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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

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ADMINISTRATIVE FUNCTIONS, PRACTICES, AND PROCEDURES

General Provisions

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

[Docket No. 75N–0001]

ADMINISTRATIVE FUNCTIONS, PRACTICES, AND PROCEDURES

General Provisions

The Food and Drug Administration (FDA) is issuing in final form the general provisions for its administrative functions, practices and procedures. The regulations shall be effective February 24, 1977.

Included within this subpart (21 CFR Part 2, Subpart A) are regulations establishing procedural requirements for public requests for agency action or challenges to agency action, for the issuance of regulations by the agency, for the compilation and maintenance of the administrative record of agency decisions and actions, and, generally, for the conduct of agency business with the public. The regulations include provisions that specify the terms on which FDA officials will meet with members of the public and provisions that govern providing advice and information to the public on agency business. The provisions of Subpart A will apply to all aspects of FDA business unless superseded by other requirements specifically applicable to a particular class of actions or decisions.

The notice of proposed rule making on which these regulations are based was published in the FEDERAL REGISTER of September 3, 1975 (40 FR 40682). In the preamble to that proposal, the Commissioner of Food and Drugs discussed the initial issuance of these and related regulations, published in the FEDERAL REGISTER of May 27, 1975 (40 FR 22950), and subsequent litigation (*American College of Neuropsychopharmacology* v. *Weinberger, et al.*, Civil Action No. 75–1187) that resulted in their withdrawal as a final regulation and republication as a notice of proposed rule making. Other subparts of Part 2 proposed on September 3, 1975, have since been published separately in the FEDERAL REGISTER as final regulations as follows: Subpart C—Public Hearing Before a Public Board of Inquiry, June 28, 1976 (41 FR 26636); Subparts E, F, and G—Procedures for Public and Regulatory Hearings and Regulations Governing Standards of Conduct and Conflict of Interest, November 2, 1976 (41 FR 48258); Subpart B—Formal Evidentiary Public Hearings, November 23, 1976 (41 FR 51706); and Subpart D—Public Hearing Before a Public Advisory Committee, November 26, 1976 (41 FR 52148).

Most of the comments received on the provisions of Subpart A were from manufacturers of regulated products, including industry trade associations, professional associations, consumer groups, and individuals. Approximately 160 comments were received, including several comments on the May 27, 1975 final regulation, which, while subsequently withdrawn, was virtually identical in substance to the September 3, 1975 proposal. A section-by-section discussion of the substantive provisions of the regulations appeared in the preamble to that proposal. A summary of the issues raised by the comments, and the Commissioner's resolution of those issues, are set forth below.

No comments were received regarding § 2.1 Scope (21 CFR 2.1), and it is adopted as proposed.

1. Two comments were received regarding § 2.3 Definitions (21 CFR 2.3), both of which addressed the definition in § 2.3(a)(12) of "interested person." As explained in the preamble to the proposed rule, "interested person" and "any person who will be adversely affected" have been defined broadly to include any person who wishes to participate in any proceeding of FDA. No particular interest, specific economic or other harm, or other indicia of "standing" is required before a person may participate in or challenge any agency action.

One of the comments supported eliminating from the definition of "interested person" the requirement of a specific showing of interest. The other comment objected to the proposed definition as too broad. The comment argued that, by not limiting participation in agency matters to those who can show a definite interest that can be adversely affected, FDA proceedings may become protracted and burdened by numerous parties seeking to participate merely on the grounds that they represent some broad public interest. This, the comment argued, will prevent FDA proceedings from being expeditiously concluded in an orderly manner.

The Commissioner disagrees with this comment and has retained the proposed definition of "interested person" in the final regulation. Contrary to the comment, he maintains that persons espousing only broad interests shared generally by the public are entitled to participate fully in agency proceedings. As noted in the preamble to the proposal, FDA activities cover a broad range and affect every citizen generally, and thus all persons are entitled to participate in, and question, actions of the agency. The Commissioner is not persuaded that many agency actions will be seriously delayed as a result of the broad definition of "interested person," but he concludes that any delay that is likely to occur will be outweighed by the advantages of permitting unimpeded access by all persons to agency proceedings.

2. One comment on § 2.4 Summaries of administrative practices and procedures (21 CFR 2.4) urged that the distribution of the summaries by the Commissioner be wide and systematic so that public awareness would not be left to chance.

While the Commissioner agrees fully with the objective expressed by the comment, he believes it undesirable to modify the provision to impose on the agency what could be viewed as a requirement to establish a special distribution procedure. Every reasonable effort will be made by the agency to distribute the material so that it reaches as many segments of the public as possible.

3. Many comments were received in response to several aspects of § 2.5 Submission of documents to hearing clerk; computation of time; availability for public disclosure (21 CFR 2.5). Several comments objected to the requirement in proposed § 2.5(b) that submissions signed by attorneys or other authorized representatives be accompanied by signed statements of authorization, unless documentation of authorization has previously been submitted as part of the administrative file in the same proceeding. The comments argued, generally, that the requirement was excessive; that it was unwarranted to assume that an attorney would undertake to represent a party before the agency when he was not authorized to do so. Many comments argued that such a requirement was obviously superfluous when the attorney is in-house counsel to a corporation or organization. One comment inquired whether such an attorney, if an officer of the company, would be required to have his authority verified by another officer, and whether the corporate seal must also be affixed. Several comments noted that the Federal courts do not require the verification contemplated by the proposed rule, and thus questioned whether there could be a valid basis for imposition of the requirement by FDA.

After consideration of the comments, the Commissioner has concluded that the requirement should be deleted. He is persuaded by those comments questioning whether unauthorized submissions have been a problem for the agency, and he concedes that they have not. In any event, he believes that sanctions already available, notably 18 U.S.C. 1001 (the "False Reports to the Government Act"), as well as the Canons of Professional Ethics, will adequately ensure that attorneys or others representing parties or interested persons before the agency are authorized to do so.

A conforming change in § 2.130 (21 CFR 2.130), which in part establishes a similar verification requirement for any person representing another in a formal evidentiary public hearing under Subpart B, will be made in a subsequent publication.

4. Several comments objected to the requirement in proposed § 2.5(c) that all data and information referred to or in any way relied upon shall be included in each submission in full and may not be incorporated by reference, and to the requirement in paragraph (c)(1) that a copy of any article or other reference or source be included in each submission.

The comments contended that these companion requirements were unduly burdensome for various reasons. Several urged that submission be considered unnecessary if the material (1) is already available in another agency file, (2) consists of rules, regulations, court decisions, or agency memoranda, or (3) includes general reference materials such as standard medical texts. A comment suggested that incorporation of published sources be permitted unless FDA later notifies the party that the source is not available to the agency. It was pointed out that in a given matter sev-

eral comments may logically wish to rely on or refer to the same material, and inquired whether the receipt of five copies of the same material with each of numerous submissions was necessary or consistent with agency purposes. Another comment similarly questioned whether requiring receipt of duplicative material was consistent with the avowed limited agency resources, as represented in the preamble to the proposal, and suggested that some discretion be left to the submitting party. One comment urged that the rule be amended to require the submission of only the relevant portions of recognized texts.

The Commissioner advises that, insofar as submissions rely on legal documents, such as FDA documents that are routinely made publicly available (e.g., staff manual guides, hearing transcripts), Federal court cases, or Federal laws or regulations, he has determined that copies of the original material need not be submitted. He considers it appropriate to adopt a similar position for submissions that rely on an established, readily available medical or scientific textbook. Section 2.5(c) of this final regulation reflects these changes. Moreover, in accordance with § 2.1(a), § 2.5 would not change other agency regulations that permit referencing of materials in other types of administrative submissions (e.g., § 310.9 Designated journals (21 CFR 310.9), waiving with respect to the agency's new drug regulations the submission of reprints and summaries appearing in the journals listed).

However, the Commissioner does not agree with other suggestions made in the comments. He advises that the agency cannot, with its limited resources, be left to ferret from its voluminous files documents to which reference is made in submissions. The filing systems used by the Hearing Clerk and most other agency offices require manual searches to locate most materials. The Commissioner advises that § 2.5(c) permits referencing of material in the administrative file of the same proceeding. He finds unworkable, however, the suggestion to allow submissions to be made without referenced documents, if the information (other than those types expressly excepted) is believed to exist in a different agency file. In such cases, the Commissioner concludes that the burden of filing duplicative material is less than the burden on the agency of manually locating identical material in other files, and, if it is not found, of notifying a party at that time to submit it.

In response to the comment urging that the rule be amended to require only the submission of relevant portions of recognized texts (and, presumably, other documents), § 2.5(c)(3) as promulgated provides specifically for the deletion of irrelevant material from references of any type. The Commissioner cautions, however, that material that is relevant but not necessarily supportive of a submission may not be omitted.

5. Several comments objected to the requirement in paragraph (c)(6) of proposed § 2.5, which provides for the rejection of submitted documents that fail to comply with any requirement of the regulations. The Commissioner advised in the preamble to the proposal that strict adherence to the requirements for submissions would be required, and that failure to comply could result in rejection of a submission by the Hearing Clerk, or its exclusion from consideration.

One comment considered the rule too inflexible, and contended that it is unjustified where the flaw is procedural and can be corrected easily. The comment further protested that no time limit was imposed on the Hearing Clerk to reject a document, and that the proposed rule did not provide for deferral of the agency decision in connection with which the document had been submitted until any defect in the submission had been corrected. Similarly, another comment inquired whether the resubmission of a rejected comment must be within the original time specified, referring to proposed § 2.112(c) in Subpart B (21 CFR 2.112(c)), which provides for resubmission of objections or requests for a hearing within the original 30-day time period. One comment suggested that 15 days be allowed from the day of rejection to allow a person to resubmit any rejected comment or other document. Still another comment urged that rejection of a comment be permitted only in the case of a serious failure to comply with reasonable requirements that are authorized by statute. Another comment suggested that the test for rejection should be that the document patently fails to comply substantially with the requirements, and complained that the case cited in the preamble to the proposal, *Municipal Light Boards* v. *Federal Power Commission*, 450 F. 2d 1341 (D.C. Cir. 1971), cert. denied, 405 U.S. 989 (1972), does not authorize rejection of a submission for failure to adhere exactly to formal submission requirements. One comment urged that a right of appeal be provided to permit challenges to the rejection of submissions. A final comment suggested that proposed § 2.5(c)(6) be revised to permit amendment of a submission as a matter of right when the submission is found to be procedurally deficient.

The Commissioner concludes that the provision be promulgated as proposed. He finds insubstantial the comments objecting to the authority of the Hearing Clerk to reject submissions for failure to adhere to the requirements of Part 2. These requirements have been imposed to facilitate agency business by avoiding the submission of requests or comments that are specious, insubstantial, or that fail to contain justification adequate to permit the Commissioner to evaluate properly the request or submission.

The Commissioner advises that the agency is not obliged to provide additional time for resubmission when a submission has been properly rejected. He believes the requirements for submission are precise enough to be met in the first instance—and that persons failing to meet them, rather than the agency, should bear the responsibility for the failure. Moreover, to provide an extended time for filing would clearly promote the filing of insubstantial submissions as a device to obtain additional time. Consequently, he disagrees as well with those comments demanding that an administrative right of appeal or right of resubmission be accorded when a submission is rejected.

The Commissioner also rejects the suggestion that he amend the requirements to permit rejection only when a submission "substantially" departs from the requirements; to do so would also invite the submission of incomplete and inadequate documents. He has essentially in this section reserved the right to reject submissions that are inadequate for the purposes for which they are submitted. At the same time, he advises that submissions will not be rejected frivolously or casually. Nor will rejection automatically preclude consideration when a corrected submission is not filed in a timely fashion. Comment closing dates in informal rule making, for example, indicate only when the Commissioner is no longer legally obligated to consider a comment; they do not prohibit him from considering comments filed late, and he frequently does so. The Commissioner advises that in implementing these requirements he intends to continue to observe a basic policy of fairness in determining whether a submission is acceptable.

6. Several comments objected to the various substantive requirements in § 2.5 for submissions to the Hearing Clerk. Some comments objected to the requirement of proposed § 2.5(a) that submissions be filed in quintuplicate. One urged that a comment or submission should not be rejected for the failure to submit the required number of copies. The comment also noted that the regulations fail to define "submission." Another comment suggested retaining the present practice of specifying the number of copies in each FEDERAL REGISTER notice.

The Commissioner advises that "submission" is intended to have its common dictionary meaning. Those documents that must be "submitted" to the Hearing Clerk for each type of contemplated agency action, moreover, are adequately described in the final regulation, and therefore no special definition of "submission" is necessary.

The Commissioner concludes that the final regulation will retain the specification of the number of copies of a submission, although as a matter of practice the number of copies will, as one of the comments suggested, also be specified in the relevant FEDERAL REGISTER notice. Based on a reassessment of agency needs, the Commissioner has reduced to four the number of copies required to be submitted, except where otherwise specified. A conforming change has been made in § 2.10(b)(4) (21 CFR 2.10(b)(4)) dealing with the submission of comments in response to a proposed regulation.

The question of the number of copies is one with which each Federal agency

must deal. Although agencies do possess duplicating facilities, most are fully utilized in duplicating agency-originated records. That FDA needs several copies of submissions is obvious—copies must not only be on display for public examination but must be forwarded to agency employees and, frequently, to agency counsel for evaluation and action. Many submissions number scores of pages and FDA lacks the resources to duplicate every one received. Because duplicating facilities are widely available, the Commissioner deems it reasonable to expect the public to undertake the task of duplication. Nonetheless, the Commissioner advises that the regulations do provide some exceptions to the general requirement that four copies be submitted. With respect to comments filed in response to proposed rule making, § 2.10 permits individuals to file one copy, on the basis of the Commissioner's experience that submissions by individuals (1) are less frequently received, (2) are submitted by persons often lacking access to duplicating facilities, and (3) are generally shorter than submissions from manufacturers, industry groups, and public interest organizations. Section 2.19(i) (21 CFR 2.19(i)) permits lesser numbers of copies to be submitted; namely, three copies of comments responding to advisory opinions. In this final regulation, that section permits individuals to submit one copy. The Commissioner believes that adequate justification has not been presented to reduce further the numbers of copies required. Rather, he views the requirements as necessary for the efficient conduct of agency business and not significantly burdensome.

In response to a comment inquiring whether comments will be rejected for failure to provide the requisite copies, the Commissioner advises that he will not normally reject these comments, although he has expressly reserved the right to do so. In most situations, where the failure to provide the required copies is not habitual, the Hearing Clerk will merely file the copy received and, depending on its length, either request the person making the submission to provide additional copies, or make copies using agency facilities. The rule must permit some flexibility, and the Hearing Clerk will exercise appropriate judgment consistent with maintaining efficiency in the filing of documents.

7. One comment protested the requirement in proposed § 2.5(e) that certain submissions shall be considered filed on the date of receipt. The comment complains that this provides an advantage to persons located in Washington, DC.

The Commissioner advises that the receipt date is considered the filing date for only a small number of actions, e.g., petitions for reconsideration under § 2.8 and requests for administrative stays of action under § 2.9, where a strict filing time is specified to facilitate a prompt administrative decision. Establishing a date other than the receipt date as the day of filing in these limited circumstances would not be workable. The Commissioner views any disadvantage to persons outside the Washington area to be minimal, and to be clearly outweighed by the agency need to act expeditiously in certain limited types of matters.

The Commissioner advises that in most proceedings, except when another date is specified, § 2.5(e), as proposed and finalized, provides that the postmark shall be considered to be the date of filing. This rule applies equally to all persons regardless of their geographic location and the Commissioner finds this rule reasonable.

8. One comment asked implicitly whether proposed § 2.112(c), specifying steps the Hearing Clerk will take in filing objections or requests for hearing, should logically be incorporated into § 2.5. The Commissioner deems the comment to be valid, but advises that, as a matter of drafting preference, the references to "Subpart B of this part" in § 2.5(j) adequately incorporate the appropriate provision of § 2.112 into § 2.5.

9. Some comments objected to certain of the bases for rejecting comments stated in proposed § 2.5(c) (3) and (5). One comment characterized the reference to intemperate matter in § 2.5(c) (5) as vague and suggested deleting the requirement. Another contended that it is impracticable to remove all irrelevant matter as specified in § 2.5(c)(3), arguing that to do so would make many documents unintelligible and put undue emphasis on the matter retained. One comment suggested that what is irrelevant, defamatory, scurrilous or intemperate could vary widely, and argued that the provisions for resubmission were therefore inadequate.

The Commissioner views the issue raised by the comments as having some merit. He believes, however, that although the meaning of these words may vary, the standards can be fairly administered. The Commissioner must retain the ability to reject submissions whose content is clearly inappropriate for a public government file. He believes that proposed § 2.5(c) (3) and (5) contains a reasonably objective statement of criteria to be used, and thus has retained them in the final regulation.

The Commissioner advises that the comment regarding deleting irrelevant material has read the requirement too narrowly. The requirement does not intend that submissions must contain only carefully screened material that eliminates every irrelevancy. He advises, rather, that submissions should not include wholly irrelevant material that can easily be excised before submission, e.g., chapters of a book that are unrelated to the matter at hand. When thus viewed, he believes the requirement to be both necessary and desirable.

10. Comments expressed most concern about the requirement in proposed § 2.5(j)(2)(i) that material consisting of safety and effectiveness data and information or a protocol for a test or study be filed with the Hearing Clerk and be made available for public examination, but not for copying, if such material is submitted: (1) With an objection or request for a hearing filed pursuant to Subpart B of Part 2; (2) at a formal evidentiary public hearing pursuant to Subpart B of Part 2; (3) at a public hearing before a Public Board of Inquiry pursuant to Subpart C of Part 2; (4) at an alternative form of public hearing before a public advisory committee; or (5) at a public hearing before the Commissioner pursuant to § 2.117(a) (2) or (3) (21 CFR 2.117(a) (2) or (3)). Section 2.5(j)(2)(iii) proposed further that such material would be on public display and available for examination only for such time as is necessary to permit public participation in the public hearing, and any related judicial review. Proposed § 2.5(j)(2)(iv) would specify, in addition, that this limited availability would not constitute prior disclosure to the public as defined in § 4.81 (21 CFR 4.81) of the FDA public information regulations under Part 4 (21 CFR Part 4), and would prohibit any such information, if improperly copied, from being resubmitted to the agency in support of a petition or other request.

The many comments on the proposed requirement expressed essentially similar objections. Several comments argued that allowing examination but not copying of confidential safety and effectiveness information would be violative of the relevant statutory provisions prohibiting disclosure of trade secret information, i.e., 18 U.S.C. 1905 and section 301 (j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)) and would be inconsistent with prior agency positions, primarily reflected in its public information regulations, and the new drug regulations under § 314.13 (21 CFR 314.13). The comments insisted that these regulations clearly provide that previously undisclosed safety and effectiveness data, at least insofar as they relate to a product subject to a new drug application (NDA) (or new animal drug application (NADA)), are trade secrets and not subject to public disclosure, citing *Morgan* v. *FDA*, 495 F. 2d 1075 (D.C. Cir. 1974). The comments insisted, further, that if such information is entitled to confidential treatment, it is entitled to full and not partial confidentiality; that the law does not provide for degrees of nondisclosure; and that making such material available simply for examination cannot fairly be characterized as anything other than disclosure.

One comment suggested that permitting public examination of safety and effectiveness data may result in a court finding that the data no longer retain their trade secret status. Still another comment maintained that submission of trade secret material to a third person destroys trade secret status under common law and may thus influence parties not to submit information because of the likelihood of disclosure.

One comment claimed that the position ignores the competitive value of the information and that even limited exposure to such data can greatly facilitate a competitor's filing an NDA for an identical or similar drug. The comment urged that mere exposure to the results of a competitor's research points to approaches found most effective and eliminates much of the trial and error experi-

enced by the originator of the data. A related comment noted that protocols and test data may often have a commercial value beyond the single product or product class for which they were submitted. Several comments indicated that a mere viewing of such documents, particularly by trained scientists, can yield much information.

Another comment questioned the view stated in the proposal that the only value of the information would be in its resubmission to FDA. The comment contended, as did others, that such data had other commercial value. The comment suggested that the data would be valuable in obtaining product approvals in foreign countries, in designing clinical studies on similar compounds, and in verifying the results of independent research.

Several comments also disputed the representation in proposed § 2.5(j)(2)(iii) that the agency would not accept such material if improperly copied and submitted, pointing out that FDA has already taken the position in the preamble to its public information regulations published in the FEDERAL REGISTER of December 24, 1974 (39 FR 44602) that it could not under present law refuse to approve an identical, similar, or related drug on the basis of information that has been disclosed. Moreover, the comments questioned whether, even if FDA could lawfully refuse to accept such data, it could effectively enforce the ban on copying, or readily determine when wrongfully copied data, effectively disguised, were being resubmitted.

One comment asked whether the agency would, for example, require a second submitter to provide evidence that the information was not obtained by unauthorized copying. One comment pointed out that the rule forced a party to face the penalty of foregoing a hearing, guaranteed him by statute, if he did not wish to disclose his data. A related comment suggested that no need existed for public display of safety and effectiveness data when a hearing involved an NDA. It contended that the principal participants in an NDA hearing are the manufacturer and the agency, and that if the data were available to these parties, there would be no need to make it otherwise available, except through the already established use of summaries. Another comment suggested that the regulations not be finalized unless the FDA public information requirements were upheld in a suit against the regulations brought by the Pharmaceutical Manufacturers Association.

Several comments opposing the adoption of proposed § 2.5(j)(2) suggested alternatives in lieu of the proposed manner of disclosure of the material. One comment suggested maintaining confidentiality by limiting any disclosure to properly concerned parties under appropriate protective orders granted by the administrative law judge or authorized presiding officer. It suggested that such an arrangement has been held valid in a freedom of information context, citing *Porter County, etc., League* v. *U.S. Atomic Energy Commission*, 380 F. Supp. 360 (N.D. Ind. 1974). The comment suggested that where parties were represented by outside counsel, the documents could be disclosed to the counsel with a prohibition against disclosure to the client. The comment insisted that this procedure would both protect confidentiality and permit full participation in the hearing process.

Another comment contended that any need to disseminate safety and effectiveness data could be satisfied through the use of summaries under § 314.14(d) (21 CFR 314.14(d)), dealing with the treatment of such information when part of an NDA, and the agency's public information regulations under Part 4. It concluded that the material in question should thus be treated under proposed § 2.5(j)(3), namely, to permit neither examination nor copying.

One comment suggested that the requirements of proposed § 2.5(j)(3), which would prohibit disclosure except as permitted by the public information regulations, should apply to disclosure where participants are concerned. The comment would, by implication, permit disclosing the material to parties, although it did not specify whether the parties would be able to do more than review the material. The comment would require any party permitted to view the material to sign a statement that all trade secrets and confidential information would be used for the hearing only, and otherwise kept in confidence.

One comment expressed views contrary to the foregoing criticisms of the proposal. The comment protested the ban on copying imposed by proposed § 2.5(j)(2), claiming it to be unwise, unnecessary, and unenforceable. The comment noted anomalies in the requirement: that it would limit access to those who regularly meet or work in Washington or regional headquarters, and would put a premium on an observer's memory. It urged the agency to "go all the way" for convenience and accuracy.

While the Commissioner does not consider each of the objections to the requirements of proposed § 2.5(j)(2) to be valid, he has, upon reconsideration of the issue, determined to withdraw the provision.

The Commissioner agrees that proposed § 2.5(j)(2) is not readily reconcilable with the agency's position under Part 4. The public information regulations assert the traditional position that previously undisclosed full reports of safety and effectiveness data and certain protocols for studies are trade secrets and are thus prohibited from disclosure under both 18 U.S.C. 1905, the basic Federal criminal statute prohibiting the disclosure of trade secrets, and section 301(j) of the act, prohibiting the revealing of any information obtained under sections 404, 406, 505, 506, 507, 510, 512, 513, 514, 515, 516, 519, 520, 704, 706, or 708 of the act (21 U.S.C. 344, 346, 355, 356, 357, 360, 360b, 360c, 360d, 360e, 360f, 360i, 360j, 374, 376, 379) concerning any method or process which as a trade secret is entitled to protection.

Because of the large number of comments addressed to this issue, the Commissioner believes a full discussion of his reasons for modifying the proposal is appropriate. His position in the proposal was not that these materials were no longer trade secrets and were thus subject to disclosure, but rather that by limiting access to them to viewing only, and by precluding their resubmission to the agency by any other party, the agency would protect those interests that gave these materials their trade secret status. The Commissioner believed that this interpretation of the Federal nondisclosure statutes was appropriate, and that making the material so available would enhance the various hearing processes by allowing all participants access to information germane to the hearing.

The Commissioner continues to believe that the public availability of the information in question could enhance the utility and fairness of the public hearings provided for in Part 2. He has changed his position on the basis of three factors: (1) Upon reconsideration, he concludes that Congress has determined that such information may not be disclosed to the general public and that he must abide by that determination even in the context of public hearings, where access to the information may have a demonstrable public benefit; (2) the "look-but-don't-copy-rule," and the concomitant prohibition against resubmission of the material, would invite circumvention through both surreptitious efforts at copying and disguised resubmission, and could not be effectively enforced; (3) the benefit to the hearing process would be problematical. The Commissioner cannot say with assurance that mere access to the data, without copying, would permit the meaningful participation in the hearing process that was the objective of the proposal.

The provision has been modified, as suggested by a comment, to subject previously undisclosed safety and effectiveness data and information, including protocols, in a hearing setting to the restrictions against disclosure in proposed § 2.5(j)(3) (redesignated as paragraph (j)(2) in this final regulation), which will make the information available to all persons in accordance with Part 4, the agency public information regulations. As a practical matter, this will provide for the display of agency-prepared or -approved summaries for unlimited viewing and copying in the office of the Hearing Clerk; or dissemination of such summaries on request.

The Commissioner has also added a new paragraph (j)(3) to § 2.5, to permit disclosure of safety and effectiveness data and information, and otherwise undisclosed protocols for tests and studies, pursuant to a protective order issued by the administrative law judge at a formal evidentiary public hearing pursuant to Subpart B, or by the presiding officer at

a public hearing before a Public Board of Inquiry pursuant to Subpart C, or an alternative form of public hearing before a public advisory committee or a public hearing before the Commissioner pursuant to § 2.117(a) (2) or (3) (21 CFR 2.117(a) (2) or (3)). Any protective order must prohibit the disclosure of such confidential data except insofar as the administrative law judge or other presiding officer determines necessary for the proper conduct of the hearing. Paragraph (j)(3) accordingly permits disclosure only in in camera proceedings from which persons not specifically permitted access to the data would be excluded. The order must specify to whom the information is to be made available, o.g., to parties or participants, or only their counsel. The regulation thus permits the administrative law judge or other presiding officer to fashion a protective order to meet the circumstances of individual proceedings so long as the stated requirements are met. The requirements of proposed § 2.5(j)(2)(iv), prohibiting the resubmission of any material so disclosed, are incorporated into new paragraph (j)(3).

The Commissioner believes the use of protective orders and in camera proceedings meets most of the objections in the comments to the disclosure of this information. He notes that the use of in camera administrative proceedings to protect the confidentiality of information is recognized in the regulations of other agencies, e.g., 16 CFR 3.45, providing for in camera orders in proceedings before the Federal Trade Commission, and he is confident that, consistent with applicable statutes, such orders can be properly used in FDA hearings. For all interested persons not permitted to participate in in camera proceedings held as part of an administrative hearing where confidential safety and effectiveness data are discussed, summaries of such material will be available for inspection and copying in the office of the Hearing Clerk.

The Commissioner has not accepted other recommendations in the comments, e.g., the suggestion that disclosure be limited only to parties to the hearings; such a step would increase the number of persons seeking to become parties to a hearing simply to obtain access to confidential information. He rejects the obvious regulatory response to such a problem—to severely limit who may become a party to individuals, organizations, etc., having a recognizable specified interest in the proceedings—because it is inconsistent with the requirements' overall intent to improve access to FDA proceedings.

Nor does the Commissioner believe that he could lawfully adopt the last suggested alternative: permit copying as well as inspection of the material in question. This would be unauthorized under 18 U.S.C. 1905 and section 301(j) of the act.

11. The final order promulgating the public information regulations under Part 4 advised that confidentiality of documents submitted voluntarily to the Hearing Clerk cannot be established by submitting documents marked "confidential" or bearing some other analogous legend, but rather can be established only through presubmission review of voluntarily submitted documents under § 4.44 (21 CFR 4.44). The Commissioner advises that the personnel of the office of the Hearing Clerk cannot make decisions regarding confidentiality. Again, the Commissioner advises that the presubmission review procedure of § 4.44 must be followed by any member of the public who wishes information submitted voluntarily to the agency in a public proceeding to be held confidential. He has incorporated language to that effect in § 2.5(c)(6). In the absence of an affirmative determination of confidentiality under § 4.44, FDA will continue to make publicly available all materials submitted to the Hearing Clerk, notwithstanding any claims of confidentiality made on the face of a document.

12. Concern was expressed within the agency during the rule making process regarding the need for submissions from standard-setting organizations in which an FDA employee is participating under § 2.21 (21 CFR 2.21). The Commissioner advises that such organizations cannot properly rely on the FDA employee to convey their views regarding an anticipated agency action. Rather, any such group should, regardless of the number or identity of agency employees participating in its activities, offer submissions in its own name in accordance with this subpart whenever the organization wishes to make its views known to the agency.

Section 2.6 Initiation of administrative proccdures (21 CFR 2.6) which specifies generally how agency action may be initiated is adopted substantially as proposed. Such action may be initiated (1) by any interested person who petitions the Commissioner in accordance with the requirements of this part or other agency regulations, (2) by the Commissioner, on his own initiative, or (3) when a court refers any such matter to the Commissioner after holding the matter in abeyance, dismissing an action regarding the matter in question, or making other appropriate judicial disposition of the matter.

13. A clarifying change has been made in § 2.6(c). As proposed, the section required the Commissioner to institute a proceeding "* * * whenever any court holds in abeyance or refers any such matter to him for * * * determination and the Commissioner concludes that the making of such a determination is feasible in light of agency priorities and resources." The phrase "holds in abeyance" might be understood to refer to a matter then before the agency and not, as was intended, simply to a matter then before the court. The referral by a court in § 2.6(c) means only those referrals not sought by the Commissioner, which are to be distinguished from referrals discussed in paragraph (b) of § 2.6. The latter result from initiatives by the Commissioner to have a matter within the agency's primary jurisdiction and pending before a court referred to the agency for decision or reconsideration. The language of § 2.6(c) has been clarified to reflect this distinction.

14. The only comment received on proposed § 2.6 urged that § 2.6(a), relating to administrative matters subject to citizen petitions, exclude food additive petitions under § 121.51 (21 CFR 121.51), NDA's under § 314.1 (21 CFR 314.1), and NADA's under § 514.1 (21 CFR 514.1). The comment argued that allowing any person to petition the Commissioner to revoke an NDA could create outside pressures inconsistent with the exercise of sound judgment, and could require that the holder of the NADA spend substantial time answering such a petition, even when the petition was without basis.

