation: location, what they do and how they work;

(c) Power plant operation and maintenance;

(d) Steering and maneuvering;

(e) Visibility;

(f) Fork and/or attachment adaption, operation and limitations of their use;

(g) Vehicle capacity;

(h) Vehicle stability;

(i) Vehicle inspection and maintenance;

(j) Refueling or charging and recharging batteries.

(k) Operating limitations.

(l) Any other operating instruction, warning, or precaution listed in the operator's manual for the type of vehicle the employee is being trained to operate.

(2) The operating environment:

(a) Floor surfaces and/or ground conditions where the vehicle will be operated;

(b) Composition of probable loads and load stability;

(c) Load manipulation, stacking, unstacking;

(d) Pedestrian traffic;

(e) Narrow aisle and restricted place operation;

(f) Operating in classified hazardous locations;

(g) Operating the truck on ramps and other sloped surfaces that would affect the stability of the vehicle;

(h) Other unique or potentially hazardous environmental conditions that exist or may exist in the workplace.

(i) Operating the vehicle in closed environments and other areas where insufficient ventilation could cause a buildup of carbon monoxide or diesel exhaust.

(3) The requirements of this OSHA Standard.

A–5. Trainee Evaluation

A–5.1. The provisions of these proposed requirements specify that an employee evaluation be conducted both as part of the training and after completion of the training. The initial evaluation is useful for many reasons, including:

(1) the employer can determine what methods of instruction will produce a proficient truck operator with the minimum of time and effort;

(2) the employer can gain insight into the previous training that the trainee has received; and

(3) a determination can be made as to whether the trainee will be able to successfully operate a powered industrial truck. This initial evaluation can be completed by having the employee fill out a questionnaire, by an oral interview, or by a combination of these mechanisms. In many cases, answers received by the employee can be substantiated by contact with other employees or previous employers.

A–6. Refresher or Remedial Training

A–6.1. (The type of information listed below would be used when the training is more than an on-the-spot correction being made by a supervisor or when multiple instances of on-the-spot corrections have occurred.) When an on-the-spot correction is used, the person making the correction should point out the incorrect manner of operation of the truck or other unsafe act being conducted, tell the employee how to do the operation correctly, and then ensure that the employee does the operation correctly.

A–6.2. The following items may be used when a more general, structured retraining program is utilized to train employees and eliminate unsafe operation of the vehicle:

(1) Common unsafe situations encountered in the workplace;

(2) Unsafe methods of operating observed or known to be used;

(3) The need for constant attentiveness to the vehicle, the workplace conditions and the manner in which the vehicle is operated.

A–6.3. Details about the above subject areas need to be expanded upon so that the operator receives all the information that is necessary for the safe operation of the vehicle. Insight into some of the specifics of the above subject areas may be obtained from the vehicle manufacturers' literature, the national consensus standards [e.g. the ASME B56 series of standards (current revisions)] and this OSHA Standard. Appendix B—Stability of Powered Industrial Trucks (Non-mandatory appendix to paragraph (d) of this section)

B–1. Definitions

To understand the principle of stability, understanding definitions of the following is necessary:

Center of Gravity is that point of an object at which all of the weight of an object can be considered to be concentrated.

Counterweight is the weight that is a part of the basic structure of a truck that is used to offset the weight of a load and to maximize the resistance of the vehicle to tipping over.

Fulcrum is the axis of rotation of the truck when it tips over.

Grade is the slope of any surface that is usually measured as the number of feet of rise or fall over a hundred foot horizontal distance (this measurement is designated as a percent).

Lateral stability is the resistance of a truck to tipping over sideways.

Line of action is an imaginary vertical line through the center of gravity of an object.

Load center is the horizontal distance from the edge of the load (or the vertical face of the forks or other attachment) to the line of action through the center of gravity of the load.

Longitudinal stability is the resistance of a truck to overturning forward or rearward.

Moment is the product of the weight of the object times the distance from a fixed point. In the case of a powered industrial truck, the distance is measured from the point that the truck will tip over to the line of action of the object. The distance is always measured perpendicular to the line of action.

Track is the distance between wheels on the same axle of a vehicle.

Wheelbase is the distance between the centerline of the front and rear wheels of a vehicle.

B–2. General

B–2.1. Stability determination for a powered industrial truck is not complicated once a few basic principles are understood. There are many factors that influence vehicle stability. Vehicle wheelbase, track, height and weight distribution of the load, and the location of the counterweights of the vehicle (if the vehicle is so equipped), all contribute to the stability of the vehicle.

B–2.2. The "stability triangle", used in most discussions of stability, is not mysterious but is used to demonstrate truck stability in a rather simple fashion.

B–3. Basic Principles

B–3.1. The determination of whether an object is stable is dependent on the moment of an object at one end of a system being greater than, equal to or smaller than the moment of an object at the other end of that system. This is the same principle on which a see saw or teeter-totter works, that is, if the product of the load and distance from the fulcrum (moment) is equal to the moment at the other end of the device, the device is balanced and it will not move. However, if there is a greater moment at one end of the device, the device will try to move downward at the end with the greater moment.

B–3.2. Longitudinal stability of a counterbalanced powered industrial truck is dependent on the moment of the vehicle and the moment of the load. In other words, if the mathematic product of the load moment (the distance from the front wheels, the point about which the vehicle would tip forward) to the center of gravity of the load times the weight of the load is less than the moment of the vehicle, the system is balanced and will not tip forward. However, if the load-moment is greater than the vehicle-moment, the greater load-moment will force the truck to tip forward.

B–4. The Stability Triangle

B–4.1. Almost all counterbalanced powered industrial trucks have a three point suspension system, that is, the vehicle is supported at three points. This is true even if it has four wheels. The steer axle of most trucks is attached to the truck by means of a pivot pin in the center of the axle. This three point support forms a triangle called the stability triangle when the points are connected with imaginary lines. Figure 1 depicts the stability triangle.

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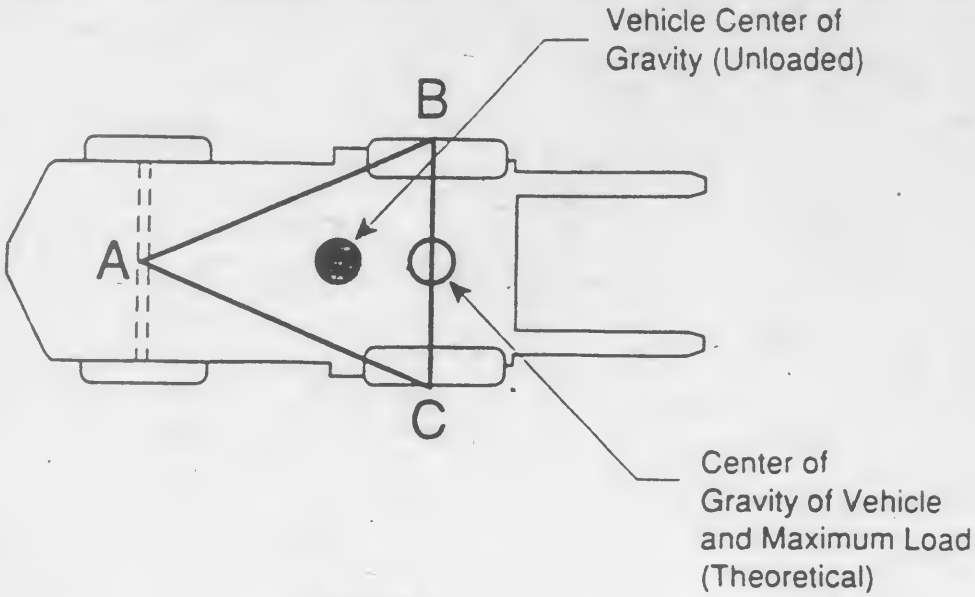

Figure 1.

NOTES:

1. When the vehicle is loaded, the combined center of gravity shifts toward line B-C. Theoretically the max load will result in the CG at the line B-C. In actual practice, the combined CG should never be at line B-C.

2. The addition of additional counterweight will cause the truck CG to shift toward point A and result in a truck that is less stable laterally.

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B–4.2. When the line of action of the vehicle or load-vehicle falls within the stability triangle, the vehicle is stable and will not tip over. However, when the line of action of the vehicle or the vehicle/load combination falls outside the stability triangle, the vehicle is unstable and may tip over. (See Figure 2.)

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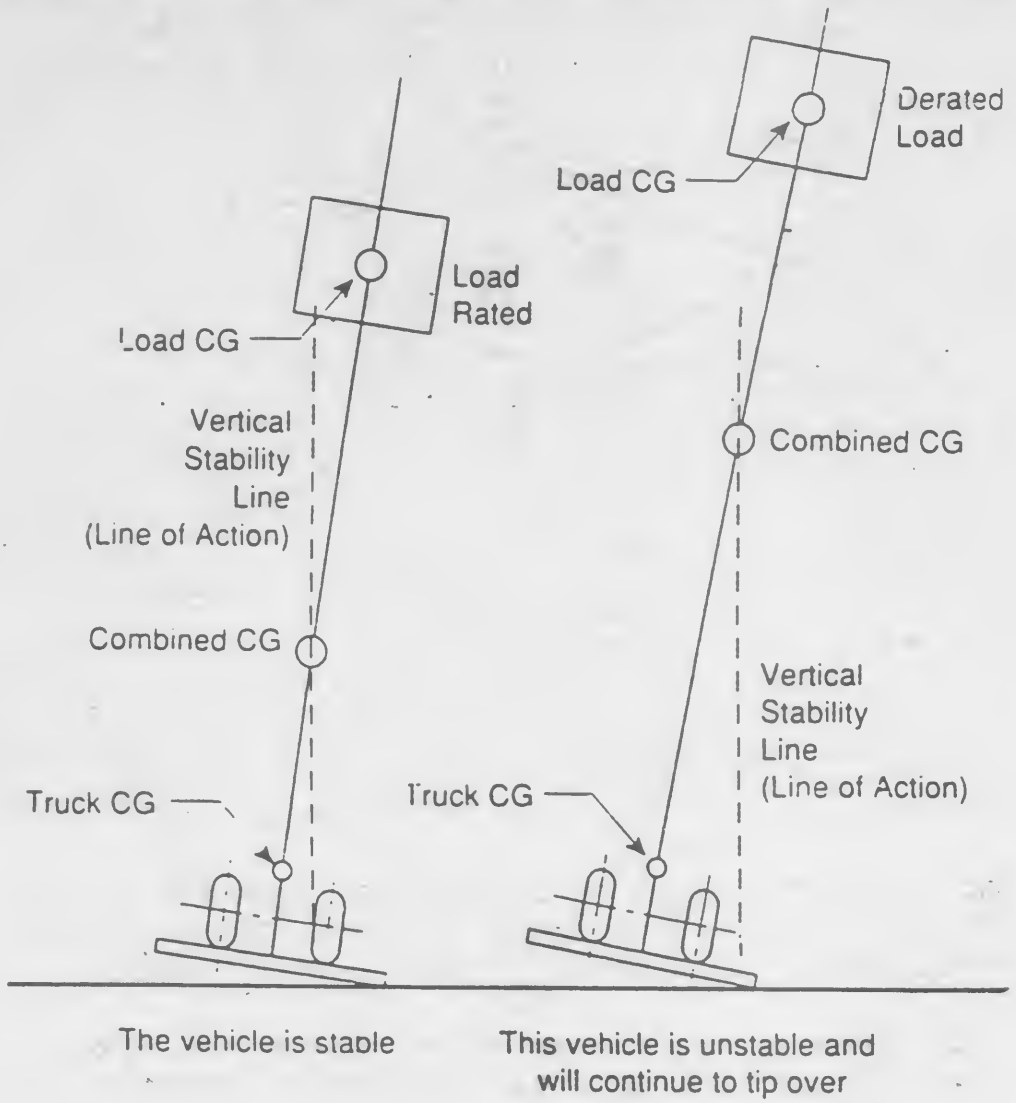

Figure 2.

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B–5. Longitudinal Stability

B–5.1. The axis of rotation when a truck tips forward is the point of contact of the front wheels of the vehicle with the pavement. When a powered industrial truck tips forward, it is this line that the truck will rotate about. When a truck is stable the vehicle-moment must exceed the load-moment. As long as the vehicle-moment is equal to or exceeds the load-moment, the vehicle will not tip over. On the other hand, if the load-moment slightly exceeds the vehicle-moment, the truck will begin the tip forward, thereby causing loss of steering control. If the load-moment greatly exceeds the vehicle-moment, the truck will tip forward.

B–5.2. In order to determine the maximum safe load moment, the truck manufacturer normally rates the truck at a maximum load at a given distance from the front face of the forks. The specified distance from the front face of the forks to the line of action of the load is commonly called a load center. Because larger trucks normally handle loads that are physically larger, these vehicles have greater load centers. A truck with a capacity of 30,000 pounds or less capacity is normally rated at a given load weight at a 24-inch load center. For trucks of greater than 30,000 pound capacity, the load center is normally rated at 36- or 48-inch load center distance. In order to safely operate the vehicle, the operator should always check the data plate and determine the maximum allowable weight at the rated load center.

B–5.3. Although the true load moment distance is measured from the front wheels, this distance is greater than the distance from the front face of the forks. Calculation of the maximum allowable load moment using the load center distance always provides a lower load moment than the truck was designed to handle. When handling unusual loads, such as those that are larger than 48 inches long (the center of gravity is greater than 24 inches), with an offset center of gravity, etc., then calculation of a maximum allowable load moment should be undertaken and this value used to determine whether a load can be handled. For example, if an operator is operating a 3000 pound capacity truck (with a 24 inch load center), the maximum allowable load moment is 72,000 inch-pounds (3,000 times 24). If a probable load is 60 inches long (30 inch load center), then the maximum weight that this load can weigh is 2,400 pounds (72,000 divided by 30).

B–6. Lateral Stability

B–6.1. The lateral stability of a vehicle is determined by the position of the line of action (a vertical line that passes through the combined center of gravity of the vehicle and the load) relative to the stability triangle. When the vehicle is not loaded, the location of the center of gravity of the truck is the only factor to be considered in determining the stability of the truck. As long as the line of action of the combined center of gravity of the vehicle and the load falls within the stability triangle, the truck is stable and will not tip over. However, if the line of action falls outside the stability triangle, the truck is not stable and may tip over.

B–6.2. Factors that affect the lateral stability of a vehicle include the placement of the load on the truck, the height of the load above the surface on which the vehicle is operating, and the degree of lean of the vehicle.

B–7. Dynamic Stability

B–7.1. Up to this point, we have covered stability of a powered industrial truck without consideration of the dynamic forces that result when the vehicle and load are put into motion. The transfer of weight and the resultant shift in the center of gravity due to the dynamic forces created when the machine is moving, braking, cornering, lifting, tilting, and lowering loads, etc., are important stability considerations.

B–7.2. When determining whether a load can be safely handled, the operator should exercise extra caution when handling loads that cause the vehicle to approach its maximum design characteristics. For example, if an operator must handle a maximum load, the load should be carried at the lowest position possible, the truck should be accelerated slowly and evenly, and the forks should be tilted forward cautiously. However, no precise rules can be formulated to cover all of these eventualities.

[FR Doc. 96–1216 Filed 1–29–96; 8:45 am]
BILLING CODE 4510–26–P

federal register

Tuesday
January 30, 1996

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 172

Food Additives Permitted for Direct Addition to Food for Human Consumption: Olestra; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 87F–0179]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Olestra

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of sucrose esterified with medium and long chain fatty acids (olestra) as a replacement for fats and oils. This action is in response to a petition filed by the Procter & Gamble Co.

DATES: The regulation is effective January 30, 1996. Submit written objections and requests for a hearing by February 29, 1996. Submit written comments on the labeling requirement (§ 172.867(c)) by April 1, 1996. The Director of the Office of the Federal Register approves the incorporations by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications at 21 CFR 172.867, effective January 30, 1996.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Helen R. Thorsheim, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3092.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

Olestra, also called sucrose polyester, is the common name for a mixture of substances formed by chemical combination of sucrose with six, seven, or eight fatty acids. The fatty acids, bound to sucrose by ester bonds, are of the type commonly found in edible oils and fats. Olestra has physical properties similar to those of natural fats. Olestra's particular physical properties depend on the specific fatty acids used and the degree of esterification.

The Procter & Gamble Co., 6071 Center Hill Rd., Cincinnati, OH 45224–1703 (the petitioner), submitted a petition to FDA on April 15, 1987, for the use of olestra in shortenings and oils as a calorie-free replacement for fats and oils. The petition (FAP 7A3997) was filed on May 7, 1987. In a notice in the **Federal Register** of June 23, 1987 (52 FR 23606), FDA announced that the food additive petition had been filed by Procter & Gamble, proposing the issuance of a food additive regulation providing for the safe use of sucrose esterified with medium and long chain fatty acids as a replacement for fats and oils. On July 6, 1990, the petitioner amended the petition to limit the intended use of olestra to a 100 percent replacement for conventional fats in the preparation of savory snacks (i.e., snacks that are salty or piquant but not sweet, such as potato chips, cheese puffs and crackers). During the course of the petition evaluation, the petitioner also amended the proposed specifications that describe the additive.

In the **Federal Register** of October 17, 1995 (60 FR 53740), FDA announced that a public meeting of the agency's Food Advisory Committee (the FAC) and a working group of the FAC would be held on November 14 through 17, 1995. The working group was asked to discuss and comment on whether all relevant issues associated with olestra had been addressed (Ref. 1). The discussion covered all aspects of the safety review of olestra, including nutrient effects and compensation, gastrointestinal effects, and labeling (Ref. 2 [1]).

In the **Federal Register** of November 16, 1995 (60 FR 57586), FDA announced that it would consider public comments on the petition, including comments on the proceedings before the FAC, only if filed on or before December 1, 1995. This action allowed the agency to identify precisely which data and information to consider in making its decision on the petition. This measure was necessary to facilitate the agency's decision making process and to come to closure on the petition. By letter dated December 8, 1995, FDA extended to December 21, 1995, the time by which such comments could be submitted. This extension was in response to a request of the Center for Science in the Public Interest (CSPI). [2]

A. Safety Testing-Background

1. Legal Context of the Safety Evaluation

Section 409 of the act (21 U.S.C. 348), sets forth the statutory requirements for approval of a food additive (21 U.S.C. 321(s)). With the enactment of the Food Additives Amendment of 1958 (the Amendment), Congress established a premarket approval system whereby the company seeking to market a food additive must first obtain approval from FDA. Through this mechanism, Congress sought to shield the public from unsafe or potentially unsafe products.

Under section 409(c)(3) of the act, 21 U.S.C. 348(c)(3), FDA is not to approve a food additive petition "* * * if a fair evaluation of the data before the Secretary [3] * * * fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe * * *. This provision is commonly referred to as the "general safety clause."

By requiring that the data concerning a food additive "establish" safety, Congress squarely placed the burden of proving safety on the sponsor of a food additive petition, in this case Procter & Gamble. FDA need not prove that the additive is unsafe in order to deny approval.

The term "safe" is not defined in the act itself. The legislative history of the Amendment makes clear, however, that a demonstration of absolute harmlessness is not required to sustain the approval of a food additive:

> Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance. This was emphasized particularly by the scientific panel which testified before the subcommittee. The scientists pointed out that it is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of any chemical substance.

H. Rept. No. 2284, 85th Cong., 2d sess. 4–5 (1958). *Accord*: S. Rept. No. 2422, 85th Cong., 2d sess. 2 (1958). FDA regulations incorporate the concept of safety articulated in the Amendment's legislative history. 21 CFR 170.3(i). ("Safe" means that "* * * there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.")

Although the concept of "harm" is central to the act's safety standard, neither the statute, nor regulations implementing the food additive provisions, define harm. Once again, however, congressional intent is clear from the legislative history of the amendment. Specifically, "harm" means the capacity to injure or otherwise damage the health of individuals consuming the additive.+

> The concept of safety used in this legislation involves the question of whether a substance is hazardous to the health of man or animal.

H. Rept. No. 2284, 85th Cong., 2d sess. 4 (1958). *See also* Letter from Assistant Secretary of Health, Education, and Welfare Elliot L. Richardson to Congressman Lister Hill, Chairman,

[1] The transcript of the Olestra Working Group and full Food Advisory Committee meetings are provided as reference. Throughout the preamble to this final rue, reference is made to comments of Committee members and presenters to the Committee; footnotes indicate the transcript volum and page numbers of these. The affiliation and credentials of the commenter are also described.

[2] On October 25, 1995, CSPI submitted a comment to the olestra petition entitiled "White Paper on Olestra" (the White Paper). (CSPI subsequently submitted revised versions of the White Paper on November 2 and 3, 1995.) The November 3, 1995, White Paper was provided to the Olestra Working Group and FAc members for consideration at the meetins of November 14–17, 1995 (Ref.3). In addition, the authors of the White Paper, Drs. Myra Karstadt and Michael Jacobson, presented data from the White Paper on all of the issues covered in the White Papers, namely, (1) consumption estimates, (2) effect of olestra on carotenoids, (3) effect of supplementation of olestra with vitamin K on coumadin therpay, (4) effect of olestra on GI symptoms, and (5) animal carcinogenicity studies.

[3] This decision has been delegated to the Commissioner of Food and Drugs, 21 CFR 5.10(a)(1).

Senate Committee on Labor and Human Resources, dated July 29, 1958. ("* * * in our opinion the bill is aimed at preventing the addition to the food our people eat of any substances the ingestion of which would expect to produce not just cancer but any disease or disability.")

The concept of harm was discussed during the Olestra Working Group and FAC meetings. One FAC member expressed the opinion that he would consider an effect that is undesirable as harmful or adverse [4]. However, the legislative history reflects that an effect is harmful if it affects health, not if it is simply an undesirable or unexpected effect that has no adverse health consequences.

The statute leaves the methods and criteria for interpreting data up to the discretion and expertise of the agency. Congress did, however, direct FDA to consider the following three factors:

(A) The probable consumption of the additive and of any substance formed in or on food because of the use of the additive;

(B) The cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet; and

(C) Safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimentation data. (21 U.S.C. 348(c)(5).)

In the case of olestra, the product's broad marketing potential and expected consumption by persons of all ages, including children, are aspects that have been considered in the safety evaluation.

Importantly, Procter & Gamble is not required to show, nor is FDA permitted to consider, that olestra has benefits, health or otherwise, for consumers of the additive. Again, the legislative history of the Amendment is clear on this point.

> The question of whether an additive produces such [a technical] effect (or how much of an additive is required for such an effect) is a factual one, and does not involve any judgement on the part of the Secretary of whether such effect results in any added 'value' to the consumer of such food or enhances the marketability from a merchandising point of view.

S. Rept. No. 2422, 85th Cong., 2d sess. 7 (1958). *Accord*: H. Rept. No. 2284, 85th Cong., 2d sess. 6 (1958).

[4] Statement of Dr. Dennis Hsieh. Dr. Hsieh is a professor of environmental toxicology at the University of California at Davis. Transcript of the November 14 to 17, 1995, meeting of FAC (hereinafter Transcript), vol. 3, p. 40.

In summary, the general safety clause places on Procter & Gamble the burden of proving that a fair evaluation of the data in the administrative record establishes that there is a reasonable certainty that olestra will not be harmful under the prescribed conditions of use. Only if Procter & Gamble meets this burden can the food additive be approved.

2. Dietary Context of Safety Evaluation

Olestra presents a different set of safety issues compared to most food additives. For example, most substances can induce toxic effects provided that the dose administered is sufficiently high. The primary purpose of most safety testing is to determine the toxic dose and to evaluate whether there is a sufficient margin of safety between the highest dose that is not toxic and the expected human exposure.

Because olestra is intended to substitute for fat, a substantial component of the diet, it is difficult, if not impossible, to feed olestra to laboratory animals in amounts sufficiently high to allow use of the 100-fold safety factor that is commonly used to ensure safety (21 CFR 170.22), when evaluating animal studies. The use of a safety factor is intended to account for the uncertainty of extrapolating from toxicity data from animals to humans. (See 21 U.S.C. 348(c)(5)(c).) FDA concludes that in the case of the olestra petition, the agency is justified in not using the 100-fold safety factor for the following reasons. First, no toxic effects from olestra consumption were observed when olestra was fed at levels up to 10 percent of the diet of laboratory animals (as discussed in section III. of this document). Second, olestra is not appreciably absorbed by the body and the minuscule amount of material that is absorbed is metabolized to substances (sucrose and fatty acids) that are further metabolized normally in the body. Thus, no major component of olestra is available to produce a toxic effect. Finally, a significant number of human studies have been performed to assess the safety of olestra, which assessment may be performed without the need for a safety factor.

The fact that olestra is not absorbed also means, however, that as food components are absorbed from the intestine, the amounts of olestra present in the intestine will become an increasingly larger fraction of the total intestinal contents. Thus, the safety issues for olestra are focused on effects in the intestine, including potential interference with absorption of nutrients.

The petitioner completed the standard toxicological testing program to demonstrate safety for a direct food additive, as outlined in FDA's guidance on such testing (Ref. 4). However, to account for the possible variations in composition, effects on composition due to heating, and inherent difficulties in extrapolating from laboratory animals to humans, the initial animal tests have been supplemented with a variety of human and additional animal studies taking into account the properties of olestra. In fact, since the original petition was submitted in 1987, Procter & Gamble has submitted more than 50 additional safety studies for review. In 1992 and 1993, the pivotal safety studies with regard to nutritional effects from the petitioned use of olestra were submitted.

B. Toxicological Studies—Overview

The petition submitted to FDA consists of data and information from toxicity studies in several animal species, including the rat, mouse, dog, and rabbit. The toxicity data base includes a battery of three mutagenicity/genotoxicity tests; subchronic feeding studies in mice, rats, hamsters, and dogs; and reproduction/teratology testing in the rat and rabbit. To determine whether olestra affects the structure and function of the gastrointestinal (GI) tract, a series of absorption, distribution, metabolism, and elimination (ADME) studies were conducted in rats, mini-pigs, and guinea pigs.

C. Nutritional Impact Studies—Overview

The limited digestibility of olestra poses a number of nutrition issues, including olestra's effect on fat-soluble vitamins and whether these effects could be compensated for by the addition of an appropriate amount of the affected vitamins. As a result, the petitioner conducted several studies, including those listed below, in both pigs and humans. Procter & Gamble conducted studies in swine because they have a digestive system similar to humans and can be evaluated for nutrient stores in the liver and bone. Five of the studies that were carried out in swine are: (1) a 12-week dose-response study (the 12-week DR study) of olestra on the status of vitamins A, D, E, and K, and on hard-to-absorb and limited-in-diet nutrients; (2) a 12-week vitamin restoration study (the 12-week VR study) to determine levels of vitamins A, D, and E needed to offset olestra effects; (3) a 26-week dose-response and vitamin restoration study (the 26-week DR/VR study) to extend

the findings of the 12-week DR and 12-week VR studies to longer times and lower olestra intake levels; (4) a 39-week study (the 39-week VR study) to confirm the effects of 0.25 percent olestra and added vitamin A and E measured in the 26-week DR/VR study over a longer exposure time; and (5) a 4-week dietary context study (the 4-week DC study) to compare olestra's effects on vitamins A and E when olestra is consumed either with the diet or between meals.

Procter & Gamble conducted studies of olestra in humans to eliminate any uncertainty related to extrapolating from pigs and to obtain subject reports on gastrointestinal effects. Those objectives were pursued in several human studies including: Two clinical studies, two studies in free-living subjects,[5] and one short-term study designed to assess olestra's effect on vitamin A and fat absorption (the vitamin A/fat study). The two human clinical studies were an 8-week study to determine the dose response of olestra on the status of vitamins A, D, E, and K, and on hard-to-absorb and limited-in-diet nutrients (the 8-week DR study) and an 8-week study to confirm the compensation levels for vitamins A and E (the 8-week VR study). The free-living studies were a 16-week study to assess the status of vitamin E in subjects consuming 18 grams/day (g/d) olestra (the 16-week vitamin E study) and a 6-week study to determine the effect of 20 g/d olestra on vitamins D and K (the 6-week vitamin D/K study).

D. GI Effects—Overview

The petitioner performed several studies to evaluate olestra's effects on the gastrointestinal (GI) tract including the following. The two clinical studies (the 8-week DR and 8-week VR studies) were used to evaluate adverse gastrointestinal effects as reported by the test subjects. In addition, the effect of olestra on intestinal microflora was measured by conducting a breath gas expiration study. Several studies were also conducted to evaluate olestra's effects on bile acid metabolism and absorption. In order to determine olestra's effects, if any, in an at-risk population, studies were conducted in inflammatory bowel disease patients. Because some drugs are lipophilic (fat-soluble) and may partition into (i.e., be partially absorbed by) olestra, olestra's potential to affect absorption of drugs was also investigated. In addition, because nonabsorbable liquid oil can separate from other fecal material in the colon and leak through the anal sphincter, a human clinical study was performed to determine the relationship between olestra's stiffness and passive oil loss.

E. FDA's Decision Process

In light of the novel issues raised by the review of the olestra data, FDA's Center for Food Safety and Applied Nutrition (CFSAN) determined that it would be valuable to obtain additional expertise in resolving certain issues that had been raised. A Regulatory Decision Team (RDT) composed of senior FDA managers was established for the purpose of recommending, to the Director of CFSAN, a decision on the olestra food additive petition. In addition, FDA retained the services of several scientific consultants from outside the agency to facilitate the agency's deliberations.

As is the case with all food additive petitions, the olestra data were reviewed by staff scientists. Because of the large number of studies and the diverse nature of the information, each of these scientists reviewed a portion of the total body of data on the additive, focusing on his particular area of expertise. These staff-level reviews, including any questions or issues raised by such reviews, were subsequently considered by the RDT, assisted by the outside consultants. In the RDT deliberations, an overall Center position on olestra's safety was synthesized; in the process, issues raised by individual reviewers were resolved, were determined to be not significant, or were incorporated into the synthesized position. During this deliberative process, the members of the RDT weighed the various pieces of scientific information and applied their scientific judgement as they developed an overall Center position.

After the conclusion of the RDT deliberations and the meetings with consultants from outside the agency, FDA convened a public meeting of its FAC and a special Olestra Working Group of the FAC on November 14 through 17, 1995, to undertake a scientific discussion of the agency's evaluation of the safety data in the petition. The membership of the standing Committee was supplemented with temporary members and consultants to the Committee, representing scientific disciplines appropriate to the evaluation of a macro-ingredient fat substitute.

At the Olestra Working Group meeting, Procter & Gamble presented a summary of the data it considered adequate to establish the safety of olestra, the experts with whom the agency had consulted presented their views on the sufficiency of the information to assess the safety of olestra, interested members of the public presented their opinions and evaluations of the data, and FDA presented its evaluation of the data. The Committee was asked to assess, in light of the state of the science relative to macro food ingredients, whether all critical safety issues with respect to the use of olestra in savory snack foods had been addressed.

As set out in detail below, having completed its evaluation of the data in the petition and having considered the deliberations of the Olestra Working Group and the FAC, including all presentations to the Committee, and the comments received on the petition, the agency is amending the food additive regulations to permit the use of olestra in place of fats and oils in prepackaged ready-to-eat savory snacks.

II. Identity and Use

Olestra is the common name for the mixture of sucrose esters formed from the addition of six, seven, or eight fatty acids to the available eight free hydroxyl moieties of sucrose. Saturated and unsaturated fatty acids of chain length C12 to C20 and higher can be used to manufacture olestra. The final product is defined by specifications which include the fatty acid composition.

The identity of sucrose octaester as the principal component of olestra has been verified by infrared, mass, and nuclear magnetic (proton and 13carbon) spectrometry (Ref. 5). The generalized structure for olestra is set forth below.

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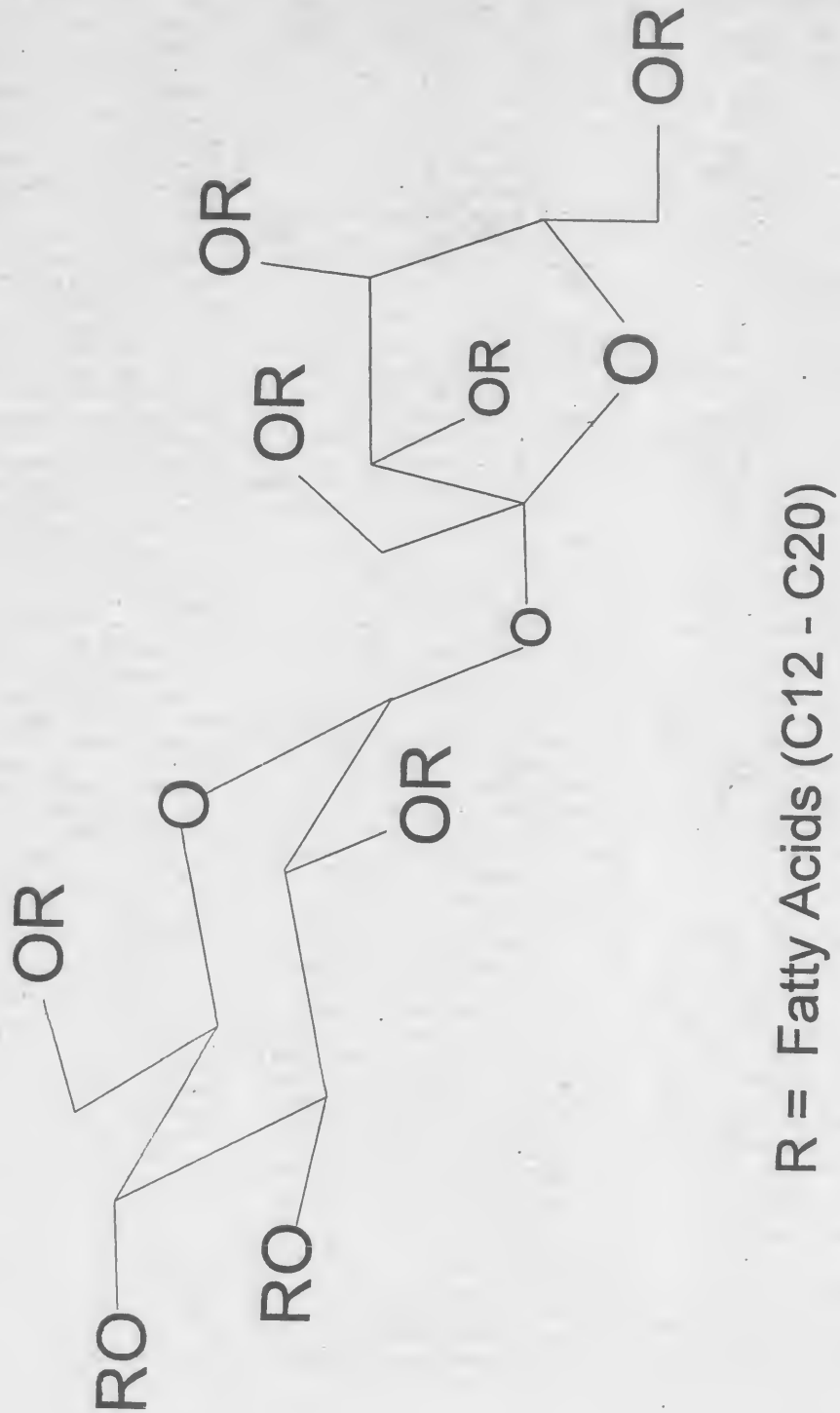
[5] Free-living subjects maintain their normal diets and eating patterns except for consumption of the test article as instructed.



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A. Manufacturing Processes

Olestra is prepared by the addition of medium- and long-chain fatty acid methyl esters to sucrose in the presence of catalysts. The postsynthesis purification steps are the same as those generally practiced in the edible oils industry. These purification steps depend upon physical separations and do not involve chemical bond rearrangement or the use of solvents or catalysts.

The methyl esters used to prepare olestra can be obtained by procedures common in the food industry such as the reaction of refined triglyceride oils with methanol in the presence of sodium methoxide or from esterification of their fatty acids. The resulting esters are washed with water to remove residual methanol, dried under vacuum, and distilled. The fats and oils can be derived from a variety of edible sources such as, but not limited to, soybean, palm, coconut, fully hydrogenated rapeseed, and cottonseed.

Sucrose and the methyl esters are mixed with an alkali metal soap of a long-chain fatty acid. A small amount of transesterification catalyst such as an alkali metal (sodium or potassium) carbonate, bicarbonate, hydride, or alkoxide is added and the mixture heated under vacuum to withdraw the volatile methanol byproduct. Following the reaction, excess methyl esters and free methanol are removed by evaporation under vacuum. Standard steam deodorization removes free fatty acids and odors. Different lots of olestra may be mixed to achieve desired properties or to meet product specifications.

The manufacture of olestra can be well controlled, based upon the petitioner's analysis of representative lots (Ref. 5).

B. Constituents

The principal trace constituents of olestra are collectively identified as the unsaponifiable fraction, ranging in concentration from 0.08 percent to 0.3 percent. These constituents are primarily aliphatic hydrocarbons and plant sterols that naturally arise from the edible triglyceride sources of fatty acids used in the synthesis of olestra. In this respect, these trace constituents of olestra do not differ from those found in typical edible oils. Additionally, difatty ketones (DFK's), formed during its manufacture, are found as trace constituents in olestra as consumed.

DFK's form in olestra during the alkaline rearrangement manufacturing process. The DFK's that are present in olestra are a family of compounds with a common general structure consisting of two fatty acid chains with a central keto group. They are formed from naturally occurring vegetable oil-derived fatty acids used to make olestra. The length and degree of unsaturation of the fatty acid chains are determined by the source oil used to make olestra.

Quantitative analysis of olestra by gas chromatography and mass spectrometry of 15 typical lots of olestra determined that olestra contains 36 to 416 parts per million (ppm) DFK's. The potential DFK range of olestra was altered to 100 to 300 ppm when the method of manufacture was updated. Qualitative analysis of soybean oil-based olestra showed that the DFK's ranged from 31 to 35 carbons in length, consistent with the predominance of C_{16} and C_{18} fatty acids in soybean oil.

Identical analytical techniques showed that similar types (C_{29}-C_{35} fatty acid chain length), but lower levels, of DFK are found in vegetables (5 to 86 ppm), cooked meat fat (0.15 to 2.73 ppm), and food-approved emulsifiers (10 to 55 ppm). Historically, the once-common commercial practice of rearranging fats and oils by base-catalyzed methods produced levels of DFK that exceeded 300 ppm. These results show that olestra is an additional dietary source of those DFK's that are now, and have been, commonly consumed in the food supply (Ref. 6).

C. Specifications

Olestra comprises a range of possible compositions that can be identified by a three-dimensional matrix defined by: (1) Fatty acid chain length; (2) the degree of fatty acid unsaturation; and (3) the distribution of full and partial esters of olestra. The petitioner has proposed specifications that include ranges for fatty acid chain length and degree of unsaturation to ensure functional products for use in savory snacks. The specified range of esterification ensures the nonabsorbable and noncaloric nature of the product.

Traditional edible oil specifications that ensure purity and safety also are incorporated into the olestra specifications. These values include specifications for free fatty acid content, total methanol residues, water, residue on ignition, peroxide value, total heavy metal content, and lead.

D. Stability

Olestra is stable under ambient and high-temperature storage conditions. In all cases, olestra is at least as stable as triglycerides with similar fatty acid composition.

Polymers form in both olestra and triglycerides during cooking, purification, or storage, when olestra or triglycerides are exposed to heat, moisture, and air. The polymers, comprised almost entirely of dimers and trimers, form by cross-linking at points of unsaturation on the fatty acid chains. This mechanism of cross-linking in olestra is the same as that which occurs in triglycerides. The amount of polymer found in olestra is less than that found in a conventional edible oil stored under identical, controlled conditions.

Typical bulk lots of olestra were demonstrated to be as stable as triglycerides of similar fatty acid composition when stored at room and elevated temperatures (120 F) for up to 1 month. These olestra batches were found to be stable based upon the lack of significant change in fatty acid composition, ester distribution, free fatty acid levels, polymer levels, and oxidative stability (Ref. 7).

Heating food fats in the presence of moisture and air results in the production of decomposition byproducts. Such byproducts are removed regularly from commercial cookers to maintain an effective frying system under good manufacturing practice. Use of olestra for frying savory snacks will similarly lead to production of byproducts. The petitioner conducted research to determine the extent of byproduct production from olestra compared to conventional frying fats, and to determine whether unique byproducts would be formed.

