DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

National Institutes of Health

Recombinant DNA Advisory Committee; Meeting

Pursuant to Pub. L. 92–463, notice is hereby given of a meeting of the Recombinant DNA Advisory Committee at the Linden Hill Hotel, Terrace Room, 5400 Pooks Hill Road, Bethesda, Maryland 20014, on May 21, 22, and 23, 1979, from 9:00 a.m. to 5.00 p.m.

The entire meeting will be open to the public for consideration of: Lower Eukaryote Host-Vector Systems, Prokaryote Host-Vectors Other Than *E. coli* K–12, Amendment of Guidelines, Actions under exemption I–E–5, Exemptions for organisms that exchange genetic information (I–E–4), *E. coli* phage-vector systems, EK2 host-vector systems, NIH risk-assessment plan, Reports of Plasmid and Phage Subcommittees, Review of protocols for required containment levels, Criteria for and the handling of characterized clones, Requests for lowering of containment levels on the basis of characterization of clones, Other matters requiring necessary action by the Committee.

Attendance by the public will be limited to space available Dr. William J. Gartland, Jr., Executive Secretary, Recombinant DNA Advisory Committee National Institutes of Health, Building 31, Room 4A52, telephone 301–496–6051, will provide materials to be discussed at the meeting, rosters of committee members and substantive program information. A summary of the meeting will be available at a later date.

Dated: March 30, 1979.

Suzanne L. Fremeau,
Committee Management Officer, NIH.

[FR Doc. 79–11369 Filed 4–11–79; 8:45 am]
BILLING CODE 4110–08–M

Recombinant DNA Research; Proposed Actions Under Guidelines

AGENCY: National Institutes of Health, PHS, DHEW.

ACTION: Notice of proposed actions under the NIH Guidelines for Research Involving Recombinant DNA Molecules.

SUMMARY: This notice sets forth proposals for actions to be taken under the 1978 NIH Guidelines for Research Involving Recombinant DNA Molecules [**Federal Register** on December 22, 1978 (43 FR 60108)]. Interested parties are invited to submit comments concerning these proposals. After consideration of these proposals and comments by the NIH Recombinant DNA Advisory Committee (RAC) at its May 21–23, 1979, meeting, the Director of the National Institutes of Health will issue decisions on these proposals in accord with the Guidelines.

DATE: Comments must be received by May 14, 1979.

ADDRESS: Written comments and recommendations should be submitted to the Director, Office of Recombinant DNA Activities, Building 31, Room 4A52, Nation Institutes of Health, Bethesda, Maryland 20205. All comments received in timely response to this notice will be considered and will be available for public inspection in the above office on weekdays between the hours of 8:30 a.m. and 5 p.m.

FOR FURTHER INFORMATION CONTACT: Additional information can be obtained from Drs. Michael Resnick or Stanley Barban, Office of Recombinant DNA Activities, National Institutes of Health, Bethesda, Maryland 20205, (301) 496–6051.

SUPPLEMENTARY INFORMATION: The National Institutes of Health will consider the following changes and amendments under the Guidelines for Research Involving Recombinant DNA Molecules (43 FR 60108), as well as actions under these Guidelines.

1. *Cloning of Eukaryotic Viruses in Saccharomyces cerevisiae and Neurospora crassa*

The RAC at its February 15–16 meeting recommended the use of *Saccharomyces cerevisiae* and *Neurospora crassa* as HV1 systems and specified certain strains and vectors of *S. cerevisiae* as HV2 host-vector systems. The RAC also recommended the following containment levels for experiments involving complete genomes of eukaryotic viruses:

Experiments involving complete genomes of eukaryotic viruses will require P3+HV1 or P2+HV2 containment.

General equivalency between both the *N. crassa* and the *S. cerevisiae* HV systems and the *E. coli* EK systems was recommended by the RAC. However, there was concern over the possible expression of eukaryotic viral genomes in the lower eukaryote host-vector systems. Therefore, the RAC has recommended that the cloning of these viruses be subject to higher levels of containment than those required for cloning in *E. coli*.

2. *Use of Unmodified Laboratory Strains of Neurospora crassa*

The RAC at its February 15–16, 1979 meeting recommended a limited use of unmodified laboratory strains of *Neurospora crassa*. The NIH accepted a conservative interpretation of the RAC's action, limiting its use as a host, at the P3 level of containment, for shotgun experiments with phages, plasmids, and DNA from Class 1 prokaryotes [1] and lower eukaryotes that do not produce polypeptide toxins.[34] The following alternate interpretation of the RAC's action is published for comment and further consideration by the RAC:

Unmodified laboratory strains of *Neurospora crassa* can be used in all experiments for which HV1 *N. crassa* systems are approved provided that these are carried out at physical containment one level higher than required for HV1. However, if P3 containment is specified for HV1 *N. crassa*, this level is considered adequate for unmodified *N. crassa*. For P2 physical containment, special care must be exercised to prevent aerial dispersal of macroconidia, including the use of a biological safety cabinet.

3. *Modification of Section III–C–6—Transfer of Cloned DNA Between Eukaryotes*

The RAC at its February 15–16, 1979 meeting recommended that a new section, III–C–6, be incorporated into the Guidelines, as follows:

III–C–6. *Return of DNA Segments to a Higher Eukaryotic Host of Origin.* DNA from a higher eukaryote (Host D) may be inserted into a lambdoid phage vector or into a vector from a certified EK2 host-vector system and propagated in *E. coli* K–12 under the appropriate containment conditions [See Section III–A–1]. Subsequently, this recombinant DNA may be returned to Host D and propagated under conditions of physical containment comparable to P1 and appropriate to the organism under study. [2A]

Several commentators had requested that this section be broadened to permit the transfer of DNA segments to a heterologous eukaryote instead of only to the host of origin. The RAC, at its February 15–16, 1979 meeting felt that the proposal of the commentators would require further consideration and more explicit formulation. Accordingly, the following section has been proposed to replace the previously recommended Section III–C–6:

III–C–6. *Transfer of cloned DNA segments to eukaryotic organisms.* DNA from any nonprohibited source [Section I–D] which has been cloned and propagated in *E. coli* under appropriate physical containment conditions, may be transferred with the *E. coli* vector used for cloning to a eukaryotic organism or cells in culture and propagated under conditions of physical containment comparable to P1 and appropriate to the organism under study. [2A]

4. *A Proposed "cosmid" EK2 vector*

A proposal from Dr. John Collins of the Gesellschaft fur Biotechnologische Forschung, West Germany, for the use of the cosmids pJC75–58, pJC78, and pJC79 as EK2 cosmid vectors will be considered by the RAC. These vectors are combinations of EK2 plasmid and lambda bacteriophage vectors which enable *in vitro* packaging of DNA. The proposal is available from the Office of Recombinant DNA Activities.

5. *Amendment of section II–D–1–a–(1)*

The Plasmid Working Group of the RAC has unanimously recommended that the phrase "when plasmid vectors are employed," be added to Section II–D–1–a–(1) of the Guidelines. This section would be amended to read:

II–D–1–a–(1). *EK1.* The host is always *E. coli* K–12 or a derivative thereof, and the vectors include nonconjugative plasmids (e.g., pSC101, Co1E1, or derivatives thereof [21–27]) and variants of bacteriophage, such as λ [28–33]. *When plasmid vectors are employed,* the *E. coli* K–12 hosts shall not contain conjugation-proficient plasmids, whether autonomous or integrated, or generalized transducing phages.

This was proposed to allow for the use of EK1 bacteriophage vectors in the presence of conjugation-proficient plasmids. The Working Group had concluded that the biological containment associated with these vectors would not be significantly altered.

6. *Proposed Exemption under I–E–5 for Experiments Involving EK1 and EK2 Host-Vector Systems*

Drs. Wallace Rowe and Allen Campbell, members of the RAC, have proposed the following action in accord with Section I–E–5 of the Guidelines. This action would exempt certain categories of recombinant DNA molecules in addition to those already stated in Sections I–E–1 to –4. The proposed exemption would read as follows:

Those recombinant DNA molecules that are propagated in *E. coli* K–12 hosts not containing conjugation-proficient plasmids or generalized transducing phages, when lambda or lambdoid bacteriophages or non-conjugative plasmids are used as vectors, are exempt from the Guidelines.