The Commissioner disagrees with the comment's contention that any interested person should not be entitled to petition to modify or reverse any agency action, including one that may have initially been taken ex parte, such as the approval of an NDA or NADA. The effects of such actions clearly extend to the public generally, and the public thus is entitled to initiate agency review of such decisions.

The Commissioner also notes that the comment appears to misunderstand the nature of the requirement. The mere submission of a petition under the section does not obligate the Commissioner to undertake agency action apart from reviewing the petition (e.g., § 2.7(e) (21 CFR 2.7(e))). Thus, the mere filing of a petition to revoke an approved NDA would not, as the comment postulates, automatically oblige the holder of the NDA to reply. Such reply would be necessary only if the Commissioner proposes to take an action on the petition adverse to the NDA holder; such action would be proposed only after his decision that the petition was meritorious. The comment is accordingly rejected.

Section 2.7 Citizen petition (21 CFR 2.7) codifies the requirements for citizen petitions, the mechanism by which any member of the public may seek agency action on any matter, except for the referral of matters to a United States attorney for the initiation of court enforcement action and related regulatory activities that are within the exclusive discretion of the Commissioner. As noted in the preamble to the proposed rule, in the past FDA has had no requirements governing the manner in which citizens might petition the agency to undertake agency action. This has resulted in confusion and uncertainty on the part of those who wish to petition the agency, as well as on the part of agency employees, on how to handle particular requests from the public.

15. The final regulation contains a new requirement, not proposed, that a citizen petitioner supply, when specifically requested by the Commissioner following review of the petition, information on the economic consequences of the action requested. Pursuant to Executive Order 11821, OMB Circular No. A-107, and HEW Guidelines, FDA is required

to consider the inflationary impact of legislative proposals and major rules and regulations that it initiates. The Commissioner has therefore added a new paragraph D, to the citizen petition form set forth in § 2.7(b) that requires citizen petitioners, when requested, to submit the type of information required under E.O. 11821 to be considered by executive agencies in assessing the inflationary impact of proposed actions. The submission of information relating to inflationary impact would not be required of every citizen petition. While evaluation of the inflationary impact of agency action is important, the one court that has addressed the issue has held that agency action is not subject to reversal because of alleged deficiencies in an inflation impact statement (*Independent Meat Packers Association* v. *Butz*, 526 F.2d 228 (8th Cir. 1975)). The Commissioner believes it justifiable, therefore, to elicit such information from petitioners only when he believes that additional information is necessary to evaluate the consequences of acting on a petition. In addition, the Commissioner will take into consideration the ability of the petitioner to provide relevant information and he recognizes that it is incumbent on the agency also to obtain such information from sources other than the petitioner.

16. Proposed § 2.7 does not obligate the Commissioner to respond definitively to citizen petitions within a given time frame, except where time limits are prescribed by statute. Several comments objected to this provision. The comments identified what they considered a lack of fairness, pointing out that other provisions of the proposed regulations (e.g., § 2.11 (21 CFR 2.11)) specify that administrative remedies be exhausted before court review can be obtained. One comment complained that a lack of a definite response period operated to the disadvantage of consumer groups as compared to industry petitioners, contending that in the past, consumer petitions filed with FDA have been forgotten.

The preamble to the proposal identified several reasons why no time period for response by the agency to petitions had been specified and explained that limited agency resources make it impractical for the agency to deal promptly with petitions concerning subjects of low priority. Moreover, the preamble noted that specifying a time period for reply might force the agency to decline requested action simply because it could not act within the time allowed.

After reviewing the various arguments, the Commissioner has determined that the agency should obligate itself to respond to a petitioner, at least preliminarily, within a specified time period. He has determined that such a requirement will on balance enhance agency efficiency in conducting its business. Moreover, the Commissioner believes that the obligation to respond to a citizen petition, when that response is overdue, must be regarded as a priority matter regardless of the petition's content, if the agency is to maintain the public confidence in its ability to deal with the issues within its jurisdiction.

Accordingly, as suggested by some comments, § 2.7(e) has been revised to require that the agency respond within 180 days to any petition submitted under that section. The response shall be either (1) approval, accompanied by some form of implementing action, e.g., the publication of a notice of proposed rule making, (2) denial, constituting final agency action, or (3) a tentative response, indicating why the agency has been unable to reach a decision on the merits of the petition, e.g., because of other agency priorities, a need for additional information, or other stated reason. The tentative response may indicate the likely agency response, and may specify when a definitive response may be given.

The Commissioner believes this modification will eliminate the uncertainty on the part of petitioners that the comments attribute to past agency handling of petitions, and thus responds to what appears to be the major objection raised by the comments.

17. Section 2.7(g), as proposed and as promulgated, permits any petitioner to supplement, amend, or withdraw his petition at any time before referral of the petition for hearing. After such a ruling or referral, however, the petition may be withdrawn only with the approval of the Commissioner. An editorial modification has been made to the section to clarify its meaning.

18. One comment suggested that § 2.7 be modified to state expressly that voluntary withdrawal of a petition shall be without prejudice to its resubmission. The Commissioner concurs that this is consistent with the intent of the section, and has revised § 2.7(g) accordingly. The Commissioner also advises, however, and has modified § 2.7(g) to provide, that when a petition may only be withdrawn with the agency's approval, the petitioner may resubmit it only with the agency's approval.

19. Section 2.7(l) requires the Hearing Clerk to maintain a chronological list of all petitions filed under that section, and under § 2.19, but excludes from the list petitions submitted to other parts of the agency pursuant to § 2.6(a)(1). The list, as proposed, would include for each petition the docket number established by the Hearing Clerk, the date the petition was filed by the Hearing Clerk, the name of the petitioner, and the subject matter involved. One comment suggested that a new item concerning the disposition of the petition be added so that interested persons might more easily determine what action FDA has taken on the petition. The Commissioner concurs with the suggestion and, as promulgated, paragraph (l) has been modified accordingly.

20. One comment urged that if petitions are permitted to be filed elsewhere in the agency and not listed by the Hearing Clerk, the regulation should provide for publication of notice in the FEDERAL REGISTER and direct communication with the holder of any NDA or NADA that is the subject of the petition.

The Commissioner advises that the procedures for revocation of an NDA or NADA are codified in both the Federal Food, Drug, and Cosmetic Act and agency regulations (section 505(e) of the act and § 314.121 (21 CFR 314.121); section 512(e) of the act and § 514.121 (21 CFR 514.121)) and already provide for notification of the holder of an approved NDA or NADA as part of any proceeding for revocation. Accordingly, no amendment to the regulations is necessary.

21. Many comments objected to the requirements in paragraph B of the proposed form for a citizen petition in § 2.7(b) that each petition include "* * * representative data and information known to the petitioner that are unfavorable to the petitioner's position." Some of the comments suggested that this requirement might violate the constitutional protection against self-incrimination, pointing out that a penal sanction may arise from the failure to comply. One comment questioned whether a violation of the False Reports to the Government Act would arise from a failure to provide required adverse information. Another comment maintained that to require a lawyer to include such information might conflict with his professional obligations. Another comment suggested that the adverse information might be misrepresented wittingly or unwittingly. That comment urged that the requirement was inappropriate; that truth in such matters should arise ultimately from the clash of opposing viewpoints. At least one comment attempted to characterize the conflict as one setting industry against consumer, and suggested that while the requirement might be fitting for an industry petition, it would have a "chilling" effect on citizen petitions. Another comment suggested the provision would give the agency an unfair advantage in court, should its decision on the petition be later subject to judicial review. Still other comments argued that the requirement was superfluous, contending that FDA would be obligated in any event to seek out adverse information on its own. A final comment suggested that the requirement, if adopted, should be revised to apply only to scientifically backed data and information, and that it not encompass unsupported lay opinion.

The Commissioner does not accept these arguments, and has promulgated the requirement as proposed. He finds that those comments that attempt to characterize administrative rule making resulting from citizen petitions as a type of litigation, and those that equate requiring inclusion of "unfavorable information" with self-incrimination, misunderstand the nature of administrative rule making. In rule making, the agency is attempting to make judgments about regulatory policy on the basis of all the scientific information that is available on a subject. There is thus no valid analogy between the interests of partici-

pants in a rule making proceeding and the interests of those involved in a criminal trial.

Equally important is the failure of the comments to recognize that divulging adverse information may advance rather than detract from a participant's position. The administrative record of a particular matter may contain information adverse to the Commissioner's decision and still be legally sufficient to support the decision. Indeed, in making many administrative decisions, the Commissioner will often choose between competing versions of the "facts." What the comments overlook is that a decision favorable to a petition that reflects a review of information and arguments both supportive of and adverse to the petition is likely to be credible, and thus ultimately more supportable, than a decision reached on the basis only of supportive information.

The Commissioner also rejects the suggestion that only scientifically backed adverse information should be required to be included. Issues that come before the Commissioner rarely turn on definitive or uncontradicated evidence, and adverse educated opinion, even if lay opinion, should be included if for no other reason than to permit the agency to explore the matter further if it so desires.

22. The Commissioner also rejects comments that protested the proposed requirement that citizen petitions, to be acceptable for requirements were demanding and that their inflexibility would discourage citizens from filing petitions. The comment contended that a document should be accepted as a petition if it includes (1) the word "petition," (2) a statement of the petitioner's request and reasons, and (3) a signature, address, and telephone number. Another comment suggested that a simple letter be accepted when the request cannot be answered simply by letter. A third comment suggested that a petition not be rejected for deficiencies of form until FDA had assisted the petitioner in bringing the petition into conformity.

The requirement that citizen petitions take a particular form and contain specifically prescribed information is not intended to create obstacles to persons who would petition for particular agency action. Given the heavy workload of the agency, the Commissioner believes it necessary to give formal petitions a status different from mere inquiries or suggestions so that he may properly respond. The agency may expend significant resources in responding to citizen petitions and the Commissioner believes it proper for any person requesting agency action to set forth with some completeness the basis for the request. The Commissioner does not find the substantive requirements of § 2.7 onerous, and believes that laymen can readily comply.

Moreover, the regulations are responsive to the comment requesting the agency to assist a petitioner in bringing a petition into compliance. Section 2.5 (c)(6), which applies to citizen petitions filed pursuant to § 2.7, provides, as proposed, that if the Hearing Clerk discerns that a petition or other submission fails to meet formal requirements, the submission will be returned to the petitioner with a copy of the applicable regulations indicating how the document fails to comply, without prejudice to the petitioner's right to resubmit the document in proper form.

23. Many comments also objected to the requirement in proposed § 2.7(b) that each petition contain an environmental impact analysis report in the form specified in § 6.1(g) (21 CFR 6.1 (g)). Some of these comments apparently misunderstood the requirement as relating to an environmental impact statement, for this reference is contained in several of the comments. The Commissioner advises that a full environmental impact statement is not required as part of a citizen petition. The report specified in § 6.1 requires general and nontechnical information on the environmental aspects of contemplated action, some of which will have been provided in other parts of a citizen petition.

Comments from some consumer groups argued that nonindustry petitioners did not have the resources to prepare environmental impact analyses, or urged that the requirement be that such a report be submitted only if the agency should later advise a petitioner of the need for an environmental impact statement. One comment suggested that in such as case the agency should prepare the environmental impact analysis report.

The Commissioner rejects the view that petitions from nonindustry sources should be exempt from the need for environmental evaluation, or that public interest or consumer groups should not conduct the review required in an environmental impact analysis report. The Commissioner regards the information provided in such a report as important in his evaluation of a petition, for the information will help determine whether the agency will be required to prepare, should it decide to undertake the requested action, an environmental impact statement. In cases where the environmental effects of an action will be minimal, the burden of preparing the required report will be correspondingly reduced.

24. A few comments objected to the requirement of proposed § 2.7(b) that a petitioner certify the truthfulness of the information contained in the petition. One comment argued that the requirement creates confusion, because it appears to limit the vigor with which a petitioner may argue against denial of his petition without violating the False Reports to the Government Act. Another comment argued that the proposed certification is unnecessary because § 2.5(i) already provides that all submissions constitute a representation that all statements therein are true and accurate.

The Commissioner has decided to retain the certification requirement in a citizen petition. He views as spurious the argument that the requirement makes impossible the obligation of a petitioner to include information unfavorable to the petition; all that is required is that a petitioner include such information as is known to him. Finally, while the requirement may be technically redundant, its inclusion will remind petitioners to verify the accuracy of their submissions.

Section 2.8 Administrative reconsideration of action (21 CFR 2.8) provides for reconsideration by the Commissioner of any administrative matter on his own initiative, and with respect to a matter initiated under § 2.6(a), on the basis of a petition submitted by any interested person. The section is adopted essentially as proposed.

25. Comments on § 2.8 objected to what they urged were unnecessarily rigid requirements of form for a petition for reconsideration. The Commissioner does not accept the objection. He has specified the form such petitions must take, not out of any preoccupation with form, but because he believes that petitions for reconsideration, given their importance and the need for prompt resolution of the issues they raise, must contain certain requisite information. The minimum requirements are set forth in the section, and the Commissioner finds them to be simple and straightforward. They are not intended to be, nor does the Commissioner find them to be, onerous in any respect.

26. Comments also objected to the requirement in proposed § 2.8(b) that a petition for reconsideration be filed within 30 days of the action that is to be reconsidered. One comment urged that the 30-day provision be extendable for good cause on the basis of new evidence; the comment argued that to require the proceeding to be reopened by the filing of a new petition would be wasteful of the resources of the petitioner and the agency. One comment also urged the addition of language to the section to require that specific notice of the Commissioner's original decision be provided to all parties to an action so that they would be assured of knowing when the 30-day period begins.

The Commissioner believes that the requirement that a petition for reconsideration be filed within 30 days of the action is reasonable. Such a petition seeks immediate review of agency action by the Commissioner on the basis of the same information as was before him at the time of his original decision. The Commissioner regards the need for prompt submission to be self-apparent. The Commissioner also does not accept the suggestion that the 30-day period be made extendable on the basis of new evidence. He advises that reconsideration is limited to the data and information on which the original action was taken. Moreover, to adopt the suggestion would undermine the finality of agency actions.

The Commissioner also rejects the suggestion that all parties to a proceeding be specifically, i.e., personally, notified so that they will know that the 30-day period has begun. The Commissioner advises that he believes publication of a decision in the FEDERAL REGISTER provides

adequate notice of when a decision has been made. A conforming change has been made in § 2.8(b) to indicate that, for purposes of computing the 30-day period, the date of publication shall be considered the date of the decision. Where the decision of the agency is not announced by FEDERAL REGISTER publication, the parties involved would be personally notified of the decision, e.g., a denial of a citizen petition under § 2.7 (e). The Commissioner's decision would also be placed in the public file of the matter. The Commissioner does not believe that further notice to the public of agency decisions is legally required, practicable, or necessary.

Section 2.9 Administrative stay of action (21 CFR 2.9) provides a mechanism by which the Commissioner may stay the effective date of any administrative action (but not including court enforcement action) on his own initiative, or on the petition of any interested person. The section is adopted without significant change.

27. One comment objected to what it considered to be unnecessary requirements for the form of these petitions. As stated in his response to similar objections regarding § 2.7 and § 2.8, the Commissioner's insistence on prescribing the form of such petitions arises from the need to assure that they contain adequate information on which to base a judgment. The requirements are not so complicated or rigid that the Commissioner feels obliged to relax them.

28. One comment urged that the proposed 30-day period for response was too short. The comment pointed to the 60-day period generally provided for seeking judicial review, and the 90-day period specified in section 701(f) of the act (21 U.S.C. 701(f)) for seeking judicial review of agency action resulting from proceedings governed by section 701(e) of the act (21 U.S.C. 701(e)).

The Commissioner believes that a 30-day period is adequate for interested persons to seek an administrative stay of agency action. It is important that such requests be reviewed expeditiously so that court review, if desired, will not be unduly delayed. The comment, moreover, fails to distinguish review of administrative action, which normally relates to the merits of the action, from a stay, which only delays implementation of the action. A petition for stay raises issues that ordinarily are far less complex than a challenge to the merits, and the references to the longer statutory periods in the comment are thus not relevant.

29. The Commissioner disagrees with comments urging that the filing of a petition for a stay should automatically stay the action for a period of time after the Commissioner's decision on the petition. These comments also urged that the regulation provide that no final order shall become effective in less than a specified time period. The result of accepting these comments would be that no action of the Commissioner could become effective until affected parties have had time to petition the agency for a stay, and if denied, to seek a stay in the courts. The comments argued, however, that the failure to so provide, given the Commissioner's stated intention to oppose any judicial stay until he has had an opportunity to review such a request administratively, would allow parties to be irreparably harmed by agency decisions without being able to seek judicial review of them.

As stated in the preamble to the proposed rule, the Commissioner's enforcement duties under the regulatory statutes for which he is responsible require that he have discretion to determine when enforcement or other regulatory action is appropriate, subject to judicial review. The requirements of § 2.9 as promulgated do not, in the Commissioner's judgment, deprive any individual of due process, and are fully consistent with applicable law.

30. One comment objected that parties are not apprised quickly when the Commissioner has made a decision, as when publication in the FEDERAL REGISTER is delayed for several days following a decision. Direct mail notice to all parties was requested.

The preamble to the proposed regulation indicates that the day of publication in the FEDERAL REGISTER will be the day of decision for purposes of petitions to stay an administrative action. The Commissioner believes this provision will minimize to the extent practicable the delay inherent in advising an entire nation of an agency decision. Some delay is unavoidable. A conforming change has been made in § 2.9(b).

31. One comment urged that the Commissioner obligate himself to respond to a petition for stay within a specified time period. The Commissioner has obligated himself to respond "promptly," and he believes further specificity is neither practicable nor necessary.

Section 2.10 Promulgation of regulations for the efficient enforcement of the law (21 CFR 2.10) specifies the procedures the Commissioner will utilize in the promulgation of regulations under the basic grant of rule making authority contained in section 701(a) of the Federal Food, Drug, and Cosmetic Act, and the rule making provisions of the Administrative Procedure Act (5 U.S.C. 553). Procedures for the promulgation of regulations pursuant to the more formal requirements of section 701(e) of the act and 5 U.S.C. 556 and 557 are contained in § 2.12 (21 CFR 2.12) and in Subpart B of Part 2, except insofar as those sections incorporate by reference some of these requirements.

32. Section 2.10(g) specifically prescribes what constitutes the record of an administrative proceeding under § 2.10. The proposal incorrectly established as the closing date of the record the day of publication of the final regulation in the FEDERAL REGISTER. This would technically have permitted new information to be submitted after the Commissioner's adoption of a regulation, but before its publication. Any such information, however, must be submitted under a new petition filed in accordance with other sections of these requirements, e.g., § 2.7. Consequently, § 2.10(h) has been revised to provide that the record shall be closed on the date the Commissioner signs a regulation.

33. Section 2.10(e) requires that, when notice and public procedure are not utilized in issuing a regulation, the notice promulgating the regulation shall provide an opportunity for comment to determine whether the regulation should subsequently be modified. In addition, the Commissioner may, in his discretion, similarly permit comment on any final regulation. However, it was the Commissioner's intention that subsequent final regulations based on such comments need not in either case, though they may, provide additional opportunity for comment or other form of public participation. Section 2.10(e)(1) has been modified to make this clear and a conforming change has been made in § 2.10(f)(10).

34. One comment objected to the predisposition against extensions of the comment period that the Commissioner acknowledged in the preamble to the proposed regulation.

The Commissioner's reasons for limiting extensions of the comment period were explained in the preamble to the proposal. Principal among them is the failure of many people to take the stated time for comment seriously. Nonetheless, the rule specifically allows for extension of the comment period in appropriate, though limited, circumstances.

35. The same comment urged also that the Commissioner not be confined to comments in establishing final rules.

The Commissioner points out that the section does not require him to rely only on comments submitted on the proposal when formulating a final regulation. Section 2.10(f) permits the Commissioner to use a wide range of administrative mechanisms to obtain information on any matter that is the subject of rule making. Moreover, that § 2.10 does not specifically provide for the generation of new information by the agency following the publication of a proposal does not preclude the agency from doing so. The authority to generate this information is implicit in the Commissioner's authority to issue regulations under section 701(a) of the act, and, indeed, is recognized in § 2.10(g)(5), which provides for filing with the Hearing Clerk "all data and information identified or filed by the Commissioner * * * as part of the administrative record supporting the final regulation."

36. Another comment suggested substituting "may" for "shall" in § 2.10(a)(2). The comment argued that not doing so would make the Commissioner's failure to publish a proposal subject to judicial review, and would then invite a court to require publication, a function that should be reserved exclusively for the legislative and executive branches.

The Commissioner does not believe that the language of the section deprives him of the discretion afforded by the law. Rather, the regulation merely specifies in general terms when the Commissioner will view a request for agency action to be sufficiently meritorious (if

consistent with law) to warrant public and agency consideration. The provision does not, as the comment mistakenly assumes, require the Commissioner to finalize such action; § 2.10(c) specifically provides for termination of a rule making proceeding as one possible outcome of review of the entire administrative record based on a proposal.

37. A comment urged that § 2.10 be amended to provide for time limits after the close of the comment period by which the Commissioner must issue a decision. The comment suggested 90 days, with provision for an additional 90 days upon a showing of good cause.

The Commissioner rejects this comment. The timetable for completion of a rule making action must remain subject to his discretion. Apart from judgments about agency priorities, which themselves may result in delays of varying length in concluding some rule making actions (but may frequently result in the expeditious handling of others), it is often not possible to predict how quickly a rule making proceeding can be concluded until after the comments on the proposal have been evaluated. The comments may reveal a need for additional proceedings, which if undertaken may prevent conclusion of the proceeding within any time period previously specified. The Commissioner thus concludes that it would be impracticable to specify such a time period.

38. The same comment also suggested that the regulation should more specifically state those narrow circumstances, e.g., where required by the public health and safety, when opportunity for notice and comment might be waived, and limit use of this procedure to situations in which alternatives such as a shorter comment period will not suffice.

The Commissioner finds the broad language in § 2.10(e)(1), "impracticable, unnecessary, or contrary to the public interest," which mirrors the standard of 5 U.S.C. 553, to be more satisfactory. Whether to dispense with notice and comment, including the use of alternative procedures, is a decision that must largely remain subject to the Commissioner's discretion. The provision would clearly permit such a decision in the situation suggested by the comment, namely, when necessary for the public health and safety.

39. One comment suggested that proposed § 2.10(l), which requires that the Hearing Clerk compile a list of regulations proposed and promulgated, include within the list the disposition of each matter. The Commissioner advises that the intent to include the disposition of each proposal is apparent in the proposed inclusion in the list of regulations "promulgated," for that would be the ordinary disposition of any prior proposed rule. In response to the comment, however, the Commissioner has determined that the list should specifically include the disposition of the petition. This change conforms to a similar change in § 2.7(l).

40. One comment objected to the statement in the preamble that the Commissioner will not take into account the number of comments but will consider, rather, repetitive comments as one. The comment states that this position demonstrates a preconceived agency bias and implies that such comments are not made in good faith.

The Commissioner intends no such implication. His statement means that it is the substance and not merely the number of comments that will be persuasive in formulating final regulations. Many similar conclusory comments will thus be less persuasive in the Commissioner's determinations than smaller numbers of thoughtful and well documented ones. However, § 2.10(c)(1) of the final regulations recognizes that the number of comments may be influential where the degree of public interest in a matter is a legitimate factor to be considered.

41. To conform with existing agency practice, § 2.10(f)(9) has been revised to provide for the publication in the FEDERAL REGISTER, when considered desirable by the Commissioner, of tentative final regulations. The proposal provided only for publication of a notice of availability of the documents.

42. Several comments objected on various grounds to the Commissioner's efforts in § 2.11 Court review of final administrative action; exhaustion of administrative remedies (21 CFR 2.11) to define for agency purposes the doctrine of exhaustion of administrative remedies. They argued that the policies set forth in § 2.11 are determined by statute, case law, and the Federal Rules of Civil Procedure, or by the court hearing a matter, and in any event are not for the Commissioner to determine by regulation. Several comments also contended that the proposal's criteria misstated applicable law.

One comment, addressing the announcement that the Commissioner will oppose requests for a judicial stay when a request for an administrative stay has not been timely filed, suggested that the exhaustion requirement is inapplicable when the administrative remedy is no longer available because it was not invoked in a timely fashion. One comment argued that no new burden would be imposed on the Commissioner if a stay were sought directly from a court, as the administrative record is the same; thus the comment requested that the requirement that a stay be sought first from the Commissioner be made optional.

Still another comment argued that proposed § 2.11(c) is without authority; that section 10(d) of the Administrative Procedure Act (5 U.S.C. 705) plainly authorizes a court to postpone the effectiveness of agency action; and that a court would not likely refuse to grant a stay simply because an administrative stay had not first been requested. Other comments argued that the provision was of no legal effect and suggested that it be revised to make clear its advisory character.

The Commissioner is aware that it is ultimately for a court to determine whether a particular agency action is "final" within the meaning of section 10(c) of the Administrative Procedure Act (5 U.S.C. 704), or whether a plaintiff has properly exhausted his administrative remedies. Nonetheless, the Commissioner believes it entirely proper to attempt, through these procedural regulations, to set forth his view of the most appropriate method of proceeding, to the end of inducing persons wishing to challenge an FDA action to do so at the agency level before seeking court review. This regulation will promote conservation of judicial resources, not only by eliminating the need for review in some cases, but also, when the Commissioner does not change his initial decision, by providing a more complete record for review of agency action. For example, when a party has petitioned for reconsideration or for a stay of agency action, the record before the reviewing court would include, under § 2.11(f), the record of such further proceeding, as well as the record of the initial decision.

The Commissioner considers the described scheme for judicial review to be a fair method of proceeding for all persons. It will encourage persons to participate at the administrative level and to advance all information and arguments at that point, and it will require the agency to identify the information on which it relies and to explain the basis for its reliance. At the same time, the scheme should preclude interposition of technical procedural objections and guarantee to a court a fixed and complete record on which to base review. In this regard, some comments specifically commended the Commissioner's decision not to raise a lack of "standing" as a basis for opposing review of agency decisions.

43. One comment identified three situations in which, it contended, judicial review may be appropriate in the absence of a final decision by the Commissioner. The comment listed: (1) the giving of an advisory opinion pursuant to § 2.19, citing *National Automatic Laundry and Cleaning Council* v. *Schultz*, 443 F.2d 689 (D.C. Cir. 1971); (2) delay of action by FDA so substantial as to constitute denial of the relief requested; and (3) initiation by FDA of a proceeding that it has no statutory authority to conduct.

After considering the comment, the Commissioner has decided to consider advisory opinions issued pursuant to § 2.19 and guidelines issued pursuant to § 2.20 (21 CFR 2.20) to be final agency action. He acknowledges that such opinions and guidelines are binding on the agency until amended or revoked. Although, under §§ 2.19(j) and 2.20(b)(8), they are not legal requirements, the Commissioner maintains that preenforcement review of such actions may be proper in appropriate cases where further administrative proceedings are not likely to clarify the scope or impact of a decision. Advisory opinions and guidelines have accordingly been included within the scope of § 2.11(d).

The other situations cited by the comment, i.e., agency delay and action taken without authority, though potentially subject to judicial review before final ac-

tion in limited circumstances, are obviously not appropriate to include within § 2.11 for they do not describe types of agency action contemplated by these procedural regulations, e.g., proposed or final regulations, or advisory opinions, but simply state legal reasons why particular agency actions may be held invalid. Accordingly, no change in the regulation has been made to reflect this part of the comment.

44. Two comments stated that § 2.11 (d) should include a reference to final regulations promulgated pursuant to § 2.10 within the list of actions considered by the Commissioner to constitute final agency action; and the final regulations have been amended accordingly.

The Commissioner advises that § 2.11 (d) should have included final regulations promulgated pursuant to § 2.10, as such regulations are ordinarily subject to immediate judicial review (*Abbott Laboratories* v. *Gardner*, 387 U.S. 136 (1967)). The preamble to the proposal, as one comment points out, refers to final regulations subject to § 2.10, and its omission from § 2.11(d) was thus in error.

45. One comment, reiterating an objection to § 2.9 argued that no final order should become effective for 30 days and that a request for stay within that period should automatically stay such order until 10 days after the Commissioner's decision. As indicated in his response to the comments on § 2.9, the Commissioner concludes that he must retain discretion to determine when an agency action is to become effective. The comment is accordingly rejected.

46. Comments reiterated an additional objection regarding § 2.9, namely that, by failing to require the Commissioner to respond to a petition for a stay within a specified time period, § 2.11 permitted him effectively to delay access to the courts by persons seeking to challenge agency action. One comment added, in an apparent reference to § 2.11(d), that access to the courts could also be limited if the Commissioner decided to reconsider a matter on his own initiative.

As stated in his response to the comments on § 2.9, the Commissioner cannot obligate himself to respond to petitions for a stay within a specified period. He believes it essential to retain discretion to be able to respond to changing demands on the agency in the manner most consistent with the public health and safety. However, the Commissioner advises that his failure to act on a petition for a stay does not limit access to court review of the merits of the original decision. Section 2.11(e) clearly contemplates that a person who desires to challenge any decision by the Commissioner can initiate a suit for review without first petitioning the Commissioner. It is only with respect to an attempt to obtain a stay of FDA action that the regulations require that a request for stay be first submitted to the Commissioner.

Nor would court review on the merits necessarily be delayed if the Commissioner determined on his own initiative to reconsider the matter, as the comment suggested. The reference in § 2.11(d) to petitions for reconsideration (§ 2.9) is intended to indicate only that the Commissioner's action on such a petition is final agency action and independently subject to judicial review.

47. One comment stated that proposed § 2.11(d)(2)(i) is unnecessary in light of the clear statement in the Administrative Procedure Act that actions committed to agency discretion by law are not subject to judicial review. The comment expressed concern that the provision may be interpreted as unduly broadening existing rules in this regard.

The Commissioner believes that the restatement of the statutory standard in these regulations is proper, and that the example of unreviewable decisions cited in § 2.11(d)(2)(i), i.e., whether or not to recommend initiation of civil or criminal enforcement proceedings under sections 302, 303 and 304 of the act (21 U.S.C. 332, 333, 334), falls clearly within his unreviewable discretion.

48. One comment urged that the reference in proposed § 2.11(d)(1)(ii) to "any interested person" should be changed to "any person."

The Commissioner finds the requested change unnecessary. "Interested person" is defined in § 2.3(a)(12) to mean, essentially, "any person."

49. One comment identified two asserted exceptions to the general rule stated in § 2.11(f), which, as promulgated, limits judicial review of agency action to the administrative record made before the agency. The comment argued that review could properly go beyond the administrative record (1) when a court decision subsequent to the initiation of judicial review plainly decides a legal issue that was not raised at the administrative level, and (2) when an issue is purely a matter of statutory construction, does not require the exercise of administrative expertise, and goes to the heart of the agency's statutory authority.