A variety of analytical techniques were employed to characterize the profile of byproducts formed during the heating of olestra and conventional frying fats. The gross identity of the heated products was determined by standard methods such as fatty acid composition, carbon number profile, and peroxide value. In addition, comprehensive analyses of changes to the fatty acid side chains were undertaken. Fatty acids were methylated by transesterification, isolated by silica gel column chromatography or solid phase extraction, and analyzed by a variety of techniques including gas chromatography (GC), GC/mass spectrometry (MS), two-dimensional GC/MS, and high performance liquid chromatography (HPLC). This battery of tests provided an analytical sensitivity to detect a component present in the heated oil at a level of 17 ppm (equivalent to 0.05 ppm in the diet of 90th percentile consumers of olestra) (Ref. 8).

For both olestra and conventional frying fats (triglycerides), the predominant chemical changes that occur under frying conditions are

oxidation reactions on the fatty acid side chains (Ref. 8). The principal byproducts of frying are polymers (dimers and trimers) which are joined primarily by bonds between unsaturated fatty acid components. Both olestra and conventional fats of similar fatty acid composition undergo a similar number of polymerization reactions under common heating conditions. For example, the amount of polymer increased 0.003 mole/100 g for olestra and 0.004 mole/100 g for a triglyceride of similar fatty acid composition.

Levels of olestra and triglyceride polymers absorbed into the cooked foods under worst-case conditions are similar and show that there is no selective concentration in food. For example, polymer levels in food fried in either olestra or triglyceride ranged from 4 to 6 percent of total lipid weight. These values correspond to the concentration of olestra and triglyceride polymer in the bulk heated oil phases (Ref. 8).

Baking conditions do not degrade olestra or triglyceride as readily as frying conditions, even though soda crackers commercially prepared with olestra may experience temperatures ranging from 250 to 350 °F. This is because crackers are exposed to such temperatures for only a few minutes (not hours), and the temperature within the body of the cracker can be expected to be substantially lower than the oven temperature.

This stability in baking assessment was confirmed when both olestra and a triglyceride of similar fatty acid composition were used to prepare soda crackers, and the crackers were baked for 6 minutes at the more common commercial temperature of about 250 °F. The neat (i.e., prior to baking) olestra and triglyceride were analytically characterized, and the profiles compared to those obtained from the fats extracted after the soda crackers were baked.

Unlike during frying, neither olestra nor the triglyceride formed any measurable polymer during the 250 F baking (Ref. 9.). Consistent with a lack of change in polymer content, results demonstrate that neither olestra nor the triglyceride experienced any significant change in primary structural composition (i.e., ester distribution for olestra; or the tri-, di-, or monoglyceride profile for the triglyceride).

The only notable change in both olestra and the triglyceride was a slight increase in free fatty acid content. This latter effect is expected because free fatty acids may be present in the cracker raw ingredients, and the alkaline chemical leavening agents used in soda cracker production can promote ester hydrolysis. The similarity of changes in olestra and triglycerides during soda cracker baking is consistent with the fact that the chemical changes in both products take place on the fatty acids, and yield the same decomposition products.

To test stability during storage after baking, both olestra and a triglyceride of similar fatty acid composition were used to make soda crackers, unflavored plain crackers, and unflavored snack crackers. All products were packed in air to reflect current market practice, aged under controlled temperatures and time to reflect common and worst-case storage conditions, and analyzed for parent, polymer, and decomposition products. The results demonstrate that the stability of olestra and triglyceride were comparable under the conditions studied (Ref. 9).

FDA concludes that use of olestra in frying media for savory snacks results in neither more nor different byproducts of the frying process than currently experienced with conventional oils. Also, olestra is as stable as triglyceride in crackers during baking and in baked crackers stored under expected and worst-case conditions.

E. Use and Intended Technical Effect

Olestra is proposed for use as a calorie-free replacement for up to 100 percent of the conventional fats and oils used in the preparation of savory snacks such as flavored and unflavored chips and crisps, flavored and unflavored extruded snacks, and crackers. These uses include substitution for fat for frying as well as sources of fat in dough conditioners, oil sprays, and flavors. Olestra will function in savory snacks as a texturizer and as a formulation aid (21 CFR 170.3(o)) at levels not in excess of that reasonably required to produce its intended effect.

F. Estimated Daily Intake for Olestra (EDI)

When conducting a food additive safety evaluation, FDA typically uses estimated 90th percentile chronic intakes. The petitioner has provided a study of probable intake for olestra, completed by the Market Research Corporation of America (MRCA), that contains sufficient information to estimate both chronic and acute exposures to olestra.

The MRCA methodology estimates the daily consumption of olestra from savory snacks for individuals by combining: (1) The individual's frequency of consumption of savory snacks; (2) the average amount eaten per eating occasion of that savory snack; and (3) the amount of olestra in that savory snack. Eating occasion frequencies were determined from 14-day dietary diaries that were kept by heads of household. The amount of food eaten per eating occasion was derived from the USDA's Nationwide Food Consumption Surveys. The amount of olestra in snacks was determined in the petitioner's laboratories.

The MRCA survey data show that at the 90th percentile, the probable lifetime-averaged intake of olestra is 6.4 g/p/d. FDA believes however, that it is appropriate to consider energy needs in estimating the daily intake of olestra. Based on the assumption that consumers of olestra will compensate for calories "lost" due to consumption of olestra by increasing their intake of food (including olestra-containing snacks), the agency has concluded that the lifetime-averaged EDI for olestra should be increased by 10 percent to 7.0 g/p/d (Ref. 10).

Any effects of olestra on nutrients or nutrient absorption could be exhibited during less than chronic exposure conditions. To evaluate sub-chronic conditions, FDA has estimated that a "high" acute consumer of olestra (every day for 12 weeks) would consume 20 g/p/d, equivalent to eating a 2-ounce (oz) bag of potato chips every day (Ref. 11). The MRCA survey information submitted by the petitioner shows that the 99th-percentile, 14-day average intake for olestra would be 14.8 g/p/d (corrected to 16.3 g/p/d for caloric compensation) in the 18 to 44 year old male group. The 99th-percentile single-day intake of olestra for the group consuming the highest level of savory snacks (13 to 17 year old male group) is 40.4 g/p/d (corrected to 45 g/p/d). It is not likely that this high single day intake would be repeated every day in the 12-week time frame previously mentioned.

In terms of consumption patterns, the MRCA data also show that approximately 9 percent of lunch and dinner meals include a snack food that could potentially contain olestra. The data also show that 63 percent of snack food eating occasions occur with a meal.

Consumption estimates of olestra-containing savory snacks were discussed at the Olestra Working Group and FAC meetings. In particular, CSPI raised three concerns about these estimates. First, CSPI presented several consumption scenarios to the Olestra Working Group [6] that the organization

[6] These CSPI comments were presented by Dr. Myra Karstadt, Ph.D. Transcript, vol. 2, p. 49. This information is also discussed in CSPI's White Paper (Ref. 3).

asserted better represented expected olestra consumption. These consumption estimates ranged from 4.2 g/p/d to 37.5 g/p/d. CSPI's higher consumption estimates included an increase in consumption of olestra-containing snacks over full-fat snacks; this increase was based on the results of a telephone survey, which survey indicated that people think they would eat 25 percent more snacks if the snacks contained lower fat. Based on these scenarios, CSPI asserted that there would likely be a substantial number of snack eaters consuming olestra in quantities similar to those fed in the 8-week human studies (8, 20, and 32 g/d).

Second, CSPI asserted that consumers usually eat an entire bag of chips at one sitting, and that bags marked "single-serving" typically contain from three-quarters of an ounce to 2 ounces. Therefore, CSPI claimed that in many cases, people would eat several ounces of chips at one sitting, and that, in evaluating olestra's for GI effects, it is important to consider single-sitting consumption levels.

Third, CSPI expressed concern that the MRCA survey population may not represent the most vulnerable high-volume consumers of snack products, such as minority teenagers resident in low socioeconomic areas, who may both consume large quantities of savory snacks and have poor nutritional status.

Dr. Gail Harrison, consultant to the petitioner,[7] presented her analysis of the MRCA survey demographics to the Olestra Working Group, which responded to CSPI's third concern. Dr. Harrison stated that the MRCA survey population is very representative of the U.S. population in terms of regional census areas, census regions, and urbanization. Further, in terms of different population groups, she said that children of all ages are appropriately represented, while young homemakers are slightly underrepresented. In addition, there is a slight, though not statistically significant underrepresentation of minority households, and the income distribution slightly underrepresents highest-income and lowest-income households by about three to four percent. Also, information was provided to the Olestra Working Group by the petitioner from an analysis of USDA's 1990–1991 Continuing Survey of Food Intake that the average intake of salty snacks (crackers, popcorn, pretzels, and corn chips) by food-stamp recipients was about 4 g/p/d while nonrecipients consumed about 7 g/p/d.[8]

After presentations by the petitioner, CSPI, FDA, and others, the members of the Olestra Working Group generally agreed that all issues with regard to the chemistry and consumption of olestra had been adequately addressed.

FDA agrees that it is appropriate to use conservative assumptions in the safety evaluation of olestra, the effect of which is likely to over-estimate consumption patterns. For this reason, FDA has assumed that 100 percent of all savory snacks will be replaced by olestra-containing snacks. That is, once olestra is approved, some consumers will eat only savory snacks containing olestra. FDA further believes that it is appropriate to rely on the MRCA survey data to estimate consumption because the survey is well designed, includes a large base of people, and a sound methodology in that the survey relies on food-intake diaries kept by participants rather than relying on participants' recall of what they ate sometime in the past. In light of the discussion before the Olestra Working Group, FDA further concludes that the MRCA survey data are sufficiently representative of the eating habits of the U.S. population and, in particular, that the eating patterns of low-income individuals are captured by the MRCA data and thus, such individuals are included in the agency's consumption estimates. In addition, FDA finds that a scenario-driven estimate of 20 g/p/d, based on consumption of 2 oz of chips per day, which is greater than the 99th percentile, 14-day average intake in the highest consuming group of snack eaters (18 to 44 year old makes), is a reasonable estimate of a "short-term" high consumer. FDA has not used the largest amount reported to have been eaten in one sitting during the MRCA survey period because that amount represents an extreme that is unlikely to be repeated for more than a few days. FDA further concludes that there are no scientific data to justify increasing the estimated olestra exposure derived from the MRCA survey in order to account for the potential consumers' increase in consumption of snacks because the snacks are low-fat.

FDA has also evaluated the potential chronic exposure to DFK's formed from the manufacture of olestra. Mean DFK intake from olestra-prepared snacks is 0.4 mg/p/d (DFK level of 125 ppm). The 90th percentile for DFK's, based on an olestra intake of 7 g/p/d, is 0.87 mg/p/d. For perspective, the mean level of DFK in foods (primarily beef, chicken, pork, and the brassica vegetables) is 9 mg/p/d and the 90th percentile background exposure (typically approximately twice the mean for commonly consumed foods such as meat and vegetables) would be 18 mg/p/d (Refs. 12 and 13).

Thus, FDA has determined that the available data and information support the use of 7 g/p/d olestra as an estimate of chronic consumption by the 90th percentile snack eater and 20 g/p/d olestra as an estimate of shorter term consumption.

III. Toxicity Data—Discussion and Evaluation

A. Absorption, Distribution, Metabolism, and Elimination

The petitioner conducted a series of preliminary studies to assess the absorption of olestra in rats. In order to identify which organs might accumulate intact olestra or metabolize olestra if absorbed, rats were intravenously (IV) injected with olestra radiolabelled with 14C on the sucrose portion of the molecule. The radiolabelled olestra initially deposited in the liver and, to a lesser extent, in the spleen. The data in these early studies show that, olestra was taken up rapidly by the reticuloendothelial system and deposited in the liver and spleen within 3 days following intravenous injection. There was a minor accumulation in the fatty tissues with only a trace amount detected in expired air. At 21 days, the concentration of olestra in the liver dropped to about 50 percent of the 3-day level. Olestra was excreted unchanged via the biliary and fecal routes.

These results demonstrate that the olestra that accumulated in the liver following intravenous injection was not metabolized because radiolabel was not accumulated in other tissues, which would have occurred if olestra had been hydrolyzed by hepatic enzymes. The absence of olestra's metabolization was confirmed by thin-layer chromatography, which showed intact olestra in the bile and feces. The half-life of olestra in the liver was about 5 days.

Examination by electron microscopy of liver tissue from rats injected intravenously with olestra showed that, at 56 days after dosing, lipid accumulation was greatest in the Kupffer cells. By 84 days post-dosing, the greatest accumulation was in the parenchymal cells, indicating that both kinds of cells handle olestra following

[7] Dr. Gail Harrison, Professor, School of Public Health, University of California-Los Angeles. Dr. Harrison presented at the petitioner's request. Transcript, vol. 2, p. 73.

[8] Information from testimony by Mr. Thomas Breaker from the Mathematica Policy Research Group before the Committee on Agriculture's Subcommittee on Department Operations and Nutrition (Transcript, vol. 2, p. 163).

iv administration. Tissue deposition studies were also conducted in rats fed one percent olestra for 30 days. Based on the data submitted, there was no significant radioactivity detected in the liver, spleen, lung, thymus, or adipose tissue from animals fed olestra.

Procter & Gamble conducted a series of studies in male and female rats to determine the fate of penta-, hexa-, hepta- and octa-ester preparations of olestra administered by gavage. The livers were removed and lipid extracts were analyzed for the various esters. No esters were detected by thin layer chromatography. However, the overall sensitivity of the method was only approximately 2 to 3 percent of the administered dose. Therefore, any olestra in rat liver extracts containing less than 3 percent of the administered olestra ester preparations could not be detected. Additional fat balance studies conducted in the rat demonstrated that enzymatic hydrolysis can convert mono- through penta-ester formulations of olestra to sucrose and fatty acids while hexa- through octa-ester formulations are not absorbed (Ref. 14).

To assess further the potential for olestra to be absorbed from the GI tract, the petitioner conducted a series of absorption studies in rats, guinea pigs, and mini-pigs. These studies used uniformly-labeled olestra with high specific activity and sensitive analytical methods to analyze tissues, especially liver, for intact olestra and urine for ^{14}C-sucrose, a metabolic product that would result from the metabolism of any absorbed olestra.

1. Rat Studies

In the rat studies, in order to detect the absorption of a very small amount of the administered dose, olestra of high chemical and radiochemical purity and high specific activity (1 millicurie/g) was dosed at high levels (0.1 millicurie/rat). Tissues were collected, combusted, and analyzed for radiolabelled CO_2, or the lipid fraction was extracted and analyzed for intact olestra by HPLC. Urine, feces, expired CO_2, and the carcass were analyzed for ^{14}C. The urine was analyzed for ^{14}C-sucrose to assess whether olestra had been absorbed and metabolized (Refs. 15 through 19).

Five samples which represented the extremes, and beyond, of the olestra specification range, as well as a typical mid-range composition, were tested. This set of samples included the following: (1) a sample in which the fatty acid chains were 100 percent saturated; (2) a sample in which the fatty acid chains were highly (85 percent) unsaturated; (3) a sample rich in short-chain length fatty acids (59 percent) and penta- and hexa-esters (84 percent); (4) a sample which represented the unheated mid-range of the olestra specification; and (5) a mid-range olestra sample which was subjected to conditions of repeated thermal stress as would occur in the commercial preparation of savory snacks. Although the short-chain length fatty acids (59 percent) and penta- and hexaesters (84 percent) sample falls outside the olestra specifications proposed in the petition, the sample was tested to determine the absorption of these components that might occur in olestra in trace amounts.

The mean recovery of unabsorbed radiolabel from the rat feces, GI tract and contents, animal wipes and animal rinse solutions, and cage wipes and cage rinse solutions was greater than 98.5 percent of the administered dose regardless of the radiolabeled olestra formulation studied (Ref. 19). This recovered amount represents olestra that is not absorbed. The recovery of absorbed radiolabel carbon from olestra ranged from 0.02 percent of the administered dose of the high saturated olestra formulation to 1.5 percent of the administered dose of the short chain length and low ester formulation. The majority of the absorbed radioactivity was found in the expired CO2 and urine. Analysis of liver lipids for intact olestra and urine for 14C-sucrose did not show any radiolabelled carbon. These data demonstrate that most of the ingested olestra remains intact and is not absorbed, but is excreted intact in the feces. The percent absorption of these olestra formulations are shown in Table 1 below.

TABLE 1.—PERCENT ABSORPTION OF OLESTRA FORMULATIONS IN RAT ABSORPTION STUDIES

Olestra Composition	Percent Absorbed
Low Chain/Low Ester	1.50
Mid-Range	0.16
Heated Mid-Range	0.14
High Unsaturates	0.05
High Saturates	0.02

The absorption measured for the sample rich in short-chain fatty acids and penta and lower esters was 1.5 percent of the administered dose. This higher value, compared to the other olestra formulations tested, resulted from the hydrolysis of the penta and lower esters to sucrose and free fatty acids in the GI tract. Sucrose molecules released by hydrolysis of the lower esters in the GI tract were further hydrolyzed by intracellular mucosal sucrase and passed into the portal system as the monosaccharides glucose and fructose. These molecules were metabolized normally and the radiolabel was excreted rapidly in expired air and urine. The only variable that significantly affected absorption was the lower chain length and lower degree of esterification. Restriction of these lower chain length and lower esters in olestra through specifications for the additive limits the absorption to less than 0.16 percent of the administered dose. Of the five radiolabelled olestra formulations studied in the rat, the heated mid-range formulation with 0.14 percent recovery of absorbed radiolabel represents the olestra formulation proposed to be marketed for human consumption. FDA concludes that the low level (0.14 percent) of absorbed radiolabelled carbon from penta- and lower esters contained in the heated olestra is biologically insignificant because the only components shown to be absorbed are metabolized to sucrose and fatty acids which are metabolized normally (Ref. 19).

2. Guinea Pig Studies

The petitioner conducted studies in male and female poligeenan-fed guinea pigs to assess the potential for increased absorption of olestra across a damaged intestinal mucosa. (Poligeenan is known to cause intestinal damage.) Male and female guinea pigs were given 3 percent poligeenan in tap water, or tap water alone (controls), for 5 weeks until GI lesions similar to those seen in acute and chronic human GI diseases (such as ulcerative colitis and Crohn's disease) were induced. The guinea pigs were then dosed with 200 microcuries of a heated olestra and the absorption of

olestra was compared between animals with normal GI tracts and those with compromised GI tracts.

The total recovery of radiolabelled olestra was greater than 97 percent of the administered dose for female guinea pigs in both the normal and compromised groups.[9] The majority of radiolabel, 87 percent to 95 percent, was found in feces and GI contents. Guinea pigs in the compromised group had comparable amounts of radiolabel in the GI tract and contents compared to the normal group. In addition, there were no consistent differences between the normal and compromised groups in the distribution of the absorbed radiolabel among various tissues, blood, urine, or expired CO_2. These findings show that the absorption of intact olestra is no greater in guinea pigs with compromised GI tracts than in guinea pigs with normal GI tracts (Refs. 20 and 21).

3. Mini-Pig Studies

The absorption of a typical, mid-range heated olestra was determined in weanling mini-pigs. The weanling mini-pig was chosen because its GI tract is physiologically and anatomically similar to humans and, like man, the mini-pig can tolerate a high fat diet. The design for the mini-pig study was similar to the design in the rat absorption studies except that expired CO2 was not collected from the mini-pigs because metabolic cages large enough to house mini-pigs were not available at the contract laboratory. In addition, the dose of radiolabelled olestra was increased to 0.35 millicuries per mini-pig so that the detection limit was comparable to that in the rat studies.

For both male and female mini-pigs, 98.9 percent of the recovered radiolabel was found unabsorbed in the feces, GI tract plus contents, and animal rinse solutions. No radiolabelled olestra was found in the lipid fraction that would have contained olestra, if present, in the lipids extracted from livers of the mini-pigs (Ref. 22).

Overall, the results from these studies in rats, guinea pigs, and mini-pigs demonstrate that while a small percentage of the olestra formulation consisting of penta- and lower esters is absorbed and metabolized to fatty acids and sucrose, nearly all of the ingested olestra remains intact and is not absorbed (Refs. 19, 21, and 22). Heating does not significantly increase olestra absorption and absorption is no greater when the GI tract is compromised than when it is intact.

B. Genetic Toxicity Studies

The petitioner conducted a battery of genetic toxicity studies with the unheated mid-range olestra formulation. Olestra was not genotoxic in any of the following test systems: An Ames Salmonella test with or without metabolic activation, a mouse lymphoma cell mutagenicity assay with or without activation, an unscheduled DNA synthesis test, and a Chinese hamster ovary cell in vitro cytogenetics test with or without activation.

Because of solubility problems with olestra in these early genetic toxicity studies, the petitioner conducted an additional battery of in vitro assays and in vivo cytogenetic studies on heated mid-range olestra with Pluronic F–68, a nontoxic, nonionic surfactant to ensure cell contact with olestra. No evidence of mutagenicity or genetic toxicity from heated olestra was observed in the following test systems: The Salmonella/mammalian microsome mutagenesis assay; the L5178Y TK +/- mouse lymphoma assay; the test for chemical induction of unscheduled DNA synthesis in rat hepatocytes; and the cytogenicity study in Chinese hamster ovary (CHO) cells. These tests were conducted in the presence and absence of liver enzyme (S–9) activation at concentrations of up to 5 mg/mL. In addition, there was no evidence of chromosomal aberrations from heated mid-range olestra observed following examination of the bone marrow in the in vivo cytogenicity assays (using both acute and chronic dosing protocols) conducted on Sprague-Dawley rats (Ref. 23). Based upon the foregoing result, FDA concludes that olestra is not genotoxic.

C. Animal Toxicity Studies

1. Teratogenicity Studies

The teratogenic potential of olestra was evaluated in studies conducted in the rat and rabbit. These studies establish that olestra was not teratogenic when fed during organogenesis in either species. Olestra was also not teratogenic nor did it affect reproduction in a multi-generation rat reproduction/teratology study.

Olestra was fed to rats (10/group) at 3.2 percent, 6.4 percent, or 12 percent of the diet beginning on the 6th day of pregnancy. Dams were sacrificed on days 13 and 20 of pregnancy, and the fetuses examined for abnormalities. The uterine contents of rats killed on day 13 of pregnancy were evaluated for implantation, resorption sites, and the number of corpora lutea. The fetuses of the dams sacrificed on day 20 were removed and corpora lutea counted; the pups were sacrificed and evaluated for anomalies. One-third of the fetuses were cleared and stained for study of the skeleton, and two-thirds were sectioned for study of the soft tissues. This study provided no evidence that olestra is teratogenic or embryotoxic (Ref. 24).

In a rabbit teratology study, heated olestra was administered via gavage at doses representing 1 percent, 5 percent, and 10 percent of the diet during the critical stages of gestation (days 6 to 19); control animals were dosed with distilled water. Dams were sacrificed on day 30 of pregnancy and the fetuses examined for abnormalities. This study provided no evidence that olestra was teratogenic (Ref. 25).

For the multi-generation study, weanling rats were maintained on diets containing 0 percent, 1 percent, 5 percent, or 10 percent olestra for a 91-day growth period. The mid- and high-dose diets were supplemented with vitamin A (2.5 times the National Research Council (NRC) requirements[10]) and vitamin E (five times the NRC requirements), in order to compensate for the reduced absorption of these nutrients in the presence of olestra. At the end of 91 days, F_0 dams were mated for a reproduction (F_{1A}) phase and then were mated again for a teratology (F_{1B}) phase. After the growth period, the F_{1A} offspring were mated for the F_{2A} and F_{2B} generations. Olestra had no effect on mating, conception, embryonic development, fetal and postnatal viability, or postnatal growth in either generation (Ref. 24).

2. Subchronic and Chronic Feeding Studies

Early feeding studies in rats with unheated olestra at levels of 4 percent, 8 percent, or 15 percent of the diet for 28 or 91 days resulted in no deaths, no decrease in the absorption of triglycerides or protein, no differences in urine or blood chemistry, hematology, or gross or microscopic histopathology. These studies are not addressed further.

a. *Ninety-Day subchronic feeding study in rats.* The petitioner conducted two subchronic toxicity studies in rats. The first subchronic olestra feeding study in rats showed no adverse effects but used unheated olestra. Therefore, the petitioner, conducted a second 90-day toxicity study in rats using olestra

[9] Incomplete collection of fecal material from support screens, sides and bottoms of cages, and fur of animals for male guinea pigs resulted in lower radiolabel recovery (88.1 percent) and greater variability in results than for female guinea pigs.

[10] NRC requirements are actually recommendations set at levels close to the amount required for good health in the subject animals.

that had been heat abused to a degree exceeding that likely to occur during the preparation of savory snacks. Specifically, olestra that had been heated for 7 days at 190 °C (representing an extreme heating condition) was fed to 6 groups of 40 rats each (20 rats per sex) at 0 percent, 0 percent, 1 percent, 5 percent, 10 percent, and 0 percent in rodent chow ad libitum for 90 days. Groups I and II were chow controls while Group VI control rats were maintained on a diet that contained 10 percent previously heated triglyceride. Diets for groups II-V were supplemented with vitamins A, D, and K (five times the NRC requirement); vitamin E was added to these four diets at 8.0 times, 0.8 times, 4.0 times, and 8.0 times the NRC recommended levels, respectively.

The study included twice-daily observations and weekly physical examinations. Body weight, body weight changes, food consumption, and olestra intake were determined weekly. Ophthalmoscopic examinations were performed pretest and at study termination. Clinical chemistry, hematology, and urinalysis parameters were measured at study termination on 10 animals/sex/group.

Complete gross postmortem examinations were performed on all animals at study termination. The brain, adrenals, ovaries, testes (with epididymides), kidneys, and liver were removed, weighed, and organ-to-body-weight and organ-to-brain-weight ratios were calculated. A full complement of tissues was examined histopathologically from all animals in Groups I, II, V, and VI surviving to study termination, and any animals in Groups III and IV dying unscheduled deaths. Lungs, liver, kidneys, and gross lesions were evaluated from Group III and IV animals surviving to study termination.

Survival, physical condition, body weight, food consumption, feed efficiency, organ weight, organ-to-body weight ratios, hematologic parameters, and histomorphology were evaluated. Olestra fed rats compensated for the decrease in caloric intake due to olestra having zero calories by consuming more food than control rats. No adverse treatment-related effects were observed. These results establish that heated olestra is not-toxic when fed to rats at levels as high as 10 percent of their diet for a period of 90 days (Ref. 26).

b. *Two-year carcinogenicity studies in rats.* Two 2-year carcinogenicity studies of olestra were conducted in rats. In the first study, Fischer 344 rats, 70 per sex per group, were fed olestra at levels of 0 percent, 1 percent, 5 percent, or 9 percent of the diet for 2 years with interim sacrifices at 12 and 18 months. In the second study, Fischer 344 rats, 50 males and 73 females per group, were fed olestra at 0 percent or 9 percent of the diet for 2 years with an interim sacrifice at 12 months. In both studies, diets were supplemented with five times the NRC recommended levels of vitamins A, D, E, and K, to offset the reduced absorption of fat-soluble vitamins in the presence of olestra. The diets in both studies also contained 2 percent fully hydrogenated palm oil to control passive oil loss (anal leakage). The studies included twice-daily observations, and weekly physical examinations. Body weight, body weight changes, food consumption, and olestra intake were determined weekly for the first 12 weeks and monthly thereafter. Feed efficiency was determined during the first 12 weeks. Ophthalmoscopic examinations were conducted pretest, and at scheduled sacrifice. Clinical chemistry, hematology, and urinalysis parameters were measured at 12 and 24 months. Complete gross postmortem examinations were performed on all animals. Selected organs were removed, weighed, and organ-to-body-weight and organ-to-brain-weight ratios were calculated for all rats surviving to scheduled sacrifice periods. Liver samples were taken from rats in the 9 percent olestra groups from both studies for analysis of olestra.

Histopathological evaluations were conducted on a full complement of tissues from animals in the control and 9 percent olestra groups from both studies. Liver, pituitary gland, gross lesions, and tissue masses were evaluated for all animals on study. The duodenum, jejunum, ileum, cecum, and colon were examined for all animals sacrificed at 12, 18, and 24 months.

Rats compensated for the caloric dilution of olestra by consuming more food than was consumed by the controls. Olestra had no effect on ophthalmology, organ weight, organ-to-body- and organ-to-brain-weight ratios, clinical chemistry, hematology, or urinalysis parameters. There was no evidence that intact olestra accumulated in the liver tissue of rats fed 9 percent olestra for 2 years.

There were no treatment-related adverse effects on growth, longevity, or general health, and there were no treatment-related neoplastic responses or evidence of chronic toxicity in either study. In the first study, there were four instances in which differences between treated groups and controls required FDA pathologists to assess whether the effect was treatment-related: male survival, incidence of pituitary adenoma (males and females), mononuclear cell leukemia (males), and basophilic liver foci (females). FDA pathologists also evaluated the following differences in incidence in the second chronic rat study: Incidence of pituitary cysts (males), mineralization of the renal cortex and bile duct hyperplasia, and basophilic liver foci in females. The differences observed between treated groups and controls in both chronic studies are marginal.

Pituitary adenomas are very common spontaneous tumors in Fischer-344 rats with a tendency for highly variable background incidences (Ref. 27). The increased incidence of pituitary adenoma in both sexes in the first chronic rat study represent expected variations in spontaneous background incidences. Thus, FDA concluded that there was no association of the pituitary adenomas with olestra treatment.

Likewise, FDA concludes that there was no association between the incidence of leukemia in male rats and treatment with olestra for several reasons. First, the possible association is not supported by the results of the second study in which there was no comparable development of leukemia. Second, the incidences in the first study, particularly the control group, are unusually low compared to historical data from the National Toxicology Program (NTP) data base and compared to the results of the second study (Ref. 27). Third, mononuclear cell leukemia in Fischer-344 rats is a common spontaneous disease in old age with considerable tendency for background variation (Ref. 27). Therefore, such differences in incidence are not unusual but rather are expected from the normal variation of spontaneous tumor incidences.

In the first rat study, there was an increase in the number of olestra-treated female rats with basophilic liver foci at the 1 year interim sacrifice without any clear increase in the severity of this lesion at the end of 2 years. However, female groups including the terminal sacrificed animals as well as the unscheduled deaths, demonstrated no clear increase in the incidence of basophilic liver foci with olestra treatment. The same phenomenon of early occurrence of basophilic liver foci in olestra-fed female rats was observed in the second study. In both studies, the basophilic foci in the control and treated rats were similar morphologically.

In presentations to the Olestra Working Group and the FAC, and in its White Paper, CSPI expressed concern about the significantly higher incidence of basophilic liver foci at the end of 12 months, although CSPI acknowledged

that the difference between control and treatment groups disappeared by 24 months. CSPI asserted that, although 24 months is the majority of a rat's lifetime, the study should have been carried out for the rats' entire lifetime because it is possible that the foci might have progressed to cancer. CSPI also recommended that an expert Committee (such as NTP review) the findings. [11]

Based upon an examination of all of the data in both studies, FDA pathologists concluded that these findings represented normal biological variability in 24-month-old rats and were not related to olestra ingestion for the following reasons. First, the findings lacked a dose-response effect and were not observed in both male and female rats in both chronic studies (Refs. 28 and 29). Second, the spontaneous occurrence of basophilic liver foci is frequent and variable in aging Fischer-344 rats (Refs. 30 and 31) and the incidence can reach 100 percent at 2 years (Refs. 32 and 33). Further, the majority of foci do not become neoplasms. Third, the most recent studies indicate that hepatocarcinogens induce more morphologically variable foci than those observed spontaneously (Refs. 30, 34, and 35). Thus, the early occurrence and morphological similarity of the basophilic liver foci in the control and the olestra-treated female rats are not indicative of hepatocarcinogenic potential for olestra in the rat.

Dr. John Doull, a clinical toxicologist and temporary member of the FAC, agreed with the FDA evaluation that the basophilic liver foci findings are not significant and that basophilic liver foci are not predictors of carcinogenicity. [12] Dr. Eugene McConnell, [13] a presenter to the Olestra Working Group, agreed with Dr. Doull, and noted that the control groups in both chronic rat studies exhibited abnormally low incidences of foci compared to the foci rate historically observed in rats at these ages; he postulated that the addition of vitamins to the feed in both chronic rat studies may have caused this low foci occurrence rate in the control groups. The rate of foci in the treatment groups was compared to historical control rates and was slightly lower than historical controls.

Dr. McConnell also noted that the slides were reviewed by (1) Board-certified pathologists in the contractor lab performing the study (2) board-certified pathologists employed by the petitioner, (3) an independent pathology laboratory,(4) a group of internationally known pathologists, and (5) FDA pathologists. All of the reviewers came to the same conclusion that none of the data suggests evidence of carcinogenic activity in either species.

Therefore, in light of the discussion of the Olestra Working Group and the presentations of CSPI and Dr. McConnell, FDA confirms its conclusion that there was no olestra-related toxicity or carcinogenicity in these studies.

c. *Two-year chronic toxicity and carcinogenicity studies in mice.* Two 2-year mouse studies were conducted to evaluate the chronic toxicity and carcinogenicity potential of olestra. The first mouse study compared three levels of olestra (2.5 percent, 5.0 percent, and 10.0 percent of the daily diet) to two control groups. Olestra was supplemented with vitamins A, D, E, and K to account for amounts which potentially would be lost due to the high levels of olestra fed. One of the two control groups provided basal levels of fat-soluble vitamins; the second control group was fed supplemental vitamins A, D, E, and K. To confirm the findings, a second mouse study was conducted with a chow-fed control group and a 10 percent olestra group supplemented with vitamins A, D, E, and K.

One hundred mice of each sex were placed in a total of seven groups in the two studies. (The first mouse study had five groups and the second mouse study had two groups.) Fifty animals/sex/group were allocated to the carcinogenicity portions of each study, and all survivors sacrificed at 24 months. Fifteen animals/sex/group were allocated to the toxicity portion of each study, and all were sacrificed at 12 months. Finally, sentinel animals (35/sex/group) were included, and seven/sex/group were sacrificed at one, two, three, six, and nine months for assessment of hepatic vitamin A and E status.

The studies included daily observations and weekly examinations. Body weights and food consumption were determined weekly. Ophthalmoscopic examinations were conducted pretest, and at scheduled sacrifice. Clinical chemistry and hematology data, gross necropsy observations, and organ weights were collected on animals sacrificed at 12 and 24 months in both studies. Complete gross postmortem examinations were performed on all animals. Selected organs were removed, weighed, and organ-to-body-weight and organ-to-brain-weight ratios were calculated for all mice surviving to scheduled necropsy. Histopathological evaluations were conducted on a full complement of tissues from all control and treated animals assigned to the carcinogenicity portion of both chronic studies.

At the end of 24 months, there were no treatment-related effects in either study as determined by mortality, body weights, clinical pathology, gross necropsy findings, organ weights, hematology, clinical chemistries, or histopathology of a comprehensive collection of tissues.

In the first study, there was an increase in the incidence of lung carcinomas and combined lung carcinomas and adenomas in mid-dose olestra-fed male mice but not in any other group. This association of olestra consumption with lung tumors in male mice in the first mouse study was not confirmed by the results of the second mouse study. Lung adenomas and carcinomas are common lesions in Swiss CD-1 mice and tend to have a high and variable background rate (Refs. 36 and 37). The increased combined incidence of lung adenomas or carcinomas in male mice in the first mouse study (Ref. 38) cannot credibly be associated with olestra consumption, and represents expected variation in spontaneous incidence of lung tumors in Swiss CD-1 mice (Ref. 37). Thus, upon review, FDA pathologists concluded that this was not an olestra-related effect because there was no other lung pathology, there was no relation between olestra exposure and time-to-onset of the tumors, the incidence of the tumors was typical for mice of this age and sex based on historical data, and there was no association between olestra exposure and lung tumors in other chronic rodent studies (Ref. 39).

At the Olestra Working Group meeting, CSPI expressed concern about the increase in the incidence of combined lung carcinomas and adenomas in the mid-dose male mice. [14] Dr. Doull noted that an analysis of the data for CSPI by Dr. Renata Kimbrough (Ref. 3) essentially agreed with FDA's conclusions. Specifically, although the mid-dose male mice in the first chronic study had an increased incidence in lung tumors, there was no dose response, the increased incidence of

[11] Transcript, vol. 2, p. 135.

[12] Dr. John Doull, Kansas University Medical Center Transcript vol. 2, p. 113.

[13] Dr. Eugene McConnell, D.V.M, D.V.B.T was chief of the Pathology Branch and Director of the Division of Toxicology Research and Testing for the NTP. Dr. McConnell is a diplomate of the American College of Veterinary Pathologists and the American Board of Toxicology. Dr. McConnell consulted for the petitioner and presented at its request. Transcript, vol. 2, p. 147.

[14] Transcript, vol. 2, p. 136. Discussion of this concern also appears in the White Paper (Ref. 3)

lung tumors was not repeated in the second study, and the lung tumor incidence rate was within the range of that observed in the NTP program in lung tumors.[15] Dr. Doull further stated his view that this data leads to the conclusion that olestra is not carcinogenic.[16]

Therefore, in light of the discussion before the Olestra Working Group, FDA confirms its conclusion that the lung tumors in this study were not an olestra-related effect.

d. *Dog feeding studies.* The petitioner conducted two short-term feeding studies of olestra in beagle dogs. Olestra was fed at a level of 4 percent of the diet for 28 days or 15 percent of the diet for 30 days. Histological examination of several tissues, including the liver, revealed no abnormalities. The olestra-fed animals consumed more food because of the caloric dilution of the diet by olestra, but there was no difference in body weight gain. In a third study, olestra was fed to dogs at 10 percent of the diet for 91 days. No adverse effects were noted among the treated animals in terms of histopathology, hematology, or blood chemistries.

The petitioner also conducted a 20 month chronic feeding study in five male and five female beagle dogs. The animals were fed a chow diet with 0 percent, 5 percent, or 10 percent olestra. Olestra diets were supplemented by adding 1.5 times the NRC recommended dietary level of vitamin A and 2.5 times the NRC recommended dietary level of vitamin E to the low-dose (5 percent) diet. The high-dose (10 percent) diet received 3.0 times the NRC recommended dietary level of vitamin A and 5.0 times the NRC recommended dietary level of vitamin E. The study included twice-daily observations, as well as weekly physical examinations, and determination of growth and food intake. Hematology, clinical chemistry, serum vitamin A and E concentrations, and ophthalmoscopic status were evaluated after 12 and 20 months of treatment.

At the end of the study, all dogs were sacrificed and their tissues subjected to complete gross and microscopic examination. Organ weights and organ-to-body-weight ratios were determined for brain, adrenals, kidney, liver, ovary, testes, and thyroid/parathyroid. A complete set of tissues from all animals was examined by light microscopy.

No evidence of toxicity was observed, and all animals survived the entire length of the study. Growth, as measured by body weight gain, was not affected by olestra ingestion. Food consumption was increased to offset the caloric dilution of the diet by olestra. No biologically significant changes were seen in any of the hematological or biochemical parameters measured. Histopathology revealed no olestra-related effects (Ref. 40).

D. Toxicology Summary

In summary, the results of the toxicological tests submitted by the petitioner support the conclusion that olestra is not toxic or carcinogenic, not genotoxic, and not teratogenic. Heating olestra, as would occur in the commercial preparation of savory snacks made using olestra, does not increase the absorption of the additive or affect its toxicity.

IV. Effect of Olestra on Absorption of Drugs

Because olestra is a fat-like material that has been shown to alter the absorption of some lipophilic nutrients, FDA considered whether the bioavailability of lipophilic drugs might also be affected by consumption of olestra. To address this question, the petitioner carried out a series of studies in both animals and humans.

The petitioner established the following criteria to use in deciding which drugs to study:

(1)The drugs should have wide spread use by the general population.

(2)The absorption, metabolism and elimination of the drugs should be similar in rats and humans.

(3)The drugs should cover a wide range of solubilities, from water-soluble to fat-soluble.

(4)The drugs should include representatives of those used to prevent life-threatening situations.

(5)Most of the drugs should have partition coefficient data already available.

(6)The drugs must be commercially available in radiolabeled form.