Drs. Rowe and Campbell stated that this action is being proposed because of the large body of information that has accumulated concerning the *E. coli* K–12 host-vector systems, all of which points to the safety of such systems. This information includes the extensive expert analyses of the biology of *E. coli* K–12 and of molecular segments cloned therein, the polyoma risk assessment experiments, the negative results of monitoring laboratory personnel for acquisition of *E. coli* K–12 and its plasmids, and a number of other risk assessment studies on the survival and pathogenicity of EK1 and EK2 host-vector systems. (Additional information is available from the Office of recombinant DNA Activities.) Experiments that are presently prohibited, including those involving more than 10 liters of culture, would remain prohibited.

7. *Proposed Exemption Under I–E–5 for Cloning in Tissue Culture Cells*

Dr. Wallace Rowe, a member of the RAC, has proposed the following action in accord with Section I–E–5 of the Guidelines. This action would exempt certain categories of recombinant DNA molecules in addition to those already exempted in Sections I–E–1 to –4. The proposed exemption would read as follows:

Those recombinant DNA molecules that are propagated in cells in tissue culture and that are derived entirely from non-viral components (that is, no component is derived from a eukaryotic virus) or that contain no more than one-fourth of the genome of a eukaryotic virus are exempt from the Guidelines.

As stated by Dr. Rowe, this action is being proposed because tissue culture experiments that do not involve production of competent microorganisms containing recombinant DNA do not represent a biohazard. There are many important experimental systems in which recombinant molecules are integrated into tissue culture cells in order to study gene function. Since these experiments do not involve the possibility of establishing recombinant molecules in the ecosystem, there is no need for them to be covered by the Guidelines. This proposed exemption would not apply to whole organisms.

8. *Use of Agrobacterium tumefaciens as a Host-Vector System*

Dr. Mary-Dell Chilton of the University of Washington has requested that the bacterium *Agrobacterium tumefaciens* be approved as an HV system for introducing recombinant DNA into plants as follows:

Non-disabled strains of *Agrobacterium tumefaciens* can be used in combinations with the cointegrate plasmid TI::RP4 as a host-vector system at the P3 level of physical containment.

The cointegrate plasmid is capable of replicating in *E. coli* in which desired genes could be inserted and cloned. It can also replicate in *A. tumefaciens* and hence be transferred, by this host's ability to induce plant tumors, to plant cells. Since the experimental procedures require maintenance of both plasmid virulence and the pathogenicity of *A. tumefaciens* for tumor induction, efforts to disarm the system will defeat its purpose. The proposal is based on the premise that P3 physical containment will compensate for the less than HV1 biological containment. (The proposal is available from the Office of Recombinant DNA Activities.)

9. *Criteria for Characterized Clones*

Footnote 3 of the Guidelines outlines the types of data to be considered by the Institutional Biosafety Committees (IBC) for reducing required containment for characterized clones. The rationale for reducing containment levels is that clones that have been characterized and which can be regarded as free from harmful genes are considered to present a lower risk than shotgun or other uncharacterized clones and, therefore, justify relaxation of biological and/or physical containment.

A Working Group of the RAC on characterized clones requested information from members of the scientific community which would provide guidance to the principal investigators and the IBC's for determining whether clones are sufficiently characterized. The following criteria which they have developed are intended to amplify Footnote 3 of the Guidelines (further information is available from the Office of Recombinant DNA Activities):

(a) *Absence of potentially hazardous genes.* Part (a) of Footnote 3 specifies examples of harmful sequences which are of special concern. In *E. coli* the risk of induced autoimmunity from exposure to clones that produce proteins that are either human hormones or other biologically active molecules is considered insignificant.

(b) *cDNAs.* These are considered characterized by definition. Since their functions will be known, judgment of potential harm will also be known. The cDNA sequences should be shown by test of size and hybridization to represent a sequence corresponding to the specified gene.

(c) *Cloned DNA carrying a specified gene.* Characterization should include data showing that the clone carries a specific gene by hybridization and, if feasible, by expression. Size measurements and restriction maps should delineate all other sequences including intervening sequences and adjacent sequences with or without control functions. In accord with current knowledge, coding, intervening, and

flanking sequences of up to 30,000 base pairs in total are eligible for reduction by IBC. Larger sequences shall be referred to ORDA for approval.

(d) *Recombinant clones.* IBC's may approve requests to recombine two or more characterized sequences from any source if the sequences have already been approved for reduced containment. Containment shall be the same level as for the characterized clone component with the highest containment.

10. Proposed Exemption for Pseudomonas putida and Pseudomonas aeruginosa under Section I–E–4

Dr. N. Ornston of Yale University has proposed, in accord with Section I–E–4 of the Guidelines, that *Pseudomonas putida* and *Pseudomonas aeruginosa* be added to the exempt list in Appendix A of gram-negative organisms that exchange DNA by known physiological processes. Further information documenting the exchange of genetic information between these two species and those in Appendix A is available from the Office of Recombinant DNA Activities.

11. Containment Levels for Experiments Involving Actinomycetes and Exemption for Streptomyces Species that Exchange Genetic Information

The RAC Working Group on Prokaryotic Host-Vectors other than *E. coli* has proposed the following actions (reports are available from the Office of Recombinant DNA Activities):

(a) P2 physical containment shall be used for DNA recombinants produced between members of the *Actinomycetes* group except for those species which are known to be pathogenic for man, animals or plants. [2A]

Members of this group of microorganisms include the *Streptomyces* and *Micromonospora* genera which produce many medically important and beneficial antibiotics. The *Streptomyces* are primarily soil organisms and none have been reported to be pathogenic in humans.

(b) *Streptomyces* species that have been shown to exchange chromosomal DNA are proposed to be included under the exemption category of Section I–E–4 of the 1978 Guidelines. Any recombinant DNA molecules that are composed entirely of DNA segments from one or more of the organisms listed below and to be propagated in any of the organisms listed below are exempt from the Guidelines. (This list is to be separate from the other lists of exempt organisms in Appendix A.)

Streptomyces aureofaciens
Streptomyces rimosus
Streptomyces coelicolor
Streptomyces griseus
Streptomyces cyaneus
Streptomyces venezuelae

12. Cloning in Bacillus subtilis and Streptomyces coelicolor.

Dr. Stanley Cohen of Stanford University has proposed the following actions:

(a) *Bacillus subtilis* strains that do not carry an asporogenic mutation can be used as hosts specifically for the cloning of DNA derived from *E. coli* K–12 and *Streptomyces coelicolor* using NIH-approved *Staphylococcus aureus* plasmids as vectors under P2 conditions.

(b) *Streptomyces coelicolor* can be used as a host for the cloning of DNA derived from *B. subtilis*, *E. coli* K–12, or from *S. aureus* vectors that have been approved for use in *B. subtilis* under P2 conditions.

Dated: April 6, 1979.

Donald S. Fredrickson,
Director, National Institutes of Health.

[FR Doc. 79–11382 Filed 4–12–79; 8:45 am]
BILLING CODE 4110–08–M

federal register

Friday
April 13, 1979

Part IV

Department of Health, Education, and Welfare

Food and Drug Administration

Administrative Practices and Procedures Amendments

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

21 CFR Parts 10, 12, 13, 14, 15, 16

Administrative Practices and Procedures Amendments

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document revises the Food and Drug Administration (FDA) regulations on administrative practices and procedures. The revisions are based on FDA's experience in using the regulations, and they incorporate editorial changes to make the regulations more concise and readable.

EFFECTIVE DATE: May 14, 1979.

FOR FURTHER INFORMATION CONTACT: Ronald J. Wylie, Compliance Regulations Policy Staff (HFC–10), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3480.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 7, 1978 (43 FR 51966), FDA proposed to revise its administrative practices and procedures regulations. The regulations appear in Parts 10, 12, 13, 14, 15 and 16 of Chapter I of Title 21 of the Code of Federal Regulations.