The comment misunderstands the Commissioner's purpose in defining the scope of the administrative record. The record is not intended to embrace all materials relevant to all of the legal objections to an agency action, including the type of legal issues which comprise the examples in the comment. Rather, the record of an administrative proceeding is intended to contain all of the factual information and data that were considered by the Commissioner in reaching his decision. While questions of legal authority may, from time to time, be raised in an administrative proceeding, the Commissioner advises that the regulations do not prohibit new issues of law including, obviously, questions of authority, from being raised in subsequent judicial proceedings.

50. One comment insisted that the procedure contemplated by proposed § 2.11 (b), under which the Commissioner may request a court to accept a further explanation of his action without further administrative proceedings, is not generally allowed by courts.

The Commissioner notes that the provision is advisory only. The provision can thus assist the public in obtaining judicial review of agency action. The Commissioner believes that the procedure described is not prohibited by any statute; however, if the procedure were not permitted by a particular court it would not, obviously, be available to the Commissioner in that instance.

51. Two comments on proposed § 2.12 Promulgation of regulations and orders after an opportunity for a formal evidentiary public hearing (21 CFR 2.12) objected to its failure to distinguish between the right to an "opportunity for a hearing," and an unqualified right to a hearing. By treating all requests for formal evidentiary public hearings uniformly, the comments argued, proposed § 2.12 overlooked important differences between the several statutory provisions in the Federal Food, Drug, and Cosmetic Act that require a hearing. The comments objected that, as proposed, § 2.12 would improperly permit use of the summary judgment mechanism upheld in *Weinberger* v. *Hynson, Westcott and Dunning, Inc.*, 412 U.S. 609 (1973), in cases in which it was not legitimately available.

One comment pointed out that certain provisions of the act require "an opportunity for a hearing," e.g., section 505; that others require that "reasonable grounds" must be stated to justify a hearing, e.g., section 507(f); and that still others purport to require a hearing without any qualification, e.g., section 701(e). The comment argued that only in two situations could the Commissioner refuse to hold a required section 701(e) hearing: (1) when objections to the Commissioner's order are a legal nullity, on the basis of *Dyestuffs and Chemicals, Inc.* v. *Fleming*, 271 F.2d 281 (8th Cir. 1959), cert. denied, 302 U.S. 911 (1960), and (2) when the objections relate exclusively to the agency's authority to take an action so that the factual basis for the action is wholly irrelevant. The comment urged that §§ 2.12 and 2.113(b) (21 CFR 2.113(b)) be revised accordingly.

The Commissioner has issued the section as proposed. He concludes that there is no basis for the comment's contention that section 701(e) absolutely guarantees a formal evidentiary public hearing whenever one is requested in a rule making proceeding conducted pursuant to that section. The Commissioner believes the act empowers him in each case to establish reasonable threshold requirements for the holding of a formal evidentiary public hearing, including a hearing on a regulation governed by section 701(e). The basis for this position has been set forth in the preamble to the publication in final form of § 2.113 in Subpart B, and interested persons are referred to the final regulation published in the FEDERAL REGISTER of November 23, 1976 (41 FR 51706) for a full statement of the Commissioner's views on the matter.

Section 2.13 Separation of functions; ex parte communications (21 CFR 2.13)

prescribes the degree to which separation of functions shall be observed between and within agency components in any matter that is subject by statute to an opportunity for a formal evidentiary public hearing and in any matter subject to a public hearing before a Public Board of Inquiry.

52. One comment suggested that proposed § 2.13(d)(3), specifying remedial measures to be taken when oral and written communications are made in contravention of the separation requirements of the section, be revised to require that copies be immediately provided to all parties to the hearing. As proposed, the requirement would have required only the filing of such communications with the Hearing Clerk.

The Commissioner accedes to the request and has modified the final regulation to provide that at the same time such a communication is filed with the Hearing Clerk, it shall also be served on all other participants in the proceeding. This change meets the objective of the comment that all participants be advised of the current status of the proceeding. Because the conduct described in the section is not likely to occur, the Commissioner believes it reasonable to provide for personal service on participants, rather than to force them to periodically examine the administrative file in the office of the Hearing Clerk. Moreover, required service of documents on other participants is already provided for by § 2.13(d)(2), which requires such service for proposals for settlement. The change can therefore be viewed as extending an existing obligation of participants to a hearing rather than as imposing a completely new obligation.

53. A comment suggested that § 2.13(b)(2)(i) and (ii) were inconsistent because the requirements bar, for example, the entire Bureau of Drugs from communicating with the office of the Commissioner after the bureau becomes a party to a hearing, while permitting all members of the Chief Counsel's office to be available to advise the Commissioner except those specifically engaged in the proceeding on behalf of the bureau. A related comment urged that the section be modified to permit a member of an involved bureau who is not personally involved in representing the bureau at the hearing to be free to discuss the matter with the office of the Commissioner. The comment suggested that this would benefit the agency in those situations where all of the agency expertise in a given field is located in a single bureau.

The Commissioner believes that the suggested inconsistency does not actually exist. A direct comparison of the treatment in the provision of the individual bureaus and of the office of the Chief Counsel is not meaningful, for each is organized to perform different functions. A bureau will normally be a party to such a hearing and thus be in the position to advocate a particular position. The Chief Counsel's office, in contrast, is not organized, except for the informal designation of attorneys to advise individual bureaus, into discrete divisions. Perhaps more important, the only attorneys available to represent a bureau and advise the Commissioner are employed in the office of the Chief Counsel. Establishment of ad hoc divisions within the office is the only practicable mechanism for assuring observance of separations of functions and at the same time making legal advice available to the bureau whose decision is the subject of the hearing, and to the Commissioner. Thus, as a general rule, the Commissioner has determined that it is both more convenient and defensible to treat, for purposes of separation of functions, each bureau as a single entity. However, in response to the comment, he is modifying § 2.13 to permit the designation, when he determines that it is necessary to ensure the best use of agency resources in deciding a particular matter, of employees of a bureau to advise him, or members of his office to advise a bureau. Any such designation will be in writing and must be filed with the Hearing Clerk no later than the time the limitations of separation of functions apply in the particular matter. An example of a situation where the procedure might be used is that cited in the comment, i.e., where all agency employees having expertise in a given field work in one bureau, leaving the Commissioner without expert assistance to assist him in deciding the matter.

54. In response to the comment, the Commissioner has modified § 2.13(b)(2)(ii) to provide for the appointment by the Chief Counsel of a "team" of attorneys to advise the Commissioner, rather than to permit that function, as proposed, to pass residually to all attorneys who have not been appointed to represent the bureau in a proceeding.

As a matter of practice the Chief Counsel has been specifically designating attorneys to advise the Commissioner in many matters for which a notice of opportunity for a hearing has been published. This approach has permitted the Chief Counsel to assess the workload of the office and avoid the appointment of an attorney to advise the Commissioner who may have assisted a bureau before the publication of the notice of hearing.

The section as issued in final form also provides that the Chief Counsel will ordinarily advise the Commissioner in a hearing proceeding. The proposal would have required the Chief Counsel to always advise the Commissioner. However, it is possible that the Chief Counsel may become involved in a matter before a notice of opportunity for hearing has been published, such as when he is called upon to advise a bureau on the initiation of a proceeding. In such cases, his subsequent service as an advisor to the Commissioner in the same matter would not be consistent with separation of functions.

The provision has also been modified, consistent with existing practice, to prevent contact on any matter that is the subject of a formal hearing between members of the office of the Chief Counsel who are advising the Commissioner and other members of the office, or any employee of the bureau involved (except one specially designated to assist the Commissioner). Although the proposed rule would have imposed this limitation only on the attorneys assigned to assist the bureau, it is clear that comparable restrictions should be imposed on counsel to the Commissioner, for the requirement is intended to maintain the independence of the Commissioner and his advisors.

55. To make the regulation comprehensive, § 2.13(b)(2)(ii) has been revised to acknowledge the Chief Counsel's specific authority to designate additional attorneys to represent a bureau or to advise the Commissioner. Such designation may be necessary where, for example, an attorney previously designated to advise one or the other is no longer able to serve in that capacity.

56. On September 13, 1976, Pub. L. 90–409, the "Government in the Sunshine Act," (5 U.S.C. 552b note) was signed into law, to become effective on March 12, 1977. The Sunshine Act imposes certain new requirements applicable to the FDA, as well as to other agencies, regarding ex parte communications between Federal officials and persons outside the Federal Government in connection with any administrative hearing subject to 5 U.S.C. 557(a). "Ex parte communication" is defined in new 5 U.S.C. 551(14) as "an oral or written communication not on the public record with respect to which reasonable prior notice to all parties is not given, but it shall not include requests for status reports on any matter or proceeding covered by this subchapter."

In sum, the Sunshine Act prohibits the making of ex parte communications by either Federal employees or outside persons within the context of a hearing subject to 5 U.S.C. 557, and requires that any ex parte communications that are made be placed in the public record, either by filing written communications or reducing to writing the substance of any oral communications, as well as any responses, either written or oral, to either of these types of communications. The Sunshine Act further requires each Federal agency to designate a particular time during the administrative process after which the prohibitions shall apply. That time may not be later, however, than the time at which a proceeding is first noticed for a hearing, and must with respect to any person with knowledge that such notice is forthcoming, be no later than the time such knowledge was acquired. The new law specifically provides that an agency may consider, consistent with the interests of justice, a violation of the section as sufficient grounds for a decision adverse to the party committing the violation or causing it to occur. The Commissioner advises, in this regard, that he will consider as a violation of this section, as a "causing to occur" of an ex parte communication, a communication by any government official outside the agency, including members or representatives of mem-

bers of Congress, made at the knowing behest of any person who would be precluded under the statute from personally making the communication.

The Sunshine Act affects the provisions of proposed § 2.13 that address ex parte communications, with respect to any matter subject to an opportunity for a formal evidentiary public hearing, as listed in § 2.12(c), and any matter subject to a public hearing before a Public Board of Inquiry pursuant to Subpart C of Part 2, and necessitates some revision of them.

Accordingly, the Commissioner has determined to modify § 2.13 (and § 2.3) in the final order as follows:

a. The Sunshine Act's definition of "ex parte communication" has been incorporated into § 2.3.

b. The times at which the prohibition against ex parte communications are to come into play are those proposed in § 2.13 (b) and (c) for the matters referred to in those sections. However a new paragraph (e) has been added, in accordance with the statute, applying the restriction to any person having knowledge that a notice of hearing is to be issued to the time such knowledge is acquired.

c. Paragraph (d) of § 2.13 has been revised to indicate that the prohibitions against making ex parte communications apply to employees of the agency involved in any manner in the decisional process as well as to persons outside the agency.

d. A new paragraph (f) has been added to reflect the statutory provision that the making of a prohibited ex parte communication may, consistent with the interests of justice and the policy of the underlying statute, justify a decision adverse to the person knowingly making or causing the making of such a communication.

No comments were received on proposed § 2.14 Referral by court (21 CFR 2.14) and it is adopted as proposed.

Section 2.15 Meetings and correspondence (21 CFR 2.15) contains requirements for meetings and correspondence between employees of the Food and Drug Administration and any person outside the Department of Health, Education, and Welfare.

57. Several comments were received regarding § 2.15(f)(1), which as proposed would have permitted any meeting initiated by FDA involving only a small number of persons, such as 1 or 2 manufacturers, to be a private meeting, but would have required a meeting involving a large number of persons, e.g., 10 manufacturers of an ingredient, to discuss appropriate testing or labeling, to be a public meeting. The comments criticized the use of the number of persons as the criterion for determining whether a meeting should be public or private, urging in general that the nature or subject matter of the meeting should determine whether it should be private or open. One comment specifically suggested that the number of different interests represented, rather than the number of persons, should determine whether the meeting is to be public or private, but urged also that meetings should be open when closing them might give particular firms a competitive advantage.

Another comment insisted that the 10-person standard was arbitrary, and that whether a meeting should be open or closed should depend on a variety of factors, e.g., the meeting site, the various interests represented, and the subject discussed. The comment stated that where a single industry or group of persons is the focus of the meeting, the willingness of that group to meet in a public forum should weigh heavily in the decision. In general the comments from manufacturers and industry associations argued that private meetings encourage input, but a comment from a consumer group contended that it is important that consumers be present at meetings with industry because proposed § 2.15 failed to require taking transcripts or recordings. One comment asked the reason for subjecting to regulation the issue of whether meetings should be public or private and urged that the decision be left to the discretion of the Commissioner.

The Commissioner has considered the objections to the section, and finds them unpersuasive. Most of the comments appear to have assumed that the requirements of § 2.15(f)(1) apply to all meetings between the FDA and persons outside the Federal government. This is not the case. In contrast with other provisions of § 2.15, paragraph (f)(1) applies only to meetings initiated by FDA. It does not apply to private meetings between the agency and outside persons or groups at the behest of the lattter. Such meetings are subject principally to the requirements of § 2.15(d). The justification for the distinction is reasonable: The agency's initiation of a meeting is generally for the purpose of seeking information on or attempting to resolve an issue regarding a regulatory matter. It would be inappropriate for FDA to seek advice from only one group on a regulatory matter that affects many manufacturers or broad segments of the public.

The "number of persons" criterion in § 2.15(f) should be viewed as an attempt to establish a readily usable "rule of thumb" for determining when an agency-initiated meeting should be open to all. It should be noted that the specfic reference in § 2.15(f)(1) to numbers of participants as the criterion is neither absolute nor arbitrary. The language of the paragraph refers to examples of the subject matter of such meetings as well as to the number of persons, and the Commissioner intends that the number of persons shall be merely one guide, rather than a firm rule, for deciding when a meeting should be public. The Commissioner retains discretion to decide whether such a meeting should be open or closed.

The Commissioner also advises that he may follow § 2.15(f)(1) in determining whether to insist that other meetings should be open to the public when opening them will avoid the implication of undue influence in an agency decision or will otherwise further the purposes of the act.

58. One comment urged that proposed § 2.15(i), requiring a written summary to be made of any meeting with a representative of Congress relating to any one of several enumerated matters, be clarified to state that it applies only to FDA employees. The Commissioner believes it obvious that the requirement is applicable only to employees of the agency, and so advises. No change in the language of the provision is necessary.

59. One comment suggested that the language of proposed § 2.15(c), which requires the summarization in writing of any meeting between agency representatives and any person outside the Department relating to a "pending court case," as well as other enumerated subjects, be amended to include specifically an "immediately anticipated court case." The Commissioner advises that an anticipated court case would be included within the reference to "pending court case," and that agency employees have been observing this interpretation in maintaining records of telephone calls and meetings. Therefore, no formal modification of the paragraph is necessary.

60. One comment urged that telephone conversations be subject to the requirements of § 2.15(c) and (d). The Commissioner advises that the definition of "meeting" in § 2.3(a)(24) includes telephone conversations, and that no amendment to paragraph (c) or (d) is called for.

61. One comment directly, and another by implication, questioned the wisdom of requiring the written documentation of all contacts with the agency. Both commented that the requirement discourages such contacts. One comment argued additionally that such memoranda contain only one side of a conversation, and suggested that the section require only the logging of contacts without the description of their substance.

The Commissioner disagrees. Even conceding that some communications to the agency may not be made because of the fear of public disclosure, the Commissioner believes it is essential for the integrity of the regulatory process that records be kept of contacts between agency employees and outside parties. The keeping of such records should increase the reliability of the information that is submitted. Moreover, written documentation is necessary for the preparation of an administrative record should any decision of the Commissioner be subsequently challenged. Most important, the Commissioner believes that public confidence in government can only be maintained if government dealings with the public are, to the extent possible, open and subject to scrutiny. There is no basis for the suggestion that memoranda of these communications prepared by government employees will reflect only one side of such contacts: § 2.15(g) provides that any participant in any meeting under any participant in

any meeting under § 2.15 may submit his own summary of the meeting and that the summary will be made part of the administrative record along with any memoranda prepared by the agency.

62. One comment suggested the deletion of the statement in proposed § 2.15 (a) that meetings and correspondence are not final agency action on the ground that it is overbroad.

The Commissioner disagrees. The statement is not overbroad, for it is difficult to visualize a circumstance in which a meeting or informal correspondence would constitute final agency action, and its inclusion is consistent with the practice of the Commissioner in these regulations of specifying those agency actions that do and do not constitute final agency action for purposes of court review.

Section 2.16 Documentation of significant decisions in administrative files (21 CFR 2.16) provides for the documentation of agency decisions by the employees involved in making them. The section as proposed represented an attempt to protect the rights of agency employees working on a matter by permitting, under paragraph (b)(2)(ii), any employee to record his views in written memoranda that would be included in the file. Proposed § 2.16(e) also guaranteed such employees access to the file as appropriate for the performance of their work, subject to reasonable restrictions to assure the proper cataloging and storage of documents.

63. One comment, submitted by the Review Panel on New Drug Evaluation of the Secretary of Health, Education, and Welfare, suggested that both of these requirements be extended to employees that have been, but may not currently be, working on a particular matter. The panel recommended that an employee's exercise of the right to record his views and to have access to the administrative file on a matter should be consistent with attention to his other assignments.

The Commissioner considers it proper that agency employees who have previously worked on a particular matter not be precluded from further participation in that matter, or denied access to the file. This, indeed, was the intent of the proposal. Not only will such access avoid charges that employees may have been transferred to prevent their continued work on a matter, but it will also make the administrative record of the resolution of controversial issues more complete. As advocated by the comment, § 2.16 (b)(2)(ii) and (e) of the final regulation have been revised to reflect the original intent of the proposal.

64. The Commissioner has clarified the effect of §§ 2.15 and 2.16 regarding the filing of the administrative record in a formal evidentiary public hearing pursuant to § 2.153 of Subpart B (21 CFR 2.153). The clarification is prompted by questions that have arisen in agency preparation for hearings of this type during recent months.

Section 2.16(b) requires that the administrative file of any matter contain the complete documentation of the agency decision (including opinions of consultants and recommendations of individual employees) and reveal any internal differences of opinion. Section 2.15 (c) requires an agency employee to prepare a written summary of any meeting with any person outside the Department which shall be included in the administrative file. Section 2.153 requires the relevant portions of the "administrative record" to be filed with the Hearing Clerk, including all documents in bureau files containing factual data and information, whether favorable or unfavorable to the bureau position.

These provisions do not require the administrative file docketed with the Hearing Clerk to contain memoranda summarizing meetings of bureau counsel with witnesses, or to contain internal agency memoranda setting forth recommendations of agency employees. While such meetings and recommendations clearly are required to be summarized in written form for the administrative file, the regulations are not intended to require all such memoranda to be made public if the matter becomes subject to a formal evidentiary public hearing. The work-product of bureau counsel are obviously protected under the attorney-client privilege and, along with recommendations of employees (as distinguished from scientific or medical data) found in internal agency documents, are not required to be disclosed under Part 4, the agency's public information regulations. Such materials will, however, continue to be prepared and to be placed in the agency administrative file for purposes of judicial or congressional inquiry, or for historical purposes.

The definition of "administrative file" in § 2.3(a)(27) of the final regulation conforms to this position. The proposal has been revised to remove the implication that the administrative record of a matter filed with the Hearing Clerk is necessarily the same as the official administrative file of the matter. The documents comprising the former are, rather, listed variously in other sections of the regulation, e.g., in § 2.8(k), for administrative reconsideration of an action; in § 2.9(h), for an administrative stay of an action, and in § 2.10(f), for regulations promulgated pursuant to that section.

65. No comments were received on proposed § 2.17 Internal agency review of decisions (21 CFR 2.17) which is adopted without change. However, some concern was expressed within the agency that § 2.17(a)(3) imposed the obligation to formally review at a supervisory level the decision of any agency employee at the request of an interested person. The Commissioner advises that no such result is intended. Review of the work of subordinates by agency supervisors is currently a matter of a supervisor's discretion and § 2.17(a)(3) is intended to reflect present agency practice. The provision recognizes that supervisory agency employees will entertain requests from interested persons to review any decision of a subordinate, but that the extent of any review will continue to be determined by the supervisor.

Section 2.18 Dissemination of draft FEDERAL REGISTER notices and regulations (21 CFR 2.18) provides for the discussion, both orally and in writing, of draft, proposed, and final rules and regulations, by representatives of FDA with interested persons, including persons outside the agency.

66. Two comments were received regarding the proposal. One comment criticized the limitations imposed by § 2.18(d) on the discussion of the details of draft notices and regulations and on the dissemination of such drafts before publication in the FEDERAL REGISTER. The comment argued that the prohibition could prevent meaningful participation in drafting complex regulations, where agency knowledge may be inadequate to draft an appropriate proposal. The comment acknowledged that proper information may be supplied by comments after publication, but suggested that there often is reluctance to make major changes in a proposed regulation. The comment contended that allowing informal contacts could often improve a published proposal and thus speed promulgation of a final regulation with a minimum of delay and modification.

The Commissioner points out that § 2.18(d) does not prohibit either the discussion or distribution of draft FEDERAL REGISTER notices. Rather, it imposes restrictions on such discussion and distribution only as necessary to ensure that all interested parties will be treated fairly and afforded uniform access to internal working documents. In situations where expert advice from outside the agency may be needed to develop a proposal, the regulation permits such information to be obtained.

67. The second comment noted that proposed § 2.18(b), although permitting the distribution of draft documents and proposed regulations following FEDERAL REGISTER publication of a notice of availability, did not explicitly permit agency employees to discuss the details of such a draft even after it became publicly available, except with the specific permission of the Commissioner.

The Commissioner acknowledges that the comment has interpreted the proposal correctly. He agrees with the comment that such a restriction on the discussion of details of a draft already publicly available is unnecessary, and believes the public interest will be safeguarded adequately if such discussions are subject only to the other provisions of the section, e.g., § 2.18(i), which applies the requirements of § 2.15 *Meetings and correspondence*, to meetings and correspondence relating to draft FEDERAL REGISTER notices and regulations. While § 2.18 will thus allow for discussion of draft proposed and final regulations and notices that have been made publicly available, it requires that summary memoranda be made of any such discussions for inclusion in the administrative file. The Commissioner regards the preparation of such memoranda in the context of discussions of draft FEDERAL REGISTER notices and regulations as essential; the requirement will assure compilation of

the full administrative record and dispel suspicions of improper influence in the development of agency regulations. The Commissioner has amended § 2.18(b) in the final regulation to allow agency employees and interested persons to discuss without his prior permission draft documents that have been properly made available to the public.

68. A primary concern expressed by many comments on § 2.19 Advisory opinions (21 CFR 2.19) was that opinions by FDA employees that are not advisory opinions do not bind the agency to the interpretation expressed in the opinion. One comment argued that this position is not supported by case law. It rejected the cases cited in the preamble to the proposal regarding the doctrine of estoppel, and cited the following several cases in which various courts have held the government estopped on the basis of advice of an employee: *United States* v. *Wharton*, 514 F. 2d 406 (9th Cir. 1975), *United States* v. *Lazy FC Ranch*, 481 F. 2d 985 (9th Cir. 1973), *United States* v. *Burton*, 472 F. 2d 757 (8th Cir. 1973), and *Moser* v. *United States*, 341 U.S. 41 (1951). The comment contended that, based on these cases, the current rule is that the government will be prevented by estoppel from taking a position inconsistent with advice provided by an employee when the damage to the private party outweighs the loss to the government or any harm to the public interest. The comment concluded by urging that the regulations be recast to state that FDA is not bound by estoppel in any case where the public health or safety would be jeopardized, but that it will take reasonable steps to protect justifiable reliance on advice provided by an ageney employee when the public health or safety will not be jeopardized.

Other comments addressed the same issue, through from different perspectives. One comment found proposed § 2.19(k) patently unfair, claiming that the regulation placed agency employees in positions of apparent authority but penalized those who relied on their advice. The same comment and one other argued that the public cannot conduct day-to-day operations by constantly requesting advisory opinions, and suggested that the agency could "grind to a halt" if responding to advisory opinions became a common practice. Both comments noted that much agency business is handled on the basis of "informal advice."

Finally, these comments requested that, should reliance on an agency employee's "informal" opinion result in regulatory action, in no event should a person so relying be subject to criminal prosecution. They urged the adoption of this position as a minimum, if the action ultimately complained of is undertaken in good faith reliance on the information provided by a representative of the agency.

The Commissioner acknowledges that these comments express a legitimate concern, but he believes that the regulation as proposed is proper. The Food and Drug Administration must be able to provide informal advice to interested persons on a staff level. Considerations of the public health and safety, as well as considerations of efficiency, however, prevent the agency from being legally bound by such representations.

The expectation that informal advice would bind the agency is unrealistic in light of the way such advice is generally requested and provided. Even when coordinated within the agency, opinions on the regulatory consequences of particular conduct may not be based on exhaustive inquiry into past agency practice or legislative intent. Moreover, many inquiries request a reply within a short period of time. In addition, circumstances are often described hypothetically, and may omit facts that the agency, in contrast to the person making the inquiry, may consider crucial. Finally, the Commissioner recognizes that some persons will "forum shop" within the agency until they obtain a desired answer. For these several reasons, the Commissioner declines to be bound by the informal responses of agency employees. Section 2.19 provides one broad exception: where a particular inquiry is of broad applicability or importance, the agency will commit its resources to providing its best institutional judgment on a matter through an advisory opinion.

The Commissioner considers the procedure established for obtaining an advisory opinion to be both realistic and fair. The procedure recognizes that, in fact, most actions taken by private firms under the statute are based on expert advice, both technical and legal, obtained outside the agency. Opinions by agency employees as to the legality of such actions are not necessarily accepted at face value, particularly if they conflict with those of the inquirer.

As a practical matter, advice provided informally by FDA employees will generally be correct, and when it is not, action in reliance will not result in the imposition of sanctions without good reason. But the risk that such advice is incorrect cannot readily be shifted to the government, and to the public. Particularly in matters involving individual compliance with the statutes administered by FDA, the ultimate burden must remain on manufacturers and distributors of regulated products. The alternative, which the Commissioner rejects, would be to preclude agency employees from furnishing advice, i.e., to require all inquiries to be subject to the procedures for advisory opinions outlined in § 2.19. This course would not work to the advantage of either the agency or affected persons.

The Commissioner will not rule out the possibility of recommending institution of criminal proceedings when an informal opinion has previously been furnished to a violator. At the same time he advises that recommendation for criminal prosecution is based on all the circumstances surrounding a violation, and it is unlikely that such prosecution would be recommended when the activity giving rise to the violation was the product of good faith reliance on advice given informally by an agency employee. Responsible exercise of the Commissioner's discretion will afford adequate protection in such circumstances.

The Commissioner does not discount the possibility, however remote, that FDA might be held by a court to be estopped by the informal advice of an employee in a given matter. However, he considers the cases cited by the comments regarding application of the doctrine of estoppel to the government to be not relevant to informal advice rendered by FDA employees pursuant to these regulations, for in none of the cases had the agency publicly indicated that informal opinions of employees were not binding, and provided an alternative procedure for obtaining formal binding opinions. More importantly, none of the cases cited involved a government agency that is entrusted to protect health and safety.

69. One comment objected that the form specified in the proposal for requesting advisory opinions is too rigid. The Commissioner disagrees that the form requirements are rigid. They require only that a request indicate that it is seeking an advisory opinion, that it clearly state the question and issue on which the opinion is requested, and that it include a statement of the facts and law relevant to the request. Moreover, the section permits the Commissioner to treat other requests, in his discretion, as requests for advisory opinions.

70. Several comments objected to the Commissioner's proposed decision not to publish advisory opinions in the FEDERAL REGISTER. They argued that it is inconsistent to urge reliance on such opinions and then not publish them. One comment urged that at least a notice of availability should be published, as well as a notice indicating the withdrawal or revocation of any advisory opinion. Another comment pointed out that reporting such opinions in the trade press is of no help to the general public. The comment also argued that the right under § 2.19(d) to comment on advisory opinions becomes illusory when the public is not aware of them.

The Commissioner believes the preamble to the proposal adequately explains the reasons for not publishing each advisory opinion in the FEDERAL REGISTER. The number of opinions makes publication of each one infeasible. Those that are contained in preambles to proposed or final regulations under § 2.19 (d)(1) will be published. Nonetheless, each advisory opinion that is not published will be publicly available and will probably receive wide publicity in the trade press. To further increase public awareness of advisory opinions, moreover, the Commissioner has modified § 2.19(g) in the final regulation to provide that a chronological index of all advisory opinions will be maintained by the Hearing Clerk. The index will include the date of the request for the advisory opinion, the date of the opinion, and identification of the appropriate file.

The Commissioner thus disagrees with the contention that the right to comment on advisory opinions is illusory. Suffi-

ciently wide publicity will be given to FDA advisory opinions so that any person with even a casual interest in the agency will be likely to learn of them. Advisory opinions that are also guidelines will be further disseminated through publication in the FEDERAL REGISTER of a notice of availability under § 2.20(b)(4) and whenever incorporated into the text of a regulation under § 2.20(a).

71. Another comment argued that the failure of the regulation to provide for the publication and indexing of informal opinions might violate paragraph (a)(2)(B) of 5 U.S.C. 552, the Freedom of Information Act. The comment contended that even informal interpretations are likely to be considered "interpretations adopted by the agency," as they are subject to internal review, and can thus fairly be considered to have been adopted by the agency. It cited as support *Tax Analysts and Advocates* v. *IRS*, 362 F. Supp. 1298 (D. D.C. 1973), aff'd, 505 F.2d 350 (D.C. Cir. 1974).

The Commissioner disagrees that informal opinions given by agency employees are subject to 5 U.S.C. 552 (a)(2)(B), insofar as that section requires the publicizing and indexing of agency interpretations. Such opinions are not considered interpretations of the agency; they do not bind FDA even for the matters that they address. The Commissioner accordingly concludes that they are subject to the requirements of 5 U.S.C. 552 to the same extent as routine agency correspondence, and are therefore not required to be indexed or publicized. They will, however, be subject to disclosure under 5 U.S.C. 552. Because informal opinions have no binding effect, they will not be used by the agency as precedent for persons other than those to whom they are issued. In this context, the sanctions imposed by 5 U.S.C. 552 for failure to index and publicize documents, namely, that the agency may not rely upon them in other cases, are inapplicable.

The Commissioner advises that he will continue to evaluate whether informal opinions receive sufficient distribution, and may decide, in the future, that some additional mechanism to assure their dissemination is desirable.

72. One comment suggested that proposed § 2.19 should be amended to provide that whenever published, an advisory opinion should reveal the identity of the person requesting the opinion and should set forth a clear statement of the facts on which the opinion is based. It urged also that any opinion state that it is based on the assumption that the facts are as represented.

The Commissioner currently contemplates that these opinions will be unpublished. However, the information requested in the comment will be contained in the request for an opinion filed with the Hearing Clerk, where the responsive opinion would also be filed, and both will be publicly available.

73. One comment suggested that the Commissioner should be authorized to decline to issue an advisory opinion when the request relates to conduct in which the requester is already engaged. The comment argued that issuing an opinion in such circumstances may interfere with enforcement efforts with respect to the practice.

The Commissioner advises that § 2.19 (a)(2)(v) authorizes him to refuse to issue an advisory opinion when it would not be in the public interest, and thus provides the authority that the comment advocates. However, the Commissioner reiterates that he may conclude that it is not improper to issue an advisory opinion in such circumstances. The fact that conduct has already commenced is not by itself reason not to issue an advisory opinion; the conduct may be entirely lawful and appropriate.