Using these criteria, the petitioner selected the following drugs for use in two rat studies: aspirin, diazepam, propranolol, and the oral contraceptives ethinyl estradiol and norethindrone. Because results of studies in rats are not definitive predictors of human conditions (Ref. 41), the petitioner also sponsored two human clinical trials to study the olestra/drug issue. In the first of these clinical trials, propranolol, diazepam, norethindrone, and ethinyl estradiol were included; in the second clinical study, the oral contraceptive Lo/Ovral-28, containing norgestrel and ethinyl estradiol, was evaluated.

A. Effect of Olestra on the Absorption of Selected Lipophilic Drugs (EC–40)

The primary objective of this study was to determine whether olestra affects absorption of drugs relative to corn oil.This study was conducted in Sprague-Dawley derived male and female rats and had three separate experimental components. The olestra used was prepared from safflower oil, while corn oil served as the triglyceride control. Hydrogenated palm oil was added to both the olestra and control diets, to mimic the earlier proposed use of olestra in combination with convention oils.

In the first experiment, 20 male rats were fed either a control diet with 6 percent added corn oil or a similar diet but with 6 percent added olestra for 13 days; the test animals were then fasted, weighed, subdivided into four groups (five rats per group), and gavaged with slurries of either the control or olestra diets to which tritiated diazepam or tritiated propranolol had been added. In the second and third experiments, no initial acclimation period was used. In the second experiment, 20 female rats were fasted, weighed, divided into four groups (five rats per group), and gavaged with slurries of either control or olestra diets to which tritiated ethinyl estradiol or tritiated norethindrone had been added. In the third experiment, 10 male rats were fasted, weighed, divided into 2 groups (5 rats per group), and gavaged with slurries of either control or olestra diets to which C14-labeled acetylsalicylic acid (aspirin) had been added.

In all three experiments, serial blood and urine samples were taken over a 48-hour period after dosing. Fecal samples were also collected at 24-hour intervals. All samples collected were assayed for drug associated radioactivity, and the results evaluated for treatment related effects on drug absorption.

The five drugs studied in these experiments cover a range of lipophilicity, from nonlipophilic (aspirin) to strongly lipophilic (ethinyl estradiol and norethindrone). The petitioner concluded that co-administration of the drugs with olestra did not affect the absorption of any of the drugs tested when compared with corn oil.

FDA concludes that the petitioner's choice of drugs, which were selected based on physico-chemical properties, was reasonable. Further, the study correctly focused on rate and extent of absorption, both of which are important factors in the overall evaluation of human drug absorption. Although the use of total radioactivity measurements,

[15] Transcript, vol. 2, p. 111.

[16] Transcript, vol. 4, p. 113.

as was done in this study, is not a comprehensive evaluation taken alone, the study design is adequate as a first exploration of olestra/drug interactions (Ref. 41).

B. Effect of Olestra on the Absorption of Selected Lipophilic Drugs (EC–41)

The objective of this study was to determine whether a single dose of olestra caused an alteration of the absorption or excretion profiles of lipophilic drugs that were orally administered prior to the olestra. This study was conducted with Sprague-Dawley derived male rats. After a 4 day acclimation period all rats were fasted, weighed, divided into treatment groups (four/group), and gavaged with either tritiated diazepam, tritiated propranolol, or C^{14}-labeled aspirin (acetylsalicylic acid). Following each drug dosing, rats were gavaged with one ml of either water, corn oil, or olestra. Additional rats dosed with propranolol and aspirin received an olestra emulsion (one of the projected final forms for initial marketing of olestra).

Serial blood and urine samples were collected over a 48-hour period, postdosing, while fecal samples were obtained at 24-hour intervals. Forty-eight hours after dosing all rats were sacrificed, their gastrointestinal tracts removed and the contents collected, selected organs excised, and carcasses frozen in liquid nitrogen and ground. All samples were assayed for drug-associated radioactivity. Results of the radioactivity assays were evaluated for treatment-related effects.

The petitioner concluded that there were no differences in rate or extent of absorption of diazepam, propranolol, or acetylsalicylic acid when administered before olestra consumption compared with administration prior to water consumption. Drug excretion profiles were also not affected by olestra. Corn oil (a control substance) reduced the rate of absorption of all drugs studied. The petitioner concludes that these results demonstrate that olestra would not be expected to affect the acute absorption of drugs such as diazepam, propranolol or aspirin, and thus are consistent with EC–40. FDA concludes that, as with EC–40, the design and conduct of this investigation are adequate as a further exploratory study of the potential for olestra/drug interactions (Ref. 41).

C. Effect of Olestra on Drug Bioavailability (EC–42)

The objective of this clinical trial, consisting of 3 experiments, was to determine whether olestra consumption alters drug bioavailability in humans when used as a substitute for absorbable dietary fat. Subjects were assigned to test one drug in a crossover design so that bioavailability of the drug was evaluated with single doses of olestra, water, or a triglyceride (partially hydrogenated soybean oil) placebo treatment. Table 2 provides basic information on subject and treatment assignment.

TABLE 2.—SUBJECT AND TREATMENT ASSIGNMENT IN EC–42

Exp. No.	Subject No. male/female	Age Range (years)	Drug and treatment amount
1	5/3	27 to 47	Propranolol, 20 mg
2	4/4	20 to 40	Diazepam, 5 mg
3	0/10	not available	Norethindrone, 1 mg and Ethinyl estradiol, 0.07 mg

In each experiment, 18 g of olestra, 18 g of triglyceride, or six ounces of water were consumed following ingestion of the respective drug under study. Serial blood samples collected from all subjects were processed and the resulting serums frozen for subsequent drug analyses. The data on peak serum concentrations, times to peak, and areas under the concentration curves (AUC) were analyzed statistically for treatment effects.

Based on its analyses of the results from the three experiments, the petitioner concluded that there were no statistically significant differences in the absorption of the drugs administered with olestra, triglyceride placebo, or water as assessed by total area under the curve (AUC) and time to peak concentration data. The time to peak concentration values for diazepam were slightly longer with the triglyceride placebo than with olestra. There was wide, although not unexpected, between-patient variability. The petitioner concluded that a single dose of 18 g of olestra did not alter the bioavailability¶characteristics of orally administered propranolol, diazepam, or norethindrone/ethinyl estradiol when compared to water or a triglyceride such as partially hydrogenated soybean oil.

FDA concludes that the design of this clinical study was excellent, and that the study may be used by itself, without any reliance on the two studies in rats, to assess olestra's potential for affecting absorption of lipophilic drugs. The results from EC-42 demonstrate that olestra does not interfere with the absorption of drugs when administered at the 18 g dose (Ref. 41).

D. Effect of Olestra on the Systemic Levels of Steroidal Hormones in Women Taking Oral Contraceptives (EC–51)

The objective of this clinical trial was to determine the effect, if any, of chronic olestra consumption (targeted at 20 g/d) on the absorption and efficacy of a low-dose oral contraceptive in normal women.

Thirty healthy, menstruating female subjects aged 20 to 38 years were assigned to two groups. A double-blind, placebo-controlled, crossover study design was used which covered two complete ovarian cycles. Subjects were instructed to begin taking the oral contraceptive Lo/Ovral-28 (0.30 mg norgestrel and 0.03 mg ethinyl estradiol), 5 days before the onset of menstruation. One group of subjects received food items with triglyceride placebo, while the other group received similar food items containing a "mid-range" olestra formulation.

Daily intake of olestra was set at 18 g with one-third (6 g) of the daily dose being consumed at each meal. At the conclusion of the first 28-day cycle, the treatments were crossed over (placebo to olestra, olestra to placebo). All subjects were asked to take their oral contraceptive only in the morning and before the morning meal. Serum progesterone levels were determined at a baseline visit, 5 to 7 days after menstruation and twice weekly for the remainder of the ovarian cycles.

Serial blood samples were collected during each of the two ovarian cycles. These samples were then processed and the serums frozen for subsequent drug analysis. Results were evaluated for treatment effects by comparing AUC, maximum drug concentration, and time to maximum concentration data.

The petitioner concluded that there were no significant effects of consuming 18 g of olestra on the absorption of either norgestrel or ethinyl estradiol, the

two steroid components of Lo/Ovral-28. Serum progesterone levels in subjects in both the olestra and triglyceride placebo groups were found to remain in a range that would prevent ovulation, thereby providing evidence that oral contraceptive efficacy was not affected by olestra. The petitioner also stated that because the oral contraceptive used in this study contains the lowest amounts of two of the most lipophilic steroid hormones (norgestrel and ethinyl estradiol), the results from this study should prove valid for "all high-dose oral contraceptives having less lipophilic constituents." In addition, the petitioner believes that the data from EC–51 provide further support generally for the conclusion from other studies in animals and humans that olestra consumption does not alter the absorption of lipophilic drugs, and therefore, will not affect the efficacy of orally administered drugs.

FDA believes that this study is an excellent extension from single-dose olestra to chronic dosing, at least for the once-a-day situation. Further, in this study, there was no evidence that olestra would affect the efficacy of orally administered drugs (Ref. 41).

E. Summary

The petitioner has submitted two animal studies and two clinical studies assessing olestra's potential to alter drug absorption. Procter & Gamble believes that these studies demonstrate that olestra does not alter the absorption nor affect the efficacy of orally administered drugs.

Members of the Olestra Working Group were unanimous that, with respect to drugs, all the issues had been identified and there were sufficient data to address each issue. [17] There was also nearly unanimous agreement that, with respect to drug interactions, there was no obstacle to approval and reasonable certainty of no harm from olestra consumption. [18]

During the Olestra Working Group and FAC meetings and in numerous comments to FDA, individuals have expressed concern about the effects of olestra on coumarin drugs (e.g., Coumadin or warfarin, Dicumarol, etc.) as well as other drugs. Dr. Ian Greaves, a specialist in environmental and occupational medicine, [19] expressed concern about persons taking anticoagulants such as coumarin drugs that antagonize Vitamin K. He asked how olestra would bind to coumarin and whether there would be difficulty in maintaining an anticoagulant status in people receiving coumarin who intermittently eat olestra-containing products. He stated that his experience with managing patients on anticoagulants is that some of them are very variable for no good reason, and he could easily foresee a patient becoming either overly anticoagulated or under-anticoagulated, depending on whether Vitamin K was being bound or whether the coumarin was being bound. Also, if a person taking coumarin happened to have an intra-cerebral bleed or bleed from his gastrointestinal tract and was also consuming olestra, he felt it would be difficult to know whether olestra had a role in the bleeding. Finally, he stated he was concerned about other fat-soluble drugs, particularly those that cross the blood-brain barrier such as anticonvulsants, psychotropic drugs, and antidepressants. Dr. Greaves's questions covered the concerns that were raised by other individuals.

FDA notes that the results concerning the hormonal preparations are extremely useful because these drugs represent extremely lipophilic substances and are substances that have a narrow therapeutic index in which a lowering of the absorbed concentration would be a concern. In addition, the drug, propranolol, is a compound that has very similar physical/chemical properties to Coumadin or sodium warfarin, [20] a drug about which FDA has received comments concerning olestra's effects. In response to a question by an FAC member, FDA noted that in the previous 5 years, there has been only one drug that FDA has reviewed that is more lipophilic than the hormone drugs tested in the human drug-interaction studies. That drug is a very specialized drug (Atovaquone), which is an anti-pneumocystis drug used in AIDS patients. [21] Therefore, FDA expects that the results observed in the reviewed studies would be representative of nearly any drug on the market.

Regarding coumarin drugs specifically, FDA notes that the effects of a variety of meals (e.g., high-protein, high-carbohydrate, and high-fat) on absorption of sodium warfarin (Coumadin), the most commonly prescribed form of coumarin, were studied and no effect was seen in the total amount of sodium warfarin absorbed. Also, there was no effect on absorption when Coumadin was consumed with high-fat or high-protein meals. When consumed with a high-carbohydrate meal, Coumadin was more slowly absorbed, but only for the first hour after ingestion of the drug [22] (Ref. 42). Therefore, FDA would not expect significant effects on Coumadin absorption from olestra consumption.

Olestra's effects on vitamin K are discussed in the Nutritional Studies section below.

FDA concludes that the test compounds studied adequately represent the range of physical properties of drugs marketed for human use, and that the magnitude of olestra's effects on drug absorption were minimal, when compared to the effects normally encountered in drug-food interaction studies. FDA further concludes, considering the results of all four studies, the discussions during the Olestra Working Group and FAC meetings, comments received, and information in the literature, that there is no evidence that consumption of olestra would significantly influence the rate or extent of absorption of drugs (including Coumadin drugs).

V. Nutritional Studies

A. Issues Associated with Olestra

The petitioner has hypothesized that olestra interferes with the absorption of fat-soluble nutrients when the nutrients partition into olestra in the GI tract. When this happens, the portion of the nutrients that is present in the olestra phase is unavailable to the micelle-mediated transport system and, rather than being absorbed by the body, is excreted in the feces along with the olestra.

Neither existing olestra data nor the partitioning mechanism suggest that water-soluble nutrients would be affected by olestra. However, certain water-soluble nutrients such as folate and vitamin B12 (hard-to-absorb nutrients) are absorbed in multi-step processes. The multi-step nature of the processes might allow the opportunity for olestra to interfere with key steps in the processes, such as binding or cleavage reactions. Calcium, zinc, and iron are limited in the U.S. diet; thus, any effect on their absorption might increase the risk of nutritional inadequacy. In addition, the nutrients would be present in the diet at levels that are small, on a mass basis, relative to the amount of olestra. Thus, if olestra has an effect on water-soluble nutrients, these five nutrients (folate, vitamin B_{12}, calcium, zinc, and iron) would be the most important water-soluble nutrients

[17] Transcript, vol. 4, p. 50.

[18] Transcript, vol. 4, p. 50.

[19] Dr. Ian Greaves is an Associate Professor and Deputy Director, Minnesota Center for Environmental and Health Policy, University of Minnesota School of Public Health. Dr. Greaves presented at the request of CSPI. Transcript, vol. 2, p. 265.

[20] Transcript, vol. p. 124.

[21] Transcript, vol. p. 124.

[22] Transcript, vol. p. 119.

to monitor and the most likely to reflect adverse nutritional effects. Therefore, folate, vitamin B_{12}, calcium, zinc, and iron were chosen as representative markers for olestra's effects on the nutritional status of water-soluble nutrients.

The potential nutritional effects of olestra consumption were studied in both humans and animals. The pig was chosen as the appropriate animal model because it has a gastrointestinal tract similar to that of man; it is able to ingest, tolerate, and metabolize fat at a level comparable to that found in the human diet; and its vitamin stores and nutritional indices are responsive to dietary changes. Where possible, FDA has relied upon the results of human consumption studies as the primary determinants of olestra's safety, thereby avoiding the uncertainties raised by extrapolating from the pig to humans. Thus, FDA is relying primarily on the human studies to assess olestra's effects on vitamins E, D, K, and B_{12}, and on folate and iron. There are certain nutrients, such as vitamin A, for which no noninvasive procedure can be used to assess status in humans. Therefore, FDA has relied upon the results of the pig studies for determining olestra's effects on vitamin A. In addition, there are certain advantages to studying olestra's nutritional status in pigs. The studies can be conducted over the major developmental and growth periods of the pig's life, dose levels higher than those in man can be studied, and invasive techniques can be used to measure nutrient stores in tissues (such as bone and liver). Therefore, results from the pig studies are valuable supportive information that expand upon the knowledge gained in the human studies.

To apply the results of the pig studies to humans, it is necessary to correlate the percent olestra fed in the pig diet to g/p/d olestra. Olestra's effects on nutrients are caused by its physical presence in the gut. If nutrients dissolve into olestra, they will be carried out of the body with the olestra rather than being absorbed. The amount of olestra's effect depends on the amount of olestra present in the GI tract compared to other fats (as well as on the solubility of the vitamins in olestra). Thus, FDA has concluded that the most appropriate means for correlating olestra's effects in animals to humans is the percentage by weight of olestra in the diet. For a person eating about 2,000 calories/d, 10 g of olestra would be about 2.4 percent of the diet (Ref. 43).

B. Effects of Olestra on Fat-Soluble Vitamins

The effect of olestra on fat-soluble vitamins was assessed in five nutritional studies with humans and five studies with pigs, as summarized in Table 3.

TABLE 3.—SUMMARY OF STUDIES DESIGNED TO ASSESS NUTRITIONAL EFFECTS OF OLESTRA CONSUMPTION

Human Studies	Pig Studies
8-week clinical dose response (8-week DR)	26-week dose response and vitamin restoration (26-week DR/VR)
8-week clinical vitamin restoration (8-week VR)	39-week vitamin restoration (39-week VR)
6-week vitamin D/K status in free-living subjects (6-week vitamin D/K)	12-week dose response (12-week DR)
16-week vitamin E status in free-living subjects (16-week vitamin E)	12-week vitamin restoration (12-week VR)
14-day vitamin A/fat absorption (14-day vitamin A/fat)	4-week dietary context (4-week DC)

In evaluating olestra's nutritional effects, FDA believes that it is appropriate to rely primarily on the two 8-week clinical studies because in these studies, there was complete control of nutrient intake, they were well designed, and most nutritional parameters were monitored. Also, these two studies were performed recently using state-of-the-art analytical techniques and were designed taking into consideration findings from previous studies.

FDA believes that the 16-week vitamin E study, the 6-week vitamin D/K study, and the 14-day vitamin A/fat study are appropriately used to support the findings in the two 8-week studies. The results of these latter three studies do not weigh as heavily in the safety evaluation because of their limitations: the 16-week vitamin E and 6-week vitamin D/K studies were conducted in free-living subjects so that it was not possible to control completely or have more than imprecise knowledge of nutrient intake; the vitamin A/fat study investigated only olestra's effects on preformed vitamin A absorption and provides less information than the pig studies for assessing olestra's long-term effects on vitamin A stores (which are derived from both preformed vitamin A and carotenoids).

Of the studies performed in the pig, FDA believes that it is appropriate to rely primarily on the results of the 26-week DR/VR and 39-week VR studies to assess olestra's nutritional effects because these studies were the longest term and were designed to confirm the results of the 12-week DR and 12-week VR studies. The 4-week DC study was more limited in scope and duration, and was intended to demonstrate how olestra's effects are modified by changes in dietary patterns.

1. Primary Human Studies

The petitioner performed two 8-week human studies, in both of which the entire diet of the subjects was controlled during the study. The first study was the 8-week DR study which was intended to determine the dose-response effect of olestra on the status of folate, zinc, iron, and vitamins A, E, D, K; on the absorption of vitamin B_{12}; and on the bioavailability of β-carotene and total carotenoids. The 8-week VR study was intended to determine the efficacy and safety of compensation with vitamins A, E, and D, and to confirm the conclusions drawn in the 8-week DR study about the effects of olestra on vitamin K, zinc, and iron status, serum 25-hydroxyvitamin D_2 (25–OHD_2) concentration, carotenoid bioavailability, and vitamin B_{12} absorption. These two studies are of similar design and the results are complementary.

a. Eight-week DR study design. The 8-week DR study was a parallel, double-blind, placebo-controlled study with controlled diets fed for 8 weeks. Subjects were normal, healthy, 18 to 44 year-old males and females. The study had four groups of 21 to 24 subjects per group (88 subjects total). Subjects were randomly assigned to treatment groups that were balanced with respect to age, sex, body mass index (BMI), serum α-tocopherol, and total serum carotenoid concentrations. Subjects were provided with all meals for 56 days.

The diets were formulated to provide about 15 percent of calories from protein, about 55 percent of calories from carbohydrate, and about 30 percent of calories from fat. The total digestible fat content was kept the same across the four treatment groups by adding

triglyceride, in the form of butter, margarine, or vegetable oil, into the diets to compensate for the amount of fat replaced by olestra in the olestra-containing foods. Therefore, the total amount of lipid (digestible fat plus olestra) increased with increasing olestra dose.

Olestra was added to food items (potato chips, muffins, biscuits, and cookies) by substituting olestra for triglyceride in recipes or in cooking oils. Because each meal contained olestra, or the corresponding placebo (triglyceride), this study design provided maximum opportunity for olestra to interfere with nutrient absorption.

The diets provided each subject with 80 percent to 120 percent of the RDA of folate, zinc, and vitamins A, D, E, and K. Calcium and iron intakes were not targeted to be within the 80 percent –120 percent RDA range, although they were controlled and kept consistent among the diets. Vitamin B_{12} levels were allowed to exceed the 80 to 120 percent RDA range in order to maintain zinc and protein consumption at the target levels. In addition to the vitamin D in the diet, subjects were given 20 µg/day (two RDA) of vitamin D_2 as a supplement, one third of which was consumed with each meal.

The dosages of olestra were 0 (placebo), 8, 20, and 32 g/d. Body weights were measured every week and the subjects were questioned daily about changes in their health, including GI symptoms. If a GI symptom was experienced, the subject completed a detailed questionnaire that asked about the type, severity, and duration of symptoms they experienced. (The monitoring and reporting methods for adverse experiences is discussed in section VI.B. of this document.) Table 4 summarizes the measurements that were made to assess the status of the various nutrients. Most parameters were measured at baseline (week 0) and at 2-week intervals throughout the 56-day study period.

TABLE 4.—MEASUREMENTS OF MICRONUTRIENT STATUS IN THE EIGHT WEEK DR STUDY

Nutrient	Measurements
Vitamin A	Serum retinol concentration [23], serum carotenoid concentration
Vitamin E	Serum α-tocopherol concentration
Vitamin D	Serum concentration of 25-OHD_2, 25-hydroxyvitamin D_3 (25-OHD_3), and 1,25-dihydroxyvitamin D (1,25-$(OH)_2D$)
Vitamin K	Serum phylloquinone concentration, urinary excretion of γ-carboxy glutamic acid, plasma concentration of des-carboxy prothrombin (PIVKA–II), plasma prothrombin concentration, and prothrombin time, and partial thromboplastin time
Folate	Serum and red blood cell folate concentration
Vitamin B_{12}	Schilling test, serum vitamin B_{12}, serum vitamin B_{12} metabolites
Zinc	Serum and urinary zinc concentrations

[23] Serum retinol concentration is the only practical measure of preformed vitamin A status that can be made in humans who have adequate liver stores. (Other measures require invasive tissue sampling, such as measurements of liver stores.)

b. Eight-week VR study design. The study design for the 8-week VR study was the same as that of the 8-week DR study, except for the following elements. The 8-week VR study had 6 groups, each containing 16 or 17 subjects (100 subjects total). The measurements of micronutrient status in the 8-week VR study differed from those in Table 4 in that folate and zinc were not monitored while iron status was monitored by measuring serum ferritin and iron concentrations and total iron binding capacity. Unlike the 8-week DR study, no vitamin D_2 supplement was consumed by the test subjects. Finally, in addition to the vitamins provided in the diet, graded levels of vitamins A, E, and D were provided, as described in Table 5.

TABLE 5.—VITAMIN DOSES EXPRESSED AS PER GRAM OF OLESTRA (/G) AND PER DAY (/D) FOR THE SIX TREATMENT GROUPS IN 8-WEEK VR STUDY

Treatment Group Olestra (g/d)	Vitamin A		Vitamin E		Vitamin D_2	
	µg/g	µg/d	mg/g	mg/d	µg/g	µg/d
0 (placebo)	0	0	0	0	0	0
8	83	664	2.5	20	0	0
20	33	660	1.5	30	0.20	4
20	83	1660	2.5	50	0	0
20	132	2640	3.5	70	0.80	16
32	83	2656	2.5	80	0	0

c. Results and conclusions from primary human studies.—i. Vitamin A. In the human diet, there are two sources of dietary vitamin A, preformed vitamin A (retinyl esters) and carotenoids such as β-carotene that are converted in the body into vitamin A (provitamin A carotenoids). Partitioning of either of these sources of vitamin A into olestra could affect vitamin A levels in the body.

The petitioner concluded that there was no effect of olestra in either of the two 8-week studies on the serum concentration of retinol. This result was not unexpected because serum retinol concentrations are relatively stable and not subject to significant change except under conditions of prolonged and inadequate vitamin A intake. Only under such extreme conditions would changes in liver vitamin A storage be reflected by changes in serum retinol. Thus, the petitioner concluded, and FDA agrees, that to establish the effect of olestra on vitamin A status in humans, data on vitamin A liver stores collected in the pig studies and data on the postprandial absorption of vitamin

A in man must be considered. Those data are discussed in sections V.B.3.c.i. and V.B.2.c. of this document.

ii. Vitamin E. The petitioner evaluated the effect of olestra on vitamin E status and found that there was a highly significant trend in decreased serum levels of vitamin E with increasing olestra dose in the 8-week DR study, an effect evident by day 14 of the study. Serum vitamin E was reduced by 6 percent, 17 percent, and 20 percent compared to control levels when olestra was consumed at 8, 20, and 32 g/d respectively in every meal. The maximum effect was obtained between 2 and 4 weeks.

The petitioner calculated, based on the results of the 8-week VR study, that the effects on tissue concentrations of vitamin E were offset by the addition of 2.07 mg of vitamin E (d-α-tocopheryl acetate) per g olestra. This level is equivalent to 1.9 mg α-tocopherol equivalents/g olestra and 0.94 RDA of vitamin E per 1 oz serving of savory snacks containing 10 g of olestra.

FDA agrees that 1.9 mg of α-tocopherol equivalents/g olestra adequately restored serum vitamin E levels in this study, as indicated in the data adjusted for baseline serum vitamin E levels[24] (Ref. 44). FDA finds that this study adequately controlled vitamin E consumption, analyzed appropriately for vitamin E levels, and was of sufficient duration to observe olestra's effect, because the effect had reached a plateau after a few weeks into the study (Ref. 43). Therefore, FDA agrees that compensation for olestra's effects on vitamin E can be calculated from the results of this study, and further agrees that 1.9 mg of α-tocopherol equivalents per g of olestra is the appropriate compensation level.

iii. Vitamin D. In the human diet, there are two sources of vitamin D, dietary (vitamin D_2) and endogenous (vitamin D_3) produced in the body via sunlight-catalyzed dermal synthesis. The nature of the dose-response effect of olestra on dietary vitamin D_2 was determined by measuring serum levels of 25-OHD_2, which is derived only from dietary vitamin D. Serum levels of 25-OHD_3 (from dermally synthesized vitamin D_3), 1,25-$(OH)_2$D, and 25-OHD were also measured to assess olestra's effects on total vitamin D status. The serum concentration of 25-OHD reflects total vitamin D status.

The petitioner found that there was an olestra treatment effect in the 8-week DR study on the serum concentration of 25-OHD_2. At the end of the study, the reductions in 25-OHD_2 were 23 percent, 13 percent, and 27 percent for 8, 20, and 32 g olestra/d, respectively, relative to control. The effect had levelled off within 4 weeks. There was no effect on serum 25-OHD_3 or 1,25-(OH)D. In this study, the diet contributed 55 to 68 percent to total vitamin D status (the remainder coming from sunlight). The amount supplied by the diet was relatively high because of excess vitamin D_2 supplied by the dietary supplement.

Although the subjects in the 8-week VR study did not receive supplements (the diet contributed 12 to 20 percent of total vitamin D), the reductions in 25-OHD_2 in the 8-week VR study were similar to those observed in the 8-week DR study: 22 percent, 29 percent, and 22 percent for 8, 20, and 32 g olestra/day, respectively, relative to control. The reductions in serum total 25-OHD were less compared to the reductions in the 8-week DR study because a larger fraction of the total vitamin D was endogenous. The petitioner concluded that olestra's effect on serum vitamin D_2 in the 8-week VR study could be offset by adding 0.07 times the RDA of vitamin D_2 per 1 oz serving of savory snack containing 10 g olestra (equivalent to .07 μg/g olestra or 2.7 IU). The petitioner further concluded that olestra's effect on vitamin D status is not nutritionally significant because the effect is relatively small (on the order of a few percent in the 18-week VR study) and sunlight synthesis is a more important contributor to total vitamin D levels.

FDA agrees with the petitioner that olestra reduced serum vitamin D in both studies. Because the effect of olestra on serum vitamin D_2 levels had levelled off within the first 4 weeks of the study, FDA considers the studies of sufficient length to assess olestra's effects (Ref. 43). However, it is difficult to quantify olestra's effect because of confounding factors, such as the lack of a strong relationship between dose and reductions in 25-OHD_2 in both studies. In addition, the effect of olestra on serum total 25-OHD levels is difficult to quantify in the 8-week VR study because total serum 25-OHD levels were falling in the control group as well as the treated group during the study. (For example, total serum 25-OHD levels in the group not consuming olestra decreased 30 percent over the course of the study.) Compensation of two of the 20 g/d olestra groups with 0.2 and 0.8 μg vitamin D_2/g olestra reduced the decrease in total serum 25-OHD (which was due to both olestra and test diet effects). At the 0.2 μg/g olestra supplementation level, the decrease in total 25-OHD was slightly less than in the group not consuming olestra (26.8 percent vs. 30 percent respectively). With the higher level of compensation (0.8 μg/g olestra) the decrease in 25-OHD was about one-half that of the group not consuming olestra (15.6 vs. 30) (Ref. 45).

Although FDA believes that the variability of the data and the "on diet" effects on vitamin D status make quantitation of the magnitude of olestra's effects difficult, the agency concludes that the 8-week VR study can be used to estimate olestra's effects on vitamin D because dietary vitamin D_2 consumption was not excessive and the effect of olestra had levelled off within 4 weeks. FDA concludes that these results show that 0.2 μg vitamin D_2/g olestra adequately compensated for olestra's effects on vitamin D status in the 8-week VR study (Ref. 45).

iv. Vitamin K. The petitioner found that in the 8-week DR study, olestra caused a dose-response decrease in serum phylloquinone (vitamin K_1) concentration that levelled out within 2 weeks. Eight, 20, and 32 g/d olestra reduced serum phylloquinone by 36 percent, 40 percent, and 47 percent, respectively. There was no effect of olestra on the status of vitamin K as measured by the plasma concentration of des-carboxylated prothrombin (PIVKA–II), urinary excretion of γ-carboxyglutamic acid (urinary Gla), and plasma prothrombin concentration, which are all measures of functional activity of vitamin K. Prothrombin time (PT) and partial thromboplastin time (PTT), the normal measures of clinical vitamin K status, were also not affected by olestra intake. The 8-week VR study showed similar results. FDA agrees with the petitioner's findings in both studies.

The petitioner concluded that the lack of any change in vitamin K functional activity indicates that the decrease in serum phylloquinone concentration does not represent a significant reduction in vitamin K status. FDA notes that, although olestra did not demonstrate any effect on the vitamin K-related functional parameters (i.e., urinary excretion of γ-carboxy glutamic acid, plasma concentration of des-carboxy prothrombin (PIVKA–II), plasma prothrombin concentration, and clotting times), the length of the study was insufficient to rule out possible effects on these vitamin K-related functional parameters after longer term consumption of olestra. Also, while serum levels in the studies after 56 days

[24] In controlled diet studies such as this, the controlled diet is often better in many respects than the free-living diet of the subjects, thus it is not unusual that the basline vitamin E levels were lower than controlled-diet levels. Therefore, adjustment for baseline levels is appropriate.

can be considered to be only marginally reduced, when compared to true deficiency levels, the potential remains for continued decrease with long-term olestra consumption.

To calculate the level of vitamin K that would compensate for the reduction of serum vitamin K levels caused by olestra consumption, the petitioner relied upon the fact that serum vitamin K levels closely reflect the most recent (within 24 hours) intake of vitamin K. (Vitamin K has a half-life in serum of approximately 2 hours.) In the 8-week DR study, a 6 day rotating menu provided different vitamin K intakes for each day. As a result, the level of vitamin K on the days before each biweekly blood draw varied. [25] The serum level of vitamin K that would result from consumption of 1 RDA (80 µg) of vitamin K in the absence of olestra was obtained from the control group measurements. The compensation level was calculated as the amount of vitamin K needed in the presence of olestra to maintain the serum vitamin K concentration at the control level. This calculation yields compensation levels of 31 µg vitamin K in the 8 g/d group (4 µg/g olestra), 68 µg vitamin K in the 20 g/d group (3.2 µg/g olestra), and 82 µg vitamin K in the 32 g/d group (2.6 µg/g olestra). The petitioner averaged these three results to yield an estimated compensation level of 3.3 µg/g olestra.

FDA concludes that the response of serum vitamin K to the previous day's dietary intake is a reasonable, though imprecise, indicator of olestra's effects on serum vitamin K levels. Thus, FDA concludes that the petitioner's calculation provides only an estimate of appropriate compensation levels. FDA's conclusion regarding the appropriate compensation level for vitamin K is addressed in section V.B.4.e. of this document.

v. Carotenoids. In the 8-week DR study, the petitioner found that carotenoid bioavailability as measured by serum β-carotene and total carotenoid concentrations fell markedly with eight g/d olestra consumption although higher levels of olestra consumption did not cause a much larger decrease. At an olestra intake of 8 or 20 g/d, there was about a 60 percent reduction in serum β-carotene within the first 4 weeks and there was essentially no further decline for the remainder of the study. Olestra's effect on total serum carotenoids was of a similar magnitude. These results were confirmed in the 8-week VR study. FDA's conclusions regarding olestra's effects on carotenoids are addressed in section V.B.4.f. of this document.

2. Other Human Studies

a. Six-week vitamin D/K study. The 6-week vitamin D/K study was a double-blind, placebo-controlled, parallel design using 221 normal, healthy, free-living subjects. The objective of this study was to assess the status of vitamins D and K in subjects consuming 20 g/d olestra. Subjects were randomly assigned to treatment groups and balanced with respect to age, sex, and body mass index (BMI). Subjects consumed a total of 20 g olestra or the corresponding triglyceride placebo per day in cookies eaten at each meal. Subjects consumed self-selected diets with an upper limit of 7 glasses of milk per day. Daily food frequency records were used to estimate phylloquinone intake. The diet was supplemented with 20 µg (800 IU) ergocalciferol (vitamin D_2), taken in capsule form with the morning meal. The study was conducted from February through April to lessen sunlight effects on vitamin D status. Vitamin K status was assessed by monitoring serum phylloquinone (vitamin K_1), serum Simplastin®/Ecarin® assay (S/E) (a measure of functional prothrombin in blood), and prothrombin (PT) and partial thromboplastin times (PTT). Vitamin D status was assessed by monitoring serum concentrations of 25-OHD_2, 25-OHD_3, and 1,25-$(OH)_2D$. All serum parameters were measured every 2 weeks, while PT and PTT were measured only at the beginning and end of the study.

The petitioner found that mean serum concentrations of 25-OHD_2 rose in both placebo and olestra-fed groups, although serum concentrations rose more slowly in the olestra-fed group. At week two and beyond, the olestra group showed serum vitamin 25-OHD_2 levels that were about 19 percent below placebo, which persisted to the end of the study. No statistically significant changes in the measurements used to assess vitamin K status (S/E, clotting times, and serum phylloquinone concentration) were observed in the study, except that at week two, serum phylloquinone levels were lower in the olestra-fed subjects. The petitioner concludes from these results that 20 g/d olestra does not affect vitamin K status or vitamin D nutritional status.

FDA disagrees with the petitioner's conclusions regarding olestra's effects on vitamins D and K. First, the 19 percent decrease in serum 25-OHD_2 is indicative of an olestra effect on nutritional status and specifically, on vitamin D status. Second, the study is of limited usefulness in assessing vitamin K status because the sensitivity of the tests used to evaluate the impact of low serum vitamin K1 on vitamin K-dependent clotting protein function is either poor (PT and PTT) or not fully validated (S/E). Furthermore, the quantitative precision of the study is diminished because the subjects were eating diets that were not controlled. Thus, FDA disagrees with the petitioner's conclusion that olestra does not affect vitamin D nutritional status and further concludes that this study does not provide sufficient information for a conclusion regarding olestra's impact on vitamin K_1 nutritional status (Ref. 46).

b. Sixteen-week vitamin E study. The 16-week vitamin E study was also a double-blind, placebo-controlled, parallel design with 194 subjects. The purpose of the study was to assess the adequacy of 1.1 mg of d-α tocopherol acetate/g olestra in maintaining vitamin E status in persons chronically consuming olestra and to determine the potential effects of 18 g/d olestra on the status of vitamins K and D, absorption of carotenoids, and concentrations of serum retinol. Test subjects were normal, healthy, male and female free-living persons between the ages of 18 to 65 who consumed 18 g/d olestra, with or without 1.1 mg tocopheryl acetate/g olestra, or triglyceride placebo for 16 weeks. The daily dose of olestra (contained in cookies and ice cream) was to be consumed with meals; meal content was not controlled and they were permitted to eat between meals foods of their own choosing. Subjects were not specifically requested to evenly divide the daily allocation of cookies and ice cream among the meals. Serum concentrations of cholesterol, α-tocopherol, β-carotene, and total carotenoids were measured biweekly. Serum 25-OHD concentration, clotting times (PT and PTT), and serum levels of functional prothrombin (S/E) were measured at weeks 0, 8, and 16.

The petitioner found that serum α-tocopherol concentration was reduced by 6 percent, relative to control, in the olestra group and by 4 percent in olestra with added α-tocopheryl acetate group. Serum concentrations of β-carotene and total carotenoids were reduced by 21 to 29 percent in both olestra groups. Serum 25–OHD, retinol concentrations, and vitamin K status were unaffected by olestra consumption.

The petitioner concludes that 1.1 mg α-tocopheryl acetate/g olestra was not sufficient to compensate for olestra's effect in this study and that olestra did

[25] In the 8-week VR study a 7-day rotating menu was used to ensure that the subjects received equivalent levels of phylloquinone on the days prior to blood draws.

not affect vitamin D or K status. FDA agrees that compensation for olestra's reduction of vitamin E status was not adequate and that there was no evidence of an olestra effect on vitamin D and K status in this study. However, the value of this study is limited because the subjects were free-living, which limits the quantitative precision of the study in predicting olestra's nutritional effects (Ref. 47).

c. Vitamin A/fat study. The vitamin A/fat absorption study was a parallel, double-blind, placebo-controlled study of 70 healthy males. The subjects consumed 0 or 10 g/d olestra in potato chips for a 30-day, free-living adaptation period. The adaptation period was followed by a 14-day in-house period in which the subjects received 0, 8, 20, or 32 g/d olestra in potato chips and cookies. One-third of this daily dose was eaten with each meal except on the days when vitamin A and fat absorption was measured; on those days, the entire dose of olestra was consumed in potato chips at breakfast along with the radiolabeled marker. The dose response of olestra on the absorption of preformed vitamin A was measured using radiolabeled retinyl palmitate.

The petitioner evaluated the results of the vitamin A aspects of this study and concluded that neither 8 nor 20 g of olestra in a single meal had any effect on the absorption of 3H-labeled retinyl palmitate contained in the meal, and further that 32 g of olestra in the test meal reduced vitamin A absorption from that meal by 19 percent relative to controls. The petitioner also calculated that when high responders (the group of subjects showing high triglyceride levels after fat ingestion) were removed from the calculation, olestra's effect on vitamin A absorption was reduced to 13 percent.

FDA finds no justification for removing a part of the subject population from the calculation and thus believes that the 13 percent reduction figure is of no value in assessing olestra's effects on vitamin A. FDA agrees, however, that the study supports the conclusion that olestra induced a 19 percent reduction, and considers this amount to be the most accurate measurement of olestra's effect on preformed vitamin A absorption in this study (Ref. 48).

The petitioner concluded that the lack of an effect at the lower olestra doses (8 and 20 g) indicates that chronic consumption of olestra at the 90th percentile estimated intake by the total population (7 g/d) or the 90th percentile estimated acute intake for the heaviest consumers of savory snacks (18 to 44 year old males, 20 g/d [26]) will have no effect on preformed vitamin A absorption. While this interpretation of the data appears to be reasonable, FDA notes that this study only addresses olestra's effects on preformed vitamin A absorption. The study cannot, by design, address the decrease in vitamin A stores that would be caused by olestra's effects on carotenoid absorption.

3. Pig Studies

The petitioner conducted five nutritional studies of varying lengths (12, 12, 26, 39, and 4 weeks) in pigs. The objective of the 12-week DR study was to confirm the hypothesized dose-response effect of olestra on fat-soluble vitamins A, D, E, and K, and to determine whether there were any effects on specific marker nutrients that are difficult to absorb or are limited in the American diet (folate, vitamin B_{12}, calcium, iron, and zinc). The purpose of the 12-week VR study was to determine whether the effects of olestra on the status of vitamins A and E that were observed in the 12-week DR study could adequately be compensated for by the addition of vitamins to the diet.