The proposed revisions were both substantive and editorial. The substantive revisions were based on FDA's experience with the regulations since they were published in 1976 and 1977. The editorial revisions were intended to make the regulations clearer and more understandable, consistent with the objectives of the Department of Health, Education, and Welfare's "Operation Common Sense." The purpose of the revisions is described in more detail in the preamble to the proposal.

In response to the proposal, comments were submitted by several individuals, trade associations, and companies. A summary of the comments and FDA's responses to them appear below. Additional changes based on the agency's continuing internal review of the procedural regulations are also noted.

General

1. Two comments stated that the proposed changes do not achieve the stated objective of making the regulations more clear and understandable.

Extensive changes in style and content were found to be unnecessary in the revision of these regulations. In their original form, the regulations were written in as straightforward and clear a style as possible consistent with the need for precise standards and instructions. The relatively small number of changes in this revision results more from the care with which the regulations were initially drafted than from any lack of purpose in the revision. Nonetheless, certain stylistic conventions were incorporated into the proposal as a means of achieving a more conversational style without sacrificing precision or clarity. The agency believes that this objective has been achieved.

Administrative Practices and Procedures (Part 10)

2. A comment suggested that § 10.1(d) (21 CFR 10.1(d)) be revised to include, in referring to the date of publication in the **Federal Register**, a reference to the phrase "to publish." Section 10.1(d) is amended accordingly.

3. A comment requested that the term "docket file" be defined separately in § 10.3 (21 CFR 10.3). It suggested as the definition the one contained in the preamble: "the file on a matter in the Hearing Clerk's office."

The agency does not believe that a separate definition for "docket file" is needed. The term is not used in the regulations to any extent apart from its use in § 10.30(c) and (d) (21 CFR 10.30(c) and (d)), where it is adequately defined.

4. A comment suggested that the definition of the term "petition" in § 10.3 (21 CFR 10.3) include the phrase "or refrain from taking" in the context of the action a petition may request the agency to take.

An interested person may request by petition that the Commissioner not take action and the phrase "or not to take" is added to the definition of "petition."

5. One comment objected to the requirement of § 10.20 (21 CFR 10.20) that four copies of submissions be filed with the Hearing Clerk. It requested that the requirement for multiple copies be eliminated.

FDA does not have the resources or facilities to copy all documents submitted to the Hearing Clerk, although more than one copy of each submission is needed. Although the agency routinely duplicates enormous amounts of material in the conduct of its business, both for internal and external uses, the burden of duplication should be shared with it by members of the public. The general requirement that four copies be submitted is tempered by the requirement of § 10.40(b)(4) (21 CFR 10.40 (b)(4)), which permits persons to file only one copy of a response to a notice of proposed rulemaking published in the **Federal Register**. In practice this rule has been applied to most **Federal Register** documents. FDA views these duplication requirements—a general requirement for four copies that is limited to one copy in the case of individuals responding to **Federal Register** documents—as a reasonable compromise in distributing the burden of duplicating submissions. FDA notes, in this regard, that the author of the comment stated that the duplication requirement was not necessarily a burden to it.

6. An editorial change originating with the agency is made to § 10.30(b) by inserting in the form "Citizen Petition" a new heading "E. CERTIFICATION." The new heading would appear immediately before the present certification statement, after the paragraph describing the requirements for a statement of economic impact. The modification is intended to facilitate specific references to the certification statement in communications regarding petitions.

7. An agency-initiated revision deletes, for purposes of clarification, the word "optional" in its reference to procedures in § 10.40(g)(6). Some of the procedures specified in paragraph (f) are not always optional, such as advisory committee reviews of medical device classifications.

8. One comment suggested that § 10.45(f) (21 CFR 10.45(f)), which lists those sections of the regulations specifying what comprises the administrative record for various types of agency action, inadvertently omits a reference to § 10.33(k) (21 CFR 10.33(k)). That section specifies the administrative record in an administrative reconsideration of action. The comment is correct, and a reference to § 10.33(k) is inserted in § 10.45(f).

9. FDA, on its own initiative, has clarified the requirement of § 10.55(d)(3) (21 CFR 10.55(d)(3)) that ex parte communications made in the context of a formal evidentiary public hearing be served on all other participants in the hearing and filed with the Hearing Clerk. The existing provision does not specify on whom this obligation rests. As revised, the section makes clear that the obligation rest with the presiding officer at the hearing or with the Commissioner. The requirements regarding ex parte communications concern those communications made between any party and the decisionmaker, which may be either the presiding officer at the hearing or,

ultimately, any person in the office of the Commissioner who is advising or assisting the Commissioner concerning the matter (§ 10.55(d)(1)). Accordingly, the obligation to file and serve written ex parte communications, or to reduce to writing and file and serve oral ex parte communications, must fall on the decisionmaker.

10. Another agency-initiated change is made in § 10.65(b)(3) (21 CFR 10.65(b)(3)), which presently appears to prohibit the taking of a transcript or recording of an informal meeting but authorizes a written memorandum summarizing the substance of the meeting. There may be situations where a transcript may be useful, such as in meetings of substantial length where minutes by themselves may not be sufficient to describe all of the suggestions, recommendations, or comments made. The making of a transcript in these situations will be discretionary with the agency, although the taking of minutes is still required.

11. One comment complained of a change in § 10.65(d) with respect to the ability of persons to obtain private meetings with government officials. The current version of the regulation states that a person "has a right" to request and obtain a meeting, while the proposed version states that a person "may request and obtain" a meeting. The comment contends that the change appears to strip away the rights of the citizenry and questions whether the change, which is considered by the agency to be editorial only, is actually substantive.

One of the objectives of Operation Common Sense is to simplify the language of the regulations through the consistent use of certain drafting conventions. There is no merit to the comment's charge that the agency intends to affect citizens' rights under the regulations. The use of "may" in the proposed version simply reflects the permissive nature of the requirement; that it is an opportunity provided to every person should he or she wish to exercise it. The phrase "has a right" is stylistically excessive. In fact, to the extent that the phrase implies a statutory or constitutional right to obtain a private meeting, it is misleading. The proposed language is therefore retained.

12. The same comment also objected to a similar change proposed in § 10.70(b)(2)(ii). This paragraph provides an agency employee working on a matter with the opportunity to record his or her views in writing and have them placed in the file on the matter. The current version of the requirement states that an employee "shall have the opportunity to record his views." The proposed version states that the employee "may record individual views."

One of the conventions employed in Operation Common Sense was to delete the verb from "shall" unless its use denoted an obligation on its subject. A second convention adopted in Operation Common Sense was to delete, where possible, the use of the masculine pronouns "his" or "he" in general references. Section § 10.70(b)(2)(ii) imposes no obligation on an employee. The provision contemplates, rather, that any employees wishing to record their views may do so. Adoption of these two conventions, that is, substituting "may" for "shall," and deleting the reference to "his," was the sole reason for the modifications to the section. The proposed revision is appropriately permissive and does not limit any of the rights afforded by the prior wording. Accordingly, § 10.70(b)(2)(ii), like the other regulations, is modified in accordance with Operation Common Sense.

13. An agency-initiated change is made to § 10.80(b) and (d) (21 CFR 10.80(b) and (d)), which presently provide that the details of a draft proposal or final notice or regulation may not be discussed with an interested person outside the executive branch except with the specific permission of the Commissioner. Both sections are amended to require that the Commissioner provide such permission in writing, and make the written permission part of the public file. Although it is necessary in some cases to discuss the details of draft documents with members of the public, doing so will be more fair to the public generally when notice of the Commissioner's permission to do so is a matter of public record.

14. One comment requested that § 10.100(a) (21 CFR 10.100(a)), which specifies requirements for prospective public calendars, retain its listing of the trial or argument of court cases. The existing regulations require such a listing, which the proposal would have deleted.

The comment is rejected. The preamble to the proposal justifies adequately the deletion of the requirement. Agency cases may be numerous at any given time and may not be significant enough to warrant inclusion on the public calendar. Nonetheless, significant court cases may be listed from time to time. Further, although not mentioned in the preamble to the proposal, court cases are otherwise a matter of public record and are frequently reported in the trade press. The benefit from listing all cases on the public calendar does not outweigh the significant burden of compiling the list.