74. One comment urged that proposed § 2.20 Food and Drug Administration regulations, guidelines, recommendations, and agreements (21 CFR 2.20) provide for full notice and comment proceedings prior to the issuance of a guideline. This comment and one other urged particularly that guidelines for product labels be subject to notice and comment rule making. The comment argued that such guidelines have considerable economic impact because of the significant expense associated with printing and design work. A related comment noted that the Supreme Court has relied heavily on agency guidelines in deciding controversies before it, referring to *"Moody* v. *Albermarle Paper Company,"* 422 U.S. 405 (1975), and urged that this too dictated observance of notice and comment rule making procedures in the development of guidelines.

The Commissioner does not agree with these comments. Guidelines ordinarily represent agency interpretations of formal legal requirements, not binding legislative rules. The Commissioner's decision not to commit the agency to provide opportunity for notice and comment in the development of guidelines is consistent with their legal status under these procedural regulations. Section 2.20(b)(8) provides that although guidelines may be relied on by both FDA and persons outside the agency in administrative or court proceedings to illustrate acceptable and unacceptable procedures, they do not establish binding legal requirements. The Commissioner therefore believes it appropriate that the agency retain authority to develop them without prior public participation. The Commissioner disagrees with the reliance on *"Moody* v. *Albermarle Paper Company,"* supra. In that case, the Court, while relying on agency guidelines of the Equal Employment Opportunity Commission, explicitly recognized, without criticism, that the guidelines were not administrative regulations promulgated pursuant to formal procedures established by Congress. Thus, the case can be read as support for administrative agencies interpreting statutory provisions under their jurisdiction through guidelines developed without formal public participation.

Moreover, these regulations do not preclude all public participation in the preparation of FDA guidelines. Section 2.20(b)(11) recognizes explicitly that draft guidelines may be disseminated in the same manner as draft FEDERAL REGISTER notices and regulations pursuant to § 2.18. In such cases, the regulations contemplate at least informal public participation through discussion of the substance of the guideline. In addition, § 2.20(b)(7) provides for the submission of comments on a guideline or amended guideline, which are to be specifically considered in determining whether further amendments to the guideline are appropriate. The Commissioner believes that these two provisions allow a degree of public participation in the formulation of guidelines commensurate with their legal status.

75. One comment raised the objection, also directed at § 2.19, that it is unfair to consider as informal the personal opinions of agency employees.

The Commissioner refers to the explanation provided in his discussion of the same comment regarding § 2.19. He there indicated his conclusion that although agency employees ought to be permitted to share their opinions with the public, such opinions cannot formally bind the agency. He believes it is clearly reasonable to limit statements of position that can bind the agency to regulations, advisory opinions, and guidelines.

76. An issue raised within the agency concerns the reliance by FDA on a government procurement standard or other standard as the criterion for determining the legality of a product. The issue is whether the agency may properly so rely if it has not previously complied with the requirements for the issuance of guidelines contained in this section.

The Commissioner advises that he will consider agency reliance on government procurement standards, or other standards, to be subject to prior compliance with the requirements of this section for guidelines, including inclusion in the public file and publication of a notice of availability in the FEDERAL REGISTER.

77. A minor correction has been made in § 2.20(b)(10) in the final regulation. The reference to "this paragraph" is changed to "paragraph (b)(4) of this section." Paragraph (b)(4), requiring the placing of guidelines in a public file in the Hearing Clerk's office and the publication of notice of their availability in the FEDERAL REGISTER, is not intended to apply to analytical methods. While considered to be guidelines under the section, analytical methods are too numerous and complex, and are amended too frequently, to subject them generally to these provisions. The Commissioner may, however, in his discretion, decide that a particular analytical method should be included in the public file.

78. A question has been raised concerning the availability under § 2.20 of draft internal guidelines contained in the FDA Staff Manual. The issue arose as a result of a freedom of information request to the agency for these guidelines.

The Commissioner advises that guidelines in staff manuals are not formal "guidelines" unless there has been compliance with the requirements of § 2.20.

They rarely involve matters of "general applicability," as that term is used in § 2.20, but generally apply to internal agency business. Accordingly, neither § 2.20 nor § 2.18 is applicable to the public availability of draft guidelines of this type. Their availability is subject only to the Freedom of Information Act and FDA public information regulations. Final staff manual guidelines are publicly available under 5 U.S.C. 552(a)(2)(C).

No comments were received regarding § 2.21 Participation in outside standard-setting activities (21 CFR 2.21), and it is issued as proposed.

79. Many comments addressed the requirement in proposed paragraph (b) of § 2.22 Public calendars (21 CFR 2.22) to exempt meetings with the working press from listing on the retrospective public calendar. The preamble to the proposal had requested specifically that comments be submitted on this issue. Most of the comments urged that meetings with the working press be listed on the calendar. Several comments concluded that there was no basis for according special treatment to meetings with the press, particularly where, as in this instance, the press consisted largely of "expensive 'insider' services" that assertedly are oriented toward industry customers and capable of exerting influence on the regulatory process. The failure to list meetings retrospectively, it was argued, would therefore not benefit the public generally, but only the press. One comment stated the exemption would revive the supposedly discredited practice of basing news on "undisclosed sources," and that responsible journalists should not need the anonymity that the proposed rule offered them. Another comment urged that a policy of nondisclosure of press meetings might lead to abuse and encourage damaging leaks.

Several contrary arguments were offered. One comment described the function of the press as seeking out information and reporting it, and contended that the press should be impeded as little as possible in this function. The comment argued that conscientious reporting would be frustrated if reporters had to disclose their sources. The comment argued, further, that agency employees who previously have been willing to discuss matters with reporters would be reluctant to continue doing so if they were required at the same time to disclose publicly that they had met with the press. The comment argued also that the idea of an open calendar is to disclose contacts with government officials by persons seeking to influence actions, a category that does not include members of the press, who do not espouse a particular viewpoint. It was also argued that the listing would not necessarily provide greater protection for trade secrets, whose disclosure would be prohibited. Rather, the information whose distribution would be restricted would likely be of a type that would cause embarrassment or annoyance. Finally, the comment maintained that listing press contacts would hamper press competition, which fosters investigative journalism.

The Commissioner has decided to retain the exception for the listing of press contacts in the retrospective calendar. He concludes that listing such contacts is not necessary to serve the purpose of listing generally, and would be unnecessarily burdensome. He views that purpose as publicizing agency contacts with persons having a direct personal or economic interest in agency decisions. He does not believe that representatives of the press, including representatives of publications that can be characterized as "trade press," fall within this category. Moreover, the Commissioner notes that representatives of the trade press as a matter of practice visit the agency on virtually a daily basis to make routine inquiries. Consequently, their contacts with the various agency officials listed in § 2.22(b)(3) are so numerous as to make recording each contact for the public calendar impractical.

The Commissioner concludes, therefore, that it is appropriate to exclude from listing on the public calendar contacts with various segments of the working press. Consistent with the purposes stated above, however, he is limiting this exclusion to those segments of the working press not considered to be "house organs," i.e., publications published by a company that manufactures or distributes a regulated product or products, or by an industry association. Contacts with representatives of such publications will be listed on the retrospective calendar.

80. One comment urged that proposed § 2.22(b), prescribing requirements for the retrospective public calendar, list meetings with persons outside the executive branch, rather than only those meetings with persons outside the entire Federal government. The Commissioner agrees. He believes there is valid reason to report retrospectively meetings between FDA officials and persons from the legislative or judicial branches of government that are held to discuss positions on regulatory issues pending before the agency. The final regulation has been modified accordingly.

81. Another comment urged that the prospective calendar described in § 2.22(a) be required to list "all meetings with persons outside Government." It argued that without advance notice of such meetings, consumer views would inevitably be presented primarily at separate meetings held subsequently, which would have only limited utility. Moreover, because such meetings are not transcribed or recorded, the comment argued, consumers should have the opportunity to be present at all meetings between the agency and industry representatives to represent consumer interests.

The Commissioner disagrees; the comment misunderstands the purpose of the prospective calendar, which is to list public meetings, conferences, etc., not private meetings. Section 2.15(d) of the regulations acknowledges the right of any person, whether a representative of industry or any other group, to meet privately with representatives of the agency. The Commissioner believes the listing on the retrospective calendar of such meetings that occur with certain agency officials, and the filing of appropriate memoranda summarizing all such meetings in the administrative file, adequately protect the interests of persons not in attendance. Such memoranda, would, except where exempt from disclosure, be publicly available through either the Hearing Clerk or the Public Records and Documents Center. The Commissioner believes these procedures fairly balance consumer interests with the rights of any citizen to meet privately with agency officials.

82. One comment contended that it should be mandatory instead of optional to list telephone calls in the retrospective calendar. It argued that the substance of a meeting or call should determine whether it should be included on the calendar, not whether it was held in person or by telephone. The comment insisted that all telephone calls that could influence agency decisions should be recorded on the calendar.

The Commissioner agrees that it is the substance of a meeting that should determine whether it is included on the calendar. However, he believes the proposed regulation is responsive to the comment. He advises that recording of calls is made optional with agency employees to eliminate the need to list calls that do not bear upon the decisionmaking process of the agency, e.g., calls to establish a time for a meeting. The expectation is that any call affecting a matter of policy will be noted. All such calls must in any event be summarized in written memoranda for inclusion in the administrative file under § 2.15, and such memoranda would be subject to disclosure under the Freedom of Information Act. Listing of telephone calls on the public calendar may, therefore, properly remain optional with individual agency employees.

83. One comment urged that the prospective public calendar be published in the FEDERAL REGISTER. The comment stated that the locations presently specified in § 2.22(a)(2) for public display of the calendar will not assure sufficiently wide dissemination of the information.

The Commissioner does not agree. Publication in the FEDERAL REGISTER is not appropriate for routine matters such as a weekly calendar. The Commissioner believes the provisions made for public display of both the prospective and retrospective public calendars are adequate. Moreover, the Commissioner assures that topical items appearing in the calendar will be noted regularly in the trade press.

84. Section 2.22(b)(3)(ix) in the final regulation has been modified to include, among the agency representatives required to list their attendance at meetings on the public calendar, any representative of the Chief Counsel's office who attends or plans to attend a public meeting on behalf of the Chief Counsel. The organization of the Chief Counsel's office is such that representatives other than the Chief Counsel or Deputy Chief Counsel frequently attend meetings with

members of the public as the designated representative of the office. The effect of the requirement will be to bring to public attention meetings that might otherwise not be reported.

85. Numerous comments on proposed § 2.23 Representation by an organization (21 CFR 2.23) objected to the distinction between "organization" in paragraphs (a) and (c), and "trade association" in paragraph (b). Several comments questioned whether these terms included professional associations, consumer groups, large food cooperatives, etc.

The Commissioner advises that the divergent references to "organization" and "trade association" were inadvertent. As proposed, the section was intended to apply to any organization, including a trade association that represents a "membership," or other clearly defined group appearing before the agency. Thus, professional and trade associations as well as consumer groups having an identifiable membership would be included.

86. A large number of comments objected to the statement in proposed § 2.-23(b) that any representation by a trade association in a petition, comment, objection, or otherwise would be treated by FDA as binding on all members except those that had excluded themselves by name. Numerous reasons were offered to support this objection. Many comments urged that the requirement was impracticable; associations, operating within existing resources and prescribed time frames, could not, it was said, determine members' individual views prior to submitting comments. The comments pointed out that associations ordinarily attempt to reflect consensus views, and that if adopted, the rule would dramatically reduce the effectiveness of associations and primarily penalize small companies that rely heavily on associations to express their views. Legal objections were also raised as well. Many comments noted that trade associations have an identity apart from their membership and do not purport to act as agents for each of their members. The comments argued that FDA could not impose an "agency" relationship by regulation.

The Commissioner is persuaded that the proposed regulation should be modified to eliminate the provision that representations, petitions, comments, or objections by trade associations are binding on all members who have not expressly excluded themselves. He is persuaded by the practical difficulties of eliciting the views of an association member within the customary comment period. He also agrees with those comments that contended that organizations, including trade associations, should be entitled to participate in agency proceedings in their own right. Consequently, the final provision does not assert that association views will be binding on association members and does not require exclusion by name of members who do not subscribe to the views of the organization.

87. An equally large number of comments objected to the requirement of proposed § 2.23(b) (1) that any submission by a trade association (or other organization representing the views of its members) be accompanied by a current membership list or that the association have such a list on file in the Hearing Clerk's office. Several associations argued that their membership was simply too large and fluid; others contended that the requirement unlawfully infringed on the constitutional right of persons to petition their government or the right to participate in agency activities under the Administrative Procedure Act and the Federal Food, Drug, and Cosmetic Act. Several comments pointed to cases that have recognized a constitutional right against disclosure of association membership, citing *NAACP* v. *Alabama*, 357 U.S. 449 (1958), *Bates* v. *Little Rock*, 361 U.S. 516 (1960), and later cases, a right that can only be overcome by a compelling governmental interest in disclosure, citing *Gibson* v. *Florida Legislative Investigation Committee*, 372 U.S. 539 (1963). Some associations stated, however, that they had no objection to filing membership lists with the Hearing Clerk.

The Commissioner does not accept the argument that the cited cases, dealing principally with potential restrictions on freedom of expression, preclude requiring disclosure of association membership in the context of administrative proceedings to establish regulations based on information submitted by parties having obvious interests in the outcome. However, because the Commissioner has elected not to consider the positions taken by associations as binding on all members, there is no compelling reason to insist on the submission of membership lists by such organizations, and the proposed requirement is not adopted. Section 2.23(c) of the final regulation requests that such lists be provided on an annual basis to the Hearing Clerk for placement in a special file that will be available for public examination. The Commissioner hopes that organizations participating regularly in agency proceedings will file membership lists for he believes that information concerning the number and identity of members of associations will facilitate his evalution of association comments.

88. Many comments also questioned the requirement in proposed § 2.23(b) (2) that would prohibit a member of a trade association from deriving any rights individually from the filing by its association of an objection or request for hearing pursuant to §§ 2.110 through 2.112. The comments claimed it was inequitable to require members to be bound by association positions and not to provide rights commensurate with the obligation imposed. The Commissioner has retained the proposed provision (§ 2.23(d) in the final regulation), because he no longer intends to consider association members bound by positions taken by their association. However, he has amplified the provision to make clear that association members who wish to file objections or requests for hearing must do so in their own name if they wish to derive any rights therefrom.

89. Many comments challenged the validity of proposed § 2.23(c), in which the Commissioner announced his intention to treat any court proceeding in which an organization participates as a class action, and to assert in any related court case the doctrines of res judicata and collateral estoppel against all organization members except those excluded by name. The comments insisted that class actions must meet specific judicial requirements whose applicability can only be determined in specific proceedings. Other comments questioned the wisdom of including such statements of litigation strategy in these regulations.

The Commissioner acknowledges that whether an organization challenge to FDA regulations or other agency action should be adjudicated as a class action, just as the application of the doctrines of res judicata or collateral estoppel, will ultimately be determined judicially. Nonetheless, he has retained the provision (§ 2.23(e) in the final regulation) to emphasize that the positions stated reflect the agency's posture in court.

No comments were received regarding § 2.24 Settlement proposals (21 CFR 2.24), and it is issued as proposed.

No comments were received regarding § 2.25 Waiver, suspension, or modification of procedural requirements (21 CFR 2.25) and it is issued as proposed.

The proposed regulations on administrative practices and procedures contained proposed conforming changes in numerous existing regulations of the agency. The Commissioner has promulgated some of the proposed conforming regulations at the time of finalizing Subparts B and F of Part 2. In this document, the Commissioner is issuing the remainder of the conforming regulations substantially as proposed, inasmuch as no comments were received on them.

The changes in § 330.10(a)(12) (21 CFR 330.10(a)(12)) set forth in the September 3, 1975 proposal have been incorporated in a final regulation to be published in the FEDERAL REGISTER in the near future.

Section 328.30 Procedure for establishing, amending or repealing standards has been recodified as § 829.30 (recodification published in the FEDERAL REGISTER of February 13, 1976 (41 FR 6907)) and the proposed conforming amendment to the section is finalized in this document under Part 829.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 201 et seq., 52 Stat. 1040 (21 U.S.C. 321 et seq.)), the Public Health Service Act (sec. 1 et seq., 58 Stat. 682. as amended (42 U.S.C. 201 et seq.)), the Comprehensive Drug Abuse Prevention and Control Act of 1970 (sec. 4, 84 Stat. 1241 (42 U.S.C. 257a)), the Controlled Substances Act (sec. 301 et seq., 84 Stat. 1253 (21 U.S.C. 821 et seq.)), the Federal Meat Inspection Act (sec. 409(b), 81 Stat. 600 (21 U.S.C. 679(b)), the Poultry Products Inspection Act (sec. 24(b), 82 Stat. 807 (21 U.S.C. 467f(b)), the Egg Products Inspection Act (sec. 2 et seq., 84 Stat. 1620 (21 U.S.C. 1031 et seq.))., the Federal Import Milk Act (44 Stat. 1101 (21 U.S.C. 141 et seq.)), the

Tea Importation Act (21 U.S.C. 41 et seq.), the Federal Caustic Poison Act (44 Stat. 1406 (15 U.S.C. 401–411 notes)), the Fair Packaging and Labeling Act (80 Stat. 1296 (15 U.S.C. 1451 et seq.)), and all other statutory authority delegated to the Commissioner (21 CFR 5.1) (recodification published in the FEDERAL REGISTER of June 15, 1976 (24262)), Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

PART 1—REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND THE FAIR PACKAGING AND LABELING ACT

1. By revising § 1.1a to read as follows:

§ 1.1a Foods, drugs, devices, and cosmetics; labeling; procedure for requesting variations and exemptions from required label statements.

Section 403(e) of the act (in this Part 1, the term "act" means the Federal Food, Drug, and Cosmetic Act) provides for the establishment by regulation of reasonable variations and exemptions for small packages from the required declaration of net quantity of contents. Section 403(i) of the act provides for the establishment by regulation of exemptions from the required declaration of ingredients where such declaration is impracticable, or results in deception or unfair competition. Section 502(b) of the act provides for the establishment by regulation of reasonable variations and exemptions for small packages from the required declaration of net quantity of contents. Section 602(b) of the act provides for the establishment by regulation of reasonable variations and exemptions for small packages from the required declaration of net quantity of contents. Section 5(b) of the Fair Packaging and Labeling Act provides for the establishment by regulation of exemptions from certain required declarations of net quantity of contents, identity of commodity, identity and location of manufacturer, packer, or distributor, and from declaration of net quantity of servings represented, based on a finding that full compliance with such required declarations is impracticable or not necessary for the adequate protection of consumers, and a further finding that the nature, form, or quantity of the packaged consumer commodity or other good and sufficient reasons justify such exemptions. The Commissioner, on his own initiative or on petition of an interested person, may propose a variation or exemption based upon any of the foregoing statutory provisions, including proposed findings if section 5(b) of the Fair Packaging and Labeling Act applies, pursuant to Part 2 of this chapter.

2. By revising § 1.8d(f) to read as follows:

§ 1.8d Food labeling; information panel.

* * * * *

(f) If the label of any package of food is too small to accommodate all of the information required by §§ 1.8a, 1.8c, 1.10, 1.13, 1.17, and 1.18, and Parts 80 and 125 of this chapter, the Commissioner may establish by regulation an acceptable alternative method of disseminating such information to the public, e.g., a type size smaller than one-sixteenth inch in height, or labeling attached to or inserted in the package or available at the point of purchase. A petition requesting such a regulation, as an amendment to this paragraph shall be submitted pursuant to Part 2 of this chapter.

PART 2—ADMINISTRATIVE PRACTICES AND PROCEDURES

3. By revising Subpart A of Part 2 to read as follows:

Subpart A—General

AUTHORITY: Sec. 201 et seq., Pub. L. 717, 52 Stat. 1040 as amended (21 U.S.C. 321 et seq.); sec. 1 et seq., Pub. L. 410, 58 Stat. 682 as amended (42 U.S.C. 201 et seq.); sec. 4, Pub. L. 91–513, 84 Stat. 1241 (42 U.S.C. 257a); sec. 301 et seq., Pub. L. 91–513, 84 Stat. 1253 (21 U.S.C. 821 et seq.); sec. 409(b), Pub. L. 242, 81 Stat. 600 (21 U.S.C. 679(b)); sec. 24(b), Pub. L. 85–172, 82 Stat. 807 (21 U.S.C. 467f (b)); sec. 2 et seq., Pub. L. 91–597, 84 Stat. 1620 (21 U.S.C. 1031 et seq.); secs. 1 through 9, Pub. L. 625, 44 Stat. 1101–1103 as amended (21 U.S.C. 141–149); secs. 1 through 10, Chapter 358, 29 Stat. 604–609 as amended (21 U.S.C. 41–50); sec. 1 et seq., Pub. L. 783, 44 Stat. 1406 as amended (15 U.S.C. 401 et seq.); sec. 1 et seq., Pub. L. 89–775, 80 Stat. 1296 as amended (15 U.S.C. 1451 et seq.).

Subpart A—General

§ 2.1 Scope.

(a) Part 2 governs practices and procedures applicable to all petitions, hearings, and other administrative proceedings and activities conducted by the Food and Drug Administration pursuant to the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and other laws with respect to which authority has been delegated to the Commissioner of Food and Drugs pursuant to § 5.1 of this chapter, except to the extent that specific provisions in other sections of this chapter state different requirements with respect to a particular matter.

(b) Where a specific provision in another section of this chapter states a different requirement with respect to a particular matter (e.g., the use of a form different from the one specified in § 2.7 (b)), the sections in this part shall apply to the extent that they do not conflict with such other provisions (e.g., the requirements for inclusion of all data and information and for translations of foreign language in § 2.5(b) shall apply regardless of which form is used).

§ 2.3 Definitions.

(a) As used in this part, the following terms shall have the meanings specified:

(1) "Act" means the Federal Food, Drug, and Cosmetic Act unless otherwise indicated.

(2) "Department" means the United States Department of Health, Education, and Welfare.

(3) "Secretary" means the Secretary of Health, Education, and Welfare.

(4) "Commissioner" means the Commissioner of Food and Drugs, Food and Drug Administration, United States Department of Health, Education, and Welfare, or his designee.

(5) "Agency" means the Food and Drug Administration.

(6) "Person" includes an individual, partnership, corporation, association, or other legal entity.

(7) "Presiding officer" means the Commissioner or his designee or an Administrative Law Judge appointed as provided in 5 U.S.C. 3105.

(8) "Hearing Clerk" means the Hearing Clerk of the Food and Drug Administration, United States Department of Health, Education, and Welfare, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

(9) "Proceeding" and "administrative proceeding" mean any undertaking to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action.

(10) "Party" means the bureau of the Food and Drug Administration responsible for the matter involved and every person who either has exercised a right to request or has been granted the right by the Commissioner to have a formal evidentiary public hearing pursuant to Subpart B of this part or a regulatory hearing before the Commissioner pursuant to Subpart F of this part, or who has waived any such right in order to obtain the establishment of a Public Board of Inquiry pursuant to Subpart C of this part, and as a result of whose action a formal evidentiary hearing or a regula-

tory hearing before the Commissioner has been granted or a Public Board of Inquiry has been established.

(11) "Participant" means any person participating in any proceeding, including each party and any other interested person.

(12) "Interested person" or "any person who will be adversely affected" means any person who submits a petition or comment or objection or otherwise requests an opportunity to participate in any informal or formal administrative proceeding or court action.

(13) "Public Board of Inquiry" or "Board" means an administrative law tribunal constituted pursuant to the provisions of Subpart C of this part.

(14) "Public advisory committee" or "advisory committee" means any committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup thereof, that is not composed wholly of full-time officers or employees of the Federal government and is established or utilized by the Food and Drug Administration to obtain advice or recommendations.

(15) "Formal evidentiary public hearing" means any hearing conducted pursuant to the provisions of Subpart B of this part.

(16) "Public hearing before a Public Board of Inquiry" means any hearing conducted by a Board pursuant to the provisions of Subpart C of this part.

(17) "Public hearing before a public advisory committee" means any hearing conducted by an advisory committee pursuant to the provisions of Subpart D of this part.

(18) "Public hearing before the Commissioner" means any hearing conducted by the Commissioner or his designee pursuant to the provisions of Subpart E of this part.

(19) "Regulatory hearing before the Food and Drug Administration" means any hearing conducted by an authorized employee of the Food and Drug Administration pursuant to the provisions of Subpart F of this part.

(20) "The laws administered by the Commissioner" means all the statutory provisions with respect to which authority has been delegated to the Commissioner pursuant to § 5.1 of this chapter.

(21) "Petition" means any petition, application, or other document requesting the Commissioner to establish, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action, under the laws administered by him.

(22) "Regulation" means any agency rule of general or particular applicability and future effect implementing or applying any law administered by the Commissioner or relating to administrative practices and procedures. Pursuant to § 2.20(a), all agency regulations shall be promulgated in the FEDERAL REGISTER and codified in the Code of Federal Regulations.

(23) "Order" means any final agency disposition, other than the issuance of a regulation, in a proceeding concerning any matter and includes action on any new drug application, new animal drug application, or biological license.

(24) "Meeting" means any oral discussion, whether by telephone or in person.

(25) "Office of the Commissioner" includes the offices of the associate and assistant commissioners and excludes the bureaus, the office of the Executive Director for Regional Operations, and all regional and district offices.

(26) "Administrative action" includes every form and kind of act, including the refusal or failure to act, involved in the implementations of the laws administered by the Commissioner, except that it does not include the referral of apparent violations to United States attorneys for the institution of civil and criminal proceedings and acts preparatory or incidental thereto.

(27) "Administrative file" means the file maintained by the Food and Drug Administration, in which all documents pertaining to an administrative proceeding, including internal working memoranda and recommendations, are retained.

(28) "Food and Drug Administration employee" or "Food and Drug Administration representative" shall be deemed to include members of the Food and Drug Division of the office of the General Counsel of the Department of Health, Education, and Welfare.

(29) "Ex parte communication" means an oral or written communication not on the public record with respect to which reasonable prior notice to all parties is not given, but it shall not include requests for status reports on any matter or proceeding.

(b) Any term which is defined in section 201 of the Federal Food, Drug, and Cosmetic Act or Part 1 of this chapter shall have that definition.

(c) Words in the singular form shall be deemed to include the plural, words in the masculine form shall be deemed to include the feminine form, and vice versa, as the case may require.

(d) Whenever any reference is made to this part to any person in the Food and Drug Administration, e.g., the director of a bureau, such reference shall also be deemed to include all persons to whom that person has delegated the specific function involved.

§ 2.4 Summaries of administrative practices and procedures.

The Commissioner shall prepare for public distribution summaries of Food and Drug Administration administrative practices and procedures in terms that are readily understood in order to encourage and facilitate participation in all agency activities.

§ 2.5 Submission of documents to Hearing Clerk; computation of time; availability for public disclosure.

(a) All submissions to the Hearing Clerk of petitions, comments, objections, notices, compilations of data and information, and any other documents pursuant to this part or other sections in this chapter shall be filed in four copies except as otherwise specifically provided in any relevant FEDERAL REGISTER notice or in other sections of this chapter. The Hearing Clerk shall be the agency custodian of such documents.

(b) All such submissions shall be signed by the person making the submission, or by an attorney or other authorized representative on his behalf. Submissions by trade associations shall also be subject to the requirements of § 2.23(b).

(c) All data and information referred to or in any way relied upon in any such submissions shall be included in full and may not be incorporated by reference, unless previously submitted as part of the administrative file in the same proceeding.

(1) A copy of any article or other reference or source cited shall be included, except where the reference or source is:

(i) A reported Federal court case,

(ii) A Federal law or regulation,

(iii) A Food and Drug Administration document that is routinely publicly available, or

(iv) A recognized medical or scientific textbook that is readily available to the agency.

(2) If any part of the material submitted is in a foreign language, it shall be accompanied by an English translation verified under oath to be complete and accurate, together with the name, address, and a brief statement of the qualifications of the person making the translation. Translations of literature or other material in a foreign language shall be accompanied by copies of the original publication.

(3) Where relevant data or information are contained in a document also containing irrelevant matter, the irrelevant matter shall be deleted and only the relevant data or information shall be submitted.

(4) Pursuant to § 4.63 (a) and (b) of this chapter, the names and other information which would identify patients or research subjects shall be deleted from any record before it is submitted to the Hearing Clerk in order to preclude a clearly unwarranted invasion of personal privacy.

(5) Defamatory, scurrilous, or intemperate matter shall be deleted from any record before it is submitted to the Hearing Clerk.

(6) The failure to comply with the requirements of this paragraph or any other requirement in this part shall result in rejection of the submission for filing or, if it is filed, in exclusion from consideration of any portion of the submission which fails to comply. If a submission fails to meet any requirement of this section and such deficiency becomes known to the Hearing Clerk, the Hearing Clerk shall return the submission with a copy of the applicable regulations indicating those provisions not complied with in the submission. A deficient submission may be corrected or supplemented and subsequently filed. The office of the Hearing Clerk is not equipped to make decisions regarding the confidentiality of submitted documents. Persons wishing to voluntarily submit information consid-

ered confidential shall do so in accordance with the presubmission review requirements of § 4.44 of this chapter.

(d) The filing of a submission shall mean only that the Hearing Clerk has not determined that it fails to meet the technical requirements for filing established in this section and in any other applicable sections in this chapter, e.g., § 2.7 relating to a citizen petition. The filing of a petition shall not mean or imply that it in fact meets all applicable requirements or that it contains reasonable grounds for the action requested or that the action requested is in accordance with law.

(e) All submissions to the Hearing Clerk shall be considered as submitted on the date on which they are postmarked or, if delivered in person during regular business hours, on the date on which they are so delivered, unless a provision in this part, an applicable FEDERAL REGISTER notice, or an order issued by an administrative law judge specifically states that such documents must be received by a specified date, e.g., § 2.8(g) relating to a petition for reconsideration, in which case they shall be considered submitted on the date actually received.

(f) All such submissions shall be mailed or delivered in person to the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, except that a submission which is required to be received by the Hearing Clerk by a specified date may be delivered in person to the Food and Drug Administration building in downtown Washington (Rm. 6819, 200 C St., SW., Washington, DC 20201) and shall be considered as received by the Hearing Clerk on the date on which it is logged in at Rm. 6819.

(g) The Food and Drug Administration ordinarily will not acknowledge or give receipt for such documents, except:

(1) Documents delivered in person or submitted by certified or registered mail with a return receipt requested.

(2) Petitions for which acknowledgement of receipt of filing is provided by regulations in this chapter or by customary practice, e.g., § 2.7(c) relating to a citizen petition.

(h) Saturdays, Sundays, and Federal legal holidays shall be included in computing the time allowed for the submission of any document, except that when such time expires on a Saturday, Sunday, or Federal legal holiday, such period shall be extended to include the next following business day.