The 26-week DR/VR and the 39-week VR studies were undertaken after the 12-week studies to evaluate olestra's effects on nutrient status in the period beyond the maximum growth phase. The purpose of the 26-week DR/VR study was three-fold: (1) To confirm the dose-response effect of olestra observed in the 12-week DR study; (2) to evaluate the effect of olestra on fat-soluble vitamins, folate, vitamin B_{12}, calcium, zinc, and iron, with longer exposure times and lower olestra levels than had been tested in the 12-week DR study; and (3) to determine the amounts of fat-soluble vitamins that would need to be added to the diet to compensate for olestra's effects. The 39-week VR study was designed to evaluate over a longer exposure period the effects of 0.25 percent olestra and added vitamins A and E that were measured in the 26-week DR/VR study. The 4-week DC study was designed to determine whether olestra's effects on vitamins A and E were dependent on the timing of olestra consumption (with meals or temporally separated from meals) or the means by which olestra enters the diet (as chips or admixed with feed).

a. Study design of 12–, 26–, and 39-week studies. The 12-week DR, 12-week VR, 26-week DR/VR, and 39-week VR pig studies used similar materials and methods. The 12-week DR study is described in depth. For the three other pig studies, only the differences from the 12-week DR study are described.

i. Twelve-week DR study. The test animals were a domestic, cross-bred strain of pigs, and were 5 to 7 weeks of age when received. All treatment groups contained equal proportions of females and castrated males. The pigs were acclimated for 14 to 16 days before being placed on experimental diets: During the first 7 to 9 days of the acclimation period, the animals were fed a 20 percent protein swine chow (University of Wisconsin-Madison) *ad libitum*; during the last 7 days they were fed the purified basal diet that was fed throughout the remainder of the study.

The basal diet was a purified diet consisting of about 25 percent casein, 24 percent starch, 24 percent sucrose, 5 percent Alphacel, 14 percent lard, and 8 percent of a vitamin/mineral premix. The diet delivered about 30 percent of calories from fat, a level equivalent to the target fat consumption level recommended for the U. S. population, but lower than current actual fat consumption. The ratio of calories from saturated:monounsaturated:polyunsaturated fats was targeted at 1:1:1.

The basal diet provided the National Research Council (NRC) requirements of micronutrients for 5 to 10 kilogram (kg) pigs. The NRC requirements, as a percentage of the feed, decline for many nutrients as a function of increasing body weight. Therefore, as the pigs grew, most nutrients were actually fed in excess of the body-weight-specific NRC requirements.

In the basal diet, vitamin A was provided as a 3:1 ratio of retinol equivalents from retinyl palmitate and β-carotene, respectively. This targeted ratio simulated the average dietary sources of vitamin A for the U. S. population. Vitamin E was provided in the form of d,l-α-tocopheryl acetate. Dietary vitamin D was supplied as ergocalciferol (vitamin D_2). In addition to dietary vitamin D, pigs in this study were exposed to 2 minutes of ultraviolet (UV) light each day. Vitamin K was provided as phylloquinone, the major source of vitamin K in the human diet, rather than as menadione, the form typically added to swine chow. [27] Folate was provided as folic acid, vitamin B_{12} was provided as cyanocobalamin, calcium as a mixture of $CaHPO_4 \cdot 2H_2O$

[26] A dose of 20 g is equivalent to the consumption of two 1-oz servings of savory snacks at a single meal.

[27] The swine NRC nutrient requirement table gives the vitamin K requirement as menadione; there is no value listed for phylloquinone. Therefore, the petitioner calculated the added amount of phylloquinone based on the assumption that phylloquinone is equivalent to menadione on a weight basis.

and $CaCO_3$, iron as $FeSO_4 \cdot 7H_2O$, and zinc as ZnSO4•7H2O. The micronutrients were added directly to the diet, separate from the olestra, during diet preparation.

The 12-week DR study consisted of 7 groups of pigs, containing 12 pigs each (except the control group of 20 pigs). Olestra was added to the diets at levels of 0 percent (control), 1.1 percent, 2.2 percent, 3.3 percent, 4.4 percent, 5.5 percent, and 7.7 percent (by weight). The olestra was heated before incorporating into the diet by frying potato chips.

Growth, feed intake, hematology, and clinical chemistry measures and the status of vitamins A, B12, D, E, and K, and folate, calcium, zinc, and iron were measured at regular intervals. Stores of vitamins A, E, B12, calcium, phosphorus, zinc, and iron were measured in the liver or bone at the termination of the study. The measurements used to assess the status of the various nutrients are summarized in Table 6.

TABLE 6.—MEASUREMENTS OF NUTRIENT STATUS IN THE 12-WEEK DR PIG STUDY

Nutrient	Measurements
Vitamin A	Liver and serum concentration
Vitamin E	Liver, serum, and adipose tissue concentration
Vitamin D	Serum concentration of 25-OHD_2, 25-OHD_3, and 1,25-$(OH)_2D$
Vitamin K	Prothrombin time
Folate	Plasma concentration
Vitamin B_{12}	Liver concentration
Calcium	Bone, serum calcium, and bone ash concentration
Phosphorus	Bone and serum concentration
Iron	Liver iron concentration and serum concentrations of hemoglobin, hematocrit, mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), and mean corpuscular hemoglobin concentration (MCHC)
Zinc	Liver, bone, and serum concentration

ii. Twelve-week VR study. The 12-week VR study consisted of 11 groups of pigs (one baseline, one control, and nine treatment groups), each containing 10 pigs (5 castrated males and 5 females). Pigs were exposed to 2 minutes of UV light each day. The amount of olestra and total amounts of vitamins A, D, and E targeted to be in the diet for the nine treatment groups is summarized in Table 7.

TABLE 7.—STUDY DESIGN FOR 12-WEEK VR PIG STUDY

Percent Olestra	Vitamin A (x NRC) [1]	Vitamin D (x NRC) [1]	Vitamin E (x NRC) [1]
0 (control)	1.00	1.00	1.00
1.1	1.05	1.20	1.20
1.1	1.35	1.80	1.90
1.1	1.65	2.40	2.60
4.4	1.65	2.40	2.60
4.4	2.40	4.20	4.60
4.4	3.15	6.00	6.60
7.7	2.05	3.80	4.15
7.7	3.45	6.60	7.30
7.7	4.85	9.40	10.45

[1] Expressed as multiples of the NRC requirements of pigs.

A premix was prepared to provide additional amounts of vitamin A as well as vitamin D for each level of olestra fed. Vitamin D was added as vitamin D_2 (ergocalciferol), while vitamin A was in the form of retinyl palmitate. Above-basal levels of vitamin E, in the form of d-α-tocopheryl acetate, were combined with the olestra instead of adding it directly to the diet because this procedure mimics that which would be used to add vitamin E to olestra for savory snack use, i.e., the vitamin would be added directly to the frying oil.

iii. Twenty-six week DR/VR study. The 26-week DR/VR study had 11 groups, each containing 10 pigs (5 castrated males and 5 females). Olestra was fed at five levels (0.25, 0.5, 1.1, 3.3, and 5.5 percent). Seven of the groups (baseline, control, 0.25, 0.5, 1.1, 3.3, and 5.5 percent olestra) did not have any additional vitamins above those present in the basal diet. The other four groups consumed added vitamins as described in Table 8.

TABLE 8.—VITAMIN DOSES FOR THE FOUR TREATMENT GROUPS IN THE 26-WEEK DR/VR PIG STUDY THAT HAD VITAMIN COMPENSATION

Percent olestra	Vitamin A (IU/kg diet)	Vitamin E (mg d-α-tocopherol acetate/g olestra)
5.5	3,300	1.71
0.25	150	1.71
0.25	300	3.42
0.25	600	5.13

Additional vitamins were added in the same manner as described for the 12-week VR study. The pigs in the vitamin-compensated 5.5 percent olestra group were exposed to 2 minutes of UV light each day. UV exposure was eliminated in the remainder of the groups in order to eliminate the possibility that the UV light might affect the magnitude of olestra's effect on dietary vitamin D_2. Instead, the diet was modified by increasing the vitamin D level to two times the NRC requirement to produce more readily measurable levels of vitamin D_2 in the serum.

In addition to the measurements of nutrient status listed in Table 6, serum parathyroid hormone (PTH) was monitored.

iv. Thirty-nine week VR study. The 39-week VR study consisted of the following four groups of 10 pigs each (5 castrated males and 5 females): baseline, control, 0.25 percent olestra, and 0.25 percent olestra with 150 IU vitamin A/kg diet (60 IU/g olestra) and 1.71 mg d-α-tocopherol acetate/g olestra. There was no UV exposure in this study and the diet was modified by increasing the vitamin D level to two times the NRC requirement to produce more readily measurable levels of vitamin D_2 in the serum. In addition, vitamin K level in the basal diet was lowered to one-fifth the level that was fed in the other three studies.

In addition to the measurements of nutrient status listed in Table 6, serum parathyroid hormone (PTH) was monitored.

b. Study design of the 4-week DC study. Young pigs, 7 to 9 weeks of age at the start of the study were fed a casein-based diet formulated to contain at least one times the NRC requirements of micronutrients. Five groups of 10 pigs each were fed 0 percent or 2.2 percent olestra for 4 weeks. A sixth group of 10 pigs provided baseline data for vitamin A, D, and E tissue concentrations. The olestra was fed either admixed in the diet, as chips prior to each meal, as chips prior to the noon meal only, or as chips fed between the noon and evening meal.

The petitioner evaluated the change in status of vitamins A, D, and E at the end of the 4-week study through serum measurements of the concentrations of vitamin A (retinol), vitamin E (α-tocopherol), and vitamin D (25-hydroxyvitamin D_2 and 25-hydroxyvitamin D_3) and liver measurements of vitamin A (total retinol and retinyl esters) and vitamin E (α-tocopherol).

c. Results and conclusions from pig studies. The results of the 4-week DC study will be discussed in section V.B.4.a. of this document.

i. Vitamin A. Data on the dose-response effect of olestra on liver vitamin A stores were collected in the 12-week DR study and the 26-week DR/VR study. The petitioner observed that olestra caused a nonlinear dose-response reduction in hepatic vitamin A stores, in which lower amounts of olestra had a greater proportional effect on stores, in both the 12-week DR and 26-week DR/VR studies. In the 26-week DR/VR study, the decreases in liver vitamin A (relative to controls) were 45 percent (0.25 percent olestra), 57 percent (0.5 percent olestra), 65 percent (1.1 percent olestra), and 88 percent (3.3 percent and 5.5 percent olestra). The reductions observed in the 12-week DR study were very similar, with the highest olestra intake (7.7 percent) causing a greater than 90 percent decrease. Serum vitamin A levels also decreased in a dose-response manner with increasing olestra intake in both studies.[28]

In both the 12-week VR and the 26-week DR/VR studies, the addition of varying levels of vitamin A to the diet resulted in a linear increase in liver vitamin A stores. For the 12-week VR study, the petitioner calculated that the effect of olestra on liver vitamin A stores could be offset by adding 58.1 IU of vitamin A/g olestra in the diet. FDA calculates the appropriate compensation level separately for each level of olestra in the diet, because the required compensation level in IU/g changed as a function of dietary olestra level, and determined that the compensation level ranged from 130.8 IU vitamin A/g olestra at 0.1 percent olestra to 45.8 IU vitamin A/g olestra at 7.7 percent olestra (Ref. 49).

For the 26-week DR/VR study, the petitioner calculated that 170 IU vitamin A/g of olestra compensates for olestra's effects on vitamin A liver status, which is equivalent to 93 μg retinyl palmitate/g olestra, or 0.34 RDA of vitamin A per 1-oz serving of snacks containing 10 g olestra. FDA agrees that this calculation is appropriate and that when olestra is present at 0.25 percent of the pig diet, approximately 170 IU of retinol/g olestra maintains the liver vitamin A levels at control values[29] (Ref. 49). One hundred and seventy IU of retinol/g olestra is equivalent to 51 retinol equivalents/g olestra.

The petitioner concluded and FDA agrees that the results of the 39-week VR

[28] Unlike adult pigs, weanling pigs do not have large stores of vitamin A so liver stores are not able to compensate for olestra's interference with absorption of vitamin A; thus the effect on vitamin A status is also manifest in the serum levels.

[29] The estimates from the 12-week study are somewhat smaller than estimates obtained from the 26-week pig study; in the 12-week study, the required supplementation level for 0.25 percent olestra was 128 IU/g olestra.

study confirm olestra's effect on vitamin A liver stores, although FDA notes that the amount of vitamin A added to the diet in the 39-week study (60 IU vitamin A/g olestra) was not sufficient to compensate for olestra's effect on vitamin A.

ii. Vitamin E. In the 26-week DR/VR study, the decreases in liver vitamin E (relative to controls) were 24 percent for 0.25 percent olestra, 31 percent for 0.5 percent olestra, 53 percent for 1.1 percent olestra, 71 percent for 3.3 percent olestra, and 75 percent for 5.5 percent olestra. In the 12-week DR study, the reductions were slightly larger (e.g., 60 percent for 1.1 percent olestra, 69 percent for 2.2 percent olestra, 75 percent for 3.3 percent olestra, 78 percent for 4.4 percent olestra, 80 percent for 5.5 percent olestra, and 81 percent for 7.7 percent olestra). Vitamin E concentration in adipose tissue showed a slightly smaller decrease in both studies; for example, with 5.5 percent olestra, adipose vitamin E concentration had fallen by about 73 percent in both the 12-week DR and 26-week DR/VR studies.

The results of the 12-week DR and 26-week DR/VR studies showed that effects of olestra on vitamin E status were similar in the serum and liver, although the percent decrease in vitamin E was slightly larger for liver than for serum. The petitioner concluded, and FDA concurs, that this relationship confirms that serum vitamin E concentration is a reliable measure of vitamin E status. The concentration of vitamin E in adipose tissue also changed in a similar fashion to the changes in serum and liver concentrations although the magnitude and rate of change were not as great.

The petitioner concludes that 2.09 IU of vitamin E/g olestra offset olestra's effects in the 12-week VR study; in the 26-week DR/VR study (where olestra was fed at a lower level), 2.79 IU of vitamin E/g olestra (which translates to 2.06 mg d-α-tocopheryl acetate/g olestra) offset olestra's effects. FDA concurs with the petitioner's general conclusions and with the calculated level of 2.79 IU vitamin E/g olestra from liver measurements in the 26-week VR/DR study. FDA's calculated compensation levels for the other studies, as shown in Table 9, differ slightly because of small differences in the choices of variables to fit the curves in the statistical analyses (Refs. 50 and 51).

TABLE 9.—FDA-CALCULATED COMPENSATION LEVELS OF VITAMIN E TO RESTORE LIVER AND SERUM LEVELS BASED ON 12-WEEK VR AND 26-WEEK DR/VR STUDIES

Study	Olestra level (%)	Vitamin E compensation (IU/g olestra)	
		Liver compensation level	Serum compensation level
26-week DR/VR	0.25	2.79	2.98
12-week VR	1.1	2.66	2.76
12-week VR	4.4	2.27	2.34

iii. Vitamin D.—a. Petitioner conclusions. The petitioner concluded that the 12-week DR study established a dose-response effect for olestra on dietary vitamin D at olestra levels up to 4.4 percent of the diet, as measured by serum concentration of 25-OHD_2; the serum concentration of 25-OHD_2 was about 10 percent less than control in the 1.1 percent olestra group and about 35 percent less than control in the 2.2 percent, 3.3 percent, and 4.4 percent groups. At higher olestra levels, changes in the dietary contribution to total circulating 25-OHD were confounded by changes in the contribution from vitamin D_3 synthesized in the skin.

The petitioner also concluded that in the 12-week VR study, serum concentration of 25-OHD_2 increased in a dose-response manner as the amount of vitamin D_2 added to the basal diet was increased, at all levels of olestra. However, interpretation of the serum 25-OHD_2 data at the mid- and high-olestra levels (4.4 and 7.7 percent) was confounded because the proportion of 25-OHD_3 in the serum decreased with increasing levels of olestra at these treatment levels. The petitioner has suggested, that this decrease in serum 25-OHD_3 may have resulted from the effect of the high levels of olestra on the reabsorption of biliary vitamin D_3. Reduced reabsorption of biliary vitamin D_3 would tend to increase the serum concentration of 25-OHD_2 because of diminished vitamin D_3 competition for the liver 25-α hydroxylase.

Using the serum 25-OHD_2 concentrations from the groups fed 1.1 percent olestra in the 12-week VR study, the petitioner calculated that the amount of vitamin D required to restore serum 25-OHD_2 to the control level was 13.0 IU vitamin D/g olestra, which is equivalent to 0.33 RDA/1 oz serving of chips containing 10 g olestra. The petitioner considers that the confounding effect of vitamin D_3 was absent or minimal when olestra was fed at 1.1 percent of the diet.

The petitioner concluded that in the 26-week DR/VR study, 5.5 percent olestra (no extra vitamins) reduced plasma 25-OHD_2 by 20 percent at week 26. At week 16, serum 25-OHD_2 levels in the 3.3 percent and 5.5 percent olestra groups were significantly lower than controls by 23 percent and 35 percent, respectively.

The petitioner concluded that in the 39-week VR study, olestra decreased serum levels of 25-OHD_2 by the same magnitude as in the 26-week DR/VR study, while serum 25-OHD_3, total serum 25-OHD, and serum 1,25-$(OH)_2D$ were not affected. Serum 25-OHD_2 levels were 13 to 15 percent lower than week 12 and week 26. At week 39, the values were 6 to 11 percent lower than controls, but this difference was not statistically significant.

b. FDA conclusions. FDA concludes that the results of the pig studies are of limited utility for quantifying olestra's effects on vitamin D, for several reasons. First, FDA notes that vitamin D levels were never measured in the diet as fed in any of the pig studies. This lack of measurement leaves open the possibility that addition or mixing errors might have occurred, affecting the vitamin D levels in the feed. Second, the confounding effect of UV exposure in several of the studies makes interpretation of the results difficult.

The 26-week DR/VR study was designed to prevent UV light exposure to any group except the 5.5 percent olestra/low vitamin group where 2 minutes of exposure were to be provided per day. However, an accidental UV light exposure (not more than 13 hours) to this group on day 23 of the study likely caused the very high 25-OHD_3 levels and very low 25-OHD_2 levels observed at week 4. In addition to the accidental exposure of the 5.5 percent olestra/low vitamin group to UV light, it appears that at least 10 other animals may have been exposed to UV light in at least the 12th week of the study, as evidenced by their elevated serum 25-OHD_3 levels. Because a definitive cause for these elevated serum 25-OHD_3 values could not be determined, FDA considers the vitamin D data from the 26-week DR/VR study to be confounded (Ref. 52).

Although pigs in the 39-week study were not exposed to UV light, pigs consumed only one level of olestra, therefore no dose-response information was obtained.

FDA agrees with the petitioner that in the 12-week VR study, serum concentration of 25-OHD_2 increased in a dose-response manner as the amount of vitamin D_2 added to the basal diet was increased, at all levels of olestra. FDA further agrees with the petitioner that the decrease in serum 25-OHD_3 observed in the mid- and high-level groups may have resulted from olestra's effects on the reabsorption of biliary vitamin D_3. However, FDA also believes that the serum 25-OHD_2 levels may have been confounded by the daily 2-minute exposure to UV light, which caused an increase in serum levels of 25-OHD_3 in both 12-week studies. Therefore, FDA concludes that the results from the mid- and high-dose groups in the 12-week VR study cannot be used to determine a quantitative compensation value for vitamin D_2 because of the apparent interaction between serum 25-OHD_3 and 25-OHD_2 levels.

FDA believes that the most useful data from the pig studies comes from a comparison of the control and 1.1 percent olestra groups in the 12-week VR study. Accordingly, FDA believes that the petitioner's calculation based on the 12-week VR study that 13 IU vitamin D/g olestra will compensate for olestra's effects in pigs exposed to daily UV light may be an approximation of appropriate supplementation level for vitamin D. However, the agency believes that it cannot rely on the 12-week VR data by themselves to establish a compensation value for vitamin D_2, because of the possible confounding effects of UV exposure and the lack of measurements of vitamin D levels in the diets as fed (Refs. 53 and 54).

iv. Vitamin K. There were no statistically significant effects of olestra on prothrombin time in any of the pig studies. The petitioner concluded, therefore, that olestra does not affect vitamin K status. Although FDA agrees that prothrombin time was not affected by olestra consumption, the agency does not believe that these results are adequate to determine the potential effects of olestra on vitamin K status, because, as discussed below, prothrombin time is not a sufficiently sensitive analytical method and the diets of the test animals appear to have been overfortified with vitamin K.

Prothrombin time is an insensitive indicator of vitamin K status. The petitioner agrees that there are more sensitive indicators of vitamin K status such as direct measurements of clotting factors in blood, urinary excretion of γ-carboxyglutamic acid, and plasma levels of des-carboxylated or under-carboxylated vitamin K-dependent proteins (the PIVKA-II assay). The petitioner states however, that these methods were not used because they had not been used previously or validated in the pig and no body of historical data exists. Nevertheless, FDA believes that use of an insensitive indicator limits the conclusions that can be drawn from these pig studies regarding vitamin K status.

FDA believes that the usefulness of the data from the 12-week and 26-week DR/VR studies is further limited because test animal diets were oversupplemented with vitamin K. Because vitamin K is a highly lipophilic fat-soluble vitamin, FDA considers it reasonable to assume that it will partition into the olestra in the GI tract, in the same manner as the other fat-soluble vitamins. Thus, oversupplementation is significant

because it could mask any effect of olestra on vitamin K status.

FDA believes the pig diets were oversupplemented with vitamin K in the 12-week and 26-week DR/VR studies for two reasons. First, the NRC requirement for vitamin K in swine is in terms of amounts of menadione, not phylloquinone (the form of vitamin K fed to the pigs). The NRC requirement for menadione, 500 µg/kg, is in a corn-soybean meal base and this likely exceeds the requirements needed for a casein-based semisynthetic diet that should not contain any substance that might inhibit vitamin K metabolism. Second, FDA disagrees with the petitioner's assumption that phylloquinone is necessarily of equal potency on a weight basis as menadione. Unlike phylloquinone, menadione is biologically inactive and must be alkylated in the liver to menaquinone to become biologically active. Phylloquinone, following intracardiac administration, was 10 times more active than menadione on a weight basis at restoring the prothrombin response in rats that were partially depleted of vitamin K (Ref. 55). Therefore, FDA cannot rule out the possibility that phylloquinone is a more potent source of vitamin K on a weight basis than menadione in swine following oral administration, which would lead to further oversupplementation (Ref. 56).

4. Overall Conclusions Regarding Olestra's Effects on Fat-Soluble Vitamins

a. Consumption scenarios. The petitioner has asserted that in the 8-week human studies and in all of the pig studies (except the 4-week DC study), olestra's effects on fat-soluble nutrients are exaggerated because the additive was always consumed with meals. In addition, in the pig studies, olestra was admixed with all the feed, rather than being present in only select dietary ingredients (such as chips). The petitioner hypothesizes that if olestra is eaten in a snack between meals (instead of being eaten with a meal), there will be fewer nutrients available with which it can interact, and that olestra's effects on nutrients would be expected to be greatest when olestra and the nutrients are intimately intermixed in the GI tract at the same time.

The petitioner has provided results of consumption surveys showing that in the United States, at the estimated 90th percentile consumption level, savory snacks are eaten only four times per week, and one-third of those occasions are between meals. With this consumption pattern, olestra savory snacks will be eaten 32 times in an 8-week period (as compared to 168 meals during that time), and 20 of those times will be with meals. (In other words, during the 8-week period, 148 meals (or 88 percent) will be consumed without a savory snack.) These data mean that, although a majority of snacks are eaten with meals, because of the infrequency of snack consumption, a majority of nutrient intake will occur in the absence of olestra savory snacks. In contrast, in both 8-week studies, olestra was eaten 165 times in 8 weeks with every meal, which means that essentially all of the nutrient intake occurred with olestra consumption.

The petitioner presented the following examples of the consequences of consumption patterns on olestra's effects on nutrients. First, the petitioner calculated the expected effect of olestra on β-carotene in consumers eating snacks with the eating patterns reported in the MRCA survey data. [30] In the first scenario, the petitioner assumed that absorption of β-carotene eaten with olestra would be decreased by 60 percent and absorption of β-carotene eaten at all other times would not be affected. In a second scenario, presented at the Olestra Working Group and FAC meetings, [31] the petitioner assumed that absorption of β-carotene eaten with olestra would be decreased by 60 percent, absorption of β-carotene eaten at eating occasions either before or after the olestra eating occasion would be decreased by 30 percent, and absorption of β-carotene eaten at all remaining times would not be affected. Using these assumptions the petitioner calculated that an average snack consumer would have a decrease in serum β-carotene levels of 5.6 percent in the first scenario and about 6.8 percent in the second scenario. For the heaviest consumers (top 10 percent), the first scenario would result in a decrease in serum levels of about 10 percent, while the second scenario would result in decreases of 13 to 14 percent.

The petitioner further asserts that the 4-week DC study in pigs and 16-week vitamin E study provide evidence that olestra's effects on fat-soluble nutrients measured in the pig studies and in the 8-week human studies exaggerate the effects expected with a normal savory snack consumption pattern. This effect is confirmed by a comparison of the 8-week DR study (where olestra and the vitamins were always consumed concurrently) with results of the 16-week vitamin E study (in which free-living subjects consumed olestra throughout the day but not necessarily concurrently with the consumption of all vitamin E or carotenoids). In the 8-week DR study, the effects on vitamin E status and serum β-carotene concentration measured in the 20 g/d olestra group are about three-fold greater than those measured in the free-living subjects in the 16-week vitamin E study consuming 18 g/d olestra.

In the 4-week DC study in pigs, the reduction of vitamin A liver stores in pigs fed 2.2 percent olestra was about 44 percent compared to controls when olestra was fed admixed in the diet and about 14 percent when olestra was fed in potato chips with all meals. Similarly, the reduction of liver and serum vitamin E concentrations in pigs fed 2.2 percent olestra admixed in the diet was about twice as large (60 percent for liver and 52 percent for serum compared to controls) when olestra was fed admixed as when olestra was fed in potato chips with all meals (30 percent and 20 percent for liver and serum, respectively). Therefore, the petitioner has concluded that the effects of olestra that were measured in the 12-week DR, 12-week VR, 26-week DR/VR, and 39-week VR pig studies were exaggerated by about 3-fold for vitamin A and about 2-fold for vitamin E over what would have been observed if the olestra were fed in chips with meals.

FDA agrees that when savory snacks containing olestra are eaten without other foods, olestra's effects on fat-soluble vitamins will be less than the effects measured in the 8-week human studies or in the 12-, 26-, and 39-week pig studies. However, FDA concludes that, given the wide variety of possible dietary patterns, the most protective approach is to ensure that compensation levels that accommodate most, if not all of those dietary patterns. Slight overcompensation with vitamins A, E, D, and K that might occur if an individual were to eat all olestra-containing snacks separate from other foods would not raise any health concerns, as discussed below. In contrast, the potential for developing vitamin deficiencies in some of the population that preferentially eat olestra-containing snacks with meals is of sufficient concern to merit this approach. Further, calculating compensation levels using the with-meal study results provides an additional measure of safety, because based on the MRCA data, it is probable that not all olestra consumed in savory snacks will be eaten with meals. Therefore, FDA is not relying on the results of the contextual studies or calculations based on eating patterns in

[30] Transcript, vol. 1, p. 84 and vol. 3, p. 234.

[31] Transcript, vol. 3, p. 234.

evaluating the safety of olestra with regard to nutrient effects.

b. Vitamin A. FDA and the petitioner agree that olestra's effects on vitamin A present significant health concerns and, therefore, compensation for olestra's interference with this vitamin's absorption should be made. The pig studies show that olestra consumption has a dose-response effect on vitamin A that is nonlinear, having the greatest effect (on a per-gram-of-olestra basis) at low olestra consumption levels. The level of vitamin A compensation was calculated using data from the pig studies in which the effect of olestra and olestra with added retinyl palmitate on vitamin status were determined. Thus, the pig studies provide the most direct measure of vitamin A status. Calculations were based on the effect at the lower olestra doses to ensure that compensation is sufficient for all consumers.

Both the petitioner and FDA have calculated that 170 IU of vitamin A/g olestra (51 retinol equivalents/g) compensates for olestra's effects on vitamin A (from both preformed vitamin A and the provitamin A carotenoids). This amount is equivalent to 0.34 times the RDA in a 1-oz serving of savory snacks containing 10 g of olestra.

The results of the vitamin A/fat study in humans showed that only the highest dose of olestra (32 g/d) had a measurable effect on preformed vitamin A absorption. This direct measurement of olestra's effect on absorption of preformed vitamin A in humans shows less of an effect than the observed effect on vitamin A stores in the pig studies, a difference likely due to the decreased absorption of carotenoids in the pig studies, which are therefore less available as provitamin A sources. Vitamin A added to olestra in the 12-week DR, 26-week DR/VR and 39-week VR pig studies compensated for both the loss of preformed vitamin A and carotenoids as provitamin A sources, as it would when olestra is compensated in savory snacks. Therefore, FDA concludes that relying on the pig data to calculate the compensation level will account for olestra's effects on absorption of both preformed vitamin A and carotenoids as contributors to the vitamin A body stores.

During the Olestra Working Group meeting, the members of the Olestra Working Group unanimously agreed that FDA had appropriately evaluated the amount of vitamin A with which olestra should be compensated. [32]

At the FAC meeting, Dr. Rodier, an embryologist and member of the FAC, expressed concern about the potential toxicity, especially teratogenicity, of the vitamin A that would be added to olestra. [33] She pointed out that since 1986, the Teratology Society has recommended that vitamin supplements not contain preformed vitamin A, but that they contain carotenoids instead. FDA is aware of a recent study investigating the teratogenicity of vitamin A intake (Ref. 57), in which an association was found between the prevalence of defects associated with cranial-neural-crest tissue in babies and consumption by their mothers of preformed vitamin A supplements during pregnancy. The researchers found an apparent threshold for the effect of about 10,000 IU of supplemental preformed vitamin A (i.e., in addition to vitamin A consumed in the diet). Consumers eating large amounts of olestra might obtain a small amount of bioavailable vitamin A from olestra because the compensation level was calculated from low olestra doses where the effect/g olestra is the highest. However, because the teratogenic effects seen by Rothman et. al., occur with vitamin A intakes more than 10,000 IU above that which is consumed in the daily diet, and because most of the vitamin A in olestra will remain in the olestra as it passes through the body, FDA concludes that there is no reasonable scenario of olestra consumption from savory snacks that would lead to vitamin A leaching out of the olestra at levels anywhere near 10,000 IU. Therefore, the agency is requiring vitamin A compensation at 170 IU/g olestra (51 retinol equivalents/g).

c. Vitamin E. FDA and the petitioner agree that olestra's effects on vitamin E present significant health concerns and, therefore, compensation for this vitamin should be made. Serum data from the human studies provide the basis for calculating the appropriate compensation level for vitamin E, and the calculations are supported by the results of the pig studies. The petitioner has calculated that 1.9 mg α-tocopherol equivalents (2.8 IU vitamin E) should be added per g of olestra to compensate for olestra's effect on vitamin E levels. This amount is equal to 0.94 times the RDA in a 1-oz serving of snack containing 10 g of olestra. The compensation level calculated from the pig studies for the lowest olestra consumption level (which shows the largest effect when calculated per g of olestra) is 2.79 IU vitamin E/g olestra, which is essentially the same as the compensation level calculated from the 8-week human studies.

During the Olestra Working Group meeting, the members of the Olestra Working Group unanimously agreed that FDA had appropriately evaluated the amount of vitamin E with which olestra should be compensated. Therefore, FDA is requiring vitamin E compensation at 2.8 IU/g olestra (1.9 mg α-tocopherol equivalents/g olestra), which will adequately compensate for olestra's effects in all realistic consumption scenarios.

d. Vitamin D. The petitioner concluded that the effects of olestra on vitamin D_2 concentration do not warrant compensation with vitamin D. As support, the petitioner cites the absence of changes in serum 1,25-OH_2D concentration in the pig studies as evidence that olestra has no significant effect on overall vitamin D status despite the decrease in dietary vitamin D_2 status. Typically, the contribution of dietary vitamin D to total vitamin D status in the general population is from 10 to 20 percent (the rest from sunlight-induced synthesis in the body). Therefore, the petitioner reasons that a 23 percent decrease in dietary vitamin D status would result in only a 2.3 to 4.6 percent reduction in overall vitamin D status in a normal healthy human under the exaggerated conditions of olestra consumption used in the studies. In worst-case situations, where dietary vitamin D can contribute up to 50 percent of total vitamin D, the petitioner calculates that the reduction in overall vitamin D status would be 11.5 percent when olestra was consumed with every meal.

FDA disagrees with the petitioner's position that the effect of olestra on vitamin D is not sufficient to warrant compensation. Although most individuals can produce vitamin D through exposure to sunlight, there are some people who may not synthesize sufficient vitamin D to compensate for potential decreases due to olestra effects, either because they are not exposed to sufficient sunlight or because they utilize sunlight poorly to synthesize vitamin D. Therefore, FDA concludes that compensation for vitamin D should also be required for olestra-containing foods.

From the 8-week human studies, the petitioner calculated that 0.07 μg vitamin D_2/g olestra (0.07 times the RDA per 10 g of olestra) would be sufficient to compensate for the olestra-induced decrease in 25-OHD_2. FDA notes that in the 8-week VR study, 0.2 μg vitamin D_2/g olestra slightly overcompensated for olestra's effects on vitamin D status, as measured by total 25-OHD levels.

[32] Transcript, vol. 3, pp. 220–225.

[33] Dr. Patricia Rodier, is a senior scientist in the Department of Obstetrics and Gynecology, University of Rochester. Transcript, vol. 4, p. 99.

However, these values are based on only two compensation levels, and may be confounded by the fact that serum vitamin D levels continued to decrease over time in the study.

The petitioner has also calculated, from the 1.1 percent olestra group of the 12-week DR pig study, that 13.0 IU vitamin D/g olestra (0.33 times the RDA per 10 g of olestra) would compensate for olestra's effects in that group. Although the design of that study also contains some weaknesses, FDA believes that the results of both the pig study and the 8-week human studies, considered together, support the need for a compensation level and provide an approximation of an appropriate level.

Given the importance of vitamin D, FDA concludes that it is preferable to compensate consistent with olestra's demonstrated effects on vitamin D, rather than risk a deficiency (Ref. 58). FDA concludes that addition at levels of 12 IU vitamin D/g olestra (0.3 µg/g olestra) or 0.3 times the RDA per 10 g of olestra, is adequate to compensate for any vitamin D that is lost due to diminished absorption caused by olestra. This level of vitamin D includes the amount that was observed to compensate for olestra's effects in the 12-week DR pig study and is slightly higher than the 0.2 µg/g that was observed to be sufficient in the 8-week VR human study. During the Olestra Working Group meeting, the members of the Olestra Working Group unanimously agreed that FDA had appropriately evaluated the amount of vitamin D with which olestra should be compensated.

This level of vitamin D compensation does not raise any toxicity concerns, even if olestra as actually consumed has no effect on the absorption of vitamin D, because it is generally accepted in the medical community that one would have to ingest five times the RDA (the RDA is 400 µg of vitamin D) before toxicity effects begin to occur (Ref. 59). Thus, slight overcompensation with vitamin D would not cause health concerns. Assuming that the daily diet contains an RDA of vitamin D, olestra would have to contribute four times the RDA (or 1,600 IU), which is equivalent to the amount added to about 13 oz of potato chips, to reach levels where toxicity effects begin. However, most of the vitamin D in olestra would not be bioavailable. Therefore, FDA is requiring compensation with 12 IU vitamin D/g olestra (0.3 µg/g olestra).

e. Vitamin K.—i. Petitioner conclusions. The petitioner concluded that the effects of olestra on serum phylloquinone levels will not pose a potential public health concern, and therefore, compensation of olestra savory snacks with vitamin K is not necessary. The petitioner based this conclusion on: (1) The absence of olestra effects on the sensitive measures of vitamin K function under exaggerated conditions of the studies conducted in humans; (2) the presence in the U.S. diet of significantly more vitamin K than the single RDA fed in the studies in which no effects on sensitive measures were observed; (3) the fact that the dietary level of vitamin K associated with detectable effects on sensitive functional parameters is well below the RDA; and (4) the absence of either a dietary pattern consistent with, or clinical evidence for, the existence of subgroups within the U.S. population at risk of vitamin K deficiency.

The petitioner concluded that functional measures of vitamin K status provide a reliable basis for public health decisions regarding this vitamin, because these measures provide a direct assessment of the ability of the vitamin K supplied to the tissues to maintain normal vitamin K function. Because, unlike vitamins A, D, and E, there are no significant phylloquinone stores in the body and serum concentrations of the vitamin fluctuate significantly throughout the day, these functional measures provide an integrated picture of the supply of vitamin K over a time period as short as 2 to 3 days. Fasting serum measures of phylloquinone, on the other hand, may not reflect the true status of vitamin K because of the very short half-life of the vitamin in the plasma (less than 2 hours). At any given time during the day, the serum concentration of phylloquinone may suggest low or inadequate vitamin K supply, while the tissues may be receiving more than adequate amounts to support maximal rates of carboxylation.

The petitioner further concluded that urinary Gla excretion and plasma *des*-γ-carboxylated prothrombin (PIVKA–II) are the markers of vitamin K function that best reflect the integrated vitamin K status of the individual over time. If the phylloquinone supply from the diet falls below a level adequate to support maximal synthesis of vitamin K-dependent proteins in the body, PIVKA–II and urinary Gla will change to reflect the inadequate supply. The half-lives of prothrombin (Factor II) and of the vitamin K-dependent proteins which contribute the majority of the urinary Gla excretion (60 hours or more) are significantly longer than the half-life of phylloquinone in plasma (about 2 hours). Therefore, the petitioner argues, these functional measures provide a sensitive index of potential chronic effects on the adequacy of vitamin K in the diet. Urinary Gla is particularly important because it reflects carboxylation of vitamin K-dependent proteins in all tissues, including bone and kidney. Although the petitioner believes that compensation for vitamin K is unnecessary, the petitioner has evaluated olestra's effect on vitamin K by comparing serum vitamin K levels with vitamin K dietary intake at varying olestra levels, and has determined that 3.3 µg vitamin K/g olestra will restore serum vitamin K levels to those of the control group. This level is less than one-half of the 80 µg RDA, when contained in a 1-oz serving of savory snacks containing 10 g olestra. Because the 8-week DR study was not designed to assess the olestra dose response for vitamin K, the compensation level calculated by the petitioner is only an estimate of an appropriate compensation level.

ii. FDA conclusions. FDA concludes that the data from the 8-week human studies show that serum vitamin K levels were decreased by consumption of olestra, and that the lack of effect on functional assays could be attributable to the use of a subject population that is not at risk for vitamin K deficiency. Similarly, as noted, the lack of an olestra effect on prothrombin time in the pig studies may be explained by the insensitivity of the analytical method and oversupplementation of the test diet with vitamin K. While olestra may not pose a health risk due to moderate reductions in serum vitamin K levels for healthy adults consuming diets that, on average, provide them with the minimum RDA for fat-soluble vitamins and other nutrients, these reductions of vitamin K could be of concern for segments of the population at risk for vitamin K deficiency or where the control of blood clotting is more critical.

There were no studies designed to assess the dose-response nature of olestra's effect on vitamin K. The pig studies are not useful in this case because of the uncertainty regarding the activity of menadione and phylloquinone in the swine diet and the likelihood that the NRC requirements for swine are much higher than actual need. In contrast, the 8-week DR study in humans is useful for estimating an appropriate compensation level because the diet contained approximately 1 RDA of vitamin K and the dietary levels of vitamin K on the day before blood draws varied for each blood draw.

FDA believes that the consequences of vitamin K depletion are sufficiently serious and their onset so sudden as to warrant addition of vitamin K to olestra-containing food. Also, it is well

recognized in the medical community that large doses of vitamin K can be tolerated with no toxic effects.[34] Thus, even if compensation with vitamin K is not necessary for all olestra consumers, such compensation poses no safety concern. FDA further believes it is appropriate to require compensation at a level somewhat higher than that calculated from the 8-week DR study, to provide a greater assurance of safety. Given that the RDA is 80 µg/d and vitamin K exhibits no known toxicity, FDA recommended at the Olestra Working Group and the FAC meetings that a level of 8 µg vitamin K/g olestra, or one times the RDA per 10 g of olestra, would provide an adequate compensation level of vitamin K and would not cause any concern over toxicity.