15. The same comment noted, with respect to proposed § 10.100(b)(3), that the list of agency officials required to list meetings on the prospective and retrospective public calendars no longer included reference to the Director of the Office of Legislative Services but did include a reference to the Director, Office of International Affairs.

The changes were not, as the comment suggests, inadvertent. As a result of an agency reorganization, the office of the Director of Legislative Services had been abolished. The successor officer is the Associate Commissioner for Legislative Affairs, who would be required to list meetings under § 10.100(b)(3)(iii). The Director, Office of International Affairs, is deleted from the final rule. Since the proposal, the Office of International Affairs has been placed within the Office of the Associate Commissioner for Health Affairs. Its director is no longer a member of the Policy Board and therefore need not list his or her meetings on the public calendar.

Formal Evidentiary Public Hearing (Part 12)

16. A comment noted that the proposed revision of § 12.20(e) (21 CFR 12.20(e)) deletes the requirement that a person who objects to a regulation and requests a hearing be "adversely affected."

FDA regulations have a potential for adversely affecting any member of the public. This view is reflected in former § 10.3(a)(12), which now appears as the definition of "interested person" in § 10.3(a). Any person who submits an objection to a regulation is considered to be "adversely affected" within the meaning of the statute and regulations. Therefore, the term "adversely affected" in § 12.20(e) is superfluous.

17. A comment questioned whether omission of former § 12.45(c) (21 CFR 12.45(c)), relating to the service of pleadings and other documents, was inadvertent. The comment observed that no explanation for the omission was provided in the preamble to the proposed revisions.

Section 12.45(c) was deleted intentionally. It duplicated the service requirements in § 12.80(c) (21 CFR 12.80(c)).

18. A comment urged that the proposed revision of § 12.45(e) be further modified to provide for an opportunity to show cause why a

person's participation should not be stricken in cases where that action is to be taken for reasons other than failure to participate in the hearing. The comment also recommended that, in all cases where participation is to be stricken, the affected person should be notified of the action.

The agency believes that a show cause procedure serves no useful purpose when a person's participation is to be stricken. If a person is participating in a hearing, and the presiding officer concludes that the person's participation should be stricken for failure to comply with the regulations, the person will be present at the time the presiding officer proposes the ruling. The person may oppose the ruling at that time. It is extremely unlikely that a person whose participation is to be stricken for reasons other than nonparticipation will require a show cause order to be made aware of the proposed action.

The agency also believes that there is little value in requiring notification of a person whose participation has been stricken. If the person is participating in the hearing, the presiding officer will advise the person of that action. If the person's participation is stricken for nonparticipation, and the person continues not to participate, there are no compelling reasons to issue a written notice stating that fact.

19. The same comment requested a fuller explanation of the term "participation" as used in proposed § 12.45(e).

"Participation" means active involvement in the hearing consistent with a person's statements of specific interest and commitment to participate, which are provided for in the notice of participation. Active involvement ordinarily includes attendance at all prehearing conferences and all sessions of the hearing itself, and the presentation of direct testimony and the submission of exhibits.

20. Comments objected to the deletion of the automatic certification requirement of § 12.75(a) (21 CFR 12.75(a)). Under this requirement, a ruling on a motion that the presiding officer be disqualified must automatically be certified for interlocutory review by the Commissioner. Elimination of that procedure requires a participant to request that the presiding officer certify the ruling for interlocutory review under § 12.97(b) (21 CFR 12.97(b)). The comments asserted that the presiding officer's decision on a motion to certify a question concerning the presiding officer's fitness to preside might not be made objectively.

It is unlikely that the presiding officer will deny a request for leave to appeal a ruling on a disqualification motion. There is a substantial likelihood, however, that participants will make disqualification motions but not seriously object to the presiding officer's rulings on them. Under the automatic certification procedure, the Commissioner would be required to review those rulings even though no one strongly disputed them. The agency believes that eliminating the automatic certification procedure fairly balances the need for review of contested rulings on disqualification motions and the interest in avoiding superfluous review of noncontroversial rulings.

21. A comment recommended that additional time be provided for filing submissions in formal hearings. Proposed § 12.80(a) provides that compliance with filing deadlines in formal hearings is to be determined by the date a submission is actually received by the Hearing Clerk, rather than by the postmark date. The comment pointed out that part of the time for responding to a submission is often lost as a result of delays in transmitting the submission by the Hearing Clerk and in the postal system. The comment suggested that the time for filing responsive submissions be measured by the date of service of the submission, rather than by the date the submission is received by the Hearing Clerk, and that 5 additional days be allowed to respond to any submission served by mail.

The agency agrees that the time for responding to a pleading should begin on the date the pleading is served and that additional time should be allowed for the filing of a pleading when the pleading responded to is served by mail. However, the agency believes that 3, rather than 5, days is sufficient to account for mail delays. A similar period of time is provided in Rule 6(e) of the Federal Rules of Civil Procedure.

Therefore, § 12.80(a) in this final rule provides that an additional 3 days may be added to any time limit for filing a pleading in response to a pleading served by mail, unless the time in which the responsive pleading is to be filed is set by the presiding officer. When the time for filing pleadings is set on a case-by-case basis, as it is for briefs (see § 12.96(a) (21 CFR 12.96(a))) and exceptions (see § 12.125(c) (21 CFR 12.125(c))), the participants may request that additional time be allowed to account for mail delays, or that service be made by physical delivery. Therefore, the change in § 12.80(a) relates primarily to motions, which are dealt with in § 12.99 (21 CFR 12.99). Section 12.99(b) is also changed to provide that the time to respond to a motion begins with the date of service. Section 12.125(c) is modified to clarify the time for filing replies to exceptions to an initial decision.

22. A comment generally objected to the date of receipt rule in § 12.80(a) because it reduces the time available to prepare complex documents, such as hearing requests and accompanying support documents.

The date of receipt rule applies only to submissions in the hearing itself, not to submissions filed before a hearing has been noticed.

23. A comment objected to the proposed revision of § 12.85(a)(2), which explicitly limits the scope of the required search for documents to be submitted in a hearing to "the principal files in the bureau in which documents relating to the issues in the hearing are ordinarily kept." The comment characterized the revision as "unacceptable" because it allows the agency to determine which files are to be searched. The comment asserted that the impracticality of searching all agency files was an inadequate justification for denying the "opposing party's right to be supplied with all documents relating to the issues." The comment noted that hearing requests are required to certify that all information, including information unfavorable to the requester's position, is included in the request. The comment said that as a matter of fairness, FDA should be required to certify that all relevant information in its files has been submitted.

The agency disagrees with this description of the revised rule and rejects the comment's recommendation. The language limiting the bureau's obligation to search agency files merely makes explicit a position announced several years ago in the preamble to the final regulations for formal evidentiary hearings. See the Federal Register of November 23, 1976, ¶ 31 (41 FR 51714).

As the agency made clear at that time, the regulation "does not require that every file under the participant's control be canvassed to identify data and information that would not be known to the participant in the ordinary course of preparing its participation, and this applies equally to the bureau director's parallel obligation." This observation was made in response to a complaint that it was too burdensome to require corporations to search out all information relating to issues in a

hearing, because a corporation's files are extensive and some information might be missed, or located only with considerable difficulty and at excessive cost.

The agency essentially agreed with that comment, and made clear that it recognized the impracticality of requiring that literally "all" files be searched for literally "all" relevant documents. If it is impractical for a corporation to conduct such a search, it is equally impractical for a government agency as large as FDA to do so.

The preamble to the proposed revision stated that the limitation on the duty to search applies both to the bureau and to other participants in formal hearings. The suggestion in the more recent comment that the regulation is unfair is therefore wrong: the obligation of the bureau and of other participants is equivalent, including the obligation to produce unfavorable, as well as favorable, information.

24. A comment requested that § 12.87(b)(1)(ii) (21 CFR 12.87(b)(1)(ii)) be revised to make clear that oral cross-examination is a matter of right, citing 5 U.S.C. 556(d).

The agency believes that the regulation accurately reflects the standard for cross-examination in 5 U.S.C. 556(d): "A party is entitled * * * to conduct such cross-examination as may be required for a full and true disclosure of the facts."