(i) All submissions to the Hearing Clerk constitute a representation that, to the best of the knowledge, information, and belief of the person making the submission, all statements made in the submission are true and accurate. All such submissions are subject to the False Reports to the Government Act, 18 U.S.C. 1001, under which a willfully false statement is a criminal offense.

(j) The availability for public examination and copying of submissions to the Hearing Clerk shall be governed by the following rules:

(1) Except to the extent provided in paragraphs (j) (2) and (3) of this section, the following submissions, including all supporting material, shall be on public display and shall be available for public examination between the hours of 9 a.m. to 4 p.m., Monday through Friday. Requests for copies of such submissions shall be filed and handled pursuant to the provisions of Subpart C of Part 4 of this chapter.

(i) Petitions.

(ii) Comments on petitions, on documents published in the FEDERAL REGISTER, and on similar public documents.

(iii) Objections and requests for hearings filed pursuant to Subpart B of this part.

(iv) Material submitted at a formal evidentiary public hearing pursuant to Subpart B of this part, a public hearing before a Public Board of Inquiry pursuant to Subpart C of this part, a public hearing before the Commissioner pursuant to Subpart E of this part, or an alternative form of hearing before a public advisory committee pursuant to § 2.117(a) (2).

(v) Material placed on public display pursuant to regulations in this chapter, e.g., agency guidelines filed pursuant to § 2.20(b).

(2) (i) Material prohibited from public disclosure pursuant to § 4.63 of this chapter (clearly unwarranted invasion of personal privacy) as interpreted and applied in Part 4 of this chapter and the regulations referenced therein, and, except as provided in paragraph (j) (3) of this section, material submitted with objections and requests for hearings filed pursuant to Subpart B of this part, or at a formal evidentiary public hearing pursuant to Subpart B of this part, a public hearing before a Public Board of Inquiry pursuant to Subpart C of this part, or an alternative form of public hearing before a public advisory committee or a public hearing before the Commissioner pursuant to § 2.117(a) (2) or (3), of the following types shall not be on public display, shall not be available for public examination, and shall not be available for copying or any other form of verbatim transcription unless they are otherwise available for public disclosure pursuant to the provisions of Part 4 of this chapter and the regulations referenced therein:

(*a*) Safety and effectiveness data and information, which include all studies and tests of an ingredient or product on animals and humans and all studies and tests on the ingredient or product for identity, stability, purity, potency, bioavailability, performance, and usefulness.

(*b*) A protocol for a test or study.

(*c*) Manufacturing methods or processes, including quality control procedures.

(*d*) Production, sales, distribution, and similar data and information, except any compilation of such data and information aggregated and prepared in a way that does not reveal confidential data and information.

(*e*) Quantitative or semiquantitative formulas.

(*f*) Data and information on design or construction of products.

(ii) Material submitted pursuant to the provisions of paragraph (j) (2) of this section shall be segregated from all other submitted material and clearly so marked. Any person who does not agree that such a submission is properly subject to the provisions of paragraph (j) (2) of this section may request a ruling thereon from the Assistant Commissioner for Public Affairs whose decision on the matter shall be final, subject to judicial review pursuant to § 4.46 of this chapter.

(3) Material listed in paragraph (j) (2) (i) (*a*) and (*b*) of this section may be disclosed pursuant to a protective order issued by the administrative law judge or other presiding officer at any hearing referenced in paragraph (j) (2) (i). The order shall only permit disclosure of the data in camera and only to the extent necessary for the proper conduct of the hearing. The order shall state to whom the information is to be made available (e.g., to parties or participants, or only to counsel for parties or participants), and persons not specifically permitted access to the data shall be excluded from the in camera part of the proceeding. The administrative law judge or other presiding officer may impose other conditions or safeguards with the requirements of this section. The limited availability of material pursuant to this paragraph shall be deemed not to constitute prior disclosure to the public as defined in § 4.81 of this chapter, and no such data and information shall be submitted to or received or considered by the Food and Drug Administration in support of a petition or other request from any other person.

§ 2.6 Initiation of administrative proceedings.

An administrative proceeding under the laws administered by the Commissioner may be initiated in any of the following three ways:

(a) Any interested person may petition the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action, under the laws administered by him. Any such petition shall be either (1) in the form specified in other applicable sections in this chapter, e.g., the form for a food additive petition in § 121.51 of this chapter or for a new drug application in § 314.1 of this chapter or for a new animal drug application in § 514.1 of this chapter, or (2) in the form for a citizen petition in § 2.7.

(b) The Commissioner may on his own initiative institute a proceeding to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action, under the laws administered by him. The Food and Drug Administration has primary jurisdiction to make the initial determination on issues within its statutory mandate, and will request a court to dismiss, or to hold in abeyance its determination of or refer to the agency for administrative determination, any such issue which has not previously been determined by the agency or which, if

it has previously been so determined, the agency concludes should be reconsidered and subject to a new administrative determination. The Commissioner may, in his discretion, utilize any of the procedures established in this part in reviewing and making a determination on any matter on his own initiative.

(c) The Commissioner shall institute a proceeding to determine whether he should issue, amend, or revoke a regulation or order, or take or refrain from taking any other form of administrative action under the laws administered by him, whenever any court, without his initiative, holds in abeyance or refers any such matter to him for an administrative determination and he concludes that such an administrative determination is feasible in light of agency priorities and resources.

§ 2.7 Citizen petition.

(a) The provisions of this section shall apply to any petition submitted by any person, except to the extent that specific provisions in other sections of this chapter state different requirements with respect to a particular matter.

(b) Any petition (including any attachments) shall be submitted in accordance with § 2.5 and in the following form:

(Date)

Hearing Clerk, Food and Drug Administration, Department of Health, Education, and Welfare, Rm. 4–65, 5600 Fishers Lane, Rockville MD 20857.

CITIZEN PETITION

The undersigned submits this petition pursuant to ---------- (relevant statutory sections, if know) of the ---------- (Federal Food, Drug, and Cosmetic Act and/or the Public Health Service Act and/or any other statutory provision with respect to which authority has been delegated to the Commissioner of Food and Drugs pursuant to 21 CFR 5.1) to request the Commissioner of Food and Drugs to ---------- (issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action).

A. *Action Requested.*

((1) If the petition requests the Commissioner to issue, amend, or revoke a regulation, the exact wording of the existing regulation (if any) and the proposed regulation or amendment requested.)

((2) If the petition requests the Commissioner to issue, amend, or revoke an order, a copy or the exact wording of and citation to the existing order (if any) and the exact wording requested for the proposed order.)

((3) If the petition requests the Commissioner to take or refrain from taking any other form of administrative action, the specific action or relief requested.)

B. *Statement of Grounds.*

(A full statement of the factual and legal grounds upon which the petitioner relies. Such grounds shall include all relevant data, information, and views on which the petitioner relies, as well as representative data and information known to the petitioner which are unfavorable to the petitioner's position, and shall be submitted in a well-organized format.)

C. *Environmental Impact.*

(An environmental impact analysis report in the form specified in 21 CFR 6.1(g), except for the types of actions specified in 21 CFR 6.1(e).)

D. *Economic Impact.*

(The following information is to be submitted only when requested by the Commissioner following review of the petition: A statement of the effect of requested action on (1) cost (and price) increases to industry, government, and consumers; (2) productivity of wage-earners, businesses, or government; (3) competition; (4) supplies of important materials, products, or services; (5) employment; and (6) energy supply or demand.)

The undersigned certifies, that, to the best of his knowledge and belief this petition includes all data, information, and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Very truly yours,

(Signature)

(Name of petitioner)

(Mailing address)

(Telephone number)

(c) Any petition which appears to meet the requirements of paragraph (b) of this section and §2.5 shall be filed by the Hearing Clerk, stamped with the date of filing, and assigned a docket number. The docket number shall be used to identify the administrative file established by the Hearing Clerk for all submissions relating to the petition, as provided in this part. All subsequent submissions relating to the matter shall refer to such docket number and shall be filed in such administrative file. Identical, similar, or related petitions may be filed together and given the same docket number. The Hearing Clerk shall promptly notify the petitioner in writing of the filing and docket number of a petition.

(d) Any interested person may submit written comments to the Hearing Clerk on any filed petition, which shall become part of the Administrative file. Such comments shall specify the docket number of the petition and may support or oppose the petition in whole or in part. Any request for alternative or different administrative action shall be in the form of a separate petition.

(e)(1) The Commissioner shall, in accordance with paragraph (e)(2) of the section, review and rule upon every petition filed pursuant to paragraph (c) of this section, taking into consideration (i) the agency resources available to handle the category of subject matter involved, (ii) the priority assigned to the petition in relation both to the category of subject matter involved and the overall work of the agency, and (iii) time requirements established by statute.

(2) A response shall be furnished to each petitioner under this section within 180 days of the receipt of the petition. Such response shall either:

(i) Approve the petition, in which case the Commissioner shall concurrently take appropriate agency action (e.g., the publication of a FEDERAL REGISTER notice) implementing the approval; or

(ii) Deny the petition; or

(iii) Provide a tentative response, indicating why the agency has been unable to reach a decision on the merits of the petition, e.g., because of the existence of other agency priorities, a need for additional information, or other stated reason. The tentative response may also indicate the likely ultimate agency response, and may specify when a final response may be furnished.

(3) The Commissioner may grant or deny such a petition, in whole or in part, and may grant such other relief or take such other action as he may determine to be warranted by the petition. The petitioner shall be notified in writing of the Comimssioner's decision on a petition. Such decision shall be placed in the public docket file in the office of the Hearing Clerk and may also be in the form of a notice published in the FEDERAL REGISTER.

(f) If a petition filed pursuant to paragraph (c) of this section requests the Commissioner to issue, amend, or revoke a regulation, the provisions of § 2.10 or § 2.12 shall also apply.

(g) A petitioner may supplement, amend, or withdraw his petition in writing without agency approval and without prejudice to its resubmission at anytime until the Commissioner rules on the petition, unless the petition has been referred for a hearing under Subparts B, C, D, or E of this part. After a ruling or referral, a petition may be supplemented amended, or withdrawn only with the approval of the Commissioner. The Commissioner may in his discretion approve withdrawal, but with prejudice against resubmission of the petition.

(h) In reviewing any matter which is the subject of a petition filed pursuant to paragraph (c) of this section, the Commissioner may, in his discretion, utilize any of the following procedures.

(1) Conferences, meetings, discussions, and correspondence pursuant to § 2.15.

(2) A formal evidentiary public hearing pursuant to Subpart B of this part.

(3) A public hearing before a Public Board of Inquiry pursuant to Subpart C of this part.

(4) A public hearing before a public advisory committee pursuant to Subpart D of this part.

(5) A public hearing before the Commissioner pursuant to Subpart E of this part.

(6) A regulatory hearing before the Food and Drug Administration pursuant to Subpart F of this part.

(7) A notice published in the FEDERAL REGISTER requesting data, information, and views.

(8) A proposal to issue, amend, or revoke a regulation, in accordance with the provisions of § 2.10 or § 2.110.

(9) Any other specific public procedure established by the provisions in other sections of this chapter and explicitly made applicable to the matter by those provisions.

(i) The record of the administrative proceeding shall consist of the following:

(1) The petition, including all data and information on which it relies, filed by the Hearing Clerk.

(2) All comments received on the petition, including all data or information submitted as a part of such comments.

(3) If the petition resulted in a proposal to issue, amend, or revoke a regulation, all of the documents specified in § 2.10(g).

(4) The record, consisting of any transcripts, minutes of meetings, reports, FEDERAL REGISTER notices, and other documents, resulting from any of the option procedures specified in paragraph (g) of this section, except that it shall not include the transcript of any closed portion of any public advisory committee meeting.

(5) The Commissioner's decision on the petition, including all data and information identified or filed by the Commissioner with the Hearing Clerk as part of the record supporting the decision.

(6) All documents filed with the Hearing Clerk pursuant to § 2.15(h).

(7) If any petition for reconsideration or for a stay of action is filed pursuant to paragraph (j) of this section, the administrative record specified in § 2.8(k) or § 2.9(h) respectively.

(j) The administrative record specified in paragraph (i) of this section shall constitute the exclusive record for the Commissioner's decision. The record of the administrative proceeding shall be closed as of the date of the Commissioner's decision unless some other date for the closing of the record is specified by the Commissioner. Thereafter any interested person may submit a petition for reconsideration pursuant to § 2.8 and a petition for stay of action pursuant to § 2.9. Any person who wishes to rely upon data, information, or views not included in the administrative record shall submit it to the Commissioner with a new petition to modify the decision pursuant to this section.

(k) The provisions of this section shall not apply to the referral of a matter to a United States attorney for the initiation of court enforcement action and related correspondence, or to requests, suggestions, and recommendations made informally in routine correspondence received by the Food and Drug Administration. Such correspondence does not constitute a petition within the meaning of this section unless it purports to meet the requirements of this section. Action with respect to such routine correspondence does not constitute final administrative action which is subject to judicial review pursuant to § 2.11.

(l) The Hearing Clerk shall maintain a chronological list of all petitions filed pursuant to this section and § 2.19, but excluding petitions submitted elsewhere in the agency pursuant to § 2.6(a)(1), showing:

(1) The docket number.

(2) The date the petition was filed by the Hearing Clerk.

(3) The name of the petitioner.

(4) The subject matter involved.

(5) The disposition of the petition.

§ 2.8 Administrative reconsideration of action.

(a) The Commissioner may at any time conclude to reconsider any matter, on his own initiative or on the petition of any interested person.

(b) Any interested person may request reconsideration of any part or all of a decision of the Commissioner on any petition submitted pursuant to § 2.6(a). Any such request shall be submitted in accordance with § 2.5 and in the following form no later than 30 days after the date of the decision involved. In the case of a decision published in the FEDERAL REGISTER, the day of publication shall be the day of decision.

(Date)

Hearing Clerk, Food and Drug Administration, Department of Health, Education, and Welfare, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852

PETITION FOR RECONSIDERATION

Docket No. ------

The undersigned submits this petition for reconsideration of the decision of the Commissioner of Food and Drugs in Docket No. ------.

A. *Decision Involved.*

(A concise statement of the decision of the Commissioner which the petitioner wishes to have reconsidered.)

B. *Action Requested.*

(The decision which the petitioner requests the Commissioner to make upon reconsideration of the matter.)

C. *Statement of Grounds.*

(A full statement of the factual and legal grounds upon which the petitioner relies. Such grounds shall demonstrate that relevant data, information, and views contained in the administrative record were not previously or not adequately considered by the Commissioner. No new data, information, or views may be included in a petition for reconsideration.)

Very truly yours,

(Signature)

(Name of petitioner)

(Mailing address)

(Telephone number)

(c) A petition for reconsideration relating to a petition submitted pursuant to § 2.6(a)(2) shall be subject to the requirements of § 2.7 (c) and (d), except that it shall be filed in the same docket file as the petition to which it relates.

(d) The Commissioner shall promptly review a petition for reconsideration. The Commissioner may grant such a petition in any proceeding when he determines that it is in the public interest and in the interest of justice. The Commissioner shall grant a petition for reconsideration in any proceeding if he determines that all of the following apply: (1) the petition demonstrates that relevant data, information, or views contained in the administrative record were not previously or not adequately considered by the Commissioner, (2) the petitioner's position is not frivolous and is being pursued in good faith, (3) the petitioner has demonstrated sound public policy grounds supporting reconsideration, and (4) reconsideration is not outweighed by public health considerations or other public interests.

(e) A petition for reconsideration shall be based only on data, information, and views contained in the administrative record on which the Commissioner made his decision. Any interested person who wishes to rely upon data, information, or views not included in such administrative record shall submit it to the Commissioner with a new petition to modify the decision pursuant to § 2.6(a).

(f) The Commissioner's decision on a petition for reconsideration shall be in writing and shall be placed on public display as part of the administrative file on the matter in the office of the Hearing Clerk. A determination to grant reconsideration shall be published in the FEDERAL REGISTER if the Commissioner's original decision was published in the FEDERAL REGISTER. Any other determination to grant or to deny reconsideration may also be published in the FEDERAL REGISTER.

(g) The Commission will consider a petition for reconsideration only if it is submitted within 30 days of the date of the decision involved and before such petitioner brings legal action in the courts to review such action, except that such a petition shall also be considered if the Commissioner has denied a petition for stay of action and such petitioner has petitioned for judicial review of the Commissioner's action and requested the reviewing court to grant a stay pending consideration of such review. A petition for reconsideration submitted later than 30 days after the date of the decision involved shall be denied as untimely. A petition for reconsideration shall be considered as submitted on the day it is received by the Hearing Clerk.

(h) The Commissioner may on his own initiative decide to reconsider all or part of any matter at any time after it has been decided or action has been taken. If review of such matter is pending in the courts, the Commissioner may request that the court refer the matter back to the agency or hold its review in abeyance pending administrative reconsideration. The administrative record of the proceeding shall include all additional documents relating to such reconsideration.

(i) After determining to reconsider a matter, whether on the petition of an interested person or on his own initiative, the Commissioner shall review and rule on the merits of the matter pursuant to § 2.7(e). The Commissioner may reaffirm, modify, or overrule his prior decision, in whole or in part, and may grant such other relief or take such other action as he may determine to be warranted.

(j) The Commissioner's reconsideration of any matter relating to a petition submitted pursuant to § 2.6(a)(2) shall be subject to the provisions of § 2.7(f) through (h), (j), and (k).

(k) The record of the administrative proceeding shall consist of the following.

(1) The record of the original petition specified in § 2.7(l).

(2) The petition for reconsideration, including all data and information on which it relies, filed by the Hearing Clerk.

(3) All comments received on such petition, including all data or information submitted as a part of such comments.

(4) The Commissioner's decision on such petition pursuant to paragraph (f) of this section, including all data and information identified or filed by the Commissioner with the Hearing Clerk as part of the record supporting the decision.

(5) Any FEDERAL REGISTER notices or other documents resulting from such petition.

(6) All documents filed with the Hearing Clerk pursuant to § 2.15(h).

(7) If the Commissioner reconsiders the matter, the administrative record relating to such reconsideration specified in § 2.7(i).

§ 2.9 Administrative stay of action.

(a) The Commissioner may at any time stay (including extend) the effective date of any relevant action pending or following his decision on any matter, on his own initiative or on the petition of any interested person.

(b) Any interested person may request the Commissioner to stay the effective date of any administrative action. Such a stay may be requested for a specific time period or for an indefinite time period. Any such request shall be submitted in accordance with § 2.5 and in the following form no later than 30 days after the date of the decision involved. In the case of a decision published in the FEDERAL REGISTER, the day of publication shall be the day of decision.

(Date)

Hearing Clerk, Food and Drug Administration, Department of Health, Education, and Welfare, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857

PETITION FOR STAY OF ACTION

The undersigned submits this petition requesting that the Commissioner of Food and Drugs stay the effective date of his action with respect to the following matter.

A. *Decision Involved.*

(The specific administrative action being taken by the Commissioner for which a stay is requested, including the docket number or other citation to the action involved.)

B. *Action Requested.*

(The length of time for which the stay is requested, which may be for a specific or indefinite time period.)

C. *Statement of Grounds.*

(A full statement of the factual and legal grounds upon which the petitioner relies for the stay.)

Very truly yours,

(Signature)

(Name of petitioner)

(Mailing address)

(Telephone number)

(c) A petition for stay of action relating to a petition submitted pursuant to § 2.6(a)(2) shall be subject to the requirements of paragraphs (c) and (d) of § 2.7, except that it shall be filed in the same docket file as the petition to which it relates.

(d) Neither the filing of a petition for a stay of action pursuant to this section nor action taken by an interested person in accordance with any other administrative procedure in this part or in any other section of this chapter, e.g., the filing of a citizen petition pursuant to § 2.7 or a petition for reconsideration pursuant to § 2.8 or a request for an advisory opinion pursuant to § 2.18, shall operate to stay or otherwise delay any administrative action by the Commissioner, including enforcement action of any kind, unless one of the following applies:

(1) The Commissioner, in his discretion, determines that a stay or delay is in the public interest and stays the action.

(2) A statutory provision requires that the matter be stayed.

(3) A court orders that the matter be stayed.

(e) The Commissioner shall promptly review a petition for stay of action. The Commissioner may grant or deny such a petition, in whole or in part, and may grant such other relief or take such other action as he may determine to be warranted by the petition. The Commissioner may grant a stay in any proceeding if he determines that it is in the public interest and in the interest of justice. The Commissioner shall grant a stay in any proceeding if he determines that all of the following apply: (1) The petitioner will otherwise suffer irreparable injury, (2) the petitioner's case is not frivolous and is being pursued in good faith, (3) the petitioner has demonstrated sound public policy grounds supporting the stay, and (4) the delay resulting from the stay is not outweighed by public health considerations or other public interests.

(f) The Commissioner's decision on a petition for stay of action shall be in writing and shall be placed on public display as part of the file on the matter in the office of the Hearing Clerk. A determination to grant a stay shall be published in the FEDERAL REGISTER if the Commissioner's original decision was published in the FEDERAL REGISTER. Any other determination to grant or to deny a stay may also be published in the FEDERAL REGISTER.

(g) A petition for a stay of action submitted later than 30 days after the date of the decision involved shall be denied as untimely. A petition for a stay of action shall be considered as submitted on the day it is received by the Hearing Clerk.

(h) The record of the administrative proceeding shall consist of the following:

(1) The record of the proceeding to which the petition for stay of action is directed.

(2) The petition for stay of action, including all data and information on which it relies, filed by the Hearing Clerk.

(3) All comments received on such petition, including all data or information submitted as a part of such comments.

(4) The Commissioner's decision on such petition pursuant to paragraph (e) of this section, including all data and information identified or filed by the Commissioner with the Hearing Clerk as part of the record supporting the decision.

(5) Any FEDERAL REGISTER notices or other documents resulting from such petition.

(6) All documents filed with the Hearing Clerk pursuant to § 2.15(h).

§ 2.10 Promulgation of regulations for the efficient enforcement of the law.

(a) The Commissioner may propose and promulgate regulations for the efficient enforcement of the laws administered by him whenever he concludes that it is necessary or appropriate to do so. The issuance, amendment, or revocation of any such regulation may be initiated in any of the ways specified in § 2.6.

(1) This section shall apply to any regulation (i) not subject to § 2.12 and Subpart B of this part or (ii) if it is subject to § 2.12 and Subpart B of this part, to the extent that those provisions make this section applicable.

(2) A regulation proposed by an interested person in a petition submitted pursuant to § 2.6(a) shall be published by the Commissioner in the FEDERAL REGISTER as a proposal if he determines that:

(i) The petition contains facts demonstrating reasonable grounds for the proposal.

(ii) The petition contains a substantial showing that the proposal is in the public interest and will promote the objectives of the act and the agency.

(iii) The requested proposal is lawful.

(3) The Commissioner may publish two or more alternative proposed regulations on the same subject in order to obtain comment on the different alternatives.

(4) The Commissioner may publish a regulation proposed by an interested person in a petition submitted pursuant to § 2.6(a) together with the Commissioner's preliminary views on the proposal and any alternative proposal.

(b) Except as provided in paragraphs (d) and (e) of this section, any such regulation shall be the subject of a notice of proposed rule making published in the FEDERAL REGISTER.

(1) Such notice shall contain (i) a general statement in the first or second paragraph describing the substance of the document in easily understandable terms, (ii) a preamble which summarizes the proposal and the facts and policy underlying it, (iii) references to all data and information on which the Commissioner relies for the proposal (copies or a full list of which shall be a part of the administrative file on the matter in the office of the Hearing Clerk), (iv) the authority under which the regulation is proposed, (v) either the terms or substance of the proposed regulation or a description of the subjects and issues involved, (vi) a proposed effective date, (vii) a reference to the existence or lack of need for an environmental impact statement pursuant to § 6.3(a)(3) (ii) or

(iii) of this chapter, (viii) the time, place, and method for interested persons to submit written comments on the proposal, and a statement that comments shall be submitted in accordance with the requirements of this part and (ix) the docket number of the matter, which shall be used to identify the administrative file established by the Hearing Clerk for all submissions relating to the matter, as provided in this part.

(2) Such proposal shall ordinarily provide 60 days for comment, although the Commissioner may reduce or extend this time period for good cause. In no event shall the time for comment be less than 10 days.

(3) After publication of the notice of proposed rule making, any interested person may request the Commissioner to extend the comment period for an additional specified period of time by submitting a written request to the Hearing Clerk stating the grounds therefor. Such requests shall be pursuant to § 2.9, except that the heading shall be "REQUEST FOR EXTENSION OF COMMENT PERIOD."

(i) Any such request shall demonstrate why comments could not reasonably be submitted within the time permitted, or that important new information will shortly be available, or that sound public policy otherwise supports an extension of the time for comment. The Commissioner may grant or deny such request or may grant an extension for a time period different than that requested. Extensions of time to comment will not ordinarily be granted. An extension of time to comment may be limited to specific persons who have made and justified such a request, but shall ordinarily apply to all interested persons.

(ii) Any extension of time to comment of 30 days or longer shall be the subject of a notice published in the FEDERAL REGISTER and shall be applicable to all interested persons. Any extension of time to comment of less than 30 days shall be the subject either of a letter or memorandum filed with the Hearing Clerk or of a notice published in the FEDERAL REGISTER.

(4) Four copies of all comments shall be submitted to the Hearing Clerk, except that individuals may submit single copies of comments. Comments will be stamped with the date of receipt and will be numbered chronologically.

(5) Persons submitting comments critical of a proposed regulation are encouraged to include alternative wording that they believe would be preferable.

(c) After the time for comment on a proposed regulation has expired, the Commissioner shall review the entire administrative record on the matter, including all comments, and shall terminate the proceeding, issue a new proposal, or promulgate a final regulation, by notice published in the FEDERAL REGISTER.

(1) The quality and persuasiveness of the comments shall determine the Commissioner's decision with respect to such comments. The number or length of comments shall not ordinarily be a significant factor in such decision. However, the number of comments may be material where the degree of public interest is a legitimate factor for consideration.

(2) The decision of the Commissioner with respect to the matter shall be based solely upon the administrative record.

(3) The preamble to a final regulation published in the FEDERAL REGISTER shall contain in the first and second paragraphs reference to prior notices relating to the same matter and a general statement describing the substance of the document in easily understandable terms, and shall summarize each type of comment submitted on the proposal and the Commissioner's conclusions with respect to each such type of comment. The preamble shall contain a thorough and comprehensible articulation of the reasons for the Commissioner's decision on each issue.

(4) The notice promulgating a final regulation published in the FEDERAL REGISTER shall specify the effective date. Such effective date shall be not less than 30 days after the date of publication in the FEDERAL REGISTER, except for:

(i) A regulation that grants an exemption or relieves a restriction.

(ii) Any other regulation where the Commissioner finds, and states in the notice, good cause for an earlier effective date.

(d) The provisions for notice and comment in paragraphs (b) and (c) of this section shall apply to interpretive rules and to rules of agency practice and procedure except as provided in paragraph (e) of this section. The provisions of paragraphs (b) and (c) of this section shall not apply to general statements of policy in the form of informational notices published in the FEDERAL REGISTER or to matters involving agency organization.

(e) The requirements of notice and public procedure in paragraph (b) of this section shall not apply in any of the following situations:

(1) When the Commissioner determines for good cause that they are impracticable unnecessary, or contrary to the public interest. In such cases, the notice promulgating the regulation shall state the reasons for such determination, and shall provide an opportunity for the submission of comments to determine whether the regulation should subsequently be modified or revoked. A subsequent notice based on those comments may, but need not, provide additional opportunity for public comment.

(2) To food additive and color additive petitions, which are subject to the provisions of § 2.110(b)(2).

(3) To new animal drug regulations, which shall be promulgated by notice pursuant to section 512(i) of the act.

(f) In addition to the notice and public procedure required pursuant to paragraph (b) of this section, the Commissioner may, in his discretion, also subject any proposed or final regulation, before or after publication in the FEDERAL REGISTER, to any of the following additional procedures, where they are reasonably applicable to the matter involved:

(1) Conferences, meetings, discussions, and correspondence pursuant to § 2.15.

(2) A formal evidentiary public hearing pursuant to Subpart B of this part.

(3) A public hearing before a public Board of Inquiry pursuant to Subpart C of this part.

(4) A public hearing before a public advisory committee pursuant to Subpart D of this part.

(5) A public hearing before the Commissioner pursuant to Subpart E of this part.

(6) A notice published in the FEDERAL REGISTER requesting data, information and views before the Commissioner determines whether to propose a regulation.

(7) A draft of a proposed regulation placed on public display in the office of the Hearing Clerk. If this procedure is used, the Commissioner shall publish an appropriate notice in the FEDERAL REGISTER stating that the document is available and specifying the time within which comments may be submitted orally or in writing on the draft of the proposed regulation.

(8) A revised proposal published in the FEDERAL REGISTER, which shall be subject to all the provisions in this section relating to proposed regulations.

(9) A tentative final regulation or tentative revised final regulation placed on public display at the office of the Hearing Clerk and, if deemed desirable by the Commissioner, published in the FEDERAL REGISTER. If the tentative regulation is placed on display only, the Commissioner shall publish an appropriate notice in the FEDERAL REGISTER stating that the document is available and specifying the time within which comments may be submitted orally or in writing on the tentative final regulation and shall mail a copy of the tentative final regulation and the FEDERAL REGISTER notice to each person who submitted comments on the proposed regulation if one has been published.

(10) A final regulation published in the FEDERAL REGISTER which provides an opportunity for the submission of further comments, in accordance with paragraph (e)(1) of this section, to determine whether the regulation should subsequently be modified or revoked.

(11) Any other specific public procedure established by the provisions in other sections of this chapter and explicitly made applicable to the matter by the terms of those provisions.

(g) The record of the administrative proceeding shall consist of all of the following:

(1) If the regulation was initiated by a petition, the administrative record specified in § 2.7(i).

(2) If any petition for reconsideration or for a stay of action is filed, the administrative record specified in § 2.8(k) and § 2.9(h) respectively.

(3) The notice of proposed rule making published in the FEDERAL REGISTER, including all data and information identified or filed by the Commissioner with

the Hearing Clerk as part of the administrative record supporting the proposal.

(4) All comments received on the proposal, including all data or information submitted as a part of such comments.

(5) The notice promulgating the final regulation, including all data and information identified or filed by the Commissioner with the Hearing Clerk as part of the administrative record supporting the final regulation.

(6) The transcripts, minutes of meetings, reports, FEDERAL REGISTER notices, and other documents resulting from any of the optional procedures specified in paragraph (f) of this section, except that it shall not include any transcript of any closed portion of any public advisory committee meeting.

(7) All documents submitted to the Hearing Clerk pursuant to § 2.15(h).

(h) The record of the administrative proceeding shall be closed as of the date of the Commissioner's decision unless some other date for the closing of the record is specified by the Commissioner. Thereafter any interested person may submit a petition for reconsideration pursuant to § 2.8 and a petition for stay of action pursuant to § 2.9. Any person who wishes to rely upon data, information, or views not included in the administrative record shall submit it to the Commissioner with a new petition to modify the final regulation.