During the Olestra Working Group meeting, the members of the Olestra Working Group unanimously agreed that FDA had appropriately evaluated the amount of vitamin K with which olestra should be compensated. Although there was no disagreement among FAC members that slight overcompensation with vitamin K would not be of concern to the general public, a Working Group member[35] and two presenters[36] expressed concern about the effect that olestra consumption (whether or not compensated with vitamin K) would have on persons for whom blood clotting should be controlled, such as persons taking coumarin drugs.

Dr. John Suttie, a researcher in the vitamin K field,[37] responded to these concerns. Dr. Suttie stated that monitoring of Coumadin therapy is a well-recognized problem, and that Coumadin doses must be titrated because of a number of adverse influences in such therapy. He and the petitioner[38] stated that diet is usually not one of the primary factors of concern in anticoagulation therapy, even though dietary vitamin K intake can vary day-to-day by three- to four-fold. Dr. Suttie asserted that changes due to consumption of vitamin K-compensated olestra would likely be within the normal range of dietary variation.

FDA concurs with Dr. Suttie's statements and concludes that olestra should be compensated with 8 µg vitamin K/g olestra. The majority of the FAC members also agreed that olestra should be compensated with vitamin K, and that the level selected by FDA is appropriate. FDA notes that if, in the future, the petitioner develops data that demonstrate that a lower level of compensation would be adequate, a petition could be submitted requesting an appropriate change in the required compensation level.

f. Carotenoids.—i. Data and information regarding carotenoids. The human studies demonstrate that consumption of olestra affects serum carotenoid levels. The petitioner concludes, and FDA concurs, that supplementing olestra with vitamin A will compensate for olestra's effects on the provitamin A function of carotenoids. There was no disagreement with this conclusion during the discussions at the Olestra Working Group and FAC meetings. The petitioner also concluded that it is not necessary to compensate olestra with any carotenoids, as there are no established beneficial health effects (aside from their provitamin A role) and further, that olestra's effect on carotenoid availability in the body is likely to be much smaller than that shown in the 8-week studies.

At the Olestra Working Group and FAC meetings, there was a thorough discussion of the possible beneficial health effects of carotenoids in preventing illnesses such as macular degeneration, prostate and lung cancer, and heart disease and whether olestra's effects on carotenoids would increase the risk of disease. In addition, the White Paper which was provided to the Committee, addressed the potential detrimental health impact of olestra's effect on carotenoids (Ref. 3). Information was also presented on whether carotenoids themselves have beneficial health effects, or whether it is other substances in the fruits and vegetables that provide the health benefits, and that carotenoids are serving solely as markers for fruit and vegetable consumption.

In his presentation to the Olestra Working Group,[39] Dr. Meir Stampfer, a professor of nutrition, stated that the results of an epidemiological study showed that higher levels of carotenoid intake, particularly lutein and zeaxanthin (which concentrate in the macula), have a marked protective effect against macular degeneration (Ref. 60). In addition, he stated that epidemiologic data show that individuals with high levels of lycopene intake were at a lower risk for developing prostate cancer a reduction that was statistically significant (Ref. 61). Dr. Stampfer also stated that there are many epidemiologic studies showing that individuals with high levels of plasma or serum carotenoids have a lower risk of lung cancer. Written information provided to the Committee also discussed the role of carotenoids in preventing cataracts, cardiovascular disease, and stroke.[40]

Dr. Alvan Feinstein critiqued the epidemiological data for carotenoids in his presentation to the FAC.[41] Dr. Feinstein stated that the epidemiologic evidence is not conclusive that carotenoids reduce the incidence of cancer or any other disease. Dr. Feinstein stated that epidemiologic case-controlled or other observational studies are problematic because the baseline state of those studied is not identified. In the studies of macular degeneration and of various cancers, for example, the health or disease state of participants before exposure is not known and differences may not be noted or adjusted for. Also, the compared agents are ascertained in retrospect, after they were taken; that ascertainment may be inaccurate or biased by a knowledge of outcome events. In addition, epidemiological studies lack reliability in terms of participants' accounts of what they ate or did not eat in the past. Finally, in such epidemiologic studies it is difficult to determine and adjust for the agent of interest (e.g., carotenoids, fruits, vegetables, or lycopenes).

Dr. Feinstein stated that, given these limitations with epidemiological studies, researchers, in general, are very reluctant to draw causal conclusions from epidemiologic data and prefer to rely, whenever possible, on randomized trials. One reason that randomized, experimental trials are preferable for

[34] FDA is not aware of any toxic effects of phylloquinone. In addition large quantities are routinely given for certain specific situations. For example, infants usually receive a single dose of 0.5 to 1.0 mg vitamin K injected intramuscularly shortly after birth to protect against bleeding.

[35] Donna Richardson, J.D., R.N., Howard University, Midlantic Women's Health Initiative. Ms. Richardson is a member of the FAC (Transcript, vol. 3, p. 255).

[36] Dr. Michael Jacobson, CSPI (Transcript, vol. 3, p. 179 and vol. 4, p. 15), and Dr. Ian Greaves, Associate Professor, and Deputy Director, Minnesota Center for Environmental and Health Policy, University of Minnesota School of Public Health. Dr. Greaves presented at the request of CSPI (Transcript, vol. 2, p. 267).

[37] Dr. John Suttie is a biochemist and nutritionist at the University of Wisconsin. Dr. Suttie consulted with the petitioner and presented at its request. Transcript, vol. 3, p. 256.

[38] Dr. John Peters, Procter and Gamble, Transcript vol. 1, p. 147.

[39] Dr. Meir Stampfer is a professor of nutrition at Harvard University School of Public Health. Transcript, vol. 1, p. 154. CSPI also provided FDA with a letter from Dr. Stampfer and Dr. Walter Willett prior to the FAC meeting. Dr. Stampfer presented at the request of CSPI.

[40] See for example Refs. 3 and 62.

[41] Transcript, vol. 1, p. 172.

establishing cause and effect relationships is that the baseline state is clearly specified by the admission criteria, and the randomization produces an equal distribution for the differences in susceptibility to disease.

Dr. Feinstein discussed the results of the randomized trials concerning the health effects of carotenoid. He stated that to date, there have been five randomized trials of the effects of carotenoid consumption on disease, and that the data thus far have shown no convincing beneficial effect. A 1994 study in Finland assessed the effects of dietary supplements containing β-carotene versus placebo with lung and other cancers and identified a possible harmful effect of the carotenoid supplements.[42] Other studies assessing the possible association between carotenoid supplement intake and nonmelanoma skin cancer (Ref. 64), and colorectal cancer (Ref. 65) also established no difference between the carotenoid and placebo groups in the selected outcome or in effects in the eye or coronary disease. Finally, a study examined the association between a combination of supplements (no placebos) and the death certificate diagnoses of cancer and found no statistically significant differences (Ref. 66).

The assessment of the significance of olestra's depletion of serum carotenoid should include consideration of the magnitude of the effect compared to variations in carotenoid utilization. Dr. James Olson, a professor of biochemistry,[43] noted in his presentation to the Olestra Working Group, that in the broader context of the diet, the effects of olestra on carotenoid utilization when used in savory snacks will be relatively minor, because a number of other factors influence carotenoid utilization, including carotenoid stability, bioavailability, and absorption. In the presence unsaturated fatty acids such as vegetable oils, for example, carotenoid are very rapidly destroyed. Similarly, carotenoid bioavailability can vary from almost zero to about 50 percent, depending on the vegetable concerned, cooking practice, and the presence and type of oils in the GI tract. (For example, in butter fat or coconut oil, carotenoid are only about 50 percent as well absorbed as in more unsaturated oils.) Inhibitors to carotenoid absorption also exist, including fiber, particularly acidic pectins, and high concentrations of vitamin E. Dr. Olson subsequently provided FDA with a published study that shows that the increase in plasma β-carotene concentration 30 hours following consumption of a controlled meal containing 25 mg β-carotene and 12 g citrus pectin was only half as large as the increase observed in the absence of citrus pectin (Ref. 67). Furthermore, Dr. Olson noted that competitions occur between various carotenoid for absorption; in particular, lutein, canthaxanthin, and β-carotene mutually inhibit each other's absorption.

Although olestra does affect carotenoid absorption, the petitioner asserted that only the more lipophilic carotenoid would likely be affected by olestra. The petitioner presented data regarding the octanol:water partition coefficients (PC's), a measurement of how fat-soluble a substance is,[44] for the various carotenoids, and noted that substances with a $\log_{10}$ PC above about 7.5 can be affected by olestra if they are consumed simultaneously with the olestra.[45] Three of the four carotenoids monitored (α-carotene, β-carotene, and lycopene) are the most lipophilic carotenoids with octanol:water PC's of approximately 17.6 each and would thus be expected to be the most affected by olestra. Indeed, the 8-week studies and 16-week vitamin E study show that the effects of olestra on the serum levels of these carotenoids are very similar. Lutein and zeaxanthin, which have more hydroxyl groups, are about 1,000 times less lipophilic (PC's of 14.82 and 14.95, respectively) than β-carotene (Ref. 68).

In addition, it is possible that serum carotenoid levels are not good indicators of carotenoid availability in the body. Dr. Olson pointed out that the plasma carotenoids amount to approximately one percent of the total tissue content of carotenoids. Plasma carotenoid concentrations can vary fairly rapidly within 1 to 4 weeks whereas tissue concentrations change much more slowly. Because protective aspects of carotenoids would be expressed at the intracellular level, plasma carotenoid concentrations, particularly in short-term studies, may not be very accurate indicators of useful carotenoid levels.[46] Similarly, Dr. Leonard Cohen,[47] in a presentation to the Olestra Working Group, also pointed out that serum measurements are single-point at a certain time of the day, but that carotenoid levels have Circadian rhythms. Therefore, one cannot tell at one point of the day whether levels will be the same at another point of the day.

Finally, Dr. Olson noted that five different conferences or reviewing groups have examined the relationship between carotenoids and disease: A U.K. Committee on the medical aspects of food policy (1987); the Life Science Research Offices of the Federated American Societies of Experimental Medicine in Biology; a European Union of Scientific Committees for Food (1992); an International Life Sciences Workshop on Antioxidants and Health (1993); and an FDA Conference on Antioxidant Nutrients (1993). He stated that all of these groups concluded that there is insufficient evidence to recommend specifically consumption of carotenoids, except to encourage the consumption of vegetables and fruit.

After considering all the presentations and information submitted by CSPI in their White Paper (Ref. 3), a substantial majority of the Olestra Working Group felt that there is a reasonable certainty of no harm from olestra's effects on serum carotenoid levels.

However, some members of the Olestra Working Group voiced concern about olestra's effects on carotenoid serum levels. Because of this concern, FDA subsequently consulted with scientists at the National Institutes of Health (NIH) and requested their views on whether olestra's effects on lipophilic carotenoids raise any significant public health issues with respect to the possible association between carotenoids and cancer risk[48] and macular degeneration[49] (Refs. 69 and 70). The agency provided these scientists with copies of letters concerning carotenoids that the agency had received (including the letter from Dr.'s Willett and Stampfer (Ref. 62)), submissions by the petitioner, excerpts discussing carotenoids from the White Paper, and relevant sections of the Transcript from the Olestra Working Group and FAC meetings.

Regarding cancer risk, Dr. Peter Greenwald stated that the effects of olestra on carotenoid utilization under

[42] Dr. Greaves mentioned that blood draws at the beginning of the Finland study showed that men in the lower quartile for serum β-carotene in the blood had significantly higher incidence rates of lung cancer than the men with the high levels of β-carotene in blood (Ref. 63).

[43] Dr. James Olson, Professor, Biochemistry and Biophysics Department of Iowa State University, researcher in the filed of carotenoid and vitamin A. Dr. Olson has consulted with the petitioner and presented at its request. Transcript, vol. 3, p. 190.

[44] Octanol:water partition coefficients (PC's) are generally expressed on a log scale so that a substance with a PC of 12 is 10 times as fat soluble as a substance with a PC of 11.

[45] Transcript, vol. 2, p. 125.

[46] Transcript, vol. 3, p. 192.

[47] Dr. Leonard Cohen, Section Head, Nutrition and Endocrinology, American Health Foundation. Transcript, vol. 3, p. 149.

[48] Dr. Peter Greenwald, Director of the Division of Cancer Prevention and Control, National Cancer Institute, NIH.

[49] Dr. Carl Kupfer, Director of the National Eye Institute, NIH.

the conditions of use would be expected to be relatively minor, that the provitamin role of carotenoids is the only function that has been adequately documented, and that plasma carotenoid concentration (which were used in the reported epidemiological studies) probably is not a reliable indicator of tissue levels and may in fact be misleading. Therefore, he concluded that no significant health issue was raised by the reported effects of olestra on lipophilic carotenoids. Furthermore, he recommended against supplementing olestra with β-carotene or other carotenoids at this time (Ref. 71).

Regarding macular degeneration, Dr. Carl Kupfer stated that although theoretical considerations have raised the possibility that carotenoids might play some protective role in macular degeneration, there are currently no convincing clinical data to substantiate the hypothesis. Furthermore, he asserted that no clear eye health benefit has been demonstrated for carotenoids (Ref. 72).

ii. *FDA's evaluation of olestra's effects on carotenoids.*

On balance, having considered all the comments, data, and information that the agency has received on this subject, FDA has determined that the information currently available show that olestra's effects on the absorption of the lipophilic carotenoids is reasonably certain to be insignificant from a public health standpoint. First, FDA has determined that the available data do not establish any identifiable nutritional or prophylactic benefits for the carotenoids, either individually or collectively. Specifically, controlled randomized studies have been performed to test the potential cancer-protective effects of carotenoid consumption and have shown no association between carotenoid consumption and cancer.[50] Also, there have been no controlled studies to examine the association between carotenoid consumption and eye disease.

The agency believes that its conclusion regarding the absence of harm from olestra's effect on some carotenoids, which conclusion is based on the scientific evidence currently available, is not inconsistent with the currently available epidemiological studies. This is because the epidemiologic studies show an association between diets rich in fruits and vegetables and decreased cancer risk and do not evaluate the association between carotenoids *per se* and lower disease risk. Thus, there is no direct evidence from these epidemiologic studies that carotenoids are the substances responsible for the protective effect. In fact, as noted by several experts, serum carotenoid levels may simply be markers for consumption of fruits and vegetables.

The agency's determination that olestra's effects on the absorption of carotenoids is reasonably certain to be insignificant is bolstered by the fact that the actual magnitude of olestra's effects on carotenoid absorption is likely to be within the range of the normal variation due to diet and bioavailability because the percentage of consumed carotenoids that are actually available to the body is highly variable and affected by a number of factors. In fact, the agency believes that it is likely that olestra's effects on carotenoid absorption will likely be substantially less that those observed in the 8-week studies and will be more similar to the effects observed in the 16-week vitamin E study.[51] Finally, the association between serum carotenoid levels and the availability of carotenoids at the cellular level is unclear. Hence, the relationship between olestra's effects on serum carotenoids and the body's utilization of carotenoids is also unclear.

Therefore, FDA has determined, based upon the scientific evidence that exists at this time, that there is currently no justification or need to require compensation of olestra-containing foods with specific carotenoids.[52]

C. Effects of Olestra on Water-soluble Nutrients that are Hard-to-Absorb or Limited in the Diet

The two 8-week clinical studies in the human and the two 12-week, the 26-week DR/VR, and the 39-week VR studies in the pig were used to assess olestra's potential effects on water-soluble nutrients. Iron, folate, vitamin B_{12}, and zinc status were measured in both the pig and human studies. Vitamin B_{12} absorption was also measured in the human studies. Calcium status was measured only in the pig studies, because there are no non-invasive methods sufficiently sensitive to assess calcium status in humans. The human and pig studies are described in section V.B. of this document, and the methods used to measure the status of calcium, zinc, iron, folate, and vitamin B_{12} are summarized in Table 4 (human studies) and Table 6 (pig studies).

1. Results and Conclusions from Human Studies

a. Vitamin B_{12}. In the 8-week human DR and VR studies, there was no change in serum measures of vitamin B_{12}. However, 8 weeks is insufficient to observe effects in serum, and the presence of excess vitamin B_{12} in the diets likely reduced the sensitivity of the studies to evaluate vitamin B_{12} status. The petitioner also found that absorption of vitamin B_{12} did not change as a result of olestra consumption in either 8-week human study, as measured by the Schilling test. FDA notes that dietary levels of vitamin B_{12} were approximately 2.2 and 1.7 times the RDA in the DR and VR studies, respectively. However, this overfortification does not affect interpretation of the results of the Schilling test because the level of vitamin B_{12} in the diet is not a factor in the Schilling test.[53] FDA concludes that the results of the Schilling test shows that olestra has no effect on vitamin B_{12} absorption in humans.

b. *Iron.* Measures of iron status were performed in the 8-week VR study. The petitioner concluded that olestra had no effect on iron status, and that sporadic, statistically significant trends with olestra dose in one or more of the measures at one or more time points resulted from differences in status at baseline or from a general decrease in iron stores resulting from phlebotomy (drawing blood for analysis). FDA agrees with the petitioner's conclusion that there were no changes in all measures of iron stores, with the exception of serum ferritin levels for both treatment and control groups. FDA further concludes that the decreased serum ferritin levels were consistent with loss due to phlebotomy (Ref. 73).

c. *Folate.* Folate status was monitored in the 8-week DR study in which folate was consumed at levels between 80 and 120 percent of its RDA. There was no olestra dose response on the indices for folate (serum and red blood cell folate concentration). FDA considers red blood cell folate levels to be excellent

[50] In fact, well-controlled studies indicate that there may be higher incidence of lung cancer in smokers consuming high levels of β-carotene.

[51] While FDA finds that the petitioner's hypothesis that actual reductions in carotenoid levels will be affected by consumption patterns and will therefore be even less than those observed in the 16-week vitamin E study is plausible, the actual magnitude of the effect is not supported with data at this time.

[52] This conclusion is consistent with the recommendations of the various conferences that have been held to examine the relationship between carotenoids and disease and is also consistent with FDA's decisions regarding health claims for antioxidant vitamins and cancer (58 FR 2622, January 6, 1993.)

[53] The Schilling test is an acute test that measures the absorption of a dose of radiolabeled vitamin B_{12}

indicators of folate status.[54] Thus, the agency agrees with the petitioner's conclusion that olestra consumption does not affect folate status.

d. *Zinc.* Zinc status was evaluated in the 8-week DR study. There was no olestra dose response on the indices for zinc that can be measured noninvasively in humans (serum and urinary concentration). FDA agrees with the petitioner's conclusion that there is no evidence that olestra affects zinc status. However, the agency notes that serum and urinary concentrations are not sensitive indicators of zinc status in humans. Although these data are not particularly sensitive indicators of zinc status, FDA finds that the data support a finding of no effect. However, FDA does not consider the data sufficiently sensitive to support, in and of themselves, a conclusion of no effect.

2. Results and Conclusions from Pig Studies

Data from the studies of olestra consumption in pigs generally corroborate the findings from the human studies regarding the effect of olestra on iron and zinc status. Although, the results of the pig studies regarding vitamin B_{12}, calcium, and folate, do not indicate any effect of olestra, these studies are of limited utility in assessing olestra's effects because of several weaknesses in study design, as discussed below.

a. *Vitamin B_{12}.* There were no statistically significant effects of olestra on liver vitamin B_{12} in the 12-week VR, the 26-week VR/DR, and the 39-week VR pig studies. In the 12-week DR study, a statistically significant downward trend in liver vitamin B_{12} levels, produced by a low value in the 7.7 percent olestra group, was observed. There were no statistically significant decreases in the 1.1 percent, 2.2 percent, 3.3 percent, 4.4 percent, or 5.5 percent olestra groups. The low value in the 7.7 percent olestra group was not accompanied by an elevation in mean corpuscular volume, and thus, the petitioner concluded that this decrease did not represent a change in vitamin B_{12} status. (FDA notes that the downward trend was not found in other pig studies.)

FDA concludes that the pig studies are limited in their usefulness in assessing olestra's effects on vitamin B12. FDA's principal reservation is that the level of vitamin B12 was measured only in the diet premix and not in the complete diets; such analysis of the premix is not as reliable as analysis of the complete diet because an accidental mixing error may have occurred or the vitamin may have been degraded or spared from degradation by an interaction with another ingredient during the mixing process or during storage. Accordingly, FDA finds that, although there was no consistent effect of olestra on vitamin B_{12}, these pig studies are inadequate by themselves to evaluate olestra's effect on vitamin B_{12}.

b. *Iron.* A battery of tests (liver iron concentration, serum total iron binding capacity, and serum total iron concentration) conducted in the 12-week VR, 26-week DR/VR, and 39-week VR studies showed no adverse effects on iron status when olestra was fed at any level (up to 7.7 percent of the diet). There were statistically significant decreases in liver iron values in the 12-week DR study in both the 5.5 percent and 7.7 percent olestra groups. However, in these groups, mean corpuscular hemoglobin, mean corpuscular hemoglobin concentration, and red blood cell count were unaffected by olestra consumption. The petitioner postulated that the trend in liver iron concentration was probably secondary to the poor vitamin A status of the animals, and thus, concluded that iron status was not affected by olestra.

FDA notes that there was a large variability in liver iron values in all pig studies. FDA postulates that the variability in liver iron levels may have been due to several factors, such as blood loss from gastric ulcers, dewclaw lesions or abscesses, or differences in the amount of blood present in the liver after sacrifice. FDA further notes that the test diets were oversupplemented with iron in that the diets contained between 1.7 to 2.4 times the NRC requirements. FDA finds that these results make it possible to rule out gross effects on iron status but the foregoing factors make it difficult to exclude subtle effects in these studies (Ref. 56). Accordingly, FDA finds that the pig studies are inadequate by themselves to evaluate olestra's effect on iron.

c. *Folate.* The petitioner stated that there were a few statistically significant differences in plasma folate concentration at week 4 in the 26-week DR/VR study, but the values in the olestra groups were greater than the control. There were no statistically significant changes in plasma folate in the two 12-week studies, nor in the 39-week VR study. Therefore, the petitioner concluded that folate status in pigs was not affected by olestra consumption.

FDA finds that a conclusion on folate status cannot be drawn from the pig studies for several reasons. First, no measurements of folacin, either in the premix or in the diet as fed, were made in any of the studies. Second, folic acid was added to the diet, rather than folylpolyglutamates, the predominant form of folate in the American diet. Folic acid (folylmonoglutamate) is absorbed directly, while folylpolyglutamates must be cleaved by folylpolyglutamate hydrolase in the intestine prior to being absorbed. Therefore, folacin is not a hard-to-absorb nutrient when it is supplied as folic acid, as in these studies. Finally, plasma folate is not as sensitive a measure of folate status as red blood cell folate (the method used in the human studies). Therefore, FDA concludes that the pig studies are of limited utility in assessing olestra's effects on folate (Ref. 56).

d. *Zinc.* There were no significant effects of olestra on liver, bone, or serum zinc levels in the 12-week DR study or the 26-week DR/VR study. The only significant differences from control values in these three measures of zinc status in the 12-week VR and 39-week VR studies were small (and probably spurious) increases in liver zinc in the 0.25 percent low vitamin group in the 39-week VR study and in serum zinc in four olestra groups at week eight in the 12-week VR study. Accordingly, the petitioner concluded that liver, bone, and serum zinc concentrations were not affected by olestra in any of the pig studies.

In general, FDA concurs with this conclusion, with some qualifications, as discussed below.

Although they did not show any significant differences, the bone zinc measurements are less than an ideal means of assessment because the methodology used to analyze the bone has several flaws that limit the power and reliability of the results. (These flaws are discussed in the calcium section below.) Because of these methodological flaws, FDA concludes that the bone zinc measurements of the pig studies do not provide a completely reliable assessment of zinc status.

FDA notes that liver and serum measurements of zinc, in controlled swine studies, are acceptable measurements of zinc status that have sensitivities comparable to properly performed bone measurements. A potential confounding factor in the assessment of zinc status in the pig studies is the amount of zinc in the test animal diets. FDA estimates that zinc consumption in the 12-week VR, 26-week DR/VR, and 39-week VR studies exceeded the NRC requirements by at least 68 percent. However, a review of the literature shows that serum and liver zinc measurements will reflect dietary zinc over a wide range of dietary

[54] Transcript, vol. 3, p. 117.

concentrations in controlled swine studies. Therefore, FDA believes that this oversupplementation would not mask any effects of olestra on zinc status. FDA concludes, therefore, based on the results of the liver and serum measurements in these studies, that there is no evidence that consumption of olestra affects zinc status.

e. *Calcium.* Bone ash and bone calcium levels were not affected by olestra consumption in the 12-week VR, 26-week DR/VR, or 39-week VR pig studies. The only change was seen in the 12-week DR study where bone ash but not bone calcium was less (60.6 ± 2.0 vs. 61.1 ± 1.0 percent) in the 4.4 percent olestra dose group than in the control group (Refs. 74 and 75), a difference that was statistically significant. The other dose groups showed no statistically significant change in bone ash or bone calcium. The petitioner concludes that these results demonstrate that olestra consumption does not have an effect on calcium status.

FDA concludes that the results from the pig studies are not useful for determining whether olestra has any subtle effects on calcium status; the results show only that there were no gross changes in calcium status. FDA's determination that these studies are seriously limited in their utility to determine calcium status changes is based on two factors: oversupplementation of calcium in the diet and flawed methodology in measuring bone ash and bone calcium.

FDA believes that the bone ash measurements are not reliable because the test animals' diet was oversupplemented with calcium. Specifically, test animals received approximately 1.0 to 1.3 times the NRC calcium requirements during the 12-week studies (with the greater amounts during the last 7 weeks) (Refs. 76 and 53), and 1.2 to 1.7 times the NRC requirement during the 26-week DR/VR and 39-week VR studies (Ref. 52). Based on published studies (Refs. 77 and 78), FDA believes that bone ash will reach maximum levels when dietary calcium is approximately 1.2 times the NRC requirement and adequate levels of phosphorus are provided (Ref. 56). Therefore, the supplementation above 1.2 times the NRC requirement would mask any subtle effect on calcium absorption.

In the 26-week DR/VR and 30-week studies, olestra would have to have inhibited the absorption of approximately 30 percent of the calcium before any adverse effects on bone ash would have been observed (Ref. 56). Thus, the bone ash data from these studies are not a stringent test of calcium status. Although the oversupplementation in the 12-week studies would not mask olestra effects on calcium as much as it would in the 26-week DR/VR and 39-week VR studies, methodological factors in obtaining the data on bone ash, as described below, in combination with the slight oversupplementation during the last 7 weeks, make the calcium data only useful in determining whether there were gross effects of olestra on calcium status.

Factors that CFSAN considers contributing to the limitations of the methodology that was used to evaluate bone ash include the following: (1) Only half of the bone selected for analysis (the L5 lumbar vertebra) was used, rather than using the whole bone; (2) after drying and grinding the half bone, an aliquot of the ground bone (approximately 1.5 g) was taken for fat extraction, rather than extracting the entire sample; (3) an aliquot (approximately 0.5 g) of the fat-free bone powder was ashed, rather than ashing the entire sample; and (4) ashing was performed at 500 °C for 8 hours, rather than more typical conditions of > 550 °C for > 12 hours (Ref. 79).

Because of these methodological flaws, FDA concludes that the bone ash and bone calcium measurements performed in the pig studies do not provide a reliable assessment of calcium status.

Although FDA finds that the data from the pig studies are of limited use in determining whether olestra affects the absorption of calcium because the test diet was overfortified with calcium and appropriate measures of bone were not made, FDA notes that the animals grew normally and all outward observations indicated that they had normal skeletal growth.

3. Overall Conclusions Regarding Olestra's Effects on Water-Soluble Nutrients

The agency received no significant comments expressing concern about olestra's effects on water-soluble nutrients. Similarly, Dr. Connie Weaver, FDA's consultant on water-soluble nutrients, also found no basis for concern (Ref. 75). FDA's specific conclusions on these nutrients follow.

a. *Vitamin B_{12}.* FDA has determined that there is no need for compensation of olestra-containing foods with vitamin B_{12}. In reaching this conclusion, the agency relied primarily on the 8-week human DR and VR studies in human to evaluate the effect of olestra on vitamin B_{12}. Both studies showed no effect of olestra on vitamin B_{12} using the Schilling test, which is a sensitive test that is not affected by dietary vitamin B12 levels. The vitamin B_{12} results of the pig studies are consistent with the results of the human studies. In the pig studies, no effect of olestra was seen in the 12-week DR, the 26-week DR/VR, or 39-week VR studies. There was a statistically significant decrease in liver B_{12} levels in the highest olestra dose group (7.7 percent) in the earliest pig study (the 12-week VR study). Because this result was not corroborated by results of any of the other studies, FDA concludes that, collectively, the data establish that olestra does not affect vitamin B_{12} absorption.

b. *Folate and iron.* The results from the 8-week human studies establish that folate and iron status were not affected by olestra consumption. These studies were well designed, the methods used were sufficiently sensitive to evaluate olestra's effects, and the duration of the studies was long enough to see any such effect. Although there were limitations in the quality of the results of the pig studies with regard to folate and iron, in general, the results of the pig studies support the conclusion drawn from the human studies that olestra consumption does not adversely affect iron or folate status.

c. *Zinc.* Zinc status was evaluated by three acceptable methods: serum and urinary zinc in the 8-week human studies, and serum and liver zinc in the pig studies. None of these analyses, in any of the studies, demonstrated an effect of olestra consumption on zinc status. The analysis for zinc in bone has methodological limitations. Therefore, although these results are consistent with the other zinc measurements, FDA is not relying on the bone results.

FDA concludes that the totality of the results, in both the human and pig, using all three methods, provides strong evidence that olestra consumption does not affect zinc absorption. In addition, FDA is not aware of any hypothesis that would support an effect of olestra on zinc status.[55] Therefore, FDA concludes that consumption of olestra does not affect zinc status.

d. *Calcium.* With respect to calcium, FDA concludes that there is no basis for concluding that calcium absorption would be adversely affected by olestra consumption. First, there is no plausible hypothesis for how olestra could affect calcium absorption other than by

[55] At the Olestra Working Group meeting, Dr. Schneemna, FDA's overarching nutritional consultant, stated that the only mechanism she could envision of olestra to affect any water-soluble nutrient would be a general mechanism causing lower bioavailability for a variety of nutrient. Transcript, vol. 2, p. 97 and vol. 3, p. 130.

vitamin D depletion. Unlike the fat-soluble vitamins, calcium is water soluble and would not be expected to partition into olestra. Other mechanisms by which olestra might affect calcium absorption are: (1) by forming a physical barrier that would prevent calcium from reaching the mucosal cell surface, where it is absorbed; or (2) by decreasing GI transit time so drastically that there is little chance for calcium to make mucosal contact. However, these mechanisms would also be expected to affect the absorption of folate, vitamin B12, and iron, yet, importantly, as discussed above, these nutrients are unaffected by olestra consumption. Also, published studies (Refs. 80 and 81) indicate that olestra does not significantly alter gastric emptying or overall GI transit time.

Further, it is likely that the effect of variations in calcium intake in the normal diet (especially as a result of dietary choices concerning calcium-rich foods such as dairy products) would be much greater than any effect from olestra consumption on calcium absorption (Ref. 75). Also, the compensatory homeostatic mechanisms the body has for calcium, and the fact that studies have shown that high-fat diets do not affect absorption of vitamin B_{12}, folate, iron, or zinc, are additional reasons for reduced concern about the potential effect olestra on the absorption of calcium. Finally, studies of mineral oil (a substance much like olestra in that, like fats, it is non-polar and is not absorbed) in the published literature support the conclusion that any effect by olestra on calcium is likely to be vitamin D-mediated rather than a direct effect on its absorption (Refs. 82 and 83). Compensating for olestra's effects on vitamin D will thus preclude any effects of olestra consumption on calcium produced by vitamin D depletion.

Thus, given the lack of effect on other water-soluble nutrients and the lack of any probable mechanism for olestra to affect calcium, FDA concludes that there is no basis for concern regarding olestra's effects on calcium status.

Effect of Olestra on the Gastrointestinal (GI) Tract

A. Introduction

Because olestra is not digested or absorbed and passes unchanged through the GI tract, it has the potential to affect GI physiology and function. Therefore, the petitioner conducted several studies to assess olestra's potential to affect the GI tract.

For example, the petitioner assessed the potential for olestra to elicit GI symptoms such as cramping, bloating, loose stools, and diarrhea-like symptoms by collecting adverse effect reports in studies designed primarily to assess potential effects of olestra on absorption of nutrients from the diet. The petitioner also collected data on GI symptoms in a human study (the oil loss study) designed to set a specification for olestra stiffness (i.e., viscosity). (The oil loss study sought to establish the viscosity that would prevent olestra from separating from other fecal contents in the colon and leaking past the anal sphincter (passive oil loss)). Other studies addressed the potential for olestra to cause GI symptoms in the young and in patients with inflammatory bowel disease (IBD). The study in patients with IBD also assessed the potential for olestra to adversely affect disease activity. Finally, the petitioner conducted several studies to assess the potential for olestra to affect the normal metabolic activity of intestinal micro flora and the potential for olestra to affect the absorption, synthesis, and excretion of bile acids.

B. Effect of Olestra on GI Symptoms

1. Study of GI Symptoms in 8-week Studies in Normal Subjects

Data on GI symptoms were collected in the two 8-week human clinical studies conducted to determine olestra's potential to affect nutritional status. The design and methodology of these studies are described above in detail in Section IV.B.1.a.The petitioner believes that data from the two 8-week studies are particularly useful in understanding the potential for olestra to produce GI symptoms because the olestra doses used were large (up to 32 g/d) and were consumed every day, the studies were lengthy (8 weeks), and details of the GI symptoms were recorded by the subjects for each day they reported symptoms. Specifically, subjects were questioned daily about changes in their health, including GI symptoms. If a GI symptom was experienced, a subject completed a detailed questionnaire which asked about the type, severity, and duration of symptoms experienced. To facilitate collection of GI symptom data, the questionnaire provided a list of common GI symptoms along with general definitions of each. This served to remind subjects of other possible symptoms in addition to the one that first prompted completion of the GI symptom report.

The petitioner noted two considerations relevant to the evaluation of the GI symptom reports. First, the subjects were prompted every day to report symptoms and were provided with a list of commonly experienced GI symptoms; this would be expected to amplify the reporting of GI symptoms, relative to data collected under unprompted conditions. In addition, the collected symptom data will closely reflect actual incidence, rather than capturing only those symptoms that subjects judged significant enough to report. Second, the petitioner stated that the two 8-week studies were not intended to examine GI symptoms under real-life consumption conditions where snacks are not consumed every day with every meal and where people may moderate intake if they experience GI symptoms; therefore, the GI symptom data from these studies may have exaggerated what will occur in young, healthy adults consuming olestra snacks under real life conditions.

a. *Petitioner's evaluation of GI symptoms.* Because the two 8-week studies were run under nearly identical protocols, the petitioner combined the GI symptom data from the two studies for analysis. GI symptoms were reported by subjects in all groups, including placebo. The petitioner stated that the number of people reporting GI symptoms in the two 8-week studies increased in a dose responsive manner with olestra dose. The number of individuals who ate eight g/d olestra [56] for 8 weeks and reported at least one GI symptom (62 percent) was greater than the number who ate a corresponding amount of a triglyceride for 8 weeks and reported at least one GI symptom (45 percent). The petitioner noted that the GI symptoms reported by the control and 8 g/d groups of subjects were essentially not different in severity, length of episodes, or total number of symptom days (number of days on which symptoms occurred times the number of symptoms). The petitioner also noted that GI symptoms reported by subjects who consumed larger amounts of olestra (20 g/d or 32 g/d) were of the same kind and severity as those reported by subjects in the placebo and eight g/d olestra groups; however, the total number of symptom days was greater in the two groups consuming the higher levels of olestra.

The petitioner concluded that none of the GI symptoms reported by subjects eating either triglyceride or olestra at any level (8, 20, or 32 g/d) were clinically significant. According to the petitioner, the GI symptoms spontaneously abated and recurred during the course of the study in all

[56] Eight g/d olestra intake approximates the lifetime average 90th-percentile intake for snack eaters.

groups and stopped within 5 days after the study ended. The petitioner also stated that the GI symptoms experienced by an individual eating olestra-containing foods are self-limiting in the sense that the symptoms either stopped in the face of continued consumption of such foods or ceased when the individual stopped eating the olestra-containing food or reduced the amount consumed. The number of subjects reporting symptoms at any given time and the severity of the symptoms remained essentially constant over time among the different treatment groups, indicating that symptoms did not worsen with prolonged consumption of olestra. In addition, clinical laboratory data collected at the time subjects were reporting symptoms did not show clinically significant effects such as hemoconcentration, electrolyte imbalance, or increased urinary creatinine or specific gravity.

The petitioner stated that the symptoms were, on average, mild to moderate in all groups. As an indication of the mildness of the symptoms, the petitioner stated that few individuals reporting GI symptoms in the two 8-week studies dropped out of the studies because of the symptoms. (Four of a total of 115 subjects in the 20 and 32 g olestra per day groups dropped out; out of these 4, only 1 was attributed to GI symptoms experienced (heartburn)).

Although most of the symptoms were reported as mild on average, the petitioner stated that at least one symptom described as severe was reported by some subjects: 5 percent (placebo), 10 percent (8 g/d olestra), 26 percent (20 g/d olestra), and 22 percent (32 g/d olestra). All severe symptoms reported by the placebo and eight g/d olestra groups were limited to 1 day. For the 20 g/d olestra group, the maximum duration of severe symptoms was 2 days, and for the 32 g/d group, it was 4 days. According to the petitioner, GI symptoms reported by people eating 20 or 32 g/d olestra are similar to those reported by people eating high amounts of common food ingredients that elicit GI symptoms. The petitioner asserted that high fiber diets produce GI symptoms such as stomach cramps, loose stools, diarrhea, bloating, and flatulence. Therefore, the petitioner concluded that persons eating olestra-containing foods, even at levels beyond the expected consumption from snacks, are unlikely to experience GI symptoms that are different from those they might normally experience consuming other foods or from dietary changes.

b. *FDA's evaluation of the GI symptoms.* Unlike the petitioner, in its original analysis, FDA evaluated the adverse effects reports from the two studies separately, because there did not appear to be any reason or need to combine the two date sets. In analyzing the two studies, FDA, however, did combine reports of loose stools and diarrhea (Ref. 84), for the following reason. The petitioner defined loose stools as bowel movements that were unformed but not watery, and diarrhea-like stools as watery stools that were difficult to control and had little or no solid material.[57] However, the difference was between loose stools and diarrhea-like stools may not have always been clear to the subjects. Further, substantial fluid and electrolyte losses could potentially result from either form of stools. Thus, FDA believes that it is preferable to combine these two reported effects for analysis.

In its presentation of the GI symptom data to the Olestra Working Group and the FAC, FDA did combine the data from the two studies; combining the data is acceptable for the following reasons: (1) Both studies used the same olestra dosages (placebo, 8 g/d, 20 g/d, and 32 g/d); (2) similar criteria were used in both studies for selecting and excluding study subjects; (3) the studies were of the same duration; and (4) the same methods were used to monitor for adverse GI experiences. By pooling the data, the statistical power of the study increased.[58]

At the Olestra Working Group and FAC meetings, there was some discussion regarding the advisability of pooling data from the two studies. For example, CSPI stated in their White Paper that the two studies were analyzed separately because one of the studies had a very high rate of GI problems in the control group that masked the difference between the placebo and the 8 g/d groups and also because the second study had a low level of GI problems in the control group.[59] Others stated that not only could the studies be combined, but that the conclusions were the same whether or not the data were pooled, i.e., there was increased reporting of GI effects with increasing olestra doses.[60]

FDA's analysis of the data from the two 8-week studies showed there was a dose-response effect for olestra with respect to two endpoints, reported diarrhea/loose stools and fecal urgency. For example, in the 8-week DR study, the percentage of subjects who experienced loose stools or diarrhea (at any time during the study) was 19 percent (control group), 45 percent (8 g/d olestra group), 74 percent (20 g/d olestra group), and 67 percent (32 g/d olestra group). In general, whether the data from the two studies were analyzed separately or together, the incidence of GI symptoms in the eight g/d olestra group was not statistically different from that of the control group; the differences in the incidences of GI symptoms between the control group on the one hand and the 20 or 32 g/d olestra groups were statistically significant.