25. A comment stated that § 12.94(c) (21 CFR 12.94(c)) could be interpreted as requiring written evidence to be identified as "written evidence" in order to be admitted, and recommended that the regulation be revised to state that written evidence is admissible if it plainly appears to be such.

The purpose of the provision in question is to require that a participant make clear which documents, from among those submitted, are intended to be offered as evidence. It does not require that written evidence bear the legend "written evidence," and the agency will not interpret § 12.94(c) in a contrary manner.

26. A comment suggested that the word "unreliable" be deleted from § 12.94(c)(1)(i) because it refers to the weight of the evidence rather than its admissibility. The comment also suggested inserting the word "unduly" before the word "repetitive."

The agency believes that the presiding officer should have the discretion to exclude evidence that is "unreliable." The agency also believes that qualifying the word "repetitive" with the word "unduly" does not make any clearer the circumstances in which evidence will be considered duplicative.

27. Comments requested that more time be provided in § 12.96(a) (21 CFR 12.96(a)) for the filing of post-hearing briefs. Section 12.96(a) as revised states that briefs are to be filed "ordinarily within 45 days of the close of the hearing."

The agency believes that 45 days should ordinarily be sufficient time to prepare post-hearing briefs. If it is not, the participants may request an extension of time.

28. A comment suggested that § 12.97(c) be revised to state that, when one participant is authorized to file a brief in an interlocutory appeal, opposing participants may file briefs as of right.

The suggestion is adopted.

29. A comment suggested that § 12.97(c) be revised to require the transcription of oral arguments on interlocutory appeals in cases in which no briefs are authorized.

The suggestion is adopted.

30. A comment suggested that § 12.98(d) (21 CFR 12.98(d)) be revised to provide for corrections within 30 days of the day when the transcript becomes available, rather than 30 days from the close of the hearing.

The suggestion is adopted.

31. A comment criticized the elimination from § 12.120(a) (21 CFR 12.120(a)) of the 90-day time limit on the issuance of decisions by the presiding officer.

The agency agrees with the comment's position that hearing decisions should be issued promptly, and that reasonable steps be taken to make this possible. The agency does not agree that a fixed time limit, which must routinely be extended when a backlog develops, is the best approach to the problem.

32. Section 12.120(d) (21 CFR 12.120(d)) is amended in this final regulation to include a specific statement that the presiding officer's jurisdiction over a matter terminates upon the filing of the initial decision with the Hearing Clerk. The change clarifies the intent of the original regulations. Motions and requests respecting a hearing matter that are submitted after the initial decision is filed will be dealt with as if they had been submitted to the Commissioner.

Public Hearing Before a Public Board of Inquiry (Part 13)

There were no comments on this part.

Public Hearing Before a Public Advisory Committee (Part 14)

33. A comment urged that § 14.7(a) (21 CFR 14.7(a)) be revised to require FDA to respond within 30 days to a petition contending that action has been illegally delayed. Proposed § 14.7(a) provides that a person who alleges noncompliance by FDA with the Federal Advisory Committee Act must do so in the form of a citizen petition submitted in accordance with § 10.30 (21 CFR 10.30), and that the filing of, and action on, a citizen petition is a prerequisite to seeking court review. Under § 10.30(e), FDA has 180 days in which to respond to a citizen petition, which, the comment contends, is too long.

The agency does not believe that it is appropriate or necessary to establish a shorter time limit for responding to petitions concerning advisory committee activities than for responding to other kinds of petitions. The 180-day time period specified in § 10.30(e)(2) is the maximum allowed. Responses will ordinarily be provided before 180 days have elapsed. If a petition makes clear why a response should be provided on an expedited basis, FDA will make every effort to do so. It should be noted that when a person challenges the validity of advisory committee actions that will take place in the future, § 14.7(a) provides for a response before the event occurs. The comment contains no support for the generality that expedited handling is needed when a person complains of events that have already occurred.

34. Comments objected to the revision in § 14.22(d) (21 CFR 14.22(d)) that allows a committee charter to provide for a quorum of less than the majority of voting committee members.

The agency believes that there is a need for the flexibility introduced by this change in that rule. The possibility that the revised regulation will lead to abuses is minimal: the rule establishing a committee's quorum is subject to several levels of review within the government because the rule must be stated in the committee's charter.

35. A comment suggested that § 14.61 (21 CFR 14.61) be revised to state explicitly that transcripts are to be kept of meetings conducted over the telephone.

The agency believes that the present language is adequate to convey the desired meaning.

36. A comment recommended that § 14.140(b) (21 CFR 14.140(b)) be revised to make clear that, even in the absence of a request from an affected person, the Commissioner may refer an issue

relating to the carcinogenicity of a color additive to a color additive advisory committee under section 706(b)(5)(C)(i) of the Federal Food, Drug, and Cosmetic Act.

The suggestion is adopted.

37. A comment suggested that § 14.155(a) (21 CFR 14.155(a)) be revised to establish the rate of compensation for the members of a color additive advisory committee as the rate for GS–18. The comment said that this change would avoid the necessity of revising the rate of pay specified in the regulations each time the Federal pay scale is changed.

The suggestion is not adopted. The rate of compensation of the members of a color additive advisory committee is not that for GS–18, but an amount determined in accordance with agency policy. The act provides that compensation of advisory committee members be set at rates "not exceeding" the rate for GS–18; it does not require payment of the GS–18 rate.

Public Hearing Before the Commissioner (Part 15)

38. Comments urged a revision of § 15.20 (21 CFR 15.20) to clarify that the notices that the agency publishes under that section are to be published in the **Federal Register**. One comment pointed out that the notice provisions in Parts 12, 13 and 14 specifically refer to publication in the **Federal Register**.

The suggestion is adopted. The comments show that it is not clear from the context that the regulation refers to publication in the **Federal Register**. In other instances, the context makes clear that "publication" refers to publication in the **Federal Register**.

39. A comment suggested that § 15.20(c) permit the submission of a comprehensive outline of a presentation as an alternative to the submission of a text since either submission could serve the purpose of permitting the panel at a public hearing to formulate useful questions.

The provision has been revised to allow the agency to require the submission of either the text or a comprehensive outline. If the agency believes that the full text, rather than a comprehensive outline, is needed to permit preparation of questions, the text can be required.

40. A comment noted that, under § 15.21(b) (21 CFR 15.21(b)), a person will ordinarily be allowed to speak only once if more than one public hearing is held on the same subject. The comment suggested that the provision be revised to permit additional testimony by the same person if "new issues" have arisen.

The agency does not believe that this change is necessary. Section 15.25 (21 CFR 15.25) provides that, unless specified otherwise, the record for the proceeding is to be open for 15 days after the end of the hearing for additional submissions. This provision is intended to allow participants to respond to any new issues that arise in the testimony of other participants.

The prohibition of multiple presentations by the same person is intended to avoid redundant testimony and to assure a fair opportunity for all interested persons to testify. The provision states only the ordinary practice. The Commissioner or the presiding officer can permit an additional opportunity to speak in particular situations, based on specific need, the practicality of allowing further testimony, the number of presentations involved, and any other factors that may appropriately be considered. A request to permit an additional presentation in order to comment on new issues should explain why a written submission is not sufficient.

Regulatory Hearing Before the Food and Drug Administration (Part 16)

41. A comment praised § 16.44 (21 CFR 16.44) for its attempt to eliminate off-the-record communications in regulatory hearings. The comment urged that the provision apply to all persons, not simply to parties and the agency personnel directly involved in a presentation at the hearing.

The agency does not believe that any further change is warranted. Even in the case of formal evidentiary public hearings, only certain employees—those engaged in the performance of investigative or prosecuting functions—are restricted by law from communicating with those involved in the agency review and decision (see 5 U.S.C. 554(d)). In reaching a sound conclusion on the issues in a regulatory hearing, agency decisionmakers may need to consult with others in the agency not involved in a presentation at the hearing. It would be inappropriate and impractical to require the presiding officer and Commissioner to reach a decision without any staff review and assistance. If the comment were adopted in its literal form, it would be necessary to reduce to writing and place in the record all comments and drafts by all staff reviewers. The present provision is appropriately limited to communications from the parties and agency employees directly involved in the presentation at the hearing; it is they who are most likely to adopt a partial position on the matters in issue.