(i) The Hearing Clerk shall maintain a chronological list of all regulations proposed and promulgated pursuant to this section and § 2.12, but excluding regulations resulting from petitions filed and assigned a docket number pursuant to § 2.7, showing:

(1) The docket number, which in the case of a petition submitted directly to a bureau shall be the number or other designation assigned by the bureau, e.g., the number assigned to a food additive petition.

(2) The name of the petitioner, if any.

(3) The subject matter involved.

(4) The disposition of the petition.

§ 2.11 Court review of final administrative action; exhaustion of administrative remedies.

(a) The provisions of this section shall apply to court review of any final administrative action taken by the Commissioner, including action taken pursuant to §§ 2.6 through 2.10 and § 2.500(b), except action subject to the provisions of § 2.12 and Subpart B of this part.

(b) Any request that the Commissioner take or refrain from taking any form of administrative action shall first be the subject of a final administrative decision based upon a petition submitted to the Commissioner pursuant to § 2.6(a) or, where applicable, a hearing pursuant to § 2.500(b) before any legal action is filed in a court complaining of the Commissioner's action or failure to act. If any court action is filed complaining of the Commissioner's action or failure to act prior to the submission of and decision on a petition pursuant to § 2.6(a) or, where applicable, a hearing pursuant to § 2.500(b), the Commissioner will request dismissal of such court action or referral to the agency for an initial administrative determination on the grounds of a failure to exhaust the administrative remedies provided in this part, the lack of final agency action as required by 5 U.S.C. 701 et seq., and the lack of an actual controversy as required by 28 U.S.C. 2201.

(c) Any request that any form of administrative action be stayed shall first be the subject of an administrative decision based upon a petition for stay of action submitted to the Commissioner pursuant to § 2.9 before any request is made that a court stay such action. If any court action is filed requesting a stay of any administrative action taken by the Commissioner prior to the Commissioner's decision on a petition submitted in a timely manner pursuant to § 2.9, the Commissioner will request dismissal of such court action or referral to the agency for an initial administrative determination on the grounds of a failure to exhaust the administrative remedies provided in this subpart, the lack of final agency action as required by 5 U.S.C. 701 et seq., and the lack of an actual controversy as required by 28 U.S.C. 2201. If any court action is filed requesting a stay of any administrative action taken by the Commissioner after a petition for a stay of action is denied because it was submitted after expiration of the 30-day time period specified in § 2.9, or after the time for submitting such a petition has expired, the Commissioner will request dismissal of such court action on the ground of a failure to exhaust the administrative remedies set out in this subpart.

(d) The Commissioner's final decision on a petition submitted pursuant to § 2.6(a), on a petition for reconsideration submitted pursuant to § 2.8, on a petition for stay of action submitted pursuant to § 2.9, on any advisory opinion issued pursuant to § 2.19, on any guideline issued pursuant to § 2.20, on any matter involving administrative action which is the subject of an opportunity for a hearing pursuant to § 2.500(b), or the issuance of any final regulation published in accordance with § 2.10, each constitutes final agency action reviewable in the courts pursuant to 5 U.S.C. 701 et seq. and, where appropriate, 28 U.S.C. 2201.

(1) It is the position of the Food and Drug Administration except as otherwise provided in paragraph (d)(2) of this section that:

(i) Any such final agency action exhausts all administrative remedies and is ripe for preenforcement judicial review as of the date of such final decision, unless applicable law explicitly requires that the petitioner take further action before judicial review is available.

(ii) Any interested person is affected by, and thus has standing to obtain judicial review of, such final agency action.

(iii) It is not appropriate to move to dismiss a suit for preenforcement judicial review of such final agency action on the ground that indispensable parties are not joined or that it is an unconsented suit against the United States if such defect could be cured by amending the complaint.

(2) The Commissioner will object to judicial review of any matter if:

(i) The matter is committed by law to the discretion of the Commissioner, e.g., a decision to recommend or not to recommend civil or criminal enforcement action under sections 302, 303, and 304 of the act.

(ii) Review is not sought in a proper court.

(e) Any interested person may request judicial review of any final decision of the Commissioner in the courts without first petitioning the Commissioner for reconsideration or for a stay of action, except that in accordance with paragraph (c) of this section such person shall request a stay by the Commissioner pursuant to § 2.9 before he may request a stay by the court.

(f) The Commissioner will take the position in any action for judicial review under 5 U.S.C. 701 et seq., whether or not it includes a request for a declaratory judgment under 28 U.S.C. 2201, or in any other case in which the validity of administrative action is properly challenged, that the validity of the action shall be determined solely on the basis of the administrative record specified in §§ 2.7(i), 2.8(k), 2.9(h), 2.10(g), and 2.513(c), or the administrative record applicable with respect to any decision or action under the regulations referenced in § 2.500(b), and that additional data, information, or views may not be considered. Any interested person who wishes to rely upon data, information, or views not included in the administrative record shall submit it to the Commissioner with a new petition to modify the action pursuant to § 2.6(a).

(g) The Commissioner requests that all petitions for judicial review of a particular matter be filed in a single United States district court. If such petitions are filed in more than one jurisdiction, the Commissioner shall take appropriate action to prevent a multiplicity of suits in various jurisdictions, such as:

(1) A request for transfer of one or more suits to consolidate separate actions, pursuant to 28 U.S.C. 1404(a) or 28 U.S.C. 2112(a).

(2) A request that actions in all but one jurisdiction be stayed pending the conclusion of one proceeding.

(3) A request that all but one action be dismissed pending the conclusion of one proceeding, with the suggestion that the other plaintiffs intervene in that one suit.

(4) A request that one of the suits be maintained as a class action in behalf of all affected persons.

(h) Upon judicial review of administrative action pursuant to this section:

(1) If a court determines that the administrative record is inadequate to support the action, the Commissioner shall determine whether he wishes to proceed with such action.

(i) If the Commissioner concludes that such action should be pursued, he

shall either request that the court remand the matter to the agency to reopen the administrative proceeding and record, or on his own initiative reopen the administrative proceeding and record upon receipt of the court determination. Any such reopened administrative proceeding shall be conducted pursuant to the provisions of this part and in accordance with any directions of the court.

(ii) If the Commissioner concludes that the public interest requires that the action remain in effect pending further administrative proceedings, he shall request that the court not stay the matter in the interim and shall expedite the further administrative proceedings.

(2) If a court determines that the administrative record is adequate, but the rationale for the action requires further elucidation:

(i) The Commissioner shall request either that such further explanation be provided in writing directly to the court without further administrative proceedings, or that the administrative proceeding be reopened pursuant to paragraph (h)(1)(i) of this section.

(ii) If he concludes that the public interest requires that the action remain in effect pending further court or administrative proceedings, he shall request that the court not stay the matter in the interim and shall expedite such further proceedings.

§ 2.12 Promulgation of regulations and orders after an opportunity for a formal evidentiary public hearing.

(a) The Commissioner shall promulgate regulations and orders after an opportunity for a formal evidentiary public hearing, in accordance with the procedures established in Subpart B of this part, whenever all of the following apply:

(1) The subject matter of the regulation or order involved is subject by statute to an opportunity for a formal evidentiary public hearing.

(2) The person requesting such a hearing has a right to an opportunity for a hearing and submits adequate justification for such a hearing as required by §§ 2.110 through 2.115 and other applicable provisions in this chapter, e.g., §§ 314.200, 430.20(b), 514.200, and 601.7(a).

(b) The Commissioner may order a formal evidentiary public hearing on any matter whenever he determines, in his discretion, that it would be in the public interest to do so.

(c) The statutory provisions which permit a person who would be adversely affected by administrative action an opportunity for a formal evidentiary public hearing are as follows (the foregoing list imparts no right to a hearing where no opportunity for a hearing is provided by the statutory sections listed):

(1) Section 401 of the act relating to definitions and standards for food.

(2) Section 403(j) of the act relating to regulations for labeling of foods for special dietary uses.

(3) Section 404(a) of the act relating to regulations providing for emergency permit control.

(4) Section 406 of the act relating to tolerances for poisonous substances in food.

(5) Section 409(c), (d), and (h) of the act relating to food additive regulations.

(6) Section 501(b) of the act relating to tests or methods of assay for drugs described in official compendia.

(7) Section 502(d) of the act relating to regulations designating habit-forming drugs.

(8) Section 502(h) of the act relating to regulations designating requirements for drugs liable to deterioration.

(9) Section 502(n) of the act relating to prescription drug advertising regulations.

(10) Section 506(c) of the act relating to insulin regulations.

(11) Section 507(f) of the act relating to regulations for antibiotic drug certification.

(12) Section 512(n)(5) of the act relating to regulations for animal antibiotic drugs and certification requirements.

(13) Section 706 (b) and (c) of the act relating to regulations for color additives listing and certification.

(14) Section 4(a) of the Fair Packaging and Labeling Act relating to food, drug, device, and cosmetic labeling.

(15) Section 5(c) of the Fair Packaging and Labeling Act relating to additional economic regulations for food, drugs, devices, and cosmetics.

(16) Section 505 (d) and (e) of the act relating to new drug applications.

(17) Section 512 (d), (e), (m)(3), and (m)(4) of the act relating to new animal drug applications.

(18) Section 515(g) of the act relating to device premarket approval applications.

(19) Section 351(a) of the Public Health Service Act relating to plant and product licenses for a biologic.

§ 2.13 Separation of functions; ex parte communications.

(a) The provisions of this section shall apply with respect to any matter which is subject by statute to an opportunity for a formal evidentiary public hearing, as listed in § 2.12(c), and any matter subject to a public hearing before a Public Board of Inquiry pursuant to Subpart C of this part.

(b) In the case of any matter listed in § 2.12(c) (1) through (10) and (12) through (15):

(1) Any interested person may meet or correspond with any representative of the Food and Drug Administration with respect to any such matter prior to publication in the FEDERAL REGISTER of a notice announcing a formal evidentiary public hearing or a public hearing before a Public Board of Inquiry on the matter. The provisions of § 2.15 shall apply to such meetings and correspondence.

(2) Upon publication in the FEDERAL REGISTER of a notice announcing a formal evidentiary public hearing or a public hearing before a Public Board of Inquiry, the following separation of functions shall apply:

(i) The bureau responsible for the matter involved in the hearing shall, as a party to the hearing, be responsible for all investigative functions and for presentation of the position of the bureau at the hearing and in any pleading or oral argument before the Commissioner. Representatives of the bureau shall not participate or advise in any decision except as witness or counsel in public proceedings. There shall be no other communication between representatives of the bureau and representatives of the office of the Commissioner with respect to the matter involved in the hearing prior to the decision of the Commissioner. The Commissioner may, however, when he determines it necessary to ensure the best use of agency resources in deciding a particular matter, designate representatives of a bureau to advise him, or representatives of his office to advise a bureau. The designation shall be in writing and shall be filed with the Hearing Clerk no later than the time specified in paragraph (b)(2) of this section for the application of separation of functions. All members of the Food and Drug Administration other than representatives of the involved bureau (except those specifically designated otherwise) shall be available to advise and participate with the office of the Commissioner in its functions relating to the hearing and the final decision.

(ii) The Chief Counsel for the Food and Drug Administration shall designate members of his office who shall advise and participate with the bureau in its functions in the hearing and members who shall advise the Commissioner in his functions related to the hearing and his final decision. The members of the office of General Counsel designated to advise and participate with the bureau shall not participate or advise in any decision of the Commissioner except as counsel in public proceedings. Such designation shall be in the form of a memorandum filed with the Hearing Clerk and made a part of the administrative record in the proceeding. There shall be no other communication between those members of the office of General Counsel designated to advise the Commissioner and any other other persons in the office of General Counsel or in the involved bureau with respect to the matter involved in the hearing prior to the decision of the Commissioner. The Chief Counsel may in his discretion assign new attorneys to advise either the bureau or the Commissioner at any stage of the proceedings. The Chief Counsel shall ordinarily advise and participate with the office of the Commissioner in its function relating to the hearing and the final decision.

(iii) The office of the Commissioner shall be responsible for the agency review of and final decision on the matter, with the advice and participation of anyone in the Food and Drug Administration other than representatives of the involved bureau and those members of the office of General Counsel who have been designated to assist in the bureau's functions relating to the hearing.

(c) In the case of any matter listed in § 2.12(c) (11) and (16) through (18),

the specific provisions relating to separation of functions set forth in §§ 314.200 (f), 430.20(b)(9), 514.200, and 601.7(a) of this chapter shall be applicable prior to publication in the FEDERAL REGISTER of a notice announcing a formal evidentiary public hearing or a public hearing before a Public Board of Inquiry. Upon publication of any such notice the rules in paragraph (b)(2) of this section shall apply.

(d) Except as provided in paragraph (e) of this section, between the date that separation of functions applies pursuant to paragraph (b) or (c) of this section and the date of the Commissioner's decision on the matter, communication with respect to the matter involved in the hearing shall be restricted as follows:

(1) No person outside the agency shall have any ex parte communication with the presiding officer or any person representing the office of the Commissioner with respect to the matter involved in the hearing. Neither the presiding officer nor any person representing the office of the Commissioner shall have any ex parte communication with any person outside the agency with respect to the matter involved in the hearing. All such communications shall be public communications, as witness or counsel, in accordance with the applicable provisions of this part.

(2) Any participant in the hearing may submit a written communication to the office of the Commissioner with respect to a proposal for settlement. Such written communications shall be in the form of pleadings and shall be served on all other participants and filed with the Hearing Clerk in the same manner as any other pleading.

(3) Any written communication contrary to this section shall immediately be served on all other participants and filed with the Hearing Clerk, and any oral communication contrary to this section shall immediately be recorded in a written memorandum served on all other participants, and filed with the Hearing Clerk to become a part of the administrative record of the proceeding. Any person, including any representative of any participant in the hearing, who is involved in any such oral communication shall, if possible, be made available for cross-examination during the hearing with respect to the substance of that conversation. Rebuttal testimony pertinent to any such written or oral communication shall be permitted. Any cross-examination and rebuttal testimony shall be transcribed and filed in the administrative record of the proceeding.

(e) The prohibitions specified in paragraph (d) of this section shall apply to any person having knowledge of a notice of hearing in advance of publication from the time such knowledge is acquired.

(f) The making of any communication contrary to this section may, consistent with the interests of justice and the policy of the underlying statute, result in a decision adverse to the person knowingly making or causing the making of such a communication.

§ 2.14 Referral by court.

(a) The provisions of this section shall apply whenever any Federal, State, or local court holds in abeyance, or refers to the Commissioner, any matter for an initial administrative determination pursuant to § 2.6(c) or § 2.11(b).

(b) The Commissioner shall promptly agree or decline to accept such referral. Whenever feasible in light of agency priorities and resources, the Commissioner shall agree to accept any such referral and shall institute a proceeding to determine the matter so referred.

(c) In reviewing such a matter, the Commissioner may, in his discretion, utilize any of the following procedures:

(1) Conferences, meetings, discussions, and correspondence pursuant to § 2.15.

(2) A formal evidentiary public hearing pursuant to Subpart B of this part.

(3) A hearing before a Public Board of Inquiry pursuant to Subpart C of this part.

(4) A public hearing before a public advisory committee pursuant to Subpart D of this part.

(5) A public hearing before the Commissioner pursuant to Subpart E of this part.

(6) A regulatory hearing before the Food and Drug Administration pursuant to Subpart F of this part.

(7) A notice published in the FEDERAL REGISTER requesting data, information, and views before the Commissioner makes his decision on it.

(8) Any other specific public procedure established by the provisions in other sections of this chapter and explicitly made applicable to the matter by those provisions.

(d) If the Commissioner's review of the matter results in the proposal of a regulation, the provisions of § 2.10 or § 2.12 shall also apply.

§ 2.15 Meetings and correspondence.

(a) In addition to the public hearings and proceedings established by the provisions of this part and in other sections of this chapter, meetings may be held and correspondence may be exchanged between representatives of the Food and Drug Administration and any interested person outside the Food and Drug Administration with respect to any matter within the jurisdiction of the laws administered by the Commissioner. Action with respect to such meetings and correspondence does not constitute final administrative action which is subject to judicial review pursuant to § 2.11.

(b) The Commissioner may conclude, in his discretion, that it would be in the public interest to hold an open public meeting to discuss a matter (or class of matters) pending before the Food and Drug Administration, at which any interested person may participate.

(1) The Commissioner shall give public notice through the public calendar described in § 2.22(a) of the time and place of the meeting and of the matters to be discussed, and may also publish such notice in the FEDERAL REGISTER.

(2) The meeting shall be conducted informally, i.e., any interested person may attend and participate fully in the discussion without giving prior notice to the agency or requesting time to make a presentation.

(3) No transcript or recording of any such meeting shall be required. A written memorandum summarizing the substance of the meeting shall be prepared by a representative of the Food and Drug Administration.

(c) Any meeting with any person outside the Department, including any person in the executive or legislative branch of the Federal government, relating to a pending court case, administrative hearing, or other regulatory action or decision, which involves more than a brief description of the matter shall be summarized in a written memorandum which shall be filed in the administrative file on the matter.

(d) Every person outside the Federal government has a right to request and obtain a private meeting with a representative of the Food and Drug Administration in agency offices to discuss any matter in which he is interested.

(1) The person requesting such a meeting may be accompanied by a reasonable number of employees, consultants, or other persons with whom he has a commercial arrangement within the meaning of § 4.81(a) of this chapter. Neither the Food and Drug Administration nor any other person may require the attendance of any person who is not an employee of the Executive Branch of the Federal Government without the agreement of the person requesting the meeting. Any person may attend by mutual consent of the person requesting the meeting and the Food and Drug Administration.

(2) The Food and Drug Administration shall determine which representatives of the Food and Drug Administration shall attend the meeting. The person requesting the meeting may request but not require or preclude the attendance of any specific Food and Drug Administration employee.

(3) Whenever appropriate (e.g., the meeting involved a matter covered by paragraph (c) of this section or any other important matter, a decision on an issue, or statements or advice or conclusions to which future reference may be required as part of an administrative record), a written memorandum summarizing the substance of the meeting shall be prepared by a representative of the Food and Drug Administration.

(4) Any person who wishes to attend a specific private meeting, but who is not permitted to attend because the person requesting the meeting or the Food and Drug Administration does not grant permission for such attendance, or because it is conducted by telephone, may request and obtain a separate meeting with the Food and Drug Administration to discuss the same matter or any additional matter.

(e) Food and Drug Administration employees have a responsibility to meet with all segments of the public in order

to promote the objectives of the laws administered by the Food and Drug Administration and the agency. In pursuing this responsibility the following general policy shall apply where agency employees are invited by persons outside the Federal Government to attend or participate in meetings outside agency offices as representatives of the agency.

(1) A person outside the Executive Branch of the Federal Government may invite an agency representative to attend or participate in a meeting outside agency offices. The agency representative is not obligated to attend or participate in any such meeting, but may do so where he concludes that it is in the public interest and will promote the objectives of the act and the agency.

(2) An agency representative may request that any such meeting be an open meeting when he concludes that this would be in the public interest. The agency representative may agree to decline to participate in any such meeting which is held as a private meeting, depending upon which action he concludes will best serve the public interest.

(3) An agency representative shall not knowingly participate in any meeting which is closed on the basis of sex, race, or religion.

(4) Any such meeting, whether open or closed, shall be subject to the requirements of paragraph (d)(3) of this section with respect to memoranda summarizing the substance of the meeting.

(f) Representatives of the Food and Drug Administration may initiate a meeting or correspondence with any person outside the Federal Government with respect to any matter relating to the laws administered by the Commissioner.

(1) Any meeting initiated by the Food and Drug Administration which involves a small number of interested persons, e.g., a meeting with a petitioner or with two manufacturers of a particular product which requires additional testing or with a trade association employee to discuss an industry labeling problem, may be a private meeting. Any meeting initiated by the Food and Drug Administration which involves a large number of interested persons, e.g., 10 manufacturers of an ingredient to discuss appropriate testing or labeling, shall be held as an open conference or meeting pursuant to paragraph (b) of this section.

(2) Whenever appropriate (e.g., the meeting involved a matter covered by paragraph (c) of this section or any other important matter, a decision on an issue, or statements or advice or conclusions to which future reference may be required as part of the administrative record), a written memorandum summarizing the substance of any meeting shall be prepared by a representative of the Food and Drug Administration.

(g) Any person who participates in any meeting described in paragraphs (b) through (f) of this section may prepare and submit to the Food and Drug Administration for inclusion in the administrative file a written memorandum summarizing the substance of the meeting.

(h) All memoranda of such meetings prepared by a representative of the Food and Drug Administration or by any other person and all correspondence which relate to any matter pending before the agency shall promptly be filed in the relevant administrative file of the proceeding.

(i) Any meeting with a representative of Congress relating to a pending or potential investigation, inquiry, or hearing by a congressional committee or a member of Congress shall be summarized in a written memorandum which shall be forwarded to the Food and Drug Administration, Office of Legislative Services. This provision shall not restrict the right of any agency employee to participate in any such meeting.

(j) Any meeting of an advisory committee shall be subject to the requirements of Subpart D of this part.

(k) Pursuant to 42 U.S.C. 263l(a)(8), a log or summary shall be made of all meetings held between representatives of the Food and Drug Administration and representatives of industry and other interested parties with respect to implementation of the Radiation Control for Health and Safety Act of 1968.

§ 2.16 Documentation of significant decisions in administrative file.

(a) The provisions of this section shall apply to every significant Food and Drug Administration decision on any matter under the laws administered by the Commissioner, whether it is raised formally, e.g., by a petition, or informally, e.g., by correspondence.

(b) The Food and Drug Administration employees responsible for handling any matter shall be responsible for assuring the completeness of the administrative file relating to it. Such file:

(1) Shall contain appropriate documentation of the basis for the decision, including relevant evaluations, reviews, memoranda, letters, opinion of consultants, minutes of meetings, and all other written documents pertinent to the matter.

(2) Shall contain the recommendations and decisions of individual employees, including supervisory personnel, responsible for handling the matter.

(i) Such recommendations and decisions shall reveal any significant controversies or differences of opinion and their resolution.

(ii) Any agency employee working on a matter and, consistent with the prompt completion of his other assignments, any agency employee who has worked on a matter shall have the opportunity to record his views on that matter in a written memorandum, which shall be included in the file.

(c) Each written document placed in such an administrative file:

(1) Shall relate to the factual, scientific, legal, or related issues under consideration.

(2) Shall be dated and signed by the author.

(3) Shall be directed to the file, to appropriate supervisory personnel, and to other appropriate employees, and shall show all persons to whom copies were sent.

(4) Shall avoid defamatory language, intemperate remarks, undocumented charges, or irrelevant matters (e.g., personnel complaints).

(5) Shall, if it records the views, analyses, recommendations, or decisions of any agency employee in addition to the author, be given to such other employees.

(6) Shall, once completed (i.e., typed in final form, dated, and signed), not be altered, added to, or removed. Subsequent additions to, or revisions of, any such document shall be accomplished by the preparation of a new document.

(d) Memoranda or other documents prepared by agency employees not contained in the administrative file shall have no status or effect.

(e) All Food and Drug Administration employees working on a matter shall have access to the administrative file on that matter, as appropriate for the conduct of their work. All Food and Drug Administration employees who have worked on a matter shall have access to the administrative file on that matter so long as their attention to their assignments is not impeded. Reasonable restrictions may be placed upon such access to assure the proper cataloging and storage of documents, the availability of the file to others, and the completeness of the file for review.

§ 2.17 Internal agency review of decisions.

(a) Any decision of a Food and Drug Administration employee, other than the Commissioner, on any matter, e.g., an informal opinion on the need for further animal toxicology tests to support a food additive regulation or new drug application, is subject to review by the employee's supervisor under any of the following circumstances:

(1) At the request of the employee.

(2) On the initiative of the supervisor.

(3) At the request of any interested person outside the agency.

(4) As required by duly promulgated delegations of authority.

(b) Such review shall be accomplished by consultation between the employee and the supervisor or by review of the administrative file on the matter, or both. Such review shall ordinarily follow the established agency channels of supervision or review for that matter.

(c) Any interested person outside the agency may request internal agency review of any such decision through the established agency channels of supervision or review for that matter. Personal review of such matters by bureau directors or the office of the Commissioner shall take place for any of the following purposes:

(1) To resolve an issue which cannot be resolved at lower levels within the agency:

(i) Between two parts of a bureau or other component of the agency, or

(ii) Between two bureaus or other components of the agency, or

(iii) Between the agency and an interested person outside the agency.

(2) To review policy matters requiring the attention of bureau or agency management.

(3) In unusual situations requiring an immediate review in the public interest.

(4) As required by duly promulgated delegations of authority.

(d) Internal agency review of any such decision shall be based upon the data and information available in the administrative file. In the event that any interested person presents new data or information not contained in such file, the matter shall be returned to the appropriate lower level within the agency for a reevaluation based upon such new information.

§ 2.18 Dissemination of draft Federal Register notices and regulations.

(a) Any representative of the Food and Drug Administration may discuss orally or in writing with any interested person ideas and recommendations for FEDERAL REGISTER notices or regulations. The Food and Drug Administration welcomes assistance in developing ideas for, and in gathering the data and information to support, notices and regulations.

(b)(1) Once it is determined that a proposed notice or regulation will be prepared, the general concepts may be discussed by a representative of the Food and Drug Administration with any interested person. Details of a draft of a proposed notice or regulation may be discussed with any person outside the Executive Branch of the Federal Government only with the specific permission of the Commissioner.

(2) A draft of a proposed notice or regulation or its preamble, or any portion thereof, may be furnished to an interested person outside the Executive Branch of the Federal Government only if it is made available to all interested persons by a notice published in the FEDERAL REGISTER. A draft of a proposed notice or regulation so made available may, without the prior permission of the Commissioner, be discussed with any interested person to clarify and resolve questions raised and concerns expressed about the proposal.

(c) After publication of a proposed regulation in the FEDERAL REGISTER, and before preparation of a draft of the final regulation, a representative of the Food and Drug Administration may discuss the proposal with any interested person as provided in paragraph (b)(2) of this section.

(d)(1) Details of a draft of a final notice or regulation may be discussed with any interested person outside the Executive Branch of the Federal Government only with the specific permission of the Commissioner.

(2) A draft of a final notice or regulation of its preamble, or any portion thereof, may be furnished to an interested person outside the Executive Branch of the Federal Government only if it is made available to all interested persons by a notice published in the FEDERAL REGISTER, except as otherwise provided in paragraphs (g) and (j) of this section. A draft of a final notice or regulation so made available to any interested person may, without the prior permission of the Commissioner, be discussed with any interested person as provided in paragraph (b)(2) of this section.

(1) The final notice or regulation and its preamble shall be prepared solely on the basis of the administrative record.

(2) If any additional technical information from a person outside the Executive Branch of the Federal government is necessary to draft the final notice or regulation or its preamble, it shall be requested by the Food and Drug Administration in general terms and furnished directly to the Hearing Clerk to be included as part of the administrative record.

(3) If direct discussion by the Food and Drug Administration of a draft of a final notice or regulation or its preamble is required with a person outside the Executive Branch of the Federal Government, appropriate protective procedures will be undertaken to make certain that a full and impartial administrative record is established. Such procedures may include:

(i) The scheduling of an open public meeting conducted pursuant to § 2.15(b) at which any interested person may participate in review of and comment on the draft document.

(ii) The preparation of a tentative final regulation or tentative revised final regulation pursuant to § 2.10(f)(9), on which all interested persons will be given an additional period of time for oral and written comment.

(e) After a final regulation is published in the FEDERAL REGISTER, a representative of the Food and Drug Administration may discuss any aspect of it with any interested person.

(f) In addition to the requirements of this section, the provisions of § 2.13 shall apply to the promulgation of any regulation subject to the provisions of § 2.12 and Subpart B of this part.

(g) A draft of a final food additive, color additive, or new animal drug regulation or a proposed or final antibiotic regulation may be furnished to the petitioner for comment on the technical accuracy of such regulation. Every meeting with a petitioner relating to such a draft shall be recorded in a written memorandum, and all such memoranda and correspondence shall be filed with the Hearing Clerk as part of the administrative record of the regulation, pursuant to the provisions of § 2.15.

(h) Pursuant to 42 U.S.C. 263f, the Commissioner is required to consult with interested persons in the development of, and with the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) before prescribing, any performance standard for an electronic product. Accordingly, the Commissioner shall publish in the FEDERAL REGISTER an announcement when a proposed or final performance standard, including any amendment thereof, is being considered for an electronic product, and thereafter any draft of any such document shall be furnished to any interested person upon request and may be discussed in detail with any interested person at any time.

(i) The provisions of § 2.15 shall apply to meetings and correspondence relating to draft FEDERAL REGISTER notices and regulations.

(j) The provisions of this section restricting discussion and disclosure of draft FEDERAL REGISTER notices and regulations shall not apply to those situations covered by §§ 4.83 through 4.89 of this chapter.

§ 2.19 Advisory opinions.

(a) Any person may request an advisory opinion from the Commissioner with respect to any matter of general applicability in which he is interested.

(1) Such request shall be granted whenever feasible.

(2) Such request may be denied if any of the following apply:

(i) The request contains incomplete information on which to base an informed advisory opinion.

(ii) The Commissioner concludes that an advisory opinion cannot reasonably be given on the matter involved.

(iii) The matter is adequately covered by a prior advisory opinion or a regulation.

(iv) The request covers a particular product or ingredient or label and does not raise a policy issue of broad applicability.

(v) The Commissioner otherwise concludes, in his discretion, that an advisory opinion would not be in the public interest.

(b) A request for an advisory opinion shall be submitted in accordance with § 2.5, shall be subject to the provisions of § 2.7(c) through (l), and shall be in the following form:

_____
(Date)

Hearing Clerk, Food and Drug Administration, Department of Health, Education, and Welfare, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857

REQUEST FOR ADVISORY OPINION

The undersigned submits this request for an advisory opinion of the Commissioner of Food and Drugs with respect to _____ (the general nature of the matter involved).

A. *Issues Involved.*

(A concise statement of the issues and questions on which an opinion is requested.)

B. *Statement of Facts and Law.*

(A full statement of all facts and legal points relevant to the request.)

The undersigned certifies that, to the best of his knowledge and belief, this request includes all data, information, and views relevant to the matter, whether favorable or unfavorable to the position of the undersigned, which is the subject of the request.

Very truly yours,

_____
(Signature)

_____
(Person making request)

_____
(Mailing address)

_____
(Telephone number)

(c) The Commissioner may, in his discretion, handle any oral or written request to the agency as a request for an advisory opinion, in which case the request shall be filed with the Hearing Clerk and shall be subject to the provisions of this section.

(d) Any statement of policy or interpretation made in any of the following documents, unless subsequently repudiated by the agency or overruled by a court, shall constitute an advisory opinion:

(1) Any portion of a FEDERAL REGISTER notice other than the text of a proposed or final regulation, e.g., a notice to manufacturers or a preamble to a proposed or final regulation.

(2) Trade Correspondence (T.C. Nos. 1–431 and 1A–8A issued by the Food and Drug Administration between 1938 and 1946.

(3) Compliance Policy Guides issued by the Food and Drug Administration beginning in 1968 and codified in the Compliance Policy Guides manual.