Although FDA agrees that, in general, the GI symptoms started and stopped in all groups, FDA notes that, in some olestra-fed subjects, the GI symptoms persisted for a long period of time. For example, over the course of the 56 days, two study subjects in the 20 g/d olestra group reported loose stools for 38 and 40 days, respectively, and another subject in the same group reported experiencing fecal urgency and loose stools for 55 days. In the 32 g/d olestra group, three subjects reported loose stools for more than 50 days. FDA agrees that these GI symptoms cease when olestra is no longer consumed. However, FDA believes it is important that consumers know that the GI symptoms they are experiencing may be due to consumption of olestra. This need for information is discussed in section VII of this document.

As noted, the petitioner contends that the nature and severity of the GI symptoms observed among the olestra-consuming participants were comparable to symptoms experienced by persons consuming diets moderate or high in fiber. FDA does not agree. While high-fiber diets have been associated with increased gas manifested as belching, flatulence, and mild abdominal distention, diarrhea and staining of underwear (discussed in following section) have not commonly been reported (Refs. 85 and 86).

Finally, FDA concurs with the petitioner that there was no evidence in either study that subjects experiencing olestra-related symptoms described as

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[57] Reporting of diarrhea was based on subjects' perception of diarrhea. There was no measurement of water-content made. However, subjects' electrolyte levels were monitored. FDA recognizes that the effect observed may not be diarrhea in the clinical sense but is using that term in this preamble because it is the term used in the study report.

[58] Transcript, vol. 2, p. 185.

[59] Statement of Dr. Michael Jacobson, CSPI, Transcript, vol. 1, p. 171.

[60] Statements of Dr. David Allison, Dr. Joann Lupton, and Dr. Karl Klontz. Dr. Allison is an Associate Research Scientist at New York Obesity Research Center, Saint Luke/Roosevelt Hospital. He was a temporary member of the FAC. Dr. Lupton is an Associate Professor of Human Nutrition at Texas A&M. She was FDA's consultant on GI issues. Dr. Karl Klontz is with FDA. Transcript, vol. 3, pp. 49–54.

"diarrhea" also experienced significant fluid and electrolyte loss.

2. GI Symptoms in the Oil Loss Study

The petitioner conducted an oil loss study.[61] This study had three objectives to determine: (1) The minimum olestra stiffness that would control passive oil loss, as measured by underwear staining, to the level experienced by a triglyceride placebo group; (2) the relationship between olestra stiffness[62] and the occurrence of oil in the toilet (OIT); and (3) whether the stiffness of olestra affected the incidence of common GI symptoms experienced by the subjects.

The oil loss study was a double-blind, placebo controlled, parallel design study with seven groups of 18 to 44 year old male and female subjects (173 to 182 per group). Six groups consumed 34 g/d of olestra of varying stiffness (18, 45, 50, 66, 78, or 103 Kpa/s) in potato chips for 5 days. A placebo group consumed an equivalent amount of potato chips prepared with triglycerides. All groups consumed the potato chips as part of a normal diet.

At the end of the 5 days, the subjects completed a questionnaire answering specific questions about underwear staining due to passive oil loss and incidence of oil droplets in the toilet (OIT) following defecation. In addition, reports of adverse GI experiences (e.g., diarrhea, abdominal pain, indigestion) were collected during the consumption period as well as the 3 days following the treatment phase.

a. *Effect of olestra stiffness on passive oil loss.* From the results of this study, the petitioner concluded that the incidence of passive oil loss in subjects who consumed olestra with a stiffness less than or equal to 45 kPa/s (i.e., those in the two lowest treatment groups) was significantly increased relative to the incidence reported by the subjects consuming triglycerides (the placebo group). The incidence of passive oil loss in subjects consuming olestra of greater that 50 kPa/s was not significantly different from the incidence reported by subjects in the placebo group. FDA's analysis of these data agreed with the petitioner's analysis.

At the Olestra Working Group and FAC meeting, CSPI stated that their analysis showed that there are statistically significant increases of passive oil loss above control with olestra at the higher stiffness levels.[63] However, no details on how the data were analyzed were given. FDA had the data from the passive oil loss study analyzed independently by Dr. Joanne Lupton, FDA's consultant on GI issues. Dr. Lupton's analysis was consistent with FDA's analysis, i.e., there would be an increase in passive oil loss in subjects consuming olestra having a stiffness of under 50 kPa/s but not in subjects consuming olestra with stiffness of 50 kPa/s or higher.[64]

Therefore, FDA concurs with the petitioner's conclusion that there would not be an increased incidence of passive oil loss in subjects consuming olestra of a stiffness greater than or equal to 50 kPa/s (Ref. 87). FDA also notes that passive oil loss is not a hazard to health or otherwise an adverse effect per se and that the purpose of conducting the study was to determine the stiffness specification of olestra above which passive oil loss would not occur.

b. *Effect of olestra stiffness on OIT.* The petitioner stated that the incidence of reported OIT was significantly increased in all olestra groups relative to the incidence in the placebo group. The incidence of OIT in the 18 kPa/s olestra group was also significantly greater than the incidence in any other olestra group. However, there was no consistent trend in the incidence of OIT reported by the subjects who consumed olestra of stiffness greater or equal to 45 kPa/s.

FDA agrees that the incidence of OIT was significantly greater in all olestra treatment groups (13.5 percent to 32 percent) compared to the placebo group (4.7 percent). FDA also agrees that there was no predictive relationship between olestra stiffness and OIT when the stiffness was greater or equal to 45 kPa/s (Ref. 87).

c. *Effect of olestra stiffness on GI symptoms.* With respect to GI symptoms, the petitioner stated that 9 percent of the subjects in the placebo group and from 10 percent to 16 percent of the subjects in the olestra groups reported GI symptoms including (in decreasing order of occurrence) gas/stomach gurgle, diarrhea, abnormal (loose, soft) stools, abdominal pain, and indigestion/heartburn. The petitioner concluded that there was no consistent trend with olestra stiffness in the number of GI symptoms reported. The petitioner also concluded that, consistent with the results of other studies, the GI symptoms do not present a safety concern because: (1) When they occur, the symptoms are generally mild or moderate in severity; (2) they subside when olestra consumption is stopped; and (3) they do not differ substantially from the GI symptoms normally experienced when diets high in fiber are consumed.

FDA agrees with the petitioner that there was no trend in reported GI effects based on olestra stiffness. However, the percentage of subjects who reported at least one of the eight gastrointestinal effects assessed was significantly greater in four of the six olestra stiffness treatment groups (18, 66, 78, 103 kPa/s) compared to the placebo group (Ref. 87).

In addition, the percentage of subjects in the olestra groups reporting GI symptoms in response to directed questions was 0 percent to 19 percent greater than the percentage of subjects reporting symptoms in the placebo group. The GI effects that were reported significantly more often in some of the olestra groups compared to the placebo group were urgent bowel movements, difficulty wiping, and soft stools (Ref. 87).

An increase in the number of daily bowel movements over that occurring in the placebo group was reported by subjects in all of the olestra stiffness treatment groups except one (45 kPa/s). Twenty-seven percent of subjects in the placebo group reported an increased number of bowel movements per day compared to a range of 35 to 48 percent for olestra recipients (Ref. 87).

FDA agrees that, when reports of loose stools and diarrhea are analyzed separately, with only one exception, no statistically significant increase in either loose stools or diarrhea-like stools was reported among olestra recipients versus placebo recipients. However, as is the case with analysis of the GI symptoms in the two 8-week studies, FDA believes that it is appropriate to combine reports of loose stools and diarrhea for analysis. This is because the difference between loose stools and diarrhea-like stools may not have always been clear to the study

[61] Passive oil loss can occur when people consume large amounts of nonabsorbable oil that is liquid at body temperature, such as mineral oil or liquid olestra; liquid oil separates from other fecal material in the colon and leaks past the anal sphincter. The petitioner observed that early formulations of olestra caused passive oil loss, but that oil loss could be decreased by increasing the stiffness of olestra at body temperature. Stiffer olestra has less of a tendency to separate from the fecal matrix.

[62] The stiffness of olestra was characterized by measuring a rheological parameter called the thixotropic area, which is determined by measuring the shear stress on olestra as the shear rate is first increased and then decreased. The area between the ascending and descending shear stress versus rate curves is the thixotropic area. Olestra that is liquid at body temperature has thixotropic areas approaching zero. Highly saturated olestra that is largely solid at body temperature has thixotropic areas well above 100 kiloPascals/sec (kPa/s). In practical terms, olestra with a stiffness of 18 kPa/s had a consistency similar to a typical catsup at room temperature; olestra with a stiffness of 50 kPa/s has a consistency similar to mayonnaise; olestra with a stiffness of 103 kPa/s is similar to cold margarine.

[63] Transcript, vol. 4, p. 163.

[64] Statement of Dr. Joanne Lupton, Transcript, vol. 2, p. 222.

subjects and may be simply variable manifestations of the same effect. When reports of loose stools and diarrhea like stools are combined, the analysis shows that during the 5 day study, 42.3 percent (447/1056) of olestra recipients experienced loose stools or diarrhea-like stools compared to 33.1 percent (57/172) of placebo group subjects; this difference is statistically significant (P=0.03). (Ref. 87).

Finally, FDA notes that, in general, the results of analysis of the GI symptoms data in the oil loss study are consistent with those obtained in the 8-week studies. In addition, FDA agrees that, like the GI symptoms reported in the 8-week studies, GI symptoms in the oil loss study subside when olestra consumption is stopped. As discussed above, however, FDA does not agree with the petitioner that the GI symptoms experienced with olestra consumption are similar to those experienced with high fiber consumption.

3. Study of Selected Fecal Parameters in Subjects Consuming Olestra

a. *Study design.* The petitioner conducted a study designed to examine fecal composition of subjects reporting diarrhea when consuming olestra. Normal healthy males and females (18 to 60 years of age) were selected for the study from a population of subjects who had reported GI symptoms while consuming olestra in previous product acceptance studies. The study consisted of two phases. A screening phase was conducted to identify subjects who reported GI symptoms from olestra consumption. The second phase was a study phase during which the identified subjects ate different amounts of olestra and GI symptoms were recorded and fecal measurements were made.

The screening phase was a 4-week, cross-over design with two treatment groups, 0 and 20 g/d olestra. Fifty-two adults who had reported GI symptoms in previous olestra studies were recruited for the study. The olestra was substituted for 20 g of triglyceride in the three daily meals with roughly one-third of the dose provided in each meal. The study participants were acclimated to the study procedures during a 3-day baseline period in which they ate placebo meals. They were then divided into two groups and ate either placebo meals or meals providing 20 g/d olestra for 5 days. After a 7-day washout period, the subjects again ate placebo meals (containing triglycerides) for 3 days, and then crossed-over to olestra or placebo meals for 5 days. After the second treatment period, the subjects were monitored for a 4-day washout period. All meals during baseline, treatment, and washout periods were eaten under supervision at the clinical site.

The frequency, duration, and severity of nine predefined GI symptoms were documented daily by the subjects, starting at the beginning of the baseline period and continuing through the final 4-day washout period. Diarrhea was defined as "excessive frequency of very loose/watery stools that are extremely difficult or impossible to control." Loose stools were defined as "a bowel movement that is easier to pass than normal, but is not watery and unformed."

At the completion of the screening phase, those subjects who reported an increase in the frequency, severity, or duration of GI symptoms during the olestra period, relative to the placebo period, were selected to take part in the study phase. Eighteen subjects met the selection criteria.

The study phase was a crossover, placebo-controlled, single-blind (subject) design with three treatment groups, 0, 10, and 20 g/d olestra. Each subject received each treatment for 7 days. The treatment periods were separated by 7-day washout periods. Subjects ate all treatment meals under supervision at the clinical site, and ate their habitual diets at home during the washout periods.

GI symptoms were ascertained during the treatment periods and the first 4 days of the washout periods by GI assessment records completed daily by the subjects. For each GI symptom episode, the subject recorded the date, time of day, and intensity. The intensity scale for GI symptoms was graded as follows: 0 (none); 1 (slight); 2 (mild); 3 (moderate); and 4 (severe). Total fecal collections were made for the last 3 days of each treatment period and the daily collections were pooled. To complete the study and have data included in the analyses, a subject had to provide at least one fecal sample for each 3-day collection period.

Stools were collected into plastic containers and immediately frozen. Wet weight, volume, and density measurements were made on each stool. Fecal samples from each subject during the 3-day collection period were then pooled. Three-day pooled fecal samples for each subject were analyzed for water concentration, dry weight, olestra analysis, Na, K, Cl, total and individual bile acids, free fatty acids, triglycerides, and total lipids.

b. *Petitioner conclusions.* Of the 15 subjects completing the study, 6 subjects reported diarrhea while eating 20 g/d olestra. The petitioner concludes that this study further confirms that the diarrhea reported by subjects consuming olestra does not present potential for harm. This conclusion is based on the observation that there was no significant increase in stool weight, water content, or number of bowel movements per day for subjects reporting diarrhea while consuming olestra at 20 g/d.

c. *FDA conclusions.* The number of subjects who reported diarrhea increased with increasing dose of olestra; three subjects (20 percent) reported diarrhea while eating 0 g/d olestra, six (40 percent) subjects while eating 10 g/d olestra, and 11 (69 percent) while eating 20 g/d olestra. The difference in incidence of reported diarrhea between the 20 g/d and 0 g/d consumption levels was statistically significant. In addition, the mean number of diarrheal bowel movements per subject reporting any diarrhea and the severity of the diarrhea both increased with increasing olestra consumption. Although there was an increase in the number of subjects reporting loose stools with increasing olestra dose, this increase was not statistically significant. FDA concludes that these results are qualitatively similar to the results of the 8-week studies.

Measurements of the concentration of stool water and electrolytes (Na, K, and Cl) suggest these parameters did not differ in persons reporting diarrhea during the 20 g/d olestra period from those of their nondiarrheal stools during the placebo period. However, it was not possible to analyze stool electrolyte values by individual stools or by individual days because the stools were pooled from the 3-day collection period, as is normally done when measuring fecal parameters. FDA notes that there appears to be an increase weight of stools in those subjects reporting diarrhea when eating 20 g/d olestra that is not completely accounted for by the presence of olestra in the stools. FDA concludes that the results of this study indicate that there is no difference in stool composition (e.g., water and electrolyte content) between those subjects consuming olestra who reported diarrhea and those who did not (Ref. 88).

4. Study in Patients with Inflammatory Bowel Disease

The petitioner conducted a multi-center study in both ulcerative colitis (UC) patients and Crohn's disease (CD) patients. The objective of the study was to assess whether the presence of olestra in the GI tract exacerbates conditions in which the GI epithelium is compromised. Inflammatory bowel

disease (IBD) represents an extreme example of such a condition. In the study the petitioner conducted, 45 IBD patients with at least a 2-year history of diagnosed disease, who were in remission (21 UC and 24 CD), were given 20 g/d of olestra in cookies and potato chips for 4 weeks. Forty-four control subjects were given cookies and potato chips prepared with conventional vegetable triglycerides. At the end of the 4-week consumption period, the disease status of each patient was assessed and classified as in remission, worsened, or relapsed. Four weeks after the end of the consumption period, the patients were contacted by telephone and asked about the status of their disease. If judged appropriate, they were seen by the investigator. In addition, bowel permeability was assessed at the beginning and end of the consumption period by measuring urinary excretion of polyethylene glycol (PEG).

The petitioner stated that IBD patients are good surrogates in which to determine whether olestra will have an adverse impact on a wide range of GI diseases involving acute and chronic inflammation, ulcerations, and possibly a compromised intestinal barrier. The petitioner also asserted that this patient population was chosen because UC and CD are thought to be exacerbated by a range of stimuli, some of which may be dietary in nature. According to the petitioner, IBD patients in remission are also good models for people who are asymptomatic but who may have underlying predisposing conditions or subclinical GI diseases which, when exacerbated, may become active.

FDA agrees that a study in persons with IBD is useful to assess whether olestra may have adverse health effects on potentially sensitive subpopulations with bowel disease. FDA believes that persons with IBD are an appropriate target population for such a study because the disease is prevalent, because the acute disease status of such patients can be significantly influenced by factors that change bowel habits, and because such patients can have increased bowel permeability which, if further increased, could have long-range health significance.

The petitioner concluded that, in the placebo group, out of 44 subjects, 40 remained in remission, disease activity worsened for 4, and none relapsed. For the olestra group, out of 45, 41 remained in remission, disease activity worsened for three and one relapsed. The petitioner concluded that the relapse was not test-related. Further, hematologic parameters indicative of disease activity were not different between the groups. The one relapse was not unexpected and is consistent with the spontaneous relapse rate among IBD patients (about 30 percent per year (Ref. 89), or about 1 per month for the population size studied). There was no increase in bowel permeability in either the UC or CD patients. Because there was no difference between olestra and placebo groups in the number of patients whose disease activity worsened during the study, the petitioner concluded that consumption of 20 g/d olestra for 4 weeks did not affect disease activity of the IBD patients.

FDA notes that for any study with a small number of subjects and relatively low background relapse rate (e.g., 2.5 percent per month projected in the control group), an effect of treatment (olestra) compared with control (triglyceride) would be seen only if the effect was large (Ref. 90). Thus, the study can be used to address the possibility that consumption of 20 g of olestra per day will consistently—about 30 percent of the time - exacerbate IBD. The study gives some reassurance that consumption of olestra at 20 g/d for up to 31 days would not cause a large detrimental effect in special populations such as UC and CD patients. This study was too small and too brief, however, to rule out a moderate detrimental effect (e.g., relapse rates that are two or three times those of control) (Ref. 91).

5. GI Symptoms in Young Children

GI symptoms in the young were reported in three studies. Two of these, a study in 5 to 8-year-old children that lasted 7 days and another in 3 to 5-year-old children that lasted 5 days, were designed to address the potential effects of olestra on GI symptoms. The third study, while conducted to determine whether children (2 to 5 years of age) adjusted their energy intake in response to variations in the proportion of energy from dietary fats, also provided information on GI symptoms. In this third study, children consumed olestra for five 2-day periods over 5 weeks.

After reviewing the reports on GI symptoms from these studies, the petitioner concluded that there were no differences in incidence of any GI symptoms among treatment groups, and no significant health effects from consumption of olestra by children.

Potential GI effects in the young were discussed at the meetings of the Olestra Working Group and FAC. CSPI commented that the studies on children were too short to provide enough meaningful data on gastrointestinal problems.[65] In addition, Dr. Herbert Needleman stated that he had reviewed the petitioner's two 8-week studies and CSPI's White Paper on olestra and that he had concluded that olestra had not been demonstrated to safe for consumption by children.[66]

On the other hand, Dr. William Klish[67] stated that he had reviewed all the relevant data on olestra and concluded stated that olestra should in no way be considered harmful to children. Dr. Klish added that, while children are born with an immature gastrointestinal tract, their digestive and absorptive physiology, as well as gastrointestinal motility, are similar to that of an adult at about 1 year of age and therefore, the adult data on olestra can be extrapolated to children. Dr. Klish also noted that the feeding of a nonabsorbable oil to children has been occurring without adverse effects for at least the last 50 years in the form of mineral oil to treat constipation, a symptom seen frequently in children. (Mineral oil was normally given in doses of about 15 g to about 45 g/d for months or years in the child who is chronically constipated.)

Dr. Charles Hargrove, a pediatric gastroenterologist with whom FDA consulted regarding pediatric GI issues, stated that, in view of the physiologic maturity of the GI tract by 9 to 12 months of age, there should be no serious harmful effect in the toddler/preschool child if the consumer parent has appropriate labeling information to associate potential GI symptoms with olestra. He added that the differential diagnosis for numerous GI upsets in the young, i.e., loose stools, stomach cramps, would have to be expanded to include olestra despite the apparently low incidence of the latter, and that physicians should be made aware of olestra's potential to induce loose stools, for example, as they should be aware that apple or grape juice can produce loose stools in some toddlers.[68]

Dr. Ronald Kleinman, a pediatric gastroenterologist and a member of the Olestra Working Group concluded that olestra does not pose any danger to health in the young. He added that the effect of excessive consumption of

[65] Statement of Dr. Myra Karstadt, CSPI, Transcript, vol. 3, p. 9.

[66] Statement of Dr. Herbert Needleman, Professor of Psychiatry and Pediatrics, University of Pittsburgh School of Medicine. Transcript, vol. 3, p. 14.

[67] Statement of Dr. William Klish, Professor of Pediatrics at Baylor College of Medicine, Head of the Section of Gastroenterology and Nutrition at the Texas Children's Hospital in Houston, TX. Transcript, vol. 2, p. 260.

[68] Statement of Captain Charles Hargrove, M.D., Transcript, vol. 2, p. 225.

potato chips with olestra by children is analogous to "toddlers' diarrhea," one of the causes of which is excess fruit-juice consumption. Dr. Kleinman observed that just as the number of stools per day decreases when consumption of the fruit juice decreases, stools will begin to firm up once consumption of olestra-containing foods decreases. Dr. Kleinman noted that as is the case for many constituents of foods and foods currently available, some individuals who are intolerant to olestra or foods containing olestra include children, and that children, like adults, can relate symptoms to foods and will be able to stop eating such foods when they have reached a level of intolerance for it.[69]

FDA notes that, in general, the GI symptoms seen in the studies in children conducted by the petitioner are consistent with those seen in the 8-week studies in adults discussed above. Although the short duration of the studies in children makes it difficult to compare the GI effects to those seen in the 8-week studies in a meaningful way, FDA has concluded that the data regarding GI effects obtained in adults can be extrapolated to the young and that this approach is fully consistent with the expert views provided at the Olestra Working Group and FAC meetings. FDA also notes that despite CSPI's criticism that the studies in children were not of adequate length, CSPI did not contradict the basis for the agency's conclusion that extrapolation from studies in adults is appropriate.

C. Effect of Olestra on Intestinal Microflora Metabolism

Olestra passes intact through the colon where it has the potential to affect adversely the normal metabolic activity of the intestinal microflora. The indigenous microflora of the colon carry out a variety of reductive, degradative, and hydrolytic processes that are important to the host. Therefore, it is important to know whether consumption of olestra affects microflora populations, alters fermentation processes or normal microflora metabolism of host-produced substrates, or acts as a substrate for microflora.

1. Effect of Olestra on Breath Gas and Microflora-Associated Characteristics

The petitioner used an analysis of breath hydrogen as a noninvasive technique for studying microbial fermentation in the human colon under "normal" and "high" dietary fiber intakes (within the range recommended as "healthy" fiber intake in the United States), with and without olestra. An analysis of breath methane was also used in this study to provide additional information on microbial fermentation activity in methanogenic individuals.

In addition, because normal metabolic function of colonic microflora can be assessed by measurement of several endpoints of metabolic activity (microflora-associated characteristics[70]), the petitioner measured microflora-associated characteristics to provide additional information on the effect of the presence of olestra in the colon on normal bacterial metabolism.

The breath gas study was a parallel, double-blind, placebo-controlled study 5 weeks in length. The subjects were 97 normal healthy males and females from 18 to 58 years of age. Subjects were randomly assigned to four treatment groups. Following an 8-day baseline period during which subjects consumed a placebo breakfast low in dietary fiber, they were fed breakfast meals daily containing moderate (7 g) or high (24 g) levels of fiber, with 24 g of either olestra or triglyceride for 28 days. Breath gas and fecal samples were collected at the end of the baseline period and at the end of the test period. The breath gas samples were analyzed for hydrogen and methane. The fecal samples were examined for viable microbial counts and direct microscopic cell counts for fecal bacteria. (Fecal bacteria have been demonstrated to be directly representative of the indigenous human intestinal microflora and their metabolic activities.) In addition, the fecal samples were analyzed for microflora-associated characteristics.

The petitioner concluded that, although there was a trend toward lower breath hydrogen production in the olestra groups (20 percent reduction in the olestra high fiber group compared to placebo high fiber group) there were no statistically significant differences in cumulative breath hydrogen production between olestra and placebo groups. Further, the petitioner stated that olestra did not affect the total number of direct or viable counts of the fecal microflora. The petitioner also stated that olestra had no statistically significant effect on cumulative breath methane production following consumption of either the moderate or high fiber meal and that breath methane production values for individuals in the olestra groups were similar to individual values in the respective placebo groups.

According to the petitioner, olestra had no effect on fecal microbial counts, and did not interfere with the normal degradation of beta-aspartylglycine, mucin, or trypsin. The concentration and distribution of short chain fatty acids (SCFA) was not consistently or significantly affected by olestra, indicating the absence of an adverse effect on microbial metabolism. Finally, the petitioner stated that urobilinogen and coprostanol concentrations were not adversely affected by olestra consumption. The petitioner concluded that the results of this study demonstrate that olestra will not interfere with normal intestinal fermentation of dietary fiber.

FDA notes that the best direct information on microbial imbalances of concern would have been adequate direct microscopic cell counts and viable cell counts. Although these tests were performed, the data cannot be used due to improper handling of the samples (Ref. 92). The study did show that the microflora-associated characteristics that are generated by the majority of the bacterial genera found in the colon (e.g., the proteases, peptidases) and production of SCFA were not affected or only slightly affected by the presence of olestra in the GI tract. However, FDA's analysis of the data further shows lowering of hydrogen breath gas in some subjects, appearance of undergraded mucin in some subjects, a reduction of microbial formation of coprostanol from cholesterol, and reduced bilirubin conversion in those subjects consuming olestra (Ref. 92). FDA notes that these variations in microflora-associated characteristics are not different from those observed from dietary changes, for example, from low to high fiber diets, and that there are large variations in normal healthy subjects with respect to microflora-related parameters (Ref. 93). In addition, although there was some dampening of hydrogen production when olestra was added to a high-fiber diet, this dampening was not significant.[71]

2. Potential for Intestinal Microflora to Metabolize Olestra

The petitioner stated that the pivotal studies that demonstrate that olestra is not metabolized by microflora in the GI tract are a clinical study in humans and the rat absorption and metabolism

[69] Statement of Dr. Ronald Kleinman, Chief of the Pediatric GI and Nutrition Unit, Massachusetts General Hospital and Associate Professor of Pediatrics, Harvard Medical Center Dr. Kleinman was a temporary member of the FAC. Transcript, vol. 4, p. 177 and 192.

[70] Microflora-associated characteristics include degradation of beta-aspartylglycine and mucin, conversion of cholesterol and bilirubin to their respective metabolites, inactivation of trypsin, and production of short-chain fatty acids (SCFA).

[71] Statement of Dr. Joanne Lupton, Transcript, vol. 4, p. 87.

studies. The clinical study showed no production of radiolabeled metabolic breakdown products, and no changes in either olestra fatty acid composition or ester distribution following incubation of radiolabeled olestra with fecal microflora from humans who consumed 7 g/d olestra for up to 31 days.

As noted, in the rat absorption studies, virtually all radiolabel was recovered in feces and GI contents, with insignificant amounts recovered as metabolic byproducts in CO_2, urine, and tissues after animals were fed olestra for 28 days and then dosed with radiolabeled olestra.

The petitioner also submitted a published study (Ref. 94) that demonstrates that olestra is not metabolized by the microflora of the GI tract. In this study, radiolabeled (^{14}C-fatty acids) olestra was incubated for 72 hours in either minimal or organically enriched anaerobic media inoculated with feces from seven healthy subjects who had consumed 9 g/d of olestra for 3 to 4 weeks. The petitioner stated that no significant quantities of $^{14}CO_2$, $^{14}CH_4$, or ^{14}C-volatile fatty acids were detected during the incubation, indicating that olestra was not metabolized by colonic microflora. At the Olestra Working Group and FAC meetings, the petitioner also pointed out that human gut microflora have never adapted to breakdown fat or cellulose. In addition, the petitioner reasoned that because the breakdown of fat requires beta oxidation, which requires oxygen, it is unlikely that in the anaerobic environment of the human intestine, microorganisms will adapt to metabolize olestra.[72]

FDA notes that there is a hypothetical possibility that an organism capable of metabolizing olestra at a low level could arise among the intestinal microflora (Ref. 95). The *in vitro* study on minimal medium did suggest that olestra might be metabolized by microflora at a low level when olestra is the only carbon source (Ref. 95). Such conditions are unlikely to exist in the intestinal tract. Because of the possibility that olestra might be metabolized, FDA asked Dr. Joann Lupton, a consultant for FDA who specializes in the effect of diet on the GI tract, to review the breath gas and *in vitro* studies. Dr. Lupton did not observe any metabolism of olestra by microflora.[73] Dr. Lupton concluded that because no long chain fatty acids were released from the olestra, and because the olestra was actually recovered without any change in chain length or degree of saturation, olestra is not metabolized by the microflora (Refs. 96 and 97). Further, given the findings in the human and animal material balance studies (discussed in section III.A of this document), which showed that olestra was excreted quantitatively and was unchanged in the feces, FDA believes that the available evidence shows that there is no metabolism of olestra by the intestinal microflora.

D. Effect of Olestra on Bile Acid Metabolism

The petitioner submitted several published and unpublished studies in animals and humans to demonstrate that consumption of olestra will have no meaningful effect on the absorption, synthesis or excretion of bile acids. The studies included: (1) A 2-year rat study where olestra was fed at 5 percent of the diet and total fecal bile acid excretion was measured after 1, 2, and 24 months; (2) a study in rats on the effect of olestra on the absorption of chenodeoxycholic acid, one of the more lipophilic bile acids; (3) studies on the effect of olestra on bile acid excretion in humans ingesting 8 to 40 g/d olestra for 30 days or 90 g/d olestra for 37 to 55 days; (4) a study in rats on olestra s effect on biliary acid profiles; and (5) a study examining the effect of olestra on bile acid pool size and bile composition in African Green Monkeys.

The petitioner stated that olestra had no effect on the rate of recovery or the amount of chenodeoxycholic acid, that neither bile acid synthesis nor excretion are affected by olestra, that the absorption of bile acids is not affected by olestra, and that olestra had no effect on biliary or fecal bile acid profiles.

FDA reviewed the studies and, although some of the studies have limitations in experimental design or execution, has concluded that the studies as a whole show that olestra would not be expected to produce major changes in bile acid metabolism and absorption (Ref. 98).

E. Overall Conclusions on Effects on the GI Tract

The issues of potential concern with respect to the effect of olestra on the GI tract are: (1) The potential for loose stools or diarrhea to result in electrolyte and fluid loss; (2) whether the GI effects have the potential to interfere with normal daily life of consumers, (3) whether the GI effects seen are of special concern to subpopulations where proper fluid control is important (e.g., individuals with underlying cardiovascular or GI diseases, the young and the elderly); and (4) whether changes observed in microflora-associated characteristics associated with olestra consumption are meaningful to health.

These issues were discussed at the meetings of the Olestra Working Group and the FAC. After presentation and discussion of the data relating to the potential GI effects that olestra may cause, most members of the Olestra Working Group and FAC, including all of the gastroenterologists, felt that there was reasonable certainty of no harm with respect to the potential for olestra to cause GI effects.[74] These members felt that, while olestra may cause certain GI effects, including loose stools, these effects are not adverse effects because they do not threaten health. For example, effects described as "diarrhea" were not diarrhea in the medical sense because they were not associated with water loss or electrolyte imbalance.

On the question of whether the "diarrhea" experienced by subjects was diarrhea in the medical sense, the petitioner presented additional data on fecal water content to the Olestra Working Group.[75] (The study from which these data were derived is described in more detail in section VI.3. of this document). According to the petitioner, the results of the study showed that, even in olestra-consumers experiencing what they described as diarrhea, these subjects had no change in the stool water content, and also, no change in electrolytes or the pH of the stool; the only difference was that the stools of these subjects had more lipid, which was completely accounted for by the olestra consumed. Dr. Lawrence Johnson, a gastroenterologist member of the Olestra Working Group, agreed with the petitioner's analysis and stated that when one looks at stool by weight, the gross weight will increase because olestra is not absorbed and increases the weight of the stool. (Increased stool weight is one criterion for diarrhea.) Dr. Johnson added that one would next determine whether fat or fluid is responsible for stool weight increase. He noted that the amount of fluid in the stool was about 200 cc, which is the amount that would be in stool in normal physiologic amounts.[76] Dr. Joanne Lupton, the FDA consultant on GI issues, added that, in looking at the clinical data, the larger the proportion of the stool that is olestra, the softer the

[72] Transcript, vol. 1, p. 152. Accordingly, the petitioner concluded that there was no evidence of degradation of the olestra (i.e., no change in ester distribution or fatty acid composition) by intestinal microflora.

[73] Statement of Dr. Joanne Lupton, Transcript, vol. 2, pp. 216–226.

[74] Transcript, vol. 3, p. 78 and vol. 4, p. 196.

[75] Transcript, vol. 1, p. 112.

[76] Statement of Dr. Larry Johnson, Professor of Medicine and Director of the Digestive Diseases Division, Uniformed Health Service University, Transcript, vol. 4, p. 83.

stool is going to be but that there is no evidence of dehydration, or electrolyte imbalance in those subjects reporting "diarrhea".[77]

In addition, at the Olestra Working Group and FAC meetings, the question of whether olestra in the feces represented steatorrhea was raised. Drs. A. R. Colon and J. S. DiPalma[78] stated that initial human studies on olestra revealed steatorrhea, in addition to diarrhea, as an apparent dose-related side effect and that there were no data that assessed 72-hour fecal fat excretion or dose-steatorrhea correlations. In response to a question of whether the effects seen with olestra are steatorrhea and not diarrhea, the petitioner stated that the effects seen with olestra are unrelated to steatorrhea, which, according to the petitioner, is the presence of unabsorbed free fatty acids in the lower bowel which results in an osmotic and an inflammatory and irritative response in the bowel.[79] The petitioner stated that the only identified change between feces from subjects consuming olestra and those consuming triglyceride was that the lipid content of the stool in the olestra group was increased, an expected result because olestra is not absorbed and is excreted in the feces. The petitioner added that their analysis showed that there was no additional lipid in the stool of subjects consuming olestra.[80] Dr. Joanne Lupton agreed that the available data do not reflect any steatorrhea.[81]

FDA notes that steatorrhea (the passage of large amounts of fat in stool) usually occurs in conjunction with pancreatic disease and malabsorption syndrome. FDA has reviewed the data on the lipid content in feces of subjects consuming olestra and concludes that there was no evidence of steatorrhea in any subject in the study (Ref. 99). Most members also felt that consumers can deal with the GI effects of olestra in the same manner as similar effects caused by other foodstuffs in the food supply, i.e., by limiting intake of the material causing the effect. For this reason, most members felt that foods containing olestra should be labeled in a manner to alert consumers to the potential GI effects of olestra but also in a manner that will not preclude the consumers from seeking health care for more serious concerns. (Labeling for olestra is discussed in more detail in section VII. of this document.)

Based upon the available data and information, FDA concludes that consumption of olestra causes GI symptoms such as bloating, loose stools, abdominal cramps, and diarrhea-like symptoms. There is no clear association between the onset of these effects and time of ingestion. In some cases, the effects occurred the few first days of consuming olestra products; in others, such products were consumed for several weeks before effects were seen. In addition, there were some people in whom the effects never were reported. With some consumers, the olestra-induced effects were seen at low olestra doses and with others, it took a higher dose to elicit the effects. In addition, the agency notes that few individuals reporting GI symptoms in the olestra clinical studies dropped out of the studies because of the symptoms and that study subjects were able to carry out their daily functions while they were on the studies.

While olestra caused GI effects such as those mentioned above, there is no evidence that these effects represent adverse health consequences. The effect of olestra on stool consistency is similar to that produced by liquid petrolatum, which softens fecal contents and interferes with the development of firm, well-formed stools. The "diarrhea" experienced by the study subjects was not diarrhea in the medical sense because it was not associated with loss of water or electrolytes. Indeed, those subjects who experienced loose stools or diarrhea continuously¶for several weeks during olestra consumption did not show any evidence of fluid loss such as hemoconcentration or electrolyte imbalance. This is consistent with published studies (Refs. 80 and 81) that show that olestra does not significantly alter gastric emptying or overall GI transit time.

With respect to whether olestra's potential to cause diarrhea-like symptoms or loose stools raises concern for special subpopulations where proper fluid and electrolyte control is important, FDA notes that, as discussed above, the soft stool and "diarrhea" appear to be caused by disruption of the fecal matrix and are not associated with clinical signs of fluid loss, which is the case in classical diarrhea. Therefore, FDA has determined that there is no basis to conclude that these subpopulations would be at special risk due to consumption of olestra.

FDA recognizes that nutritionists generally do not recommend reduced-calorie products for consumption by children. Nevertheless, there is the potential that olestra-containing products may be eaten by children. Although the studies FDA reviewed with respect to the effect of olestra on GI symptoms in the young were not sufficiently long, FDA notes that the GI physiology of children older than approximately 9 months is comparable to that of adults[82] (Ref. 100). Therefore, FDA concludes that there is no basis to conclude that the effect of olestra on the GI tract would be any different in children than in adults, and thus, the results of studies conducted in adults to address the effects of olestra consumption on the GI tract can be extrapolated to the young (Ref. 101).

With respect to differences seen in microflora-associated characteristics as a result of olestra consumption, FDA notes that such variations are no different than those observed with other dietary changes (for example, from low to high fiber diets), and that there are large variations in normal healthy subjects with respect to microflora-related parameters. Also, FDA believes that the available evidence shows that there will be no significant metabolism of olestra by the intestinal microflora. Therefore, FDA concludes that, collectively, the data do not establish an adverse effect of olestra consumption on microbial metabolism or function.

Notwithstanding the fact that FDA finds no safety concerns with respect to the effect of olestra on the GI tract, FDA believes that it is important for consumers to be aware of the GI symptoms associated with ingestion of olestra-containing foods so that they are able to associate olestra with the GI symptoms that it may cause. This information would also preclude unnecessary concerns and inappropriate medical treatment. Appropriate labeling for olestra-containing foods is discussed in section VII. of this document.

VII. Labeling of Foods Containing Olestra

As discussed above, because olestra is not absorbed and passes through the GI tract intact, it affects the absorption of certain fat-soluble vitamins and nutrients, which partition into it. Olestra also has the potential to cause certain GI effects such as abdominal cramping and loose stools. The agency has considered whether these effects warrant special labeling of foods containing olestra. As discussed in detail below, FDA has determined that

[77] Statement of Dr. Joanne Lupton, Transcript, vol. 3, p. 89.

[78] Letter from Drs. A. R. Colon and J. S. DiPalma, Georgetown University Medical Center, read at the FAC meeting; Transcript, vol. 3, p. 19.

[79] Statement of the petitioner, Transcript, vol. 1, p. 141.

[80] Transcript, vol. p. 97.

[81] Statement of Joanne Lupton, Transcript, vol. 3, p. 24.

[82] Statements of Drs. Charles Hargrove and Dr. William Klish, Transcript, vol. 2, pp. 226 and 260, respectively.

foods containing olestra shall be labeled with the following statement:

This Product Contains Olestra. Olestra may cause abdominal cramping and loose stools. Olestra inhibits the absorption of some vitamins and other nutrients. Vitamins A, D, E, and K have been added.

A. Labeling Authority

Under the act, the agency has the mandate to ensure that labeling provides truthful and nonmisleading information to consumers. Thus, the law provides the agency with authority to require specific label statements when needed for reasons other than to ensure the safe use of food. [83] Specifically, section 409(c)(3)(B) of the act (21 U.S.C. 348 (c)(3)(B)) prohibits FDA from approving a food additive if the proposed use would result in the misbranding of food within the meaning of the act (21 U.S.C. 348(c)(3)(B)). Under section 403(a)(1) of the act (21 U.S.C. 343(a)(1)), a food is misbranded if its labeling is false or misleading in any particular.