42. Paragraph (c) is being added to § 16.44 to require the parties to a hearing, and the presiding officer, to provide each other copies of any official correspondence or communications concerning the hearing. Thus, if one party requests the presiding officer to change the time for the hearing, a copy of the letter and the response from the presiding officer should be sent to all participants. Also, § 16.80 (21 CFR 16.80) has been amended to make these communications part of the record.

43. Section 16.60(a)(2) is modified to make clear that FDA employees, and employees of the office of the Chief Counsel, may attend a private regulatory hearing as long as they have a direct professional interest in the subject matter of the proceeding. The provision as currently worded limits attendence to "FDA representatives." That term has been construed to relate only to persons responsible for presenting the bureau's case at a hearing. The agency believes that this result was not intended, and that FDA employees should be permitted to attend a private hearing when the matter in issue relates to their professional duties.

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 (secs. 1 through 9, 44 Stat. 1101–1103 as amended (21 U.S.C. 141–149)), the Tea Importation Act (secs. 1 through 10, 29 Stat. 604–607 (21 U.S.C. 41–50)), 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 under authority delegated to the Commissioner (21 CFR 5.1), Subchapter A is amended by revising Parts 10, 12, 13, 14, 15, and 16, to read as follows:

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

Subpart A—General

Subpart B—General Administrative Procedures

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. 604–607 as amended (21 U.S.C. 41–50); sec. 2 et seq., Pub. L. 783, 44 Stat. 1406 as amended (15 U.S.C. 401 et seq.); sec. 1 et seq., Pub. L. 89–755, 80 Stat. 1296 as amended (15 U.S.C. 1451 et seq.).

Subpart A—General Provisions

§ 10.1 Scope.

(a) Part 10 governs practices and procedures for petitions, hearings, and other administrative proceedings and activities conducted by the Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and other laws that the Commissioner of Food and Drugs administers under § 5.1.

(b) If a requirement in another part of Title 21 differs from a requirement in this part, the requirements of this part apply to the extent that they do not conflict with the other requirements.

(c) References in this part and Parts 12, 13, 14, 15, and 16 to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

(d) References in this part and Parts 12, 13, 14, 15, and 16 to "publication," or to the day or date of publication, or use of the phrase "to publish," refer to publication in the **Federal Register** unless otherwise noted.

§ 10.3 Definitions.

(a) The following definitions apply in this part and Parts 12, 13, 14, 15, 16, and 19:

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

"Administrative action" includes every act, including the refusal or failure to act, involved in the administration of any law by the Commissioner, except that it does not include the referral of apparent violations to U.S. attorneys for the institution of civil or criminal proceedings or an act in preparation of a referral.

"Administrative file" means the file or files containing all documents pertaining to a particular administrative action, including internal working memoranda, and recommendations.

"Administrative record" means the documents in the administrative file of a particular administrative action on which the Commissioner relies to support the action.

"Agency" means the Food and Drug Administration.

"Commissioner" means the Commissioner of Food and Drugs, Food and Drug Administration, U.S. Department of Health, Education, and Welfare, or the Commissioner's designee.

"Department" means the U.S. Department of Health, Education, and Welfare.

"Ex parte communication" means an oral or written communication not on the public record for which reasonable prior notice to all parties is not given, but does not include requests for status reports on a matter.

"FDA" means the Food and Drug Administration.

"Food and Drug Administration employee" or "Food and Drug Administration representative" includes members of the Food and Drug Division of the office of the General Counsel of the Department of Health, Education, and Welfare.

"Formal evidentiary public hearing" means a hearing conducted under part 12.

"Hearing Clerk" means the Hearing Clerk of the Food and Drug Administration, U.S. Department of Health, Education, and Welfare, Room 4–65, 5600 Fishers Lane, Rockville, Md. 20857.

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

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

"Office of the Commissioner" includes the offices of the associate commissioners but not the bureaus, the office of the Executive Director for Regional Operations, or the regional or district offices.

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

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

"Party" means the bureau of the Food and Drug Administration responsible for a 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 hearing under Part 12 or Part 16 or who has waived the right to a hearing to obtain the establishment of a Public Board of Inquiry under Part 13 and as a result of whose action a hearing or a Public Board of Inquiry has been established.

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

"Petition" means a petition, application, or other document requesting the Commissioner to establish, amend, or revoke a regulation or order, or to take or not to take any other form of administrative action, under the laws administered by the Food and Drug Administration.

"Presiding officer" means the Commissioner or the Commissioner's designee or an administrative law judge appointed as provided in 5 U.S.C. 3105.

"Proceeding" and "administrative proceeding" means any undertaking to issue, amend, or revoke a regulation or

order, or to take or refrain from taking any other form of administrative action.

"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 of an advisory committee, that is not composed wholly of full-time employees of the Federal Government and is established or utilized by the Food and Drug Administration to obtain advice or recommendations.

"Public Board of Inquiry" or "Board" means an administrative law tribunal constituted under Part 13.

"Public hearing before a public advisory committee" means a hearing conducted under Part 14.

"Public hearing before a Public Board of Inquiry" means a hearing conducted under Part 13.

"Public hearing before the Commissioner" means a hearing conducted under Part 15.

"Regulations" means an agency rule of general or particular applicability and future effect issued under a law administered by the Commissioner or relating to administrative practices and procedures. In accordance with § 10.90(a), each agency regulation will be published in the **Federal Register** and codified in the Code of Federal Regulations.

"Regulatory hearing before the Food and Drug Administration" means a hearing conducted under Part 16.

"Secretary" means the Secretary of Health, Education, and Welfare.

"The laws administered by the Commissioner" or "the laws administered by the Food and Drug Administration" means all the laws that the Commissioner is authorized to administer under § 5.1.

(b) A term that is defined in section 201 of the Federal Food, Drug, and Cosmetic Act of Part 1 has the same definition in this part.

(c) Words in the singular form include the plural, words in the masculine form include the feminine, and vice versa.

(d) Whenever a reference is made in this part to a person in FDA, e.g., the director of a bureau, the reference includes all persons to whom that person has delegated the specific function involved.

§ 10.10 Summaries of administrative practices and procedures.

To encourage public participation in all agency activities, the Commissioner will prepare for public distribution summaries of FDA administrative practices and procedures in readily understandable terms.

§ 10.19 Waiver suspension, or modification of procedural requirements.

The Commissioner or a presiding officer may, either voluntarily or at the request of a participant, waive, suspend, or modify any provision in Parts 12 through 16 applicable to the conduct of a public hearing by announcement at the hearing or by notice in advance of the hearing if no participant will be prejudiced, the ends of justice will thereby be served, and the action is in accordance with law.

Subpart B—General Administrative Procedures

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

(a) A submission to the Hearing Clerk of a petition, comment, objection, notice, compilation of information, or any other document is to be filed in four copies except as otherwise specifically provided in a relevant **Federal Register** notice or in another section of this chapter. The Hearing Clerk is the agency custodian of these documents.

(b) A submission is to be signed by the person making it, or by an attorney or other authorized representative of that person. Submissions by trade associations are also subject to the requirements of § 10.105(b).

(c) Information referred to or relied upon in a submission is to be included in full and may not be incorporated by reference, unless previously submitted in the same proceeding.

(1) A copy of an article or other reference or source cited must be included, except where the reference or source is—

(i) A reported Federal court case;

(ii) A Federal law or regulation;

(iii) An FDA document that is routinely publicly available;

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

(v) A designated journal listed in § 310.9 or § 510.95.

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

(3) Where relevant information is contained in a document also containing irrelevant information, the irrelevant information is to be deleted and only the relevant information is to be submitted.

(4) Under § 20.63 (a) and (b), the names and other information that would identify patients or research subjects are to 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 is to be deleted from a record before it is submitted to the Hearing Clerk.