(4) Other documents specifically identified as advisory opinions, e.g., advisory opinions on the performance standard for diagnostic x-ray systems, issued prior to July 1, 1975, and filed in a permanent public file for such prior advisory opinions maintained in the Public Records and Documents Center.

(5) Guidelines issued by the Food and Drug Administration pursuant to § 2.20 (b).

(e) An advisory opinion represents the formal position of the Food and Drug Administration on the matter involved, and except as provided in paragraph (f) of this section obligates the agency to follow it until it is amended or revoked. The Commissioner shall not recommend legal action against any person or product with respect to any action taken in conformity with an advisory opinion which has not been amended or revoked.

(f) In unusual situations involving an immediate and significant danger to health, the Commissioner may take appropriate civil enforcement action contrary to an advisory opinion issued pursuant to this section prior to amending or revoking such advisory opinion as provided in paragraph (g) of this section. Such action shall be taken only with the approval of the Commissioner, which may not be delegated. Appropriate amendment or revocation of the advisory opinion involved shall be expedited.

(g) An advisory opinion may be amended or revoked at any time after it has been issued. Notice of such amendment or revocation shall be given in the same manner in which notice was originally given of the advisory opinion or in the FEDERAL REGISTER, and in any event shall be placed on public display as part of the file on the matter in the office of the Hearing Clerk. The Hearing Clerk shall maintain a separate chronological index of all advisory opinions filed. The index shall specify the date of the request for the advisory opinion, the date of the opinion, and identification of the appropriate file.

(h) Action undertaken or completed in conformity with an advisory opinion issued pursuant to this paragraph which has subsequently been amended or revoked shall remain acceptable to the Food and Drug Administration unless the Commissioner determines that substantial public interest considerations preclude such continued acceptance. Whenever possible, an amended or revoked advisory opinion shall state when it has been determined that action previously undertaken or completed in conformity with a prior advisory opinion does not remain acceptable, and any transition period that may be applicable.

(i) Any interested person may submit written comments on an advisory opinion or modified advisory opinion. Three copies of any comments shall be sent to the Hearing Clerk for inclusion in the public file on the advisory opinion. Individuals may submit only one copy. Such comments shall be considered in determining whether further modification of an advisory opinion is warranted.

(j) An advisory opinion may be used in administrative or court proceedings to illustrate acceptable and unacceptable procedures or standards, but not as a legal requirement.

(k) A statement made or advice provided by an employee of the Food and Drug Administration shall constitute an advisory opinion only if it is issued in writing pursuant to this section. A statement or advice given by a Food and Drug Administration employee orally, or given in writing but not pursuant to this section or § 2.20, is an informal communication that represents the best judgment of that employee at that time but does not constitute an advisory opinion, does not necessarily represent the formal position of the Food and Drug Administration, and thus does not bind or otherwise obligate or commit the agency to the views expressed.

§ 2.20 Food and Drug Administration regulations, guidelines, recommendations, and agreements.

(a) *Regulations.* All Food and Drug Administration regulations having general applicability and legal effect shall be promulgated in the FEDERAL REGISTER pursuant to § 2.10 or § 2.12 and codified in the Code of Federal Regulations. Regulations may contain provisions which will be enforced as legal requirements, or which are intended only as guidelines and recommendations, or both. The dissemination of draft notices and regulations shall be subject to the provisions of § 2.18.

(b) *Guidelines.* All Food and Drug Administration guidelines having general applicability shall be included in the public file of guidelines established by the Hearing Clerk, pursuant to this paragraph, unless they have been published in the FEDERAL REGISTER as regulations pursuant to paragraph (a) of this section.

(1) Guidelines establish principles or practices of general applicability and do not include decisions or advice limited to particular situations. Guidelines relate to such matters as performance characteristics, preclinical and clinical test procedures, manufacturing practices, product standards, scientific protocols, compliance criteria, ingredient specifications, labeling, or other technical or policy criteria. Guidelines state procedures or standards of general applicability that are not legal requirements but that are acceptable to the Food and Drug Administration for a subject matter which falls within the laws administered by the Commissioner, e.g., a protocol for a particular type of animal toxicity test or human clinical trial.

(i) A person may rely upon a guideline with assurance that it is acceptable to the Food and Drug Administration, or may folow different procedures or standards. Where a person chooses to use different procedures or standards, he may, but is in no instance required to, discuss the matter in advance with the Food and Drug Administration to prevent the expenditure of money and effort on activity that may later be determined to be unacceptable.

(ii) Use of testing guidelines established by the Food and Drug Administration assures acceptance of a test as scientifically valid, if properly conducted, but does not assure approval of any ingredient or product so tested. The results of any such test or other available information may require disapproval or that additional testing be undertaken.

(2) A guideline represents the formal position of the Food and Drug Administration on the matter involved, and except as provided in paragraph (b)(3) of this section, obligates the agency to follow it until it is amended or revoked. The Commissioner shall not recommend legal action against any person or product with respect to any action taken in conformity with a guideline issued pursuant to this section that has not been amended or revoked.

(3) In unusual situations involving an immediate and significant danger to health, the Commissioner may take appropriate civil enforcement action contrary to a guideline issued pursuant to paragraph (b) of this section prior to amending or revoking such guideline as provided in paragraph (b)(5) of this section. Such action shall be taken only with the approval of the Commissioner, which may not be delegated. Appropriate amendment or revocation of the guideline involved shall be expedited.

(4) A guideline shall be included in the public file upon approval of the guideline by the relevant bureau director and publication by the Commissioner in the FEDERAL REGISTER of a notice of its availability. The notice shall state (i) the title of the guideline, (ii) the subject matter it covers, and (iii) the office or individual responsible for maintaining the guideline.

(5) A guideline may be amended or revoked upon approval of the amended guideline or revocation of the guideline by the relevant bureau director and publication by the Commissioner in the

FEDERAL REGISTER of a notice of such amendment or revocation. The notice shall state (i) the title of the guideline, (ii) the subject matter it covers, and (iii) the office or individual responsible for maintaining the guideline. All original guidelines and subsequent amendments shall be retained in the public file on a permanent basis so that a complete record of the development of each guideline remains available.

(6) Action undertaken or completed in conformity with a guideline issued pursuant to paragraph (b) of this section which has subsequently been amended or revoked shall remain acceptable to the Food and Drug Administration unless the Commissioner determines that substantial public interest considerations preclude such continued acceptance. Such determination may be made at the time of or subsequent to amendment or revocation of the guideline. Whenever possible, the notice of an amended or revoked guideline published pursuant to paragraph (b)(3) of this section shall state when it has been determined that action previously undertaken or completed in conformity with a prior guideline does not remain acceptable, and any transition period that may be applicable.

(7) The notice of a guideline or amended or revoked guideline published pursuant to paragraph (b) (2) or (3) of this section shall state that any interested person may submit written comments on the guideline or amended guideline. Two copies of any comments shall be sent to the Public Records and Documents Center for inclusion in the public file on the guideline and two copies shall be sent to the office or individual designated in the notice as responsible for maintaining the guideline. Such comments shall be considered in determining whether further amendments to or reinstitution of a guideline are warranted.

(8) A guideline may be used in administrative or court proceedings to illustrate acceptable and unacceptable procedures or standards, but not as establishing a legal requirement.

(9) A statement relating to acceptable procedures or standards given by a Food and Drug Administration employee orally, or in writing but not pursuant to § 2.19 or this section, is an informal communication that represents the best judgment of that employee at that time but does not constitute a guideline, does not necessarily represent the formal position of the Food and Drug Administration, and thus does not bind or otherwise obligate the agency to the views expressed.

(10) Because of the large number of analytical methods involved in Food and Drug Administration activities, their length and complexity, and the volume and frequency of amendment, the provisions of paragraph (b)(4) of this section shall not apply to such material except to the extent that the Commissioner concludes, in his discretion, that particular analytical methods should be included in the public file for a particular purpose. Food and Drug Administration analytical methods are available for public disclosure pursuant to the provisions of Part 4 of this chapter.

(11) The dissemination of draft guidelines shall be subject to the same provisions as the dissemination of draft notices and regulations pursuant to § 2.18.

(c) *Recommendations.* In addition to the guidelines subject to paragraph (b) of this section, the Food and Drug Administration often formulates and disseminates recommendations about matters which are authorized by, but do not involve direct regulatory action under, the laws administered by the Commissioner, e.g., model state and local ordinances, or personnel practices for reducing radiation exposure, issued pursuant to 42 U.S.C. 243 and 263d(b). Such recommendations may, in the discretion of the Commissioner, be handled pursuant to the procedures established in paragraph (b) of this section, except that such recommendations shall be included in a separate public file of recommendations established by the Public Records and Documents Center and shall be separated from the guidelines in the notice of availability published in the FEDERAL REGISTER, or be published in the FEDERAL REGISTER as regulations pursuant to paragraph (a) of this section.

(d) *Agreements.* All formal agreements, memoranda of understanding, or other similar written documents executed by the Food and Drug Administration and another person shall be included in the public file on agreements established by the Public Records and Documents Center pursuant to § 4.108 of this chapter. Any such document not included in the public file shall be deemed to be rescinded and shall have no force or effect whatever.

§ 2.21 Participation in outside standard-setting activities.

(a) *General.* This section applies to participation by Food and Drug Administration employees in any standard-setting activities outside the Food and Drug Administration. Standard-setting activities include such matters as the development of performance characteristics, testing methodology, manufacturing practices, product standards, scientific protocols, compliance criteria, ingredient specifications, labeling, or other technical or policy criteria. The Food and Drug Administration encourages employee participation in outside standard-setting activities that are in the public interest.

(b) *Standard-setting activities by other Federal government agencies.* (1) Any Food and Drug Administration employee may participate in such activities after the approval by the appropriate bureau director or the Commissioner of Form PHS–3763 "Request for approval of appointment as liaison representative."

(2) The Form PHS–3763 and all pertinent background information describing such activities shall be included in the public file on standard-setting activities established in the Public Records and Documents Center.

(3) If any members of the public are invited by the Food and Drug Administration to present views to, or to accompany, the Food and Drug Administration employee at any meeting, such invitations shall be extended to a representative sampling of the public, including consumer groups, industry associations, professional societies, and academic institutions.

(4) A Food and Drug Administration employee appointed as the liaison representative to such an activity shall refer all requests for information about or participation in the activity involved to the group or organization responsible for such activity.

(c) *Standard-setting activities by State and local government agencies and by United Nations organizations and other international organizations and foreign governments pursuant to treaty.* (1) Any Food and Drug Administration employee may participate in such activities after the approval by the appropriate bureau director or the Commissioner of Form PHS–3763.

(2) The Form PHS–3763 and all pertinent background information describing such activities shall be included in the public file on standard-setting activities established in the Public Records and Documents Center.

(3) The availability for public disclosure of records relating to such activities shall be governed by the regulations in Part 4 of this chapter.

(4) If any members of the public are invited by the Food and Drug Administration to present views to, or to accompany, the Food and Drug Administration employee at any meeting, such invita-

tions shall be extended to a representative sampling of the public, including consumer groups, industry associations, professional societies, and academic institutions.

(5) A Food and Drug Administration employee appointed as the liaison representative to such an activity shall refer all requests for information about or participation in the activity involved to the group or organization responsible for such activity.

(d) *Standard-setting activities by private groups and organizations.* (1) Any Food and Drug Administration employee may engage in such activities after the approval by the appropriate bureau director or the Commissioner of Form PHS–3763. A request for such official participation shall be made by the group or organization in writing, shall describe the scope of the activity involved, and shall demonstrate that the minimum standards set out in paragraph (d) (5) of this section are met by the activity involved. Except as provided in paragraph (d) (7) of this section, any such request that is granted shall be the subject of a letter from the Commissioner or the bureau director to the organization stating:

(i) Whether participation by the individual will be as a voting or nonvoting liaison representative.

(ii) That participation by the individual shall not connote Food and Drug Administration agreement with, or endorsement of, any decisions reached.

(iii) That participation by the individual disqualifies him from serving as the deciding official on the standard involved if it should later come before the Food and Drug Administration. The "deciding official" is the person who signs a document ruling upon such standard.

(2) The letter requesting official Food and Drug Administration participation, the Form PHS–3763, and the Commissioner's or bureau director's letter, together with all pertinent background information describing the activities involved, shall be included in the public file on standard-setting activities established in the Public Records and Documents Center.

(3) The availability for public disclosure of records relating to such activities shall be governed by the regulations in Part 4 of this chapter.

(4) A Food and Drug Administration employee appointed as the liaison representative to such an activity shall refer all requests for information about or participation in the activity involved to the group or organization responsible for such activity.

(5) The following minimum standards shall apply to all outside private standard-setting activities in which Food and Drug Administration employees participate.

(i) The activities shall be based upon consideration of sound scientific and technological information, shall permit revision on the basis of new information, and shall be designed to protect the public against unsafe, ineffective, or deceptive products or practices.

(ii) The activities and resulting standards shall not be designed for the economic benefit of any company, group, or organization, shall not be used as devices for such antitrust violations as fixing prices or hindering competition, and shall not involve establishment of certification or specific approval of individual products or services.

(iii) The group or organization responsible for the standard-setting activities shall have a procedure through which any interested person shall have an opportunity to provide information and views on the activities and standards involved, without the payment of fees, and such information and views shall be considered. The manner in which this is accomplished, including whether such presentation shall be in person or in writing, shall be decided by the group or organization responsible for the activities.

(6) Membership of a Food and Drug Administration employee in an organization that also conducts standard-setting activities does not invoke the provisions of this paragraph unless the employee participates in such standard-setting activities. Participation in any standard-setting activity shall be subject to the provisions of this paragraph.

(7) The Commissioner may determine in writing that, because direct involvement by the Food and Drug Administration in a particular standard-setting activity is in the public interest and will promote the objectives of the act and the agency, such participation shall be exempt from the requirements set forth in paragraph (d) (1) (ii) and/or (iii) of this section. Any such determination shall be included in this public file on standard-setting activities established by the Public Records and Documents Center and in any relevant administrative file. Such activities may include the establishment and validation of analytical methods for regulatory use, drafting uniform laws and regulations, and the development of recommendations concerning public health and preventive medicine practices by national and international organizations.

(8) Because of the close daily cooperation between the Food and Drug Administration and the associations of State and local government officials listed below, and the large number of agency employees who are members of or work with these associations, such participation in the activities of these associations shall be exempt from the provisions of paragraphs (d) (1) through (d) (7) of this section, except that a list of all committees and other groups of these associations shall be included in the public file on standard-setting activities established in the Public Records and Documents Center:

(i) Association of Food and Drug Officials.

(ii) International Association of Milk, Food and Environmental Sanitarians, Inc.

(iii) Conference of Radiation Control Program Directors.

(iv) Association of American Feed Control Officials, Inc.

(v) National Environmental Health Association.

(vi) National Conference on Weights and Measures.

(vii) American Public Health Association.

(viii) Conference of State Sanitary Engineers.

(ix) National Conference on Interstate Milk Shipments.

(x) National Shellfish Sanitation Program.

(xi) Interstate Seafood Seminar.

(xii) Association of Official Analytical Chemists.

§ 2.22 Public calendar.

(a) *Prospective public calendar of public proceedings.* (1) A public calendar shall be prepared and made publicly available each week showing, to the extent feasible, for the following 4 weeks all public meetings, public conferences, public hearings, public advisory committee meetings, public seminars, and other public proceedings of the Food and Drug Administration, and other significant public events involving the Food and Drug Administration, e.g., congressional hearings and trial or argument of court cases.

(2) A copy of this public calendar shall be placed on public display in the following places:

(i) Office of the Hearing Clerk.

(ii) Office of the Assistant Commissioner for Public Affairs.

(iii) A central place in each bureau.

(iv) A central place in each field office.

(v) A central place at the National Center for Toxicological Research.

(b) *Retrospective public calendar of meetings.* (1) A public calendar shall be prepared and made publicly available each week showing for the previous week all meetings with persons outside the Executive Branch of the Federal Government and other significant events involving the representatives of the Food and Drug Administration designated

under paragraph (b)(3) of this section, except that telephone conversations shall be included on an optional basis and meetings with the working press, except for "house organs" (i.e., publications of firms that manufacture or distribute regulated products, or industry associations), and with on-site contractors shall not be included. Meetings with members of the judiciary, representatives of Congress, or staffs of congressional committees shall be included when the meeting relates to a pending court case, administrative hearing, or other regulatory action or decision and involves more than a brief description of the matter.

(2) Such calendar shall include all meetings, conferences, seminars, social events sponsored by the regulated industry, and speeches. The calendar shall specify the date, the person involved, and the subject matter involved. Where more than one Food and Drug Administration representative is in attendance, only the presiding or head representative shall report the meeting on the public calendar. If a large number of persons are involved, the name of each need not be specified. Meetings the existence of which would prejudice law enforcement activities (e.g., a meeting with an informant) or invade privacy (e.g., a meeting with a candidate for possible employment in the Food and Drug Administration) shall not be reported.

(3) The following Food and Drug Administration representatives and their deputies shall be subject to the requirements of paragraphs (b) (1) and (2) of this section:

(i) Commissioner of Food and Drugs.

(ii) Deputy Commissioner.

(iii) Associate Commissioners.

(iv) Assistant Commissioners.

(v) Executive Director for Regional Operations.

(vi) Director, Office of Legislative Services.

(vii) Director, National Center for Toxicological Research.

(viii) Bureau Directors.

(ix) Chief Counsel for the Food and Drug Administration, or any representative of his office attending in his behalf.

(4) A copy of this public calendar shall be placed on public display in the following places:

(i) Office of the Hearing Clerk.

(ii) Office of the Assistant Commissioner for Public Affairs.

(iii) A central place in each bureau.

(iv) A central place in each field office.

(v) A central place at the National Center for Toxicological Research.

§ 2.23 Representation by an organization.

(a) An organization may represent its members by filing petitions, comments, and objections, and otherwise participating in any administrative proceeding subject to this part.

(b) Any such petitions, comments, objections, or other representations by an organization shall not abridge the right of any member to take any action of a similar type in its own name.

(c) It is requested that each organization participating in Food and Drug Administration administrative proceedings file annually a current list of all of the members of such organization with the Hearing Clerk for permanent filing.

(d) The filling by an organization of an objection or request for hearing pursuant to §§ 2.110 through 2.112 shall not provide to any member any legal right with respect to such objection or request for hearing that the member may exercise in its own name. Any member of an organization wishing to so file an objection or request for a hearing to obtain legal rights thereunder shall do so in its own name.

(e) In any court proceeding in which an organization participates, the Commissioner will take appropriate legal measures to have the case brought or considered as a class action or otherwise as binding upon all members of the organization except those specifically excluded by name for the reason that the organization does not represent their views. Regardless whether the case is brought or considered as a class action or as otherwise binding upon all members of the organization except those specifically excluded by name, the Commissioner will take the position in any subsequent suit involving the same issues and any member of the organization that such issues are precluded from further litigation by such member pursuant to the doctrines of collateral estoppel or res judicata.

§ 2.24 Settlement proposals.

At any time in the course of any proceeding subject to this part, any person may propose settlement of any of the issues involved. All participants in any proceeding shall have an opportunity to consider any proposed settlement. Unaccepted proposals of settlement and related matters, e.g., proposed stipulations not agreed to, shall not be admissible in evidence in any administrative proceeding of the Food and Drug Administration. The Food and Drug Administration will oppose the admission in evidence of any such information in any court proceeding or in any other administrative proceeding.

§ 2.25 Waiver, suspension, or modification of procedural requirements.

The Commissioner or the presiding officer, with respect to matters pending before him, may on his own initiative or at the request of any participant waive, suspend, or modify any provision in Subparts B through F of this part applicable to the conduct of a public hearing by announcement at the hearing or by notice in advance of the hearing, if he determines that no participant will be prejudiced, the ends of justice will thereby be served, and such action is in accordance with law.

PART 6—ENVIRONMENTAL IMPACT CONSIDERATIONS

§ 6.4 [Amended]

4. In Part 6, by amending § 6.4(a)(2) to change the reference to "§ 2.121" to read "Subpart B of Part 5".

PART 8—COLOR ADDITIVES

5. In Part 8, by revising § 8.12 to read as follows:

§ 8.12 Advisory committee on the applicability of the anticancer clause.

All requests for and procedures governing any advisory committee on the anticancer clause shall be subject to the provisions of Subpart D of Part 2, and particularly §§ 2.360 through 2.364, of this chapter.

§§ 8.13, 8.14 [Revoked]

6. By revoking §§ 8.13 and 8.14.

7. By revising §§ 8.18 and 8.19 to read as follows:

§ 8.18 Petition for exemption from certification.

A manufacturer, packer, or distributor of a color additive or color additive mixture may petition for an exemption from certification pursuant to Part 2 of this chapter. Any such petition shall show why such certification is not necessary for the protection of public health.

§ 8.19 Procedure for objections and hearings.

(a) Objections and hearings relating to color additive regulations under sections 706 (b) and (c) of the act shall be governed by Part 2 of this chapter.

(b) The fees specified in § 8.50 shall be applicable.

§§ 8.20, 8.21 [Revoked]

8. By revoking §§ 8.20 and 8.21.

PART 10—DEFINITIONS AND STANDARDS FOR FOOD

9. In Part 10, by revising § 10.2 to read as follows:

§ 10.2 Procedure for establishing a food standard.

(a) The procedure for establishing a food standard under section 401 of the act shall be governed by Part 2 of this chapter.

(b) Any petition for a food standard shall show that the proposal, if adopted, would promote honesty and fair dealing in the interest of consumers.

(c) Any petition for a food standard shall assert that the petitioner commits himself to substantiate the information in the petition by evidence in a public hearing, if such a hearing becomes necessary.

(d) If a petitioner fails to appear, or to substantiate the information in his petition, at a public hearing on the matter, the Commissioner may either (1) withdraw the regulation and terminate

the proceeding or (2) if he concludes that it is in accordance with the requirements of section 401 of the act, continue the proceeding and introduce evidence to substantiate such information.

PART 11—STANDARDS OF QUALITY FOR FOODS FOR WHICH THERE ARE NO STANDARDS OF IDENTITY

10. In Part 11, by revising § 11.1(e) to read as follows:

§ 11.1 General principles.

* * * * *

(e) The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may establish, amend, or repeal, under Subpart B of this Part, a regulation prescribing a standard of quality for a food pursuant to Part 2 of this chapter.

PART 80—DEFINITIONS AND STANDARDS OF IDENTITY FOR FOOD FOR SPECIAL DIETARY USES

11. In Part 80, by amending § 80.1 (as published in the FEDERAL REGISTER of October 19, 1976 (41 FR 46156)) by revising paragraph (a) (5) to read as follows:

§ 80.1 Dietary supplements of vitamins and minerals.

* * * * *

(a) * * *

(5) *Amendments to this standard.* Amendment of the permissible combinations of vitamins and/or minerals, as established in paragraph (b) of this section, or of the permitted range of potency for any vitamin(s) or mineral(s) in a dietary supplement as established in paragraph (c) of this section, or any other amendments to this section, may be proposed by the Commissioner of Food and Drugs on his own initiative or upon petition by an interested person in accordance with the procedure set forth in Part 2 of this chapter. Any such petition shall show that such amendment will promote honesty and fair dealing in the interest of consumers.

* * * * *

PART 90—EMERGENCY PERMIT CONTROL

12. In Part 90, by revising § 90.2(a) to read as follows:

§ 90.2 Establishment of requirements for exemption from section 404 of the act.

(a) Whenever the Commissioner finds after investigation that the distribution in interstate commerce of any class of food may, by reason of contamination with microorganisms during the manufacture, processing, or packing thereof in any locality, be injurious to health, and that such injurious nature cannot be adequately determined after such articles have entered interestate commerce, he shall promulgate regulations in Subpart B of this part establishing requirements and conditions governing the manufacture, processing, or packing of the food necessary to protect the public health. Such regulations may be proposed by the Commissioner on his own initiative or in response to a petition from any interested person pursuant to Part 2 of this chapter.

* * * * *

PART 100—NUTRITIONAL QUALITY GUIDELINES FOR FOODS

13. In Part 100, by revising § 100.2 to read as follows:

§ 100.2 Petitions.

The Commissioner of Food and Drugs, on his own initiative, on the advice of the National Academy of Sciences or other experts, or on behalf of any interested person who has submitted a petition, may issue a proposal to issue, amend, or revoke a regulation prescribing a nutritional quality guideline for a class of foods, pursuant to Part 2 of this chapter.

PART 102—COMMON OR USUAL NAMES FOR NONSTANDARDIZED FOODS

14. In Part 102, by revising § 102.2 to read as follows:

§ 102.2 Petitions.

(a) The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may publish a proposal to issue, amend, or revoke, under Subpart B of this Part, a regulation prescribing a common or usual name for a food, pursuant to Part 2 of this chapter.

(b) If the principal display panel of a food for which a common or usual name regulation is established is too small to accommodate all mandatory requirements, the Commissioner may establish by regulation an acceptable alternative, e.g., a smaller type size. A petition requesting such a regulation, which would amend the applicable regulation, shall be submitted pursuant to Part 2 of this chapter.

PART 121—FOOD ADDITIVES

15. In Part 121, by revising the introductory text of § 121.40(c)(1) to read as follows:

§ 121.40 Affirmation of generally recognized as safe (GRAS) status.

* * * * *

(c)(1) Persons seeking the affirmation of GRAS status of substances as provided for in § 121.3(e), except those subject to the NAS–NRC GRAS list survey (36 FR 20546), shall submit a petition for GRAS affirmation pursuant to Part 2 of this chapter. Such petition shall contain information to establish that the GRAS criteria as set forth in § 121.3(b) have been met, in the following form:

* * * * *

16. By revising § 121.4(b)(1) to read as follows:

§ 121.41 Determination of food additive status.

* * * * *

(b)(1) The Commissioner, on his own initiative or on the petition of any interested person, pursuant to Part 2 of this chapter, may issue a notice in the FEDERAL REGISTER proposing to determine that a substance is not GRAS and is a food additive subject to section 409 of the act. Any petition shall include all relevant data and information of the type described in § 121.74(b). The Commissioner will place all of the data and information on which he relies on public file in the office of the Hearing Clerk and will include in the FEDERAL REGISTER notice the name of the substance, its known uses, and a summary of the basis for the determination.

* * * * *

17. By revising § 121.55 to read as follows:

§ 121.55 Procedure for objections and hearings.

Objections and hearings relating to food additive regulations under section 409 (c), (d), or (h) of the act shall be governed by Part 2 of this chapter.

§§ 121.56, 121.57, 121.58, 121.59, 121.60, 121.61, 121.62, 121.63, 121.64, 121.65, 121.66, 121.67, 121.68 121.69, 121.70, 121.71, 121.73 [Revoked]

18. By revoking §§ 121.56, 121.57, 121.58, 121.59, 121.60, 121.61, 121.62, 121.63, 121.64, 121.65, 121.66, 121.67, 121.68, 121.69, 121.70, 121.71, and 121.73.

19. By revising § 121.72(b) to read as follows:

§ 121.72 Adoption of regulation on initiative of Commissioner.

* * * * *

(b) Action upon a proposal made by the Commissioner shall proceed as provided in Part 2 of this chapter.

20. By revising § 121.74 to read as follows:

§ 121.74 Procedure for amending and repealing tolerances or exemptions from tolerances.

(a) The Commissioner, on his own initiative or on the petition of any interested person, pursuant to Part 2 of this chapter, may propose the issuance of a regulation amending or repealing a regulation pertaining to a food additive or granting or repealing an exception for such additive.

(b) Any such petition shall include an assertion of facts, supported by data, showing that new information exists with respect to the food additive or that new uses have been developed or old uses abandoned, that new data are available as to toxicity of the chemical, or that experience with the existing regulation or exemption may justify its amendment or repeal. New data shall be furnished in the form specified in § 121.51 for submitting petitions.

21. By revising the introductory text of § 121.4000(c) to read as follows:

§ 121.4000 General.

* * * * *

(c) The Commissioner, on his own initiative or on the petition of any inter-

ested person, pursuant to Part 2 of this chapter, may propose an interim food additive regulation. A final order promulgating an interim food additive regulation shall provide that continued use of the substance in food is subject to each of the following conditions:

* * * * *

PART 310—NEW DRUGS

22. In Part 310, by revising § 310.200 (b) to read as follows:

§ 310.200 Prescription-exemption procedure.

* * * * *

(b) *Prescription-exemption procedure for drugs limited by a new drug application.* Any drug limited to prescription use under section 503(b)(1)(C) of the act shall be exempted from prescription-dispensing requirements when the Commissioner finds such requirements are not necessary for the protection of the public health by reason of the drug's toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, and he finds that the drug is safe and effective for use in self-medication as directed in proposed labeling. A proposal to exempt a drug from the prescription-dispensing requirements of section 503(b)(1)(C) of the act may be initiated by the Commissioner or by any interested person. Any interested person may file a petition seeking such exemption, which petition may be pursuant to Part 2 of this chapter, or in the form of a supplement to an approved new drug application.

* * * * *

23. By revising § 310.303(b) to read as follows:

§ 310.303 Continuation of long term studies, records, and reports on certain drugs for which new drug applications have been approved.

* * * * *

(b) A proposal to require additional or continued studies with a drug for which a new drug application has been approved may be made by the Commissioner on his own initiative or on the petition of any interested person, pursuant to Part 2 of this chapter. Prior to issuance of such a proposal, the applicant will be provided an opportunity for a conference with representatives of the Food and Drug Administration. When appropriate, investigators or other individuals may be invited to participate in the conference. All requirements for special studies, records, and reports will be published in § 310.304.

PART 314—NEW DRUG APPLICATIONS

24. In Part 314, by revising the introductory paragraph of § 314.115 to read as follows:

§ 314.115 Withdrawal of approval of an application.

The Commissioner shall notify the person holding an approved new drug application, and all other persons who manufacture or distribute identical, related, or similar drug products as defined in § 310.6 of this chapter, and afford an opportunity for a hearing on a proposal to withdraw approval of the application as provided in section 505(e) of the act and in accordance with the procedure in §§ 314.200 and 314.201, if:

* * * * *

25. By revising § 314.200 to read as follows:

§ 314.200 Notice of opportunity for hearing; notice of participation and request for hearing; grant or denial of hearing.

(a) The notice to the applicant, and to all other persons who manufacture or distribute identical, related, or similar drug products as defined in § 310.6 of this chapter, of an opportunity for a hearing on a proposal by the Director of the Bureau of Drugs to refuse to approve an application or to withdraw the approval of an application will state the reasons for his action and the grounds upon which he proposes to issue his order.

(1) Such notice may be general (i.e., simply summarizing in a general way the information resulting in the notice) or specific (i.e., either referring to specific requirements in the statute and regulations with which there is a lack of compliance, or providing a detailed description and analysis of the specific facts resulting in the notice).

(2) The notice will be published in the FEDERAL REGISTER and will state that the applicant, and other persons subject to the notice pursuant to § 310.6 of this chapter, has 30 days after the date of publication of the notice within which he is required to file a written notice of participation and request for hearing if he elects to avail himself of the opportunity for a hearing. The failure to file such a written notice of participation and request for hearing within that 30 days constitutes an election by the applicant, and other persons subject to the notice pursuant to § 310.6 of this chapter, not to avail himself of the opportunity for a hearing.