Section 201(n) of the act (21 U.S.C. 321(n)) amplifies what is meant by "misleading" in section 403(a)(1) of the act. Section 201(n) of the act states that in determining whether labeling is misleading, the agency shall take into account not only representations made about the product, but also the extent to which the labeling fails to reveal facts material in light of such representations made or suggested in the labeling or material with respect to consequences which may result from use of the article to which the labeling relates under the conditions of use prescribed in the labeling or under such conditions of use as are customary or usual (see 21 CFR 1.21). Thus the omission of certain material facts from the label or labeling of a food causes the product to be misbranded within the meaning of 21 U.S.C. 343(a)(1) and 321(n). In general, the agency believes the concept of "material fact" is one that must be applied on a case-by-case basis. The agency has required special labeling in cases where information is necessary to ensure that consumers are aware of special health risks associated with consumption of a particular product. For example, although protein products intended for use in weight reduction are not inherently unsafe, FDA requires a warning statement for such products that states, in part, that very low calorie protein diets may cause serious illness or death. Another example of required information is the use of the term "milk derivative" following the ingredient declaration of sodium caseinate when used in a product labeled "non dairy" (21 CFR 101.4(d)).

FDA believes that such a labeling statement is appropriately established as part of the rulemaking for a food additive approval under section 409 of the act. As noted, under section 409(c)(3)(B) of the act a food additive regulation cannot issue if the available data show that "the proposed use of the additive would *** result in *** misbranding of food within the meaning of the Act." Thus, the status of foods containing a particular additive, in terms of misbranding under the act, is always an issue to be considered and determined by the agency for each food additive petition. (In most cases, the proposed use of the additive presents no issue regarding misbranding of foods that contain the additive.) Accordingly, the notice of filing of a food additive petition published under 21 U.S.C. 348(b)(5) necessarily includes notice that proper labeling under the act of foods containing such additive is a question before the agency. In the case of olestra, the notice of filing published in the **Federal Register** of June 23, 1987 (52 FR 23606), was a public announcement that the olestra food additive petition had been filed, and that all issues regarding the approval of the proposed use, including the proper labeling of foods containing olestra, would be considered by FDA. [84]

As discussed below, FDA has determined that all foods containing olestra should bear a label disclosing olestra's GI effects and its effects on nutrients, and disclosing that certain vitamins have been added back. The agency believes that these labeling statements can be imposed as final requirements as part of the food additive petition process of section 409 of the act, and that it is important that once approved, products containing olestra be properly labelled so as not to be misbranded. Thus, FDA is imposing an immediately effective labeling requirement. However, the agency acknowledges the importance of the opportunity for interested members of the public to express their views on the labeling for olestra. In addition, the petitioner, Procter & Gamble, intends conduct focus group testing of the required olestra label (Ref. 103). Accordingly, the labeling requirement for foods containing olestra, while immediately effective, is an interim requirement only. The agency requests comments on this label from interested persons, on such issues as the need for such labeling, the adequacy of its content, the agency's word choice, and the configuration of the label. Three copies of such comments shall be submitted to the Dockets Management Branch (address above) April 1, 1996. FDA will then evaluate and respond to any comments received, as well as any studies or other information from focus group testing conducted by the petitioner. As noted below, under section 409(f)(1) of the act, interested persons have the opportunity to file objections to the final rule; such objections shall be filed within 30 days of the final rule, and shall conform to certain requirements in terms of format and content, which are articulated below. Commenters on the labeling for olestra who intend their comments to be treated and function as objections under section 409(f)(1) of the act shall conform to the time restrictions, format, and content requirements for objections. Any labeling comments received more than 30 days from the date of this final rule and any comments not otherwise conforming to the requirements for objections shall be considered by FDA as simply a comment and not an objection under 409(f)(1) of the act and addressed by the agency accordingly.

In these circumstances, FDA has concluded that it is appropriate for the agency to establish labeling requirements for olestra-containing foods that are effective concurrent with the promulgation of a final rule regulating the additive.

B. Labeling with Respect to GI Effects

As discussed in section VI. of this document, consumption of olestra may cause GI symptoms such as abdominal cramping and loose stools. However, there is no evidence that these effects represent adverse health consequences. As noted, the effect of olestra on stool consistency is similar to that produced by mineral oil, which softens fecal contents and interferes with the development of firm, well-formed stools. Further, the "diarrhea" experienced by the study subjects was not diarrhea in the usual medical sense because it was not associated with loss

[83] Under section 409(c)(1)(A) of the act (21 U.S.C. 348(c)(1)(A)), the agency has the authority to prescribe the conditions of safe use of a food additive, including the authority to require label statements needed to ensure safety. Thus, in a food additive regulation, the agency may rely on this provision for requiring statements to appear on labels of products containing food additives. In the case of olestra, however, FDA is not requiring the labeling of olestra-containing foods in order to ensure the safe use of olestra.

[84] FDA's regulation regarding the failure to reveal material facts, (21 CFR 1.21), states that "affirmative disclosure of material facts *** may be required, among other appropriate regulatory procedures, by *** regulations in this chapter promulgated pursuant to section 701(a) of the act; or direct court enforcement action (emphasis added)." Thus, establishing a requirement for a label statement for olestra-containing foods as part of a section 409 proceeding is consistent with 21 CFR 1.21.

of water or electrolytes. Nonetheless, while the agency has concluded that based upon the evaluation of the available evidence there are no safety concerns with respect to the effect of olestra on the GI tract, the agency believes that consumers should be provided with information to enable them to associate olestra with the GI symptoms that it may cause. The agency believes that providing this information to consumers would preclude unnecessary concerns about the origin of GI effects, were they to be observed, and may also prevent unnecessary or inappropriate medical treatment of those symptoms. Accordingly, FDA has determined that the relationship between GI symptoms and consumption of foods containing olestra is a fact that is material in light of the consequences of consuming olestra in savory snacks. In such circumstances, this relationship must be disclosed to consumers consistent with sections 201(n) and 403(a)(1) of the act.

C. Labeling with Respect to Effects on Nutrients

As discussed in section V. of this document, olestra interferes with the absorption of the fat-soluble vitamins A, E, D, and K and therefore, these vitamins will be required to be added to olestra-containing foods to compensate for that amount of the vitamins that is not absorbed due to olestra's effects. As required under section 403(i)(2) of the act, these vitamins will be declared in the ingredient listing.

The added vitamins, however, may not be considered in determining nutrient content of the food for the nutritional label or for any nutrient claims, express or implied. This is because the added vitamins will simply compensate for the amounts lost due to decreased absorption of the vitamins from other foods but will not contribute significant amounts of these vitamins to the diet. In other words, the purpose of adding the four fat-soluble vitamins is to ensure that no significant change in vitamin availability (neither decrease nor increase) occurs.

Olestra also decreases absorption of some lipophilic carotenoids, which can lead to lower serum levels of those nutrients. As noted, the agency has concluded that supplementing olestra with vitamin A will compensate for olestra's effects on the provitamin A function of carotenoids. Except for the provitamin A function (which is taken care of by addition of vitamin A), other specific health benefits for carotenoids have not been established.

As noted, labeling may be considered misleading not only if it fails to reveal facts that are material in light of consequences which may result from use of a food, but also if it fails to reveal facts that are material in light of representations made. As discussed above, FDA concludes that no consequences will result from inhibition of lipophilic nutrients by olestra because vitamins A, D, E and K will be added back to compensate. However, the mandatory listing of these vitamins on the ingredient statement could confuse consumers by implying that the food would provide significant amounts of these vitamins. Therefore, FDA is requiring a statement indicating that olestra inhibits the absorption of vitamins and other nutrients to set the context for why they are added. FDA is including the term other nutrients because any nutrient that is as lipophilic as these vitamins would also be affected, although there is currently no basis for adding them back. Thus, in light of the disclosure in the ingredient statement that vitamins A, D, E, and K have been added, FDA has determined that the label statement explaining such compensation must be made.

FDA is not requiring a specific statement on carotenoids in this labeling statement because doing so could falsely imply that their decreased absorption is known to be of significance. As stated previously, the current evidence does not show that inhibition of carotenoid absorption would result in any significant health consequences. This decision is consistent with FDA's policy for nutrient content claims, as required by 21 CFR 101.54. In that regulation, claims that a food is a "good source" of, "high" in, or contains "more" of a nutrient can be made only if the difference is significant with respect to a recommended daily intake (RDI) or daily reference value (DRV) for a nutrient, as established by regulation, so that consumers are not confused by implications that are of no nutritional significance. Such claims may not be made for substances for which a RDI or DRV has not been established. FDA believes that its policy concerning when a company may state that a food provides more of a nutrient should guide FDA in when it requires a company to disclose that a food would decrease availability of a nutrient. Therefore, FDA concludes that the label of foods containing olestra should not state that olestra inhibits the availability of carotenoids because to do so may imply that the inhibition of carotenoid absorption is of nutritional significance.

D. FAC Discussions Regarding Labeling

1. GI Effects

Both the Olestra Working Group and the FAC discussed the importance of labeling that would disclose the association between olestra and the additive's potential GI effects. The FAC members agreed with the agency that it is important that consumers be able to associate the GI effects that olestra may cause with the additive. Committee members, however, recommended some amendments to a tentative label statement discussed at the FAC meeting ("Foods containing olestra may cause intestinal discomfort or a laxative effect").

First, members of the Committee suggested [85] that the label read "Olestra may cause***" instead of "Foods containing olestra may cause***" to make clear that the GI effects experienced are caused by the additive, olestra. The agency agrees that the suggested change results in a clearer and more succinct label, and thus is following this suggestion.

Second, some Committee members felt that significant increases in the frequency of GI effects were seen only at the higher olestra doses (20 and 32 g olestra/day) in the 8-week studies (see discussion in section VI.B.1 of this document) and therefore, that the label statement should be amended to state that it is excess consumption of olestra that may cause the GI symptoms. [86] Others felt that a test of trends might show a dose-response effect, i.e., that the more olestra one consumes the more one experiences symptoms; in addition, significant differences might be observed at eight g/d olestra if the power of the study was increased sufficiently. [87]

The agency agrees that there is a clear dose response effect with respect to olestra's ability to elicit GI effects. The agency also agrees that the lack of statistical difference between the placebo group and the eight g/d group in the two 8-week studies might be due only to the lack of power of the studies. In addition, the agency notes that consumption of 20 g/day olestra (equivalent to two 1-oz bags of potato chips, for example), for which there was a clearly significant difference from the placebo group with respect to GI effects, may not be considered excessive consumption by many consumers. As noted above, a scenario-driven estimate of 20 g/p/d, based on consumption of 2 oz of chips per day is a reasonable

[85] Transcript, vol. 3, p. 91.
[86] Transcript, vol. 3, p. 93.
[87] Transcript, vol. 3, p. 52.

estimate of a "short-term" high consumer. Therefore, the agency does not agree that the label statement should be amended to indicate that only excessive consumption could lead to GI symptoms.

Third, some Committee members expressed concern that the presence of a label statement could lead some consumers to disregard GI symptoms caused by factors other than olestra consumption and that erroneous attribution to olestra might unnecessarily cause them to delay consulting their healthcare provider.[88] Therefore, several Committee members recommended that a second sentence be added to the proposed label to advise consumers that they should consult their healthcare provider should symptoms persist after consumption of olestra-containing foods ceases.

Data submitted in the petition show that GI symptoms caused by olestra do not persist more than 2 days after consumption of olestra ceases. Thus, the agency agrees that persistent GI symptoms are unlikely to be related to consumption of olestra. Nevertheless, the agency believes that it should not require a label to bear information about medical advice unrelated to the food in the package.

Finally, some Committee members questioned whether it is appropriate to refer to the stool softening effect of olestra as a "laxative effect."As discussed above, the effect of olestra on stool consistency is similar to that produced by mineral oil, an over the counter laxative that works by lubricating the intestinal tract, softening the fecal contents, and facilitating the passage of feces. However, unlike mineral oil, olestra would be consumed for a purpose other than its potential laxative effect. In this case, FDA believes that requiring use of the term laxative may imply the therapeutic use of a laxative.

Therefore, instead of the term "laxative effect," the agency believes it is more appropriate to use "may cause loose stools" on the label to indicate clearly to consumers, olestra's potential to affect stool consistency.

2. Fat-Soluble Vitamins and Carotenoids

Some Committee members felt that consumers, upon seeing vitamins A, E, D, and K in the ingredient listing of olestra-containing foods, could be confused into thinking that the product is fortified with these vitamins. Therefore, they suggested that the ingredient list ought to contain a parenthetical note explaining that the vitamins were added to restore what would be lost due to olestra's interference with vitamin absorption.[89] Other Committee members recommended that the agency handle this issue consistent with similar prior cases.[90]

With respect to olestra's potential to decrease the bioavailability of carotenoids, most members of the Committee agreed with the agency that, given the current state of knowledge, the observed degree of reduction in carotenoid bioavailability does not raise concern. Given this conclusion, most Committee members further agreed that the effect of olestra on the bioavailability of carotenoids is not a fact material in light of consequences that may result from consumption of foods containing olestra and therefore, does not warrant disclosure on the labels of such foods.[91] Others felt that it was necessary to inform consumers that consumption of olestra may lower serum carotenoid levels.[92]

The agency notes that there are no prior cases on which to base how labeling with respect to the vitamins that are added to olestra-containing foods might be handled. The agency has not previously approved an additive which interferes with the absorption of vitamins to a degree that necessitates requiring that foods containing the additive be compensated with such vitamins to mitigate the effect of olestra.

As stated above, the agency believes that consumers who see the added vitamins listed on the ingredient listing could be misled and believe that the food is fortified with the vitamins unless they are given information explaining why the vitamins are added to the olestra-containing food. Therefore, the agency believes that the fact that the olestra inhibits vitamin absorption and that vitamins have been added back are material facts that should be disclosed to consumers.

E. Agency Conclusions Regarding Labeling of Foods Containing Olestra

Based on the entire record before the agency, FDA has concluded that foods containing olestra should bear the following label statement:

This Product Contains Olestra. Olestra may cause abdominal cramping and loose stools. Olestra inhibits the absorption of some vitamins and other nutrients. Vitamins A, D, E and K have been added.

In the absence of such labeling, the agency would consider olestra-containing foods to be misbranded (21 U.S.C. 343(a) and 321(n)). FDA believes that this information will be used by consumers both in their decisions on purchases and to help them adjust their consumption to minimize side effects. To ensure that the required labeling statement will be readily recognized and easy to read, FDA is requiring a standardized format that specifies among other things, type style and type size. FDA's recent experience with graphic requirements for the new Nutrition Facts label, as well as focus group discussions of the new Nutrition Facts label requirements, show that messages put in a boxed area help consumers distinguish the message from other information as well as draw attention to it (see 60 FR 67176 at 67181, December 28, 1995). Therefore, FDA is requiring that the message on the label of olestra-containing foods be surrounded by a box. Additionally, FDA is also specifying the minimum type size to ensure proper prominence. FDA welcomes any comments on the adequacy of this label requirement, including the format, as it reassesses this interim rule.

The agency would not object to any additional truthful nonmisleading information that a manufacturer may wish to include in the label statement, including, for example, a telephone number that consumers can call to obtain additional information regarding GI effects caused by olestra or olestra's effect on the absorption of fat-soluble nutrients.

VIII. Response to Comments

FDA received approximately 2,300 comments on the olestra petition. Comments were received from health care professionals, scientists, nutritionists, members of academia, consumer organizations, and professional associations as well as individual consumers. These comments, together with the Olestra Working Group and the FAC deliberations on the issues raised by the comments, have been taken into account in FDA's final decision on the olestra petition.

Most of the comments opposing olestra's approval (about 2,000 comments) were from individual consumers who identified themselves as members of CSPI and simply stated that fat substitutes must be absolutely safe and urged the agency to reject the "petition to approve the unsafe fat substitute olestra." These comments did not provide any factual information or any rationale to support the opinion expressed. Because these comments raise no factual issue, they will not be discussed further.

[88] Transcript, vol. 3, p. 90.

[89] Transcript, vol. 3, p. 218, 259, 261.

[90] Transcript, vol. 3, p. 263.

[91] Transcript, vol. 3, p. 271.

[92] Transcript, vol. 3, p. 258.

Most of the remaining comments opposing olestra's approval (the majority of which were form letters with some of the writers declaring affiliation with CSPI) expressed similar views on one or more of the following issues that were discussed extensively at the meetings of the Olestra Working Group and the FAC: (1) The potential for olestra to cause GI effects (including the nature of the GI effects); (2) the potential for olestra to deplete fat soluble vitamins, carotenoids, and other phytochemicals, and ¶whether such depletion increases the risk for certain cancers and other diseases such as coronary heart disease, stroke, macular degeneration, and other eye diseases; (3) whether adding vitamins to olestra-containing foods to compensate for depletion is efficacious or raises vitamin toxicity issues; (4) whether olestra, with or without supplemented vitamin K, interferes with coumadin therapy; (5) whether labeling with respect to GI issues and nutrient issues should be required for foods containing olestra (including the nature of the information that should be included in the label statement); (6) adequacy of the length of the studies to assess long term effects of olestra consumption and whether adequate studies have been conducted in special populations; (7) whether liver lesions seen in two rat studies and lung tumors in one mouse study are meaningful to human health; (8) whether vitamin A-supplemented olestra raises teratogenic concerns; and (9) whether the petitioner's estimates of olestra intake from savory snacks are credible.

Because the agency's analysis of these comments has already been incorporated at the appropriate places throughout this document, that analysis will not be repeated here. Comments raising issues that have not been previously discussed in this document and the agency's responses are given below.

The agency also received many comments supporting the approval of olestra. These comments were from individual consumers as well as scientists, clinicians, and nutritionists. Several of the comments cited problems with obesity in the population and the need for a fat replacer such as olestra and that the health benefits from lower fat intake far outweigh the perceived adverse side effects. These comments stated that under the intended conditions of use, olestra is safe and that it provides those who wish to use products made with olestra with an option for low fat, low saturated fat salty snacks. One comment signed by nine scientists and clinicians countered point-by-point arguments made in the CSPI White Paper; the comment added that their in-depth review of the olestra research program shows that olestra is safe for use as a fat replacer. Other comments stated that the Olestra Working Group and FAC meetings were conducted in an open and fair manner, that the meetings permitted a thorough exchange of scientific information, that all issues were adequately addressed, and that the commenters concurred with the majority of the FAC members who concluded that olestra was safe for its intended use.

A. Comments on Procedures

CSPI made several comments about the agency's process for review of the olestra petition. None of these procedural comments raise issues regarding the olestra safety data. Nevertheless, because the agency greatly values public participation and has provided a substantial opportunity for such participation regarding FDA's review of the olestra petition, FDA is addressing these procedural comments in this preamble. Importantly, however, none of these comments, even if correct, undermines the agency's safety determination here.

1. One comment from CSPI stated that the period allotted for comments following the Olestra Working Group and FAC meetings of November 14 through 17, 1995, was unjustifiably brief. The comment added that the comment period was too brief a time for review of transcripts and other data to prepare a thoughtful and complete postmeeting comment. The comment suggested that an additional 50 days be provided for comment.

The point raised by this comment is moot because FDA granted CSPI additional time (Ref. 105) to prepare its comments. The agency notes that CSPI did submit extensive comments prepared after the Olestra Working Group and FAC meetings on December 1, 1995, the date for submission of comments announced in the **Federal Register** of November 16, 1995 (60 FR 57586), the deadline to which CSPI objected. The agency granted CSPI additional time because the agency accepted CSPI's representation that it needed additional time to obtain and review a new study presented by the petitioner at the Olestra Working Group and FAC meeting, and to prepare comments on the study. The data were delivered to CSPI on December 8, 1995, with the letter extending the time for submission of comments (Ref. 105). FDA notes that CSPI submitted additional comments on December 21, 1995, but that these additional comments did not mention the new study.

2. One comment from CSPI asserted that FAC members could not reach well-reasoned positions because they did not receive copies of CSPI's White Paper until noon on Friday, November 17, 1995.

The agency believes that both Working Group and FAC members had sufficient access to CSPI's White Paper and the organization's views and thus, FDA does not agree with this comment. FDA distributed copies of a revised draft that the agency had received from CSPI the week preceding the November meetings to each Olestra Working Group member, guest, or consultant prior to convening of the Olestra Working Group meeting. Nine FAC members served on the Olestra Working Group and received copies of the CSPI White Paper. Also, several other FAC members attended part or all of the Olestra Working Group meeting and therefore, heard CSPI's presentations and responses to questions during the Working Group meeting. Thus, the assertion that *no* Committee member had access to or time to consider CSPI's views prior to noon on Friday, November 17, 1995, is incorrect. [93]

Finally, it is important to consider the roles of the FAC and the Olestra Working Group. The Olestra Working Group was composed of FAC members with expertise directly relevant to the safety issues for olestra and of additional temporary members with needed expertise not available from standing FAC members. FDA fully expected that this specialized subgroup would conduct the focused consideration of the olestra petition; under the FAC charter, however, subgroup views can only be passed on to FDA through the full FAC. Thus, the purpose of the FAC meeting was to apprise FAC members of the Working Group discussion, and for the FAC to consider whether to pass the Working Group views on to FDA, to pass the views on with additional commentary, or to return the matter to the Working Group for further discussion.

3. One comment from CSPI challenged the way in which

[93] In addition, CSPI itself selectively sent a draft of the White Paper document to 11 of the standing 18 FAC members who participated in the Friday, November 17, 1995, meeting. (This direct distribution was squarely contrary to the applicable regulations, 21 CFR 14.35(d).) Of the other seven, two were also members of the Working Group and received copies of the revised draft on the first day of that meeting. Three of the seven attended the Working Group meeting (and therefore heard CSPI's oral presentations). Only 2 of the 18 FAC members potentially were unaware of CSPI's written or oral views until the public hearing on the morning of Friday, November 17, 1995.

consultants and special, temporary members were appointed to the Olestra Working Group and FAC. CSPI contended that FDA failed to consider experts on vitamin K and carotenoids that CSPI had suggested for the Olestra Working Group, and that FDA did not appoint any other experts in those subject areas to either the Working Group or the FAC. CSPI alleged that therefore, the FAC was ill-prepared to discuss these matters.

The agency carefully considered CSPI's suggested experts on carotenoids and vitamin K. However, several of these experts had already provided written views on the issues to CSPI (apparently in response to a solicitation by CSPI). Statements by some of these experts were included as part of CSPI's mailing to selected FAC members, and statements by some or all of these experts were included in materials distributed during the Olestra Working Group and FAC meetings. Because the individuals appear to have had previously established views regarding olestra, FDA concluded that they could not appropriately be included in the Olestra Working Group. Furthermore, there is no reason to believe that the nutrition (10 members or consultants) and toxicology (3 members) experts participating at the Committee meeting were not able to comprehend or interpret the information and views on carotenoids and vitamin K presented orally or in writing by experts on behalf of either CSPI or the petitioner.

4. Another comment from CSPI argued that Dr. Fergus Clydesdale was an inappropriate choice as chair of the Olestra Working Group, asserting that Dr. Clydesdale had a pro-industry stance.

First, it is significant to note that CSPI does not allege that Dr. Clydesdale conducted the Olestra Working Group meeting unfairly or did not allow for an open and orderly exchange of views. Second, FDA notes that all advisory committee members undergo an evaluation for conflicts of interest with respect to specific issues to be presented to a committee. Dr. Clydesdale was subjected to that review, and his participation was ultimately determined to be consistent with the applicable conflict of interest laws and regulations.

5. A comment from CSPI asserted that FDA's interpretation of conflict of interest is too restrictive in that it only applies to interests in the petitioner or its competitors. CSPI would disqualify any member who holds strong views, pro or con, regarding the food industry or food additives.

FDA believes that the agency's policies, procedures, and practices comport with the applicable conflicts of interest laws and regulations and thus, disagrees with CSPI's comment on this point.

6. CSPI also claimed that the amount of time Olestra critics were allotted at the Olestra Working Group and Committee meetings was insufficient in contrast to the "ample amounts" of time given to the petitioner and to FDA staff.

FDA disagrees with this comment for several reasons. First, the agency believes that the appropriate question is whether there was ample opportunity for public participation, not whether a particular participant had enough time. Second, CSPI was provided with substantial opportunities to present its views to both the Olestra Working Group and Committee, much more than customarily provided to any single group or individual during advisory committee public hearings and much more than that provided to any other group or individual during the public hearing portions of the meetings.

FDA notes that at a typical advisory committee meeting concerning a product approval application or petition, FDA presents its analysis of the data, and the applicant/petitioner is permitted to "defend" its application or petition. Although there is always a public hearing portion to the meeting, the bulk of the meeting is devoted to Committee discussion, including questioning by committee members of FDA, the applicant/petitioner, or other presenters.

FDA policy is to provide a minimum of 1 hour of public hearing time at each advisory committee hearing. Because of the substantial interest in olestra, and because FDA desired comments focussed on specific issues, considerably more public hearing time that the minimum was allotted. (A total of nearly 6 hours of public hearing time occurred during the Olestra Working Group and FAC meetings.) A significant portion of that time was allotted to CSPI or other participants who presented views consistent with those of CSPI. In addition to time specifically allotted to it, CSPI was permitted to respond to questions posed by the Working Group and the FAC. Finally, CSPI participated in an unscheduled public hearing session along with the petitioner near the close of the FAC meeting.

7. One comment urged that the FAC should be reconstituted because of a perceived strong pro-industry orientation of its members and Dr. Clydesdale (chair of the Working Group), and the "lack of consumer health activists." The comment added that advisory committees should include "a preponderance of public-health advocates" in order to provide the best advice to the agency.

FDA disagrees with this comment. FDA appoints Committee members based on their scientific, medical, or other technical expertise, members are screened before each meeting with respect to conflict of interest in the particular matters to be brought before them, and members are expected to provide an unbiased evaluation of the information presented to them. Furthermore, consumer representatives were members of both the Working Group and the FAC, members who were nominated by a consumer consortium for consideration by FDA. Finally, the FACA requires that advisory committees be fairly balanced. The agency believes that both the Working Group and the FAC meet this standard. Thus, FDA does not agree with this comment.

8. One comment from CSPI stated that the Committee could not formulate well-reasoned positions because CFSAN staff failed to provide Committee members with a study published in the *American Journal of Clinical Nutrition* 2 months earlier demonstrating that 3 g of olestra caused remarkable declines in serum carotenoid levels, and a second study published in the *New England Journal of Medicine* in early November that found a strong correlation between low lycopene levels in blood and optic neuropathy. In addition, the comment stated that CFSAN staff failed to mention that olestra caused premature liver foci in rats and a statistically significant increase in lung tumors in male mice and further failed to provide any evidence that carotenoids may reduce the risk of cancer, cardiovascular diseases, and age-related macular degeneration.

The agency disagrees with this comment in its entirety. First, with regard to the first published study, the agency notes that the effect of olestra on serum carotenoids was discussed at length at the Olestra Working Group and FAC meeting. Not only were the results of the study cited by the comment presented by CSPI, a study conducted by the petitioner showing olestra effects on serum carotenoids that were much greater than those shown in the cited study were presented by FDA.

With regard to the second published study, FDA notes that CSPI and other presenters submitted and presented detailed information regarding the potential relationship between carotenoids and disease, and after consideration of this information, most Olestra Working Group and FAC members determined that there is a reasonable certainty of no harm with

respect to olestra's effects on serum carotenoids.

Finally, with regard to liver foci and lung tumors, FDA presented data on olestra's effect on liver foci in rats and in on lung tumors in male mice. In addition, this topic was thoroughly discussed at the Olestra Working Group and FAC meetings.

B. Substantive Comments

9. One comment questioned whether an acceptable daily intake (ADI) based on a "no observed-effect level" has been established for olestra. One comment asserted that even applying even a minimal safety factor of 10 to the 8 g/d consumption level tested by the petitioner, and at which carotenoids were depleted by up to 60 percent within 2 weeks after the start of olestra consumption, would preclude the approval of olestra for use in snack foods, because the estimated daily intake (EDI) would greatly exceed the 0.8 g/d ADI.

The agency acknowledges that it has not established a numerical value for an ADI for olestra. First, as noted earlier, safety factors are applied to toxic effects observed in animal studies; the purpose of the safety factor is to allow for any discrepancy when extrapolating from animals to humans. Because olestra is intended for use as a macroingredient, it is not possible to feed it to test animals at sufficiently high amounts to elicit toxic effects and thereby establish an ADI using the traditional 100-fold safety factor. The agency notes, however, that no toxic effects were observed when test animals were fed olestra at up to 10 percent of the diet. Furthermore, as discussed at length in this preamble, the clinical data establishing the safety of olestra for its intended use are nutrition studies conducted in humans to which the traditional 100-fold safety factor is not applied.

With respect to olestra's effect to decrease serum carotenoid levels, the agency has concluded, as discussed in detail above, that based upon the available data, this effect does not represent an adverse health effect and therefore, cannot appropriately be used for establishing an ADI for olestra.

10. A comment stated that the NCI and other public health leaders have been encouraging Americans to eat at least five servings a day of fruits and vegetables. The comment added that this advice is grounded, in part, on the presence of carotenoids in fruits and vegetables and the belief of senior scientists at the NCI and elsewhere on chemoprotective activities of carotenoids and similar nutrients. The comment asserted that if FDA were to approve olestra, it would be undercutting NCI's scientific judgement and stand in favor of protecting public health. Another comment stated, specifically with respect to the carotenoids and their potential importance, that the issue receive an impartial review by the National Research Council or a specially convened advisory group of researchers in the carotenoid field.

FDA agrees with the comments that the issue with respect to the potential importance of carotenoids deserves special attention. This is why FDA convened a working group for olestra and the full FAC to examine the issue along with others. The Olestra Working Group and the full FAC were supplemented with appropriate experts in the field of nutrition; in addition, noted experts in the carotenoid field as well as epidemiology experts who could speak to the epidemiological data on carotenoids and incidence of diseases such as cancer and macular degeneration made presentations to the Olestra Working Group and FAC. Finally, because of significant discussion of this issue and because the agency received additional comments since the Olestra Working Group and FAC meetings on the potential chemoprotective function of carotenoids, FDA consulted with Dr. Greenwald at NCI and Dr. Kupfer at the NEI regarding whether olestra's effects on carotenoids raise any significant health issues (Refs. 69 and 70). FDA provided letters concerning carotenoids that the agency had received and excerpts discussing carotenoids from: (1) Submissions from the petitioner, (2) the White Paper, (3) FDA's briefing document for the Olestra Working Group, and (4) the transcript of the Olestra Working Group and FAC meetings to Dr.'s Greenwald and Kupfer.

After reviewing the data, Dr. Greenwald concluded that there is no significant public health issue raised by the effects of olestra on lipophilic carotenoids and that supplementing olestra with beta carotene or other carotenoids was not warranted (Ref. 71). Dr. Kupfer from NEI concluded that although theoretical considerations have raised the possibility that carotenoids might play some protective role in macular degeneration, there are currently no convincing clinical data to support the hypothesis, and there are no demonstrated eye health benefits for carotenoids (Ref. 72). Given the NIH conclusions, FDA does not agree that FDA would be undercutting NCI's scientific judgement if it were to approve olestra. Further, FDA notes that by approving olestra, FDA is not contradicting or undercutting the NCI advice to eat fruits and vegetables.

11. One comment stated that 30–300 mg/day of beta-carotene was used to prevent or lessen the photosensitivity characteristic of the disease erythropoietic protoporphyria (EPP). The comment added that if a significant amount of the beta-carotene taken by the EPP patients, who also eat foods containing olestra, is not absorbed, the patients will suffer from photosensitivity and will have to curtail markedly the activities the beta-carotene ingestion would permit. The comment added that it was not enough to theorize that supplementation of olestra with carotenoids will cure the problem and suggested the design of two studies on the effect of olestra on the absorption of beta-carotene, which should be conducted and evaluated before approval of olestra is considered.

The comment raises the issue of food-drug interactions; in this instance, beta-carotene is being used as a drug, i.e., to treat patients with EPP. Food-drug interactions are generally handled through labeling for the drug product or through advice of the physician prescribing the drug. The agency fully intends to apprise physicians regarding the effect of olestra on the absorption of beta-carotene and other lipophilic carotenoids so that physicians will in turn be able to advise EPP patients appropriately. Further, because the agency believes that this potential drug-food interaction problem can be adequately addressed through education of physicians and their patients, the agency does not agree that the suggested studies on the effect of olestra on the absorption of supplemented beta-carotene are necessary.

12. One comment cited an association between retinitis pigmentosa and steatorrhea and asserted that olestra causes steatorrhea and that chronic consumption of olestra may result in retinitis pigmentosa. The comment also stated that the studies show that vitamin supplementation results in reversal of the condition.

The agency does not agree that olestra causes steatorrhea; the basis for that conclusion is discussed above. However, the agency acknowledges that loss of fat soluble vitamins due to the presence of olestra in the GI tract has the potential for harm. For this reason, the agency is requiring, as a condition of safe use, that olestra be supplemented with vitamins A, D, E and K in such a way that the bioavailability of these vitamins from the diet remains unchanged. Thus, any potential consequence of decreased absorption of

fat-soluble vitamins will be offset by the vitamin compensation required by the final rule.

13. Some comments stated that approval of the petition will result in unnecessary medical care associated with olestra's GI effects. Another comment questioned whether FDA has evaluated the potential impact of olestra on the health care delivery system, specifically, on the cost of office visits and diagnostic procedures by primary care physicians and gastroenterologists who evaluate GI disturbances that may occur from the use of the additive. The comment added that it seemed ill advised for FDA to approve the introduction of a product which may increase expenditures for healthcare.

The agency does not agree that approval of the petition will result in unnecessary medical care associated with olestra's GI effects and therefore, does not agree that use of the additive will lead to increased costs associated with medical care for these effects. This is because the agency has determined that foods containing olestra shall be labeled so that consumers will be able to associate olestra with the GI symptoms that it may cause. The agency believes that this will significantly reduce or eliminate any unnecessary or inappropriate medical treatment. Therefore, the agency does not believe that it is necessary to evaluate the potential impact of olestra on the cost to the health care delivery system.

14. One comment stated that while a general reduction in fat intake, especially saturated fat, is desirable, it seems unlikely that substituting olestra for part of the fat in a few products will have, or can be shown to have substantial benefit and added that benefits should be substantial to warrant the use of materials like olestra. Other comments stated that when GI disturbances are considered in conjunction with depletion of fat-soluble vitamins that are critical to the maintenance of health and depletion of other fat-soluble materials whose importance is not yet fully understood, the potential benefits that could result form the use of olestra are outweighed by the risk to the public health.

The agency notes that, unlike approval of drugs, the law applicable to the approval of food additives does not permit consideration of, or require a showing of, benefits. As stated above, before a food additive can be approved, it has to be established that there is a reasonable certainty that the additive will not be harmful under the prescribed conditions of use. Further, as discussed in detail above, the agency does not agree that the GI symptoms that may occur due to consumption of foods containing olestra represent risk to the public health. Similarly, as discussed above, because the agency is requiring that olestra be supplemented with the affected vitamins, the agency does not agree that olestra's potential to decrease the absorption of fat-soluble vitamins and other nutrients with purported uses represent risk to the public health.

Finally, the agency notes that the petitioner is not required to show that olestra has health or other benefits for consumers of the additive. Likewise, FDA is not permitted to consider such benefits in its evaluation of the safety of olestra for its intended use.

15. Several comments stated that once approved for use in savory snacks, olestra will be used in everything and urged the agency to prevent its use in other products such as fat-free cakes and fast-food fries.

The agency notes that the final rule that is being promulgated restricts the use of olestra for only in prepackaged ready-to-eat savory (i.e., salty or piquant but not sweet) snacks. Use of olestra in any other foods, including fat-free cakes and fast-food fries, is not permitted. Any additional use will require an evaluation of that use through a food additive petition in accordance with 21 CFR 171.1.

16. Two comments expressed concern that olestra may cause allergic reactions in many people and, therefore, should not be approved.

These comments did not provide any data to substantiate the assertion that olestra would be an allergen. FDA does not agree with these comments. FDA notes that, in general, food allergens are known to be protein or glycoprotein in nature. Olestra, composed of six, seven, or eight fatty acids esterified to sucrose, is neither a protein nor a glycoprotein and does not contain these substances even as minor constituents. Therefore, the agency believes that olestra is unlikely to cause any allergic reactions and finds that these comments are without merit.

17. One comment stated that unless olestra can be converted into an acceptable energy source for livestock/poultry and pet rations or properly removed from the environment, a major disposal problem would result. The comment added that since olestra has no energy value, neither the spent frying olestra nor the waste savory snacks will be recycled. The comment asserted that this issue needs to be addressed prior to approval of olestra.

The agency agrees that the question of whether disposal of olestra or olestra-containing products raises environmental concerns needs to be addressed before olestra can be approved. In fact, the National Environmental Policy Act (NEPA) mandates that FDA review the environmental consequences of its actions. In accordance with NEPA, FDA required the submission of, and reviewed, an environmental assessment (EA) for olestra prepared by the petitioner. Among other things, the EA addresses whether disposal of olestra or olestra-containing products has the potential to cause adverse environmental effects. As discussed below, the agency has consulted with the U.S. Environmental Protection Agency (EPA), has reviewed the petitioner's EA, and has concluded that approval of olestra will not have any significant adverse environmental impacts from its manufacture, use, or disposal.

IX. Environmental Impact Considerations

The petitioner submitted an environmental assessment (EA) with its food additive petition for the use of olestra as a replacement for fats and oils in food. In May 1987, shortly after the food additive petition was filed, FDA was contacted by EPA regarding olestra. EPA was interested in whether the use of olestra would have an adverse effect on water quality and wastewater treatment processes. FDA agreed to consult with EPA regarding olestra and give EPA an opportunity to comment on the petitioner's environmental submission after FDA had completed its evaluation. In July 1990, the petitioner submitted a request to limit the intended use of olestra to substitution for conventional fat in the preparation of savory snacks. At that time, the petitioner submitted a revised EA for the limited use of olestra in savory snacks.

The expected route of environmental introduction for olestra is through wastewater treatment systems and, subsequently, to aquatic and terrestrial environments. The petitioner performed studies on primary and secondary wastewater treatment processes which demonstrated that olestra does not have an adverse effect on the effective functioning of wastewater treatment plants. The petitioner provided studies on the fate and effects of olestra in aquatic and terrestrial systems which establish that, at the expected concentrations, olestra would not have an adverse effect upon organisms exposed in the water column, in sediments, or in soil following land application of sewage sludge. After analysis of the information provided,

FDA tentatively concluded that approval of this petition would not cause significant environmental effects.

Before reaching a final conclusion on the environmental effects of olestra, however, FDA requested that EPA review the information provided by the petitioner on the potential effect of olestra on wastewater treatment systems; exposed aquatic organisms, such as fish and sediment dwelling animals; soil physical and chemical properties subsequent to sewage sludge applications; and possible effects resulting from an accidental spill or treatment plant malfunction. EPA concluded that these issues had been satisfactorily addressed by the petitioner in the EA for the olestra food additive petition, and did not raise any environmental objection to the use of olestra in savory snacks. In light of the consultations with EPA, and based upon its own review, FDA has concluded that adverse environmental effects are not expected to result from the manufacture of olestra or from production or consumption of savory snacks containing olestra.

Accordingly, the agency has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

X. FDA's Overall Conclusions

The question before FDA regarding olestra is whether the additive is safe for its intended use as a fat substitute in savory snacks. (21 U.S.C. 409(c)(3)(a).) To determine that olestra is safe, the agency must conclude, based upon a fair evaluation of the evidence of record, that there is a reasonable certainty that olestra is not harmful under the intended conditions of use. (21 CFR 170.3(i).) This determination of reasonable certainty of no harm necessarily involves the application of scientific judgement. Under the act, the agency has a duty to deny approval to an additive that has not been shown to be safe within the meaning of the act; the agency has a parallel duty to permit the marketing of those additives where the available scientific record establishes safety.

It is not uncommon for an agency safety decision regarding a regulated product, including a food additive, to be very difficult. The decision regarding the food additive olestra is one such decision. The difficulty presented by the olestra food additive petition results from a relatively unique intersection of a number of factors, including the following.

First, the volume of available safety evidence for olestra is enormous, all of which FDA was obligated to review, evaluate, and synthesize. Second, as a macro-ingredient, olestra is intended to replace a sizeable portion of the diet, and thus, will likely be consumed in relatively large amounts; this alone sets olestra apart from almost all food additives previously reviewed by FDA. Third, olestra presents a number of questions regarding nutritional effects, most of which have not been presented previously to FDA. Fourth, much of the pivotal scientific safety evidence for olestra comes from studies in humans; human studies, even well conducted ones like those for olestra, are necessarily limited in terms of the number of subjects that can reasonably be tested in a clinical trial conducted prior to marketing, the length of the trial, and the endpoints measured. Finally, under the act, once approved, olestra may be consumed by the entire U.S. population of 250 million people. This potentially widespread consumption for olestra does not, of course, set it apart from other foods and food additives. It does, however, distinguish this decision from those that FDA makes regarding drug and medical device products.