(6) The failure to comply with the requirements of this part will result in rejection of the submission for filing or, if it is filed, in exclusion from consideration of any portion that fails to comply. If a submission fails to meet any requirement of this section and the deficiency becomes known to the Hearing Clerk, the Hearing Clerk shall not file the submission but return it with a copy of the applicable regulations indicating those provisions not complied with. A deficient submission may be corrected or supplemented and subsequently filed. The office of the Hearing Clerk does not make decisions regarding the confidentiality of submitted documents. Persons wishing to voluntarily submit information considered confidential shall follow the presubmission review requirements of § 20.44.

(d) The filing of a submission means only that the Hearing Clerk has identified no technical deficiencies in the submission. The filing of a petition does not mean or imply that it 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 will be considered as submitted on the date they are postmarked or, if delivered in person during regular business hours, on the date they are delivered, unless a provision in this part, an applicable **Federal Register** notice, or an order issued by an administrative law judge specifically states that the documents must be received by a specified date, e.g., § 10.33(g) relating to a petition for reconsideration, in which case they will be considered submitted on the date received.

(f) All submissions are to be mailed or delivered in person to the Hearing Clerk, Food and Drug Administration, room 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 FDA building in Washington (room 6819, 200 C Street SW., Washington, D.C. 20201) and will be considered as received by the Hearing Clerk on the date on which it is delivered.

(g) FDA ordinarily will not acknowledge or give receipt for documents, except—(1) Documents delivered in person or by certified or registered mail with a return receipt requested; and

(2) Petitions for which acknowledgement of receipt of filing is provided by regulation or by customary practice, e.g., § 10.30(c) relating to a citizen petition.

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

(i) All submissions to the Hearing Clerk are representations that, to the best of the knowledge, information, and belief of the person making the submission, the statements made in the submission are true and accurate. All 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 is 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, will be on public display and will be available for public examination between 9 a.m. and 4 p.m., Monday through Friday. Requests for copies of submissions will be filed and handled in accordance with Subpart C of Part 20:

(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 under Part 12.

(iv) Material submitted at a hearing under § 12.32(a)(2) and Parts 12, 13, and 15.

(v) Material placed on public display under the regulations in this chapter, e.g., agency guidelines filed under § 10.90(b).

(2)(i) Material prohibited from public disclosure under § 20.63 (clearly unwarranted invasion of personal privacy) and, except as provided in paragraph (j)(3) of this section, material submitted with objections and requests for hearing filed under Part 12, or at a hearing under Part 12 or Part 13, or an alternative form of public hearing before a public advisory committee or a hearing under § 12.32(a) (2) or (3), of the following types will not be on public display, will not be available for public examination, and will not be available for copying or any other form of verbatim transcription unless it is otherwise available for public disclosure under Part 20:

(*a*) Safety and effectiveness information, which includes 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 information, except any compilation of information aggregated and prepared in a way that does not reveal confidential information.

(*e*) Quantitative or semiquantitative formulas.

(*f*) Information on product design or construction.

(ii) Material submitted under paragraph (j)(2) of this section is to be segregated from all other submitted material and clearly so marked. A person who does not agree that a submission is properly subject to paragraph (j)(2) may request a ruling from the Associate Commissioner for Public Affairs whose decision is final, subject to judicial review under § 20.46.

(3) Material listed in paragraph (j)(2)(i) (*a*) and (*b*) of this section may be disclosed under a protective order issued by the administrative law judge or other presiding officer at a hearing referenced in paragraph (j)(2)(i). The administrative law judge or presiding officer shall permit disclosure of the data only in camera and only to the extent necessary for the proper conduct of the hearing. The administrative law judge or presiding officer shall direct 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 will be excluded from the in camera part of the proceeding. The administrative law judge or other presiding officer may impose other conditions or safeguards. The limited availability of material under this paragraph does not constitute prior disclosure to the public as defined in § 20.81, and no information subject to a particular order is to be submitted to or received or considered by FDA in support of a petition or other request from any other person.

§ 10.25 Initiation of administrative proceedings.

An administrative proceeding may be initiated in the following three ways:

(a) An 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. A petition must be either: (1) In the form specified in other applicable FDA regulations, e.g., the form for a color additive petition in § 71.1, for a food additive petition in § 171.1, for a new drug application in § 314.1, for a new animal drug application in § 514.1, or (2) in the form for a citizen petition in § 10.30.

(b) The Commissioner may initiate a proceeding to issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action. FDA 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 issue which has not previously been determined by the agency or which, if it has previously been determined, the agency concluded should be reconsidered and subject to a new administrative determination. The Commissioner may utilize any of the procedures established in this part in reviewing and making a determination on any matter initiated under this paragraph.

(c) The Commissioner will institute a proceeding to determine whether to issue, amend, or revoke a regulation or order, or take or refrain from taking any other form of administrative action whenever any court, on its own initiative, holds in abeyance or refers any matter to the agency for an administrative determination and the Commissioner concludes that an administrative determination is feasible within agency priorities and resources.

§ 10.30 Citizen petition.

(a) This section applies to any petition submitted by a person (including a person who is not a citizen of the United States) except to the extent that other sections of this chapter apply different requirements to a particular matter.

(b) A petition (including any attachments) must be submitted in

accordance with § 10.20 and in the following form:

(Date)———

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

Citizen Petition

The undersigned submits this petition under ——— (relevant statutory sections, if known) of the ——— (Federal Food, Drug, and Cosmetic Act or the Public Health Service Act or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs under 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 of the exact wording of the 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, in a well organized format, of the factual and legal grounds on which the petitioner relies, including all relevant information and views on which the petitioner relies, as well as representative information known to the petitioner which is unfavorable to the petitioner's position.)

C. Environmental impact

(An environmental impact analysis report in the form specified in 21 CFR 25.1(g), except for the types of actions specified in 21 CFR 25.1(d).)

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.)

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all 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.

(Signature) ———
(Name of petitioner) ———
(Mailing address) ———
(Telephone number) ———

(c) A petition which appears to meet the requirements of paragraph (b) of this section and § 10.20 will be filed by the Hearing Clerk, stamped with the date of filing, and assigned a docket number. The docket number identifies the file established by the Hearing Clerk for all submissions relating to the petition, as provided in this part. Subsequent submissions relating to the matter must refer to the docket number and will be filed in the docket file. Related petitions may be filed together and given the same docket number. The Hearing Clerk will promptly notify the petitioner in writing of the filing and docket number of a petition.

(d) An interested person may submit written comments to the Hearing Clerk on a filed petition, which comments become part of the docket file. The comments are to specify the docket number of the petition and may support or oppose the petition in whole or in part. A request for alternative or different administrative action must be submitted as a separate petition.

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

(2) The Commissioner shall furnish a response to each petitioner within 180 days of receipt of the petition. The response will either—(i) Approve the petition, in which case the Commissioner shall concurrently take appropriate action (e.g., publication of a **Federal Register** notice) implementing the approval;

(ii) Deny the petition; or

(iii) Provide a tentative response, indicating why the agency has been unable to reach a decision on the petition, e.g., because of the existence of other agency priorities, or a need for additional information. 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 other action as the petition warrants. The petitioner is to be notified in writing of the Commissioner's decision. The decision will 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 under paragraph (c) of this section requests the Commissioner to issue, amend, or revoke a regulation, § 10.40 or § 10.50 also apply.

(g) A petitioner may supplement, amend, or withdraw a petition in writing without agency approval and without prejudice to resubmission at anytime until the Commissioner rules on the petition, unless the petition has been referred for a hearing under Parts 12, 13, 14, or 15. After a ruling or referral, a petition may be supplemented, amended, or withdrawn only with the approval of the Commissioner. The Commissioner may approve withdrawal, with or without prejudice against resubmission of the petition.

(h) In reviewing a petition the Commissioner may use the following procedures:

(1) Conferences, meetings, discussions, and correspondence under § 10.65.

(2) A hearing under Parts 12, 13, 14, 15, or 16.

(3) A **Federal Register** notice requesting information and views.

(4) A proposal to issue, amend, or revoke a regulation, in accordance with § 10.40 or § 12.5.

(5) Any other specific public procedure established in this chapter and expressly applicable to the matter.

(i) The record of the administrative proceeding consists of the following:

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

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

(3) If the petition resulted in a proposal to issue, amend, or revoke a regulation, all of the documents specified in § 10.40(g).