(3) It is the responsibility of every manufacturer or distributor of a drug product to review every notice of opportunity for heating published in the FEDERAL REGISTER to determine whether it covers any drug product he manufactures or distributes. Any person may request an opinion of the applicability of such a notice to a specific product he manufactures or distributes that may be identical, related, or similar by writing to the Food and Drug Administration, Bureau of Drugs, Division of Drug Labeling Compliance, HFD–310, 5600 Fishers Lane, Rockville, MD 20857. If such an opinion is requested, the time for filing an appearance and request for hearing and supporting studies and analyses shall begin as of the date or receipt of the opinion from the Food and Drug Administration.

(b) The notice of opportunity for hearing shall be provided to applicants and to other persons subject to the notice pursuant to § 310.6 of this chapter:

(1) To any person who has submitted a new drug application, by delivering the notice in person or by sending it by registered or certified mail to the last address shown in the new drug application.

(2) To any person who has not submitted a new drug application but who is subject to the notice pursuant to § 310.6 of this chapter, by publication of the notice in the FEDERAL REGISTER.

(c)(1) If the applicant, or any other person subject to the notice pursuant to § 310.6 of this chapter, elects to avail himself of the opportunity for a hearing, he shall file with the Hearing Clerk (i) within 30 days after the date of the publication of the notice (or of the date of receipt of an opinion requested pursuant to paragraph (a)(3) of this section) a written notice of participation and request for hearing, and (ii) within 60 days after the date of publication of the notice, unless a different period of time is specified in the notice of opportunity for hearing, the studies on which he relies to justify a hearing as specified in paragraph (d) of this section. The raw data underlying a study submitted may be incorporated by reference from a prior submission as part of a new drug application or other report.

(2) No data or analysis submitted after such 60 days will be considered in determining whether a hearing is warranted unless they are derived from well-controlled studies begun prior to the date of the notice of opportunity for hearing, the results of which were not in existence during that 60 days. Exceptions may be made on the basis of a showing of inadvertent omission and hardship. All studies in progress, the results of which the person requesting the hearing intends later to submit in support of the request for hearing, shall be listed. A copy of the complete protocol, a list of the participating investigators, and a brief status report of the studies shall be included in the submission made pursuant to paragraph (c)(1)(ii) of this section.

(3) Any other interested person who is not subject to the notice of opportunity for hearing may also submit comments on the proposal to withdraw approval of the new drug application. Such comments shall be submitted within the time and pursuant to the requirements specified in this section.

(d) A request for hearing shall be supported by a submission as specified in paragraph (c)(1)(ii) of this section containing the studies (including all protocols and underlying raw data) on which the person relies to justify a hearing with respect to his drug product.

(1) If effectiveness is at issue, a request for hearing shall be supported only by adequate and well-controlled clinical studies meeting all of the precise requirements of § 314.111(a)(5) and, for combination drug products, § 300.50 of this chapter, or by other studies not meeting those requirements for which a waiver has been previously granted by the Food and Drug Administration pursuant to the provisions of § 314.111(a)(5). All adequate and well-controlled clinical studies on the drug product known to the person requesting the hearing shall be sub-

mitted. Any unfavorable analyses, views, or judgments with respect to such studies known to such person shall also be submitted. No other data, information, or studies shall be submitted.

(2) Such submission shall include a factual analysis of all studies submitted. If effectiveness is at issue, such analysis shall specify how each such study accords, on a point-by-point basis, with each criterion required for an adequate well-controlled clinical investigation established in § 314.111(a)(5) and, if the product is a combination drug product, with each of the requirements for a combination drug established in § 300.50 of this chapter, or shall be accompanied by an appropriate waiver previously granted by the Food and Drug Administration. If a study deals with a drug entity or dosage form, or condition of use, or mode of administration other than the one(s) in question, such fact(s) shall be clearly stated. Any study conducted on the final marketed form of the drug product shall be so designated.

(3) Such analysis shall be submitted in the following format, except that the required information relating either to safety or to effectiveness shall be omitted if the notice of opportunity for hearing does not raise any issue with respect to that aspect of the drug; and information on compliance with § 300.50 shall be omitted if the drug product is not a combination drug product. Submissions not made in this format or not containing the required analyses will not be considered and will result in denial of a hearing, except that minor technical deficiencies may be excused if it is apparent that a good faith attempt has been made to comply with the requirements of this section and any deficiencies noted are immediately corrected upon request.

I. Safety data.

A. Animal safety data.

1. Individual active component(s).

a. Controlled studies.

b. Partially controlled or uncontrolled studies.

2. Combinations of the individual active components.

a. Controlled studies.

b. Partially controlled or uncontrolled studies.

B. Human safety data.

1. Individual active component(s).

a. Controlled studies.

b. Partially controlled or uncontrolled studies.

c. Documented case reports.

d. Pertinent marketing experiences that may influence a determination as to the safety of each individual active component.

2. Combinations of the individual active components.

a. Controlled studies.

b. Partially controlled or uncontrolled studies.

c. Documented case reports.

d. Pertinent marketing experiences that may influence a determination as to the safety of each individual active components.

II. Effectiveness data.

A. Individual active components: Controlled studies, with an analysis showing clearly how each such study satisfies, on a point-by-point basis, each of the criteria required by § 314.111(a)(5).

B. Combinations of individual active components.

1. Controlled studies, with an analysis showing clearly how such study satisfies, on a point-by-point basis, each of the criteria required by § 314.111(a)(5).

2. An analysis showing clearly how each requirement of § 300.50 of this chapter has been satisfied.

III. A summary of the data and views setting forth the medical rationale and purpose for the drug and its ingredients and the scientific basis for the conclusion that the drug and its ingredients have been proven safe and/or effective for the intended use. If there is an absence of controlled studies in the material submitted, or the requirements of any element of § 300.50 of this chapter or § 314.111(a)(5) have not been fully met, such fact(s) shall be clearly stated, and a waiver obtained pursuant to § 314.111(a)(1) shall be enclosed.

IV. A statement signed by the person responsible for such submission, that it includes in full (or incorporates by reference as permitted in § 314.200(c)(2)) all studies and information specified in § 314.200(d). (Warning: A willfully false statement is a criminal offense, 18 U.S.C. 1001).

(e) A notice of opportunity for hearing encompasses all issues relating to the legal status of the drug product(s) subject to it, including identical, related, and similar drug products as defined in § 310.6 of this chapter. Any contention that any such product is not a new drug because it is generally recognized as safe and effective within the meaning of section 201(p) of the act, or because it is exempt from part or all of the new drug provisions of the act pursuant to the exemption for products marketed prior to June 25, 1938, contained in section 201 (p) of the act, or pursuant to section 107 (c) of the Drug Amendments of 1962, or for any other reason shall be stated in a notice of appearance and request for hearing pursuant to paragraph (c)(1)(i) of this section and supported by a submission pursuant to paragraph (c)(1)(ii) of this section and shall be the subject of an administrative determination by the Commissioner. The failure of any person subject to a notice of opportunity for a hearing, including any person who manufactures or distributes an identical, related, or similar drug product as defined in § 310.6 of this chapter, to submit a notice of participation and request for hearing or to raise all such contentions on which he relies shall constitute a waiver of any such contentions not so raised.

(1) A contention that a drug product is generally recognized as safe and effective within the meaning of section 201 (p) of the act must be supported by submission of the same quantity and quality of scientific evidence as is required to obtain approval of a new drug application for the product, unless a waiver has been obtained from such requirement for effectiveness (as provided in § 314.111(a)(5)) and/or safety for good cause shown. Such submission shall be in the format and with the analyses required by paragraph (d) of this section. The failure to submit such scientific evidence or a submission that is not in the format or does not contain the analyses required by paragraph (d) of this section shall constitute a waiver of any such contention. General recognition of safety and effectiveness shall ordinarily be based upon published studies which may be corroborated by unpublished studies and other data and information.

(2) A contention that a drug product is exempt from part or all of the new drug provisions of the act pursuant to the exemption for products marketed prior to June 25, 1938 contained in section 201 (p) of the act, or pursuant to section 107 (c) of the Drug Amendments of 1962, shall be supported by submission of evidence of past and present quantitative formulas, labeling, and evidence of marketing, on which reliance is made for such contention. The failure to submit such formulas, labeling, and evidence of marketing in the following format shall constitute a waiver of any such contention.

I. Formulation.

A. A copy of each pertinent document or record to establish the exact quantitative formulation of the drug (both active and inactive ingredients) on the date of initial marketing of the drug.

B. A statement whether such formulation has at any subsequent time been changed in any manner. If any such change has been made, the exact date, nature, and rationale for each change in formulation, including any deletion or change in the concentration of any active ingredient and/or inactive ingredient, shall be submitted, together with a copy of each pertinent document or record to establish the date and nature of each such change including but not limited to the formula which resulted from each such change. If no such change has been made, a copy of representative documents or records showing the formula at representative points in time shall be submitted to support the statement.

II. Labeling.

A. A copy of each pertinent document or record to establish the identity of each item of written, printed, or graphic matter used as labeling on the date the drug was initially marketed.

B. A statement whether such labeling has at any subsequent time been discontinued or changed in any manner. If such discontinuance or change has been made, the exact date, nature, and rationale for each discontinuance or change and a copy of each pertinent document or record to establish each such discontinuance or change shall be submitted, including but not limited to the labeling which resulted from each such discontinuance or change. If no such discontinuance or change has been made, a copy of representative documents or records showing labeling at representative points in time shall be submitted to support the statement.

III. Marketing.

A. A copy of each pertinent document or record to establish the exact date the drug was initially marketed.

B. A statement whether such marketing has at any subsequent time been discontinued. If such marketing has been discontinued, the exact date of each such discontinuance shall be submitted, together with a copy of each pertinent document or record to establish each such date.

IV. Verification.

A statement signed by the person responsible for such submission, that all appropriate records have been searched and to the best of his knowledge and belief it includes a true and accurate presentation of the facts (Warning: A willfully false statement is a criminal offense, 18 U.S.C. 1001).

(3) No drug product, including any active ingredient, which is identical, related, or similar, as defined in § 310.6, to a drug product, including any active ingredient for which a new drug application is or at any time has been effective or deemed approved, or approved under section 505 of the act, will be determined to be exempt from part or all of the new drug provisions of the act.

(4) A contention that a drug product is not a new drug for any other reason must be supported by submission of such factual records, data, and information as is necessary and appropriate to support such contention.

(5) It is the responsibility of every person who manufactures or distributes a drug product in reliance upon a "grandfather" provision(s) of the act to maintain in his files, organized as required by this paragraph, the data and information necessary fully to document and support such status.

(f) Upon receipt of any request for hearing, the Director of the Bureau of Drugs shall prepare an analysis of the request and a proposed order ruling upon the matter. The analysis and proposed order, the request for hearing, and any proposed order denying a hearing and response pursuant to paragraph (g) (2) or (3) of this section, shall be submitted to the office of the Commissioner for independent review and decision. No representative of the Bureau of Drugs shall participate or advise in the review and decision by the Commissioner. The office of the General Counsel shall observe the same separation of functions.

(g) A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing with respect to the particular drug product(s) specified in the request for hearing.

(1) Where a specific notice of opportunity for hearing (as defined in paragraph (a)(1) of this section) is used, it shall state that, if it conclusively appears from the face of the data, information, and factual analyses in the request for the hearing that there is no genuine and substantial issue of fact which precludes the refusal to approve the application or the withdrawal of approval of the application, e.g., no adequate and well-controlled clinical investigations meeting each of the precise elements of § 314.111(a)(5) and, for a combination drug product, § 300.50 of this chapter, showing effectiveness have been identified, or when a request for hearing is not made in the required format or with the required analyses, the Commissioner will enter summary judgment against the person(s) who requests the hearing, making findings and conclusions, denying a hearing. Any such order entering summary judgment shall set forth the Commissioner's findings and conclusions in detail and shall specify why each study submitted fails to meet the requirements of the statute and regulations or why the request for hearing does not raise a genuine and substantial issue of fact or shall specify the requirements of this section with respect to format or analyses with which there is a lack of compliance.

(2) Where a general notice of opportunity for hearing (as defined in paragraph (a)(1) of this section) is used and the Director of the Bureau of Drugs concludes that summary judgment against the person(s) requesting a hearing should be considered, he shall serve upon such person(s) by registered mail a proposed order denying a hearing. Such person(s) shall have 60 days after receipt of such proposed order to respond with sufficient data, information, and analyses to demonstrate that there is a genuine and substantial issue of fact which justifies a hearing.

(3) Where a general or specific notice of opportunity for hearing is used and the person(s) requesting a hearing submits data or information of a type required by the statute and regulations, and the Director of the Bureau of Drugs concludes that summary judgment against such person(s) should be considered, he shall serve upon such person(s) by registered mail a proposed order denying a hearing. Such person(s) shall have 60 days after receipt of such proposed order to respond with sufficient data, information, and analyses to demonstrate that there is a genuine and substantial issue of fact which justifies a hearing.

(4) If review of the data, information, and analyses submitted warrants the conclusion that the ground(s) cited in the notice are not valid, e.g., that substantial evidence of effectiveness exists, the Commissioner shall deny the hearing, enter summary judgment for the person(s) requesting the hearing, and rescind the notice of opportunity for hearing.

(5) If a hearing is requested and is justified the hearing will commence no more than 90 days after the expiration of such 30 days unless the parties otherwise agree in the case of denial of approval, and as soon as practicable in the case of withdrawal of approval.

(6) A hearing shall be granted if there exists a genuine and substantial issue of fact or if the Commissioner concludes, in his discretion, that a hearing would otherwise be in the public interest.

(7) If the manufacturer or distributor of a drug product that may be an identical, related, or similar drug product requests and is granted a hearing the issue whether the product is in fact identical, related, or similar to the drug subject to new drug application is properly encompassed within the hearing.

(8) A request for hearing, and any subsequent grant or denial of a hearing, shall be applicable only to the particular drug product(s) named in such documents.

(h) Any drug product subject to a notice of opportunity for hearing, including any identical, related, or similar drug product as defined in § 310.6 of this chapter, for which an opportunity for a hearing is waived or for which a hearing is denied shall promptly be the subject of a notice withdrawing the new drug application approval and declaring all such products unlawful. The Commissioner may, in his discretion, defer or stay such action pending a ruling on any related request for a hearing or pending any related hearing or other administrative or judicial proceeding.

26. By adding a new § 314.201 to read as follows:

§ 314.201 Procedure for hearings.

Hearings relating to new drugs under section 505 (d) and (e) of the act shall be governed by Part 2 of this chapter.

§§ 314.202, 314.203, 314.204, 314.205, 314.206, 314.220, 314.221, 314.222, 314.230, 314.231, 314.232, [Revoked].

27. By revoking §§ 314.202, 314.203, 314.204, 314.205, 314.206, 314.220, 314.221, 314.222, 314.230, 314.231 and 314.232.

28. By revising § 314.235 to read as follows:

§ 314.235 Judicial review.

(a) The transcript and record shall be certified by the Commissioner. In any case in which the Commissioner enters an order without a hearing pursuant to § 314.200(g), the requests for hearing together with the data and information submitted and the Commissioner's findings and conclusions shall be included in the record certified by the Commissioner.

(b) Judicial review of an order withdrawing approval of a new drug application, whether or not a hearing has been held, may be sought by a manufacturer or distributor of an identical, related, or similar drug product, as defined in § 310.6 of this chapter, in a United States court of appeals pursuant to section 505 (h) of the act.

PART 501—ANIMAL FOOD LABELING

28a. By revising § 501.2(f) to read as follows:

§ 501.2 Information panel of package for animal food.

* * * * *

(f) If the label of any package of food is too small to accommodate all of the information required by §§ 501.4, 501.5, 501.8, and 501.17, the Commissioner may establish by regulation an acceptable alternative method of disseminating such information to the public, e.g., a type size smaller than one-sixteenth inch in height, or labeling attached to or inserted in the package or available at the point of purchase. A petition requesting such a regulation, as an amendment to this paragraph shall be submitted pursuant to Part 2 of this chapter.

PART 503—COMMON OR USUAL NAMES FOR NONSTANDARDIZED FOODS

28b. In Part 503, by revising § 503.22 to read as follows:

§ 503.22 Petitions.

(a) The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has

submitted a petition, may publish a proposal to issue, amend, or revoke, under Subpart B of this part, a regulation prescribing a common or usual name for a food, pursuant to Part 2 of this chapter.

(b) If the principal display panel of a food for which a common or usual name regulation is established is too small to accommodate all mandatory requirements, the Commissioner may establish by regulation an acceptable alternative, e.g., a smaller type size. A petition requesting such a regulation, which would amend the applicable regulation, shall be submitted pursuant to Part 2 of this chapter.

PART 508—EMERGENCY PERMIT CONTROL

28c. In Part 508, by revising § 508.19 (a) to read as follows:

§ 508.19 Establishment of requirements for exemption from section 404 of the act.

(a) Whenever the Commissioner finds after investigation that the distribution in interstate commerce of any class of food may, by reason of contamination with microorganisms during the manufacture, processing, or packing thereof in any locality, be injurious to health, and that such injurious nature cannot be adequately determined after such articles have entered interstate commerce, he shall promulgated regulations in Subpart B of this part establishing requirements and conditions governing the manufacture, processing, or packing of the food necessary to protect the public health. Such regulations may be proposed by the Commissioner on his own initiative or in response to a petition from any interested person pursuant to Part 2 of this chapter.

* * * * *

PART 514—NEW ANIMAL DRUG APPLICATIONS

29. In Part 514, by revising § 514.201 to read as follows:

§ 514.201 Procedure for hearings.

Hearings relating to new animal drugs under section 505 (d), (e), (m)(3), and (m)(4) of the act shall be governed by Part 2 of this chapter.

§§ 514.202, 514.203, 514.204, 514.205, 514.206 514.220, 514.221, 514.222, 514.230, 514.231, 514.232 [Revoked]

30. By revoking §§ 514.202, 514.203, 514.204, 514.205, 514.206, 514.220, 514.221, 514.222, 514.230, 514.231, and 514.232.

31. By revising § 514.235 as follows:

§ 514.235 Judicial review.

(a) The transcript and record shall be certified by the Commissioner. In any case in which the Commissioner enters an order without a hearing pursuant to § 314.200(g) of this chapter, the request(s) for hearing together with the data and information submitted and the Commissioner's findings and conclusions shall be included in the record certified by the Commissioner.

(b) Judicial review of an order withdrawing approval of a new drug application, whether or not a hearing has been held, may be sought by a manufacturer or distributor of an identical, related, or similar drug product, as defined in § 310.6 of this chapter, in a United States court of appeals pursuant to section 505 (h) of the act.

PART 564—DEFINITIONS AND STANDARDS FOR ANIMAL FOOD

31a. In Part 564, by revising § 564.5 to read as follows:

§ 564.5 Procedure for establishing a food standard.

(a) The procedure for establishing a food standard under section 401 of the act shall be governed by Part 2 of this chapter.

(b) Any petition for a food standard shall show that the proposal, if adopted, would promote honesty and fair dealing in the interest of consumers.

(c) Any petition for a food standard shall assert that the petitioner commits himself to substantiate the information in the petition by evidence in a public hearing, if such a hearing becomes necessary.

(d) If a petitioner fails to appear, or to substantiate the information in his petition, at a public hearing on the matter, the Commissioner may either (1) withdraw the regulation and terminate the proceeding or (2) if he concludes that it is in accordance with the requirements of section 401 of the act, continue the proceeding and introduce evidence to substantiate such information.

31b. By adding a new paragraph (1) to § 564.17 to read as follows:

§ 564.17 Temporary permits for interstate shipment of experimental packs of food varying from the requirements of definitions and standards of identity.

* * * * *

(1) Any person who contests denial, modification, or revocation of a temporary permit shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Subpart F of Part 2 of this chapter.

PART 570—FOOD ADDITIVES

31c. By revising § 570.15(b) to read as follows:

§ 570.15 Adoption of regulation on initiative of Commissioner.

* * * * *

(b) Action upon a proposal made by the Commissioner shall proceed as provided in Part 2 of this chapter.

31d. In Part 570, by revising the introductory text of § 570.35(c)(1) to read as follows:

§ 570.35 Affirmation of generally recognized as safe (GRAS) status.

* * * * *

(c)(1) Persons seeking the affirmation of GRAS status of substances as provided for in § 570.30(e), except those subject to the NAS–NRC GRAS list survey (36 FR 20546), shall submit a petition for GRAS affirmation pursuant to Part 2 of this chapter. Such petition shall contain information to establish that the GRAS criteria as set forth in § 570.30(b) have been met, in the following form:

* * * * *

31e. By revising § 570.38(b)(1) to read as follows:

§ 570.38 Determination of food additive status.

* * * * *

(b)(1) The Commissioner, on his own initiative or on the petition of any interested person, pursuant to Part 2 of this chapter, may issue a notice in the FEDERAL REGISTER proposing to determine that a substance is not GRAS and is a food additive subject to section 409 of the act. Any petition shall include all relevant data and information of the type described in § 571.130(b) of this chapter. The Commissioner will place all of the data and information on which he relies on public file in the office of the Hearing Clerk and will include in the FEDERAL REGISTER notice the name of the substance, its known uses, and a summary of the basis for the determination.

* * * * *

PART 571—FOOD ADDITIVE PETITIONS

31f. By revising § 571.110 to read as follows:

§ 57.110 Procedure for objections and hearings.

Objections and hearings relating to food additive regulations under section 409 (c), (d), or (h) of the act shall be governed by Part 2 of this chapter.

§ 571.120 [Revoked]

31g. By revoking § 571.120.

31h. By revising § 571.130 to read as follows:

§ 571.130 Procedure for amending and repealing tolerances or exemptions from tolerances.

(a) The Commissioner, on his own initiative or on the petition of any interested person, pursuant to Part 2 of this chapter, may propose the issuance of a regulation amending or repealing a regulation pertaining to a food additive or granting or repealing an exception for such additive.

(b) Any such petition shall include an assertion of facts, supported by data, showing that new information exists with respect to the food additive or that new uses have been developed or old uses abandoned, that new data are available as to toxicity of the chemical, or that experience with the existing regulation or exemption may justify its amendment or repeal. New data shall be furnished in the form specified in § 571.1 for submitting petitions.

§§ 571.200, 571.202, 571.203, 571.204, 571.205, 571.206, 571.208, 571.210, 571.212, 571.214, 571.220, 571.221, 571.222, 571.230 571.232, 571.235 [Revoked]

31i. By revoking §§ 571.200, 571.202, 571.203, 571.204, 571.205, 571.206, 571.208, 571.210, 571.212, 571.214, 571.220, 571.221, 571.222, 571.230, 571.232, and 571.235.

PART 601—LICENSING

32. In Part 601, by revoking §§ 601.4, 601.5, and 601.6(c), by redesignating the remainder of § 601.6 as § 601.12, by adding new §§ 601.4 through 601.9, and by revising § 601.22 to read as follows:

§ 601.4 Issuance and denial of license.

(a) An establishment or product license shall be issued upon a determination by the Commissioner that the establishment or the product, as the case may be, meets the applicable standards established in this chapter. Licenses shall be valid until suspended or revoked.

(b) If the Commissioner determines that the establishment or product does not meet the standards established in this chapter, he shall deny the application and inform the applicant of the grounds for, and of an opportunity for a hearing on, his decision. If the applicant so requests, the Commissioner shall issue a notice of opportunity for hearing on the matter pursuant to § 2.111(b) of this chapter.

§ 601.5 Revocation of license.

(a) An establishment or product license shall be revoked upon application of the manufacturer giving notice of intention to discontinue the manufacture of all products or to discontinue the manufacture of a particular product for which a license is held, and waiving an opportunity for a hearing on the matter.

(b) If the Commissioner finds that (1) authorized Food and Drug Administration employees after reasonable efforts have been unable to gain access to an establishment or a location for the purpose of carrying out the inspection required under § 600.21 of this chapter, (2) manufacturing of products or of a product has been discontinued to an extent that a meaningful inspection or evaluation cannot be made, (3) the manufacturer has failed to report a change as required by § 601.12, (4) the establishment or any location thereof, or the product for which the license has been issued, fails to conform to the applicable standards established in the license and in this chapter designed to ensure the continued safety, purity, and potency of the manufactured product, (5) the establishment or the manufacturing methods have been so changed as to require a new showing that the establishment or product meets the standards established in this chapter in order to protect the public health, or (6) the licensed product is not safe and effective for all of its intended uses or is misbranded with respect to any such use, he shall notify the licensee of his intention to revoke the license, setting forth the grounds for, and offering an opportunity for a hearing on, the proposed revocation. Except as provided in § 601.6 and in cases involving willfulness, the notification required in this paragraph shall provide a reasonable period for the licensee to demonstrate or achieve compliance with the requirements of this chapter, before proceedings will be instituted for the revocation of the license. If compliance is not demonstrated or achieved and the licensee does not waive the opportunity for a hearing, the Commissioner shall issue a notice of opportunity for hearing on the matter pursuant to § 2.111(b) of this chapter.

§ 601.6 Suspension of license.

(a) Whenever the Commissioner has reasonable grounds to believe that any of the grounds for revocation of a license exist and that by reason thereof there is a danger to health, he may notify the licensee that his license for the establishment or the product is suspended and require that the licensee (1) notify the selling agents and distributors to whom such product or products have been delivered of such suspension, and (2) furnish to the Director, Bureau of Biologics, complete records of such deliveries and notice of suspension.

(b) Upon suspension of a license, the Commissioner shall either (1) proceed pursuant to the provisions of § 601.5(b) to revoke the license, or (2) if the licensee agrees, hold revocation in abeyance pending resolution of the matters involved.

§ 601.7 Procedure for hearings.

(a) A notice of opportunity for hearing, notice of appearance and request for hearing, and grant or denial of hearing for a biological drug pursuant to this Part, for which the exemption from the Federal Food, Drug, and Cosmetic Act in § 310.4 of this chapter has been revoked, shall be subject to the provisions of § 314.200 of this chapter except to the extent that the notice of opportunity for hearing on the matter issued pursuant to § 2.111(b) of this chapter specifically provides otherwise.

(b) Hearings pursuant to §§ 601.4 through 601.6 shall be governed by Part 2 of this chapter.

(c) When a license has been suspended pursuant to § 601.6 and a hearing request has been granted, the hearing shall proceed on an expedited basis.

§ 601.8 Publication of revocation.

Notice of revocation of a license, with statement of the cause therefor, shall be issued by the Commissioner and published in the FEDERAL REGISTER.

§ 601.9 Licenses; reissuance.

(a) *Compliance with standards.* An establishment or product license, previously suspended or revoked, may be reissued or reinstated upon a showing of compliance with required standards and upon such inspection and examination as may be considered necessary by the Commissioner.

(b) *Exclusion of noncomplying location.* An establishment or product license, excluding a location or locations that fail to comply with required standards, may be issued without further application and concurrently with the suspension or revocation of the license for noncompliance at the excluded location or locations.

§ 601.22 Products in short supply; initial manufacturing at other than licensed establishment.

Licenses issued to a manufacturer for an establishment shall authorize persons other than such manufacturer to conduct at places other than such establishment the initial, and partial manufacturing of a product for shipment solely to such manufacturer only to the extent that the names of such persons and places are registered with the Commissioner of Food and Drugs and he finds upon application of such manufacturer, that (a) the product is in short supply due either to the peculiar growth requirements of the organism involved or to the scarcity of the animal required for manufacturing purposes, and (b) such manufacturer has established with respect to such persons and places such procedures, inspections, tests or other arrangements as will assure full compliance with the applicable regulations of this subchapter related to continued safety, purity, and potency. Such persons and places shall be subject to all regulations of this subchapter except §§ 601.1 to 601.6, 601.9, 601.10, 601.20, 601.21, 601.30 to 601.33, and 610.60 to 610.65 of this chapter. Failure of such manufacturer to maintain such procedures, inspections, tests, or other arrangements, or failure of any person conducting such partial manufacturing to comply with applicable regulations shall constitute a ground for suspension or revocation of the authority conferred pursuant to this section on the same basis as provided in §§ 601.6 to 601.8 with respect to the suspension and the revocation of licenses.

§§ 601.40, 601.41, 601.42, 601.43, 601.44 [Revoked].

33. By revoking §§ 601.40 through 601.44.

PART 701—COSMETIC LABELING

34. In Part 701, by revising § 701.3 (b) and (e) to read as follows:

§ 701.3 Designation of ingredients.

* * * * *

(b) The declaration of ingredients shall appear with such prominence and conspicuousness as to render it likely to be read and understood by ordinary individuals under normal conditions of purchase. The declaration shall appear on any appropriate information panel in letters not less than 1/16 of an inch in height and without obscuring design, vignettes, or crowding. In the absence of sufficient space for such declaration on the package, or where the manufacturer or distributor wishes to use a decorative container, the declaration may appear on a firmly affixed tag, tape, or

card. In those cases where there is insufficient space for such declaration on the package, and it is not practical to firmly affix a tag, tape, or card, the Commissioner may establish by regulation an acceptable alternate, e.g., a smaller type size. A petition requesting such a regulation as an amendment to this paragraph shall be submitted pursuant to Part 2 of this chapter.

* * * * *

(e) Interested persons may submit a petition requesting the establishment of a specific name for a cosmetic ingredient pursuant to Part 2 of this chapter. The Commissioner may also propose such a name on his own initiative.

PART 809—IN VITRO DIAGNOSTIC PRODUCTS FOR HUMAN USE

35. In Part 809, by revising § 809.30(a) (formerly § 328.30 prior to recodification published in the FEDERAL REGISTER of February 13, 1976 (41 FR 6907)) to read as follows:

§ 809.30 Procedure for establishing, amending or repealing standards.

(a) *Basis for standards and available approaches to developing standards.* Whenever in the judgment of the Commissioner the establishment of a product class standard is necessary to reduce or eliminate unreasonable risk of illness or injury associated with exposure to or use of an in vitro diagnostic product and there are no other more practicable means to protect the public from such risk, he may propose such a standard. In proposing a product class standard he shall consider, and publish in the FEDERAL REGISTER findings on, the degree of risk or injury associated with the use of the product, the availability of information relating to the sciences upon which the products or their uses are based, the approximate number of products subject to the standard, the medical need for the products, and the probable effect of the standard upon the utility, cost, or availability of the product, and available means of achieving the objective of the standard with a minimal disruption of supply and of reasonable manufacturing and other commercial practices. Three procedures are available for developing product class standards and may be proposed on the initiative of the Commissioner or by petition of interested persons, pursuant to Part 2 of this chapter: (1) An existing standard may be utilized, (2) interested persons outside of the Food and Drug Administration may develop a proposed standard or (3) the Food and Drug Administration may develop the standard.

* * * * *

Effective date: These regulations shall be effective February 24, 1977.

Dated: January 14, 1977.

SHERWIN GARDNER,
Acting Commissioner of Food and Drugs.

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