It is important to emphasize that the coalescing of the foregoing factors does not preclude an agency decision at this time; it does, however, make the determination challenging. Similarly, it is worth noting that because of the challenge presented by olestra, the agency used an expanded approach to its evaluation of the petition, and established and utilized the internal Regulatory Decision Team, sought out and utilized the expertise of five subject-specific experts, and held a lengthy public meeting of the agency's Food Advisory Committee and a subgroup of that Committee (the Olestra Working Group) to foster an open and public discussion of the safety issues presented by olestra.

Consistent with the act and its applicable standards, FDA has conducted an evaluation and synthesis of the evidence of record concerning olestra, including the proceedings of the FAC and comments submitted to the agency. In this process, FDA has applied its best scientific judgement, aided by the scientific judgement of the experts and public participants who contributed to the evaluation process. As the foregoing discussion makes clear, and as the proceedings of the FAC illustrate, olestra presents a number of important scientific questions. For some questions, there is arguably evidence, including support from recognized experts, on both sides of the question, ultimately requiring FDA to evaluate and weigh the data currently available and apply its scientific judgement. The agency has, as a result of this process, determined that there is a reasonable certainty that no harm will result from the use of olestra in savory snacks.

Based upon a fair evaluation of the evidence of record, FDA concludes that olestra is not toxic, carcinogenic, genotoxic, or teratogenic. Olestra is essentially not absorbed or metabolized. Heating olestra, as would occur in the commercial preparation of snacks made using olestra, does not increase the absorption of the additive. FDA further concludes that the studies conducted show that olestra has an effect on the absorption of vitamins A, E, D, and K. FDA also concludes that it is possible to supplement foods containing olestra with all four vitamins in such a way as to compensate for the amounts that are not absorbed from the diet due to the action of olestra. FDA concludes that the amounts that should be provided are those listed below:

TABLE 10.—COMPENSATION LEVELS FOR VITAMINS A, D, E, AND K

Vitamin	Compensation level
Vitamin A	51 retinol equivalents/g olestra as retinyl palmitate or retinyl acetate)(170 IU/g olestra or 0.34 X RDA/10 g olestra
Vitamin E	1.9 mg α-tocopherol equivalents/g olestra (0.94 X RDA/10 g olestra)
Vitamin D	12 IU vitamin D/g olestra (0.3 X RDA per 10 g olestra)
Vitamin K	8 μg vitamin $K_1$1/g olestra (1.0 X RDA per 10 g olestra)

As discussed previously, in order to avoid confusion about the purpose of the added vitamins in olestra-containing foods, FDA is requiring a label statement to indicate that olestra affects the absorption of some nutrients and that in order to compensate for olestra's effects on vitamins A, D, E, and K, these vitamins have been added.

As discussed above, at present, carotenoids have no identifiable health benefit role (except for the provitamin A role of beta carotene.) Further, randomized studies have failed to show an association between selective carotenoid repletion and cancer. Although epidemiological studies show an association between diets rich in fruits and vegetables (including those that contain carotenoids) and decreased cancer risk, there is no direct evidence that carotenoids themselves are responsible for or contribute in a significant way to that protective benefit. In addition, the level of effects on carotenoids from olestra may well be within the normal variation due to diet and bioavailability. In light of the current state of the scientific evidence, FDA believes that there is a reasonable certainty of no harm from olestra's effects on carotenoid absorption. Accordingly, the agency concludes that there is currently no justification or need to require compensation of olestra-containing foods with specific carotenoids.

Regarding water soluble nutrients, given the totality of the study results, FDA concludes that there is a reasonable certainty that olestra will not cause any harmful effects on vitamin B_{12}, calcium, iron, zinc, or folate or other water soluble nutrients. Collectively, the clinical data on the water-soluble vitamins that are hard to absorb (folate and vitamin B_{12}) show that olestra does not affect the absorption of these nutrients. Similarly, the data on two of the nutrients that are limited in the diet (iron and zinc) show that olestra does not interfere with their absorption.

Although the data on the third nutrient that is limited in the diet, calcium, are not sufficiently rigorous to detect possible subtle changes, the lack of any plausible argument for expecting an effect, the lack of any olestra effect on folate, iron, or zinc, the fact that supplementation with vitamin D will preclude any vitamin D-mediated calcium depletion, and the insignificance of any subtle effect compared to variations in the human diet, lead FDA to conclude that there is a reasonable certainty that olestra will not have any harmful effect on calcium absorption.

With respect to the potential effect of olestra on the GI tract, FDA concludes that the effects seen do not represent significant adverse health consequences and therefore, do not preclude approval of the petition. However, while FDA believes that there are no direct safety concerns with respect to olestra's potential effect on the GI tract, FDA concludes that the GI symptoms associated with ingestion of olestra-containing foods are material fact information within the meaning of 201(n) of the act. Disclosing this information on food labels will enable consumers to associate olestra with any GI effects that it may cause. Consequently, FDA is requiring that such information be disclosed on the label of foods containing olestra to preclude consumers from being misled about consequences which may result from the consumption of the olestra-containing foods. Therefore, in the final rule, FDA concludes that foods containing olestra should bear an appropriate label statement.

In summary, FDA concludes that all safety issues have been addressed adequately and that based upon the currently available evidence, the use of olestra in savory snacks will be safe when used in accordance with the final rule.

FDA's determination will permit the use of olestra in savory snacks. In order for olestra to be lawfully used in other foods (e.g., cakes and pies), a new food additive petition would need to be filed and approved. In conjunction with that review, the agency would then conduct a separate and independent safety evaluation of the additional proposed uses.

Procter and Gamble has notified FDA that the company will be conducting additional studies of olestra exposure (both amounts consumed and patterns of consumption) and the effects of olestra consumption (Ref. 103).

FDA believes that Procter and Gamble's plans to continue to study the consumption and effects of olestra are both prudent and responsible. It is likewise prudent and responsible for FDA to evaluate the results of such studies as it monitors the on-going marketing and distribution of olestra. Only with data from the broader marketing of olestra can the agency, be in the position to evaluate in the future whether there continues to be reasonable certainty of no harm from the use of olestra in savory snacks. Therefore, as a condition of approval, Procter and Gamble is to conduct the studies that it has identified in its letter to FDA (Ref. 103), consistent with the timetables identified in that letter. Furthermore, consistent with the terms of that letter, Procter and Gamble is to provide the Food and Drug Administration with access to all data, information, and reports of those studies as such information becomes available.

It is the agency's responsibility as a public health agency to review and evaluate the data generated by Procter and Gamble's studies, as well as any new data that bear on the safety of olestra (such as data and information on the health significance of carontenoids)[94] to determine whether there continues to be a basis for a reasonable certainty that the use of olestra in savory snacks is not harmful. Thus, consistent with the agency's continuing obligation to oversee the safety of the food supply, FDA will, within 30 months of this approval, review and evaluate any new data and information bearing on the safety of olestra and present such information to the agency's Food Advisory Committee (or a working group of the FAC). To the extent that additional data and information bearing on olestra's safety are submitted to and reviewed by the agency, FDA will, in its discretion, hold any additional meetings of the FAC that may be necessary to consider such information.

This future meeting of the FAC (and any subsequent FAC meetings) will be open public meetings with an opportunity for participation by FDA, Procter and Gamble, and interested members of the public, and will provide an opportunity for public discussion and deliberation of the newly developed data regarding olestra.

As an indication of the agency's view of the importance of this review, evaluation, and public discussion by the FAC of future data on olestra, as well as an indication of the depth of the agency's commitment to do so, the final rule established by this decision includes a statement concerning FDA's commitment in this regard. FDA has used the word "will" in § 172.867(f) with respect to the agency's commitment to conduct such review and evaluation. The agency has thus legally bound itself to institute this review and evaluation. (*See CNI* v. *Young*, 818 F.2d 943 (D.C. Cir. 1987).)

The decision embodied in this document necessarily articulates certain

[94] The record of this proceeding, particularly the meeting of the Olestra Working Group and the FAC, demonstrates that the question of the role of carotenoids in disease prevention or health maintenance is an issue of intense interest and the focus of continuing scientific study and evaluation. It is thus likely that there will be additional scientific data and information that bears on the question of the role of carotenoids in the future.

baseline parameters concerning the safety data for olestra, particularly parameters with respect to the finding of a reasonable certainty of no harm. These parameters include the exposure to olestra (both amount of consumption and patterns of consumption), and the nature, severity, incidence, and prevalence of any effects of olestra consumption, including any effects on fat-soluble nutrients and any gastrointestinal effects. If, as a result of the agency's review and evaluation and its consultation with the FAC, FDA determines that the results reflected in the new data and information are not consistent with the parameters that form the basis of this decision, or the agency otherwise concludes that the available safety evidence for olestra shows that there is no longer reasonable certainty of no harm from the use of this substance, FDA will institute appropriate regulatory proceedings.

It is important to recognize that to institute a proceeding to limit or revoke the approval of olestra, FDA would not be required to show that olestra is unsafe. Rather, the agency would only need to show that based upon new evidence, FDA is no longer able to conclude that the approved use of olestra is safe, i.e., that there is no longer a reasonable certainty of no harm from the use of the additive. Further, in any proceeding to withdrawal or limit the approval of olestra, Procter and Gamble would have the burden to establish the safety of the additive. 21 CFR 12.87(c).

Imposing a condition of approval such as this is not without precedent in the area of food additive approvals. At the time that FDA reinstated the approval of the artificial sweetener, aspartame, the Commissioner of Food and Drugs required that the petitioner for aspartame (G.D. Searle & Co.) develop data and other information on the actual use levels of the additive so that the estimated use levels of aspartame that formed the basis of the agency's safety decision could be compared with levels of actual use. (46 FR 38283, 38303; July 24, 1981).

This condition of approval is not, and should not be interpreted as, an indication that FDA has somehow not determined that there is a reasonable certainty that no harm will result from the use of olestra in savory snacks. As discussed in great detail above, the agency has determined, based upon a fair evaluation of the evidence in the record at this time, that such certainty exists. Having so concluded, however, the agency cannot responsibly ignore its continuing obligation to monitor the safety of the food supply and hence, has imposed the condition of approval set forth above.

As noted, olestra presents several new challenges. It is a is a macro-ingredient that it not metabolized, one of the first of its type to be subject to FDA review. In addition, olestra's effects on nutrient absorption are not routinely presented by food additives reviewed by FDA. The safety decision for olestra is in large part based on the data from human studies. These studies are more than sufficient to provide a basis to conclude that olestra is safe. The agency recognizes, however, that olestra has the potential to be consumed by the bulk of the U.S. population of 250 million. In these circumstances, FDA believes that it is not only consistent with the agency's mandate under the act to protect the public health to condition the approval of olestra on the conduct of future studies, *see United States* v. *Bacto-Unidisk*, 394 U.S. 784 (1969), but it is also the most responsible course for the agency to take in these circumstances.

The Procter and Gamble Co. has made a commitment to the agency that it will conduct the studies outlined in the letter to FDA (Ref. 103), and FDA doubts neither the company's independent interest in conducting these studies nor the good faith of its commitment to the agency to do so. Nevertheless, FDA believes that it is important to articulate here the agency's view of the consequences of a failure of the company to adhere to its commitment. That is, if Procter and Gamble does not conduct the identified studies and does not conduct them according to the articulated timetable, FDA will consider the approval set forth in this document to be void *ab initio* and will institute appropriate proceedings, judicial or otherwise, consistent with that view.

XI. Administrative Record and Inspection of Documents

The administrative record for this final rule consists of the food additive petition (FAP 7A3997), all documents filed in that petition, and any items cited in this preamble.

In accordance with §§ 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the CFSAN (address above) by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

XII. Objections

Any person who will be adversely affected by this regulation may at any time on or before February 29, 1996 file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to ¶the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FDA will publish notice of the objections that the agency has received or lack thereof in the **Federal Register**.

XIII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m. Monday through Friday.

1. Charge to Olestra Working Group, Draft, Nov. 13, 1995.

2. Transcript of meeting of the Olestra Working Group (vols. 1–3) and Food Advisory Committee (vol. 4), Alexandria, VA, November 14 through 17, 1995.

3. Myra Karstadt, Ph.D. and Michael F. Jacobson, Ph.D., "White Paper on Olestra," Center for Science in the Public Interest, November 3, 1995.

4. "Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food," Draft, (Redbook II), U.S. Food and Drug Administration, 1993.

5. Memorandum from M. DiNovi, FDA to J. Gordon, FDA, June 28, 1989.

6. Memorandum from M. DiNovi, FDA to J. Gordon, FDA, April 17, 1989.

7. Memorandum from M. DiNovi, FDA to J. Gordon, FDA, July 14, 1989.

8. Memorandum from M. DiNovi, FDA to J. Gordon, FDA, January 17, 1991.

9. Memorandum from M. DiNovi, FDA to F. O. Fields, FDA, June 6, 1994.
10. Memorandum from M. DiNovi, FDA to J. Gordon, FDA, October 3, 1990.
11. Memorandum from M. DiNovi, FDA to F. O. Fields, FDA, February 5, 1993.
12. Memorandum from M. DiNovi, FDA to H. Thorsheim, FDA, March 13, 1995.
13. Memorandum from M. DiNovi, FDA to H. Thorsheim FDA, May 4, 1995.
14. Mattson, F. H. and Volpenhein, R.A., "Hydrolysis of Fully Esterified Alcohols Containing from One to Eight Hydroxyl Groups by the Lipolytic Enzymes of Rat Pancreatic Juice," *Journal of Lipid Research*, 13:325–328, 1972.
15. Memorandum from L. S. Pellicore, FDA, to F. O. Fields, FDA, July 6, 1993.
16. Memorandum from L. S. Pellicore, FDA, to F. O. Fields, FDA, August 1, 1993.
17. Memorandum from L. S. Pellicore, FDA, to F.O. Fields, FDA, August 2, 1993.
18. Memorandum from L. S. Pellicore, FDA, to F. O. Fields, FDA, August 4, 1993.
19. Memorandum from L. S. Pellicore, FDA, to F. O. Fields, FDA, August 5, 1993.
20. Memorandum from L. S. Pellicore, FDA, to F. O. Fields, FDA, January 25, 1995.
21. Memorandum from L. S. Pellicore, FDA, to F. O. Fields, FDA, July 28, 1995.
22. Memorandum from L. S. Pellicore, FDA, to F. O. Fields, FDA, July 28, 1995.
23. Memorandum from E. J. Matthews, FDA to F. O. Fields, FDA, December 16, 1993.
24. Memorandum from T. F. X. Collins, FDA, to F. O. Fields, FDA, October 23, 1993.
25. Memorandum from J. J. Welsh, FDA, to L. S. Pellicore, FDA, March 1, 1994.
26. Memorandum from M. J. Bleiberg, FDA, to F. O. Fields, FDA, February 8, 1993.
27. Goodman, D. G., J. M. Ward, R. A. Squire, K. C. Chu, and M. S. Linhart, "Neoplastic and Nonneoplastic Lesions in Aging F344 Rats," *Toxicology and Applied Pharmacology*, 48:237–248, 1979.
28. Memorandum from F. S. D. Lin, FDA, to R. Lorentzen, FDA, February 4, 1988.
29. Memorandum from R. W. Moch, FDA, to F. O. Fields, FDA, April 5, 1993.
30. Harada, T., R. P. Maronpot, R. W. Morris, K. A. Stitzel, and G. A. Boorman, "Morphological and Stereological Characterization of Hepatic Foci of Cellular Alteration in Control Fischer 344 Rats," *Toxicology and Pathology* 17(4):579–593, 1989.
31. Harada, T., R. R. Maronpot, R.W. Morris, and G. A. Boorman, "Observations on Altered Hepatocellular Foci in National Toxicology Program 2-Year Carcinogenicity Studies in Rats," *Toxicology and Pathology*, 17(4):690–708, 1989.
32. Maronpot, R. R., T. Harada, A. S. K. Murthy, and G. A. Boorman, "Documenting Foci of Hepatocellular Alteration in 2–Year Carcinogenicity Studies: Current Practices of the National Toxicology Program," *Toxicology and Pathology*, 17(4):675–684, 1989.
33. Mahon, D. C., "Altered Hepatic Foci in Rat Liver as Weight of the Evidence of Carcinogenicity: The Canadian Perspective," *Toxicology and Pathology*, 17(4):709–715, 1989.
34. Squire, R. A., "Evaluation and Grading of Rat Liver Foci in Carcinogenicity Tests," *Toxicology and Pathology*, 17(4):685–689,1989.
35. Moch, R. W. and T. P. O'Neill, "Hepatocellular Foci-A Regulator's Gordian," *Toxicology and Pathology*, 17(4):724–728, 1989.
36. Lang, P. L., "Spontaneous Neoplastic Lesions in the Crl:CD–1(1CR)BR Mouse," *Charles River Breeding Laboratories*, Wilmington, MA, February 1, 1987.
37. Maita, K., M. Hirano, T. Harada, K. Mitsumori, A. Yoshida, K. Takahashi, N. Nakashima, T. Kitazawa, A. Enomoto, K. Inui, and Y. Shirasu, "Mortality, Major Cause of Morbidity and Spontaneous Tumors in CD–1 Mice," *Toxicology and Pathology*, 16(3):340–349, 1988.
38. Memorandum from M. J. Bleiberg, FDA, to F. O . Fields, FDA, November 1994.
39. Memorandum from M. A. Bryant, FDA to N. Beru, August 17, 1995.
40. Memorandum from M. J. Bleiberg, FDA, to J. Gordon, FDA, August 8, 1990
41. Memorandum from J. M. Collins, FDA to F. O. Fields, FDA, April 12, 1994.
42. Musa, M. M. and L. L. Lyman, "Absorption and Disposition of Warfarin: Effects of Food and Liquids," *Current Therapeutic Research*, 20:630–633, 1976.
43. Memorandum of Meeting, May 3, 1995.
44. Memorandum from J. Judd, USDA to G. N. Biddle, FDA, August 7, 1995.
45. Memorandum of Telephone Conversation between J. Judd, USDA, and H. Thorsheim, FDA, September 17 and 18, 1995.
46. Memorandum from M. S. Calvo, FDA to J. Gordon, FDA, August 8, 1989.
47. Memorandum from M. Jenkins, FDA to G. Biddle, FDA, August 14, 1995.
48. Memorandum from R. Chanderbhan, FDA, to K. N. Biddle, FDA, July 11, 1995.
49. Memorandum from C. Barton, FDA to H. Thorsheim, FDA, May 23, 1995.
50. Memorandum from C. Barton, FDA to H. Thorsheim, FDA, May 18, 1995.
51. Memorandum from C. Barton, FDA to H. Thorsheim, FDA, May 19, 1995.
52. Memorandum from R. Lovell, FDA to H. Thorsheim, FDA, March 21, 1995.
53. Memorandum from Randall Lovell, FDA to F. O. Fields, FDA, March 22, 1994.
54. Memorandum from Randall Lovell, FDA to F. O. Fields, FDA, January 27, 1995.
55. Matschiner, J. T. and W. V. Taggart, "Bioassay of Vitamin K by Intracardial Injection in Deficient Adult Male Rats," *Journal of Nutrition*, 94:57–59, 1968.
56. Memorandum from R. Lovell, FDA to H. Thorsheim, FDA, September 13, 1995.
57. Rothman, K. J., L. L. Moore, M. R. Singer, U.S.D.T. Nguyen. S. Mannino, and A. Milunsky, "Teratogenicity of High Vitamin A Intake," *New England Journal Medicine*, 333:1369–1373, 1995.
58. Memorandum of Conference, August 1, 1995.
59. Recommended Dietary Allowances, National Research Council, National Academy of Sciences Press; pp. 96 and 97.
60. Seddon M. J., et. al., "Dietary Carotenoids, Vitamins A, C, and E, and Advanced Age-Related Macular Degeneration," *Journal of the American Medical Association*, 272:1413–1420, 1994.
61. Giovannucci E., et. al., "Intake of Carotenoids and Retinol in Relation to Risk of Prostate Cancer," *Journal of the National Cancer Institute* 87:1767–1776, 1995.
62. Letter from W. Willett and M. Stampfer, Harvard School of Public Health to D. Kessler, FDA, November 1, 1995.
63. The Alpha-tocopherol Beta-carotene Cancer Prevention Study Group, "The Effect of Vitamin E and Beta Carotene on the Incidence of Lung Cancer and Other Cancers in Male Smokers," *New England Journal of Medicine*, 330:1029–1035, 1994.
64. Greenberg, E. R., et.al., "A Clinical Trial of Beta Carotene to Prevent Basal-Cell and Squamous-Cell Cancers of the Skin," New England Journal of Medicine, 323:789–795, 1990.
65. Greenberg, E. R., et.al., "A Clinical Trial of Antioxidant Vitamins to Prevent Coloractal Adenoma," *New England Journal of Medicine*, 331:141–147, 1994.
66. Blot, W. J. et.al., "Nutrition Intervention Trials in Linxian, China: Supplementation with Specific Vitamin/ Mineral Combinations, Cancer Incidence, and Disease Specific Mortality in the General Population," *Journal of the National Cancer Institute*, 85:16–30, 1993.
67. Rock, C. L. and M. E. Swendseid, "Plasma -Carotene Response in Humans after Meals Supplemented with Dietary Pectin," *American Journal Clinical Nutrition*, 55:96–99, 1992.
68. Letter from J. Peters, Procter & Gamble to H. Thorsheim, FDA, January 16, 1996.
69. Letter from J. E. Vanderveen, FDA to P. Greenwald, NCI, November 30, 1995.
70. Letter from J. E. Vanderveen, FDA to C. Kupfer, NEI, December 4, 1995.
71. Letter from P. Greenwald, NCI, to J. Vanderveen, FDA, December 5, 1995.
72. Letter from C. Kupfer, NEI to J. Vanderveen, FDA, January 17, 1995.
73. Letter from S. R. Lynch, VAMC to J. Vanderveen, FDA, June 19, 1995.
74. Memorandum from C. Barton, FDA to O. Fields, FDA, September 20, 1993.
75. Memorandum of Meeting, May 31, 1995.
76. Memorandum from M. S. Calvo, FDA and W.V. Rumpler, USDA to F. O. Fields, October 13, 1993.
77. Maxson, P. F. and D. C. Mahan, "Dietary Calcium and Phosphorus Levels for Growing Swine from 18 to 56 Kilograms Body Weight," *Journal of Animal Science*, 56:1124–1134, 1983.
78. Cromwell, G. L., V. W. Hays, C. W. Scherer, and J. R. Overfield, "Effects of Dietary Calcium and Phosphorus on Performance and Carcass, Metacarpal and Turbinate Characteristics of Swine," *Journal of Animal Science*, 34:746–751, 1972.
79. Memorandum from L. Lutwak, FDA to K. Biddle, FDA, January 6, 1995.
80. Cortot, A., S. F. Phillips, and J. Malagelada, "Parallel Gastric Emptying of Nonhydrolyzable Fat and Water after a Solid-Liquid Meal in Humans," *Gastroenterology*, 82:877–881, 1982.
81. Aggarwal, A. M., M. Camilleri, S. F. Phillips, T. G. Schlagheck, M. L. Brown, and G. M. Thomforde, "Olestra, a Nondigestible, Nonabsorbable Fat/Effects on Gastrointestinal and Colonic Transit," *Digestive Diseases and Sciences*, 38:1009–1014, 1993.
82. Smith, M. C. and H. Spector, "Calcium and Phosphorus Metabolism in Rats and

Dogs as Influenced by the Ingestion of Mineral Oil," *Journal of Nutrition*, 20:19–30, 1940.

83. Smith, M. C. and H. Spector, "Further Evidence of the Mode of Action of Vitamin D," *Journal of Nutrition*, 20:197–202, 1940.

84. Memorandum from K. Klontz, FDA to F. O. Fields, FDA, January 11, 1995.

85. Anderson, J. W., L. Story, B. Sieling, W. J. L. Chen, M. S. Petro, J. Story, "Hypocholesterolemic Effects of Oat-Bran or Bean Intake for Hypercholesterolemic Men," *American Journal of Clinical Nutrition*, 40:1146–1155, 1984.

86. Stasse-Wolthuis, M., et.al., "The Effect of a Natural High-Fiber Diet on Serum Lipids, Fecal Lipids, and Colonic Function," *American Journal of Clinical Nutrition*, 32:1881–1888, 1979.

87. Memorandum from K. Klontz, FDA to F. O. Fields, FDA, August 9, 1994.

88. Memorandum from K. Klontz, FDA to H. Thorsheim, FDA, December 26, 1995.

89. Jalan, K. N., et. al., "An Experience of Ulcerative Colitis. III. Long Term Outcome," *Gastroenterology*, 59:598–609, 1970.

90. Memorandum of Conference, October 4, 1994.

91. Memorandum from S. Fredd, FDA to F. O. Fields, FDA, January 3, 1995.

92. Memorandum from R. Pertel, FDA to N. Beru, FDA, September 6, 1995.

93. Memorandum of Meeting, May 26, 1995.

94. Nuck, B. A., T. G. Schlagheck, and R. W. Federle, "Inability of the Human Fecal Microflora to Metabolize the Nonabsorbable Fat Substitute, Olestra," *Indian Journal of Pathology and Microbiology*, 13:328–334, 1994.

95. Memorandum from R. Pertal, FDA to N. Beru, FDA, September 6, 1995.

96. Letter from J. Lupton, Texas A&M to L. Pellicore, FDA, December 15, 1995.

97. Memorandum of telephone conversation between L. Pellicore, FDA, and J. Lupton, Texas A&M, January 17, 1995.

98. Memorandum from R. Chanderbhan, FDA, to G. N. Biddle, FDA, August 24, 1995.

99. Memorandum for the Record, January 18, 1996.

100. Memorandum of Meeting, June 16, 1995.

101. Memorandum of Conference, June 26, 1995.

102. Swinyard, E. A. (1990) Gastrointestinal Drugs In: Remington's Pharmaceutical Sciences, 18th Edition. A. R. Gennaro (ed.). Mack Publishing Co., Easton, PA, pp 783–799).

103. Letter from Procter & Gamble, to FDA, January 24, 1996.

104. Letter from W. Schultz, FDA to M. Jacobson, CSPI, December 8, 1995.

List of Subjects in 21 CFR 172

Food additives, Incorporation by reference, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: Secs. 201, 401, 402, 409, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 348, 371, 379e).

2. New § 172.867 is added to subpart I to read as follows:

§ 172.867 Olestra.

Olestra, as identified in this section, may be safely used in accordance with the following conditions:

(a) Olestra is a mixture of octa-, hepta-, and hexa-esters of sucrose with fatty acids derived from edible fats and oils or fatty acid sources that are generally recognized as safe or approved for use as food ingredients. The chain lengths of the fatty acids are no less than 12 carbon atoms.

(b) Olestra meets the following specifications:

(1) The total content of octa-, hepta-, and hexa-esters is not less than 97 percent as determined by a method entitled "Determination of Olestra by Size Exclusion Chromatography," dated December 19, 1995, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Premarket Approval, Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 200 C St. SW., Washington, DC, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(2) The content of octa-ester is not less than 70 percent as determined by a method entitled "Measurement of the Relative Ester Distribution of Olestra Test Material" dated December 19, 1995, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Premarket Approval, Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 200 C St. SW., Washington, DC, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(3) The content of hexa-ester is not more than 1 percent as determined by the method listed in paragraph (b)(2) of this section.

(4) The content of penta-ester is not more than 0.5 percent as determined by the method listed in paragraph (b)(2) of this section.

(5) The unsaturated fatty acid content is not less than 25 percent (thus not more than 75 percent saturated fatty acid) and not more than 83 percent as determined by a method entitled "Measurement of the Fatty Acid Composition of Olestra Test Material," dated December 19, 1995, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Premarket Approval, Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 200 C St. SW., Washington, DC, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(6) The content of C12 and C14 fatty acids is each not more than 1 percent, and total C20 and longer fatty acids is not more than 20 percent. C16 and C18 fatty acids make up the remainder with total content not less than 78 percent as determined by the method listed in paragraph (b)(5) of this section.

(7) The free fatty acid content is not more than 0.5 percent as determined by a method entitled "Free Fatty Acids" published in the *Official Methods and Recommended Practices of the American Oil Chemists' Society*, 3d Ed. (1985) vol. 1, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the American Oil Chemists Society, 1608 Broadmoor Dr., Champaign, IL 61821, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(8) The residue on ignition (sulfated ash) is not more than 0.5 percent.

(9) Total methanol content is not more than 300 parts per million as determined by the "Total Availabie Methanol Method," dated December 19, 1995, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Premarket Approval, Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 200 C St. SW., Washington, DC or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North

Capitol Street, NW., suite 700, Washington, DC.

(10) The total heavy metal content (as Pb) is not more than 10 parts per million.

(11) Lead is not more than 0.1 part per million, as determined by a method entitled "Atomic Absorption Spectrophotometric Graphite Furnace Method," Food Chemicals Codex, 3d Ed. 3d Supp. p. 168 (1992), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Research Council Press, 2101 Constitution Ave. NW., Washington, DC, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(12) Water is not more than 0.1 percent, as determined by a method entitled "Moisture," *Official Methods and Recommended Practices of the American Oil Chemists' Society*, 4th Ed. (1989), vol. 1, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the American Oil Chemists Society, 1608 Broadmoor Dr., Champaign, IL 61821, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(13) Peroxide value is not more than 10 meq/kg as determined by a method entitled "Peroxide Value," *Official Methods and Recommended Practices of the American Oil Chemists' Society*, 4th Ed. (1989) vol. 1, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the American Oil Chemists Society, 1608 Broadmoor Dr., Champaign, IL 61821, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(14) The stiffness is not less than 50 kiloPascals/second, as determined by a method entitled "Method for Measurement of the Stiffness of Olestra," dated December 19, 1995, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Premarket Approval, Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 200 C St. SW., Washington, DC, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c) Olestra may be used in place of fats and oils in prepackaged ready-to-eat savory (i.e., salty or piquant but not sweet) snacks. In such foods, the additive may be used in place of fats and oils for frying or baking, in dough conditioners, in sprays, in filling ingredients, or in flavors.

(d) To compensate for any interference with absorption of fat soluble vitamins, the following vitamins shall be added to foods containing olestra: 1.9 milligrams alpha-tocopherol equivalents per gram olestra; 51 retinol equivalents per gram olestra (as retinyl lacetate or retinyl palmitate); 12 IU vitamin D per gram olestra; and 8 µg vitamin K^1 per gram olestra.

(e)(1) The label of a food containing olestra shall bear the following statement in the manner prescribed in paragraph (e)(2) of this section:

This Product Contains Olestra. Olestra may cause abdominal cramping and loose stools. Olestra inhibits the absorption of some vitamins and other other nutrients. Vitamins A, D, E, and K have been added.

(2) The statement required by paragraph (e)(1) of this section shall:

(i) Appear either on the principal display panel or on the information panel of the label;

(ii) Be enclosed by a 0.5 point box rule with 2.5 points of space around the statement.

(iii) Utilize at least one point leading;

(iv) Have type that is kearned so the letters do not touch;

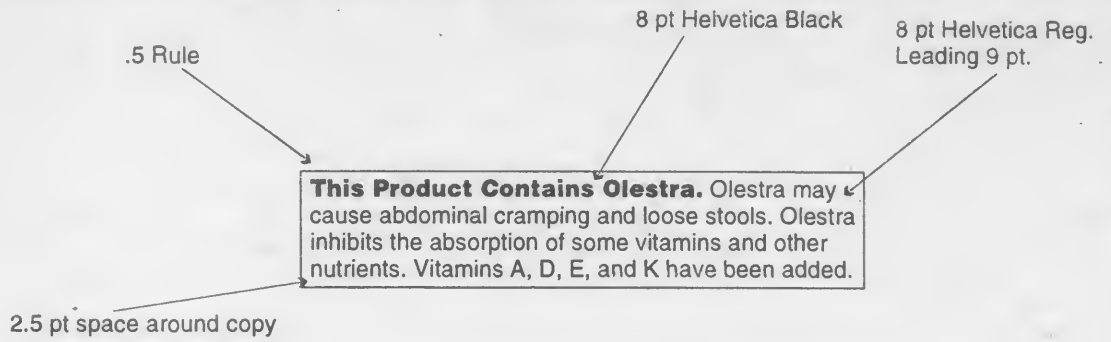
(v) Be all black or one color type, printed on a white or other neutral contrasting background whenever possible;

(vi) Utilize a single easy-to-read type style such as Helvetica Regular and upper and lower case letters; and

(vii) Be in type size no smaller than 8 point.

(3) The sentence "This Product Contains Olestra." shall be highlighted by bold or extra bold type, such as Helvetica Black. The label shall appear as follows:

BILLING CODE 4160–01–F



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(4) Vitamins A, D, E, and K present in foods as a result of the requirement in paragraph (d) of this section shall be declared in the listing of ingredients. Such vitamins shall not be considered in determining nutrient content for the nutritional label or for any nutrient claims, express or implied.

(5) Olestra shall not be considered as a source of fat or calories for purposes of §§ 101.9 and 101.13 of this chapter.

(f) Consistent with its obligation to monitor the safety of all additives in the food supply, including olestra, the Food and Drug Administration will review and evaluate all data and information bearing on the safety of olestra received by the agency after the effective date of this regulation, and will present such data, information, and evaluation to the agency's Food Advisory Committee within 30 months of the effective date of this regulation. The purpose of such presentation will be to receive advice from the Committee on whether there continues to be reasonable certainty that use of olestra in compliance with this regulation is not harmful. The agency will hold such additional Food Advisory Committee meetings on olestra as the agency determines, in its discretion, to be necessary. Based upon the results of this entire process, the FDA will initiate any appropriate regulatory proceedings.

Dated: January 24, 1996.

David A. Kessler,

Commissioner of Food and Drugs.

[FR Doc. 96–1584 Filed 1–25–96; 8:45 am]

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Federal Register

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Tuesday, January 30, 1996

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FEDERAL REGISTER PAGES AND DATES, JANUARY

CFR PARTS AFFECTED DURING JANUARY

At the end of each month, the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

REMINDERS

The rules and proposed rules in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance.

RULES GOING INTO EFFECT TODAY

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Foreign Agricultural Service
Freedom of Information Act; implementation; revision and CFR chapters removed; published 1-30-96

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Farm Service Agency
Organization, functions, and authority delegations:
Rural Housing Service and Rural Business-Cooperative Service; agency name changes; published 1-30-96

AGRICULTURE DEPARTMENT
Rural Business-Cooperative Service
Organization, functions, and authority delegations:
Rural Housing Service and Rural Business-Cooperative Service; agency name changes; published 1-30-96

AGRICULTURE DEPARTMENT
Rural Housing Service
Organization, functions, and authority delegations:
Rural Housing Service and Rural Business-Cooperative Service; agency name changes; published 1-30-96

AGRICULTURE DEPARTMENT
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Organization, functions, and authority delegations:
Rural Housing Service and Rural Business-Cooperative Service; agency name changes; published 1-30-96

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Animal drugs, feeds, and related products:
New drug applications--
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Food additives:
Sucrose esterified with medium and long chain fatty acids (olestra); published 1-30-96

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H.R. 2880/P.L. 104–99

The Balanced Budget Downpayment Act, I (Jan. 26, 1996; 110 Stat. 26)

Note: A cumulative list of Public Laws for the First Session of the 104th Congress will be published in Part I of the **Federal Register** on February 1, 1996.

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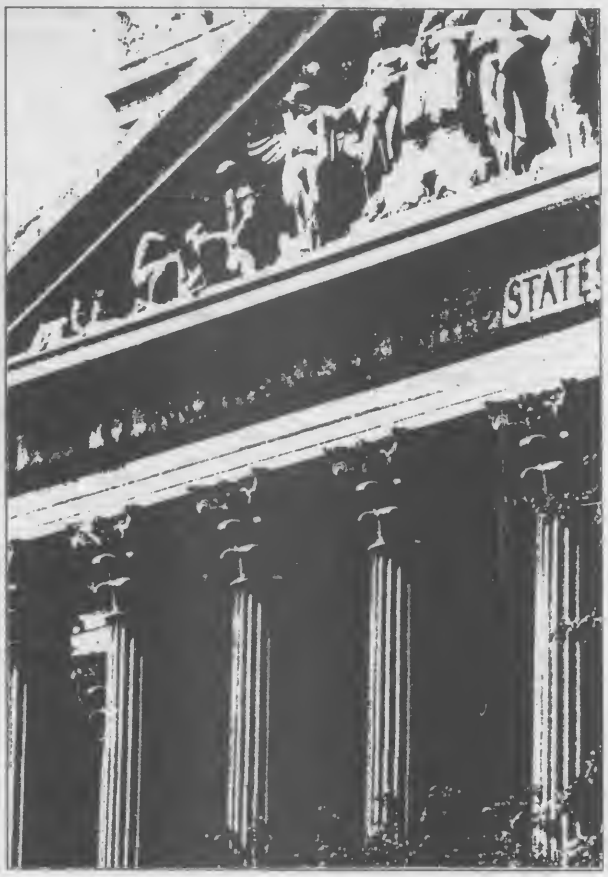

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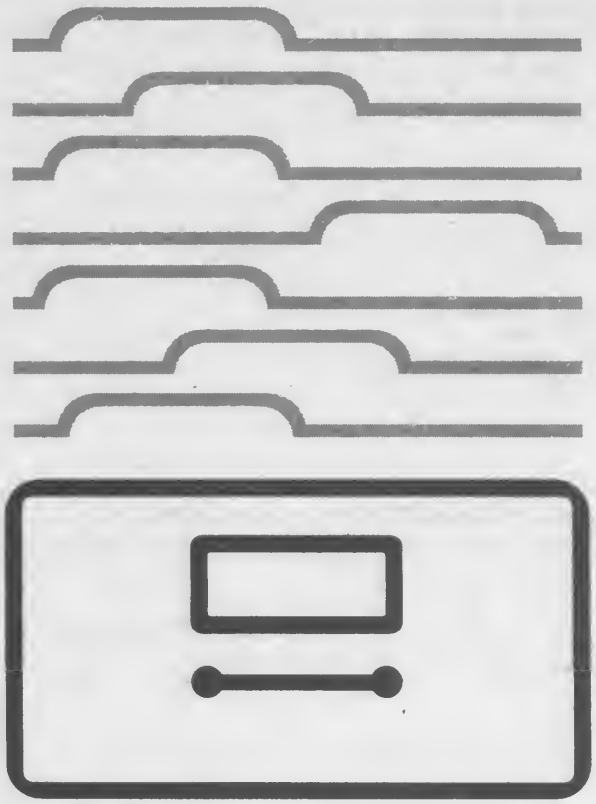

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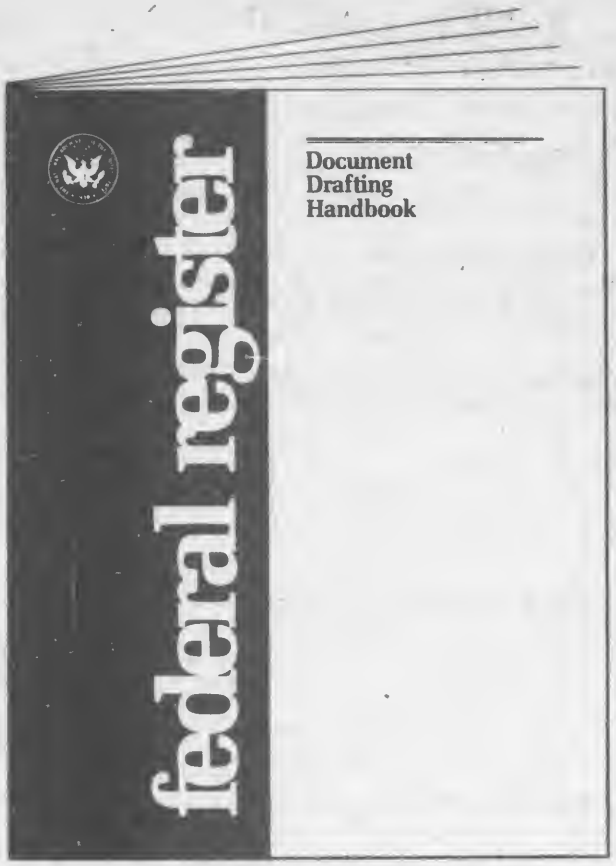

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