(4) The record, consisting of any transcripts, minutes of meetings, reports, **Federal Register** notices, and other documents resulting from the optional procedures specified in paragraph (g) of this section, except a transcript of a closed portion of a public advisory committee meeting.

(5) The Commissioner's decision on the petition, including all 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 under § 10.65(h).

(7) If a petition for reconsideration or for a stay of action is filed under paragraph (j) of this section, the administrative record specified in § 10.33(k) or § 10.35(h).

(j) The administrative record specified in paragraph (i) of this section is the exclusive record for the Commission's decision. The record of the administrative proceeding closes on the date of the Commissioner's decision unless some other date is specified. Thereafter any interested person may submit a petition for reconsideration under § 10.33 or a petition for stay of action under § 10.35. A person who wishes to rely upon information or views not included in the administrative record shall submit them to the Commissioner with a new petition to modify the decision in accordance with this section.

(k) This section does 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 FDA. Routine correspondence does not constitute a petition within the meaning of this section unless it purports to meet the requirements of this section. Action on routine correspondence does not constitute final administrative action subject to judicial review under § 10.45.

(l) The Hearing Clerk will maintain a chronological list of each petition filed under this section and § 10.85, but not of petitions submitted elsewhere in the agency under § 10.25(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; and

(5) The disposition of the petition.

§ 10.33 Administrative reconsideration of action.

(a) The Commissioner may at any time reconsider a matter, on the Commissioner's own initiative or on the petition of an interested person.

(b) An interested person may request reconsideration of part or all of a decision of the Commissioner on a petition submitted under § 10.25. Each request for reconsideration must be submitted in accordance with § 10.20 and in the following form no later than 30 days after the date of the decision involved. The Commissioner may, for good cause, permit a petition to be filed after 30 days. In the case of a decision published in the **Federal Register**, the day of publication is the day of decision.

(Date) _____

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

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, in a well-organized format, of the factual and legal grounds upon which the petitioner relies. The grounds must demonstrate that relevant information and views contained in the administrative record were not previously or not adequately considered by the Commissioner.

No new information or views may be included in a petition for reconsideration.)

(Signature) _____
(Name of petitioner) _____
(Mailing address) _____
(Telephone number) _____

(c) A petition for reconsideration relating to a petition submitted under § 10.25(a)(2) is subject to the requirements of § 10.30 (c) and (d), except that it is 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 the petition when the Commissioner determines it is in the public interest and in the interest of justice. The Commissioner shall grant a petition for reconsideration in any proceeding if the Commissioner determines all of the following apply:

(1) The petition demonstrates that relevant information or views contained in the administrative record were not previously or not adeqately considered.

(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.

(4) Reconsideration is not outweighed by public health or other public interests.

(e) A petition for reconsideration may not be based on information and views not contained in the administrative record on which the decision was made. An interested person who wishes to rely on information or views not included in the administrative record shall submit them with a new petition to modify the decision under § 10.25(a).

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

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

(h) The Commissioner may initiate the reconsideration of all or part of a matter at any time after it has been decided or action has been taken. If review of the 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 is to include all additional documents relating to such reconsideration.

(i) After determining to reconsider a matter, the Commissioner shall review and rule on the merits of the matter under § 10.30(e). The Commissioner may reaffirm, modify, or overrule the prior decision, in whole or in part, and may grant such other relief or take such other action as is warranted.

(j) The Commissioner's reconsideration of a matter relating to a petition submitted under § 10.25(a)(2) is subject to § 10.30 (f) through (h), (j), and (k).

(k) The record of the administrative proceeding consists of the following:

(1) The record of the original petition specified in § 10.30(i).

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

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

(4) The Commissioner's decision on the petition under paragraph (f) of this section, including all 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 the petition.

(6) All documents filed with the Hearing Clerk under § 10.65(h).

(7) If the Commissioner reconsiders the matter, the administrative record relating to reconsideration specified in § 10.30(i).

§ 10.35 Administrative stay of action.

(a) The Commissioner may at any time stay or extend the effective date of an action pending or following a decision on any matter.

(b) An interested person may request the Commissioner to stay the effective date of any administrative action. A stay may be requested for a specific time period or for an indefinite time period. A request for stay must be submitted in accordance with § 10.20 and in the following form no later than 30 days after the date of the decision involved. The Commissioner may, for good cause, permit a petition to be filed after 30 days. In the case of a decision published in the **Federal Register**, the day of publication is the date of decision.

(Date)_____

Hearing Clerk, Food and Drug Administration, Department of Health, Education, and Welfare, Room 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 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 whch the stay is requested, which may be for a specific or indefinite time period.)

C. Statement of grounds

(A full statement, in a well-organized format, of the factual and legal grounds upon which the petitioner relies for the stay.)

(Signature) _____
(Name of petitioner) _____
(Mailing address) _____
(Telephone number) _____

(c) A petition for stay of action relating to a petition submitted under § 10.25(a)(2) is subject to the requirements of § 10.30 (c) and (d), except that it will 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 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 under § 10.30 or a petition for reconsideration under § 10.33 or a request for an advisory opinion under § 10.80, will 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 determines that a stay or delay is in the public interest and stays the action.

(2) A statute 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 a petition, in whole or in part; and may grant such other relief or take such other action as is warranted by the petition. The Commissioner may grant a stay in any proceeding if it is in the public interest and in the interest of justice. The Commissioner shall grant a stay in any proceeding if 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.

(4) The delay resulting from the stay is not outweighted by public health or other public interests.

(f) The Commissioner's decision on a petition for stay of action is to be in writing and 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 will be published in the **Federal Register** if the Commissioner's original decision was so published. 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 will be denied as untimely unless the Commissioner permits the petition to be filed after 30 days. A petition for a stay of action is considered submitted on the day it is received by the Hearing Clerk

(h) The record of the administrative proceeding consists 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 information on which it relies, filed by the Hearing Clerk.

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

(4) The Commissioner's decision on the petition under paragraph (e) of this section, including all 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 the petition.

(6) All documents filed with the Hearing Clerk under § 10.65(h).

§ 10.40 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 FDA whenever it is necessary or appropriate to do so. The issuance, amendment, or revocation of a regulation may be initiated in any of the ways specified in § 10.25.

(1) This section applies to any regulation (i) not subject to § 10.50 and Part 12, or (ii) if it is subject to § 10.50 and Part 12, to the extent that those provisions make this section applicable.

(2) A regulation proposed by an interested person in a petition submitted under § 10.25(a) will be published in the **Federal Register** as a proposal if—

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

(ii) The petition substantially shows that the proposal is in the public interest and will promote the objectives of the act and the agency.

(3) Two or more alternative proposed regulations may be published on the same subject to obtain comment on the different alternatives.

(4) A regulation proposed by an interested person in a petition submitted under § 10.25(a) may be published together with the Commissioner's preliminary views on the proposal and any alternative proposal.

(b) Except a provided in paragraphs (d) and (e) of this section, each regulation must be the subject of a notice of proposed rulemaking published in the **Federal Register**.

(1) The notice will contain (i) the name of the agency; (ii) the nature of the

action, e.g., proposed rule, or notice; (iii) a summary in the first paragraph describing the substance of the document in easily understandable terms; (iv) relevant dates, e.g., comment closing date, and proposed effective date(s); (v) the name, business address, and phone number of an agency contact person who can provide further information to the public about the notice; (vi) an address for submitting written comments; (vii) supplementary information about the notice in the form of a preamble that summarizes the proposal and the facts and policy underlying it, includes references to all information on which the Commissioner relies for the proposal (copies or a full list of which are a part of the docket file on the matter in the office of the Hearing Clerk), and cites the authority under which the regulation is proposed; (viii) either the terms or substance of the proposed regulation or a description of the subjects and issues involved; (ix) a reference to the existence or lack of need for an environmental impact statement under § 25.25(a)(3) (ii) or (iii); and (x) the docket number of the matter, which identifies the docket file established by the Hearing Clerk for all relevant submissions.

(2) The proposal will provide 60 days for comment, although the Commissioner may shorten or lengthen this time period for good cause. In no event is the time for comment to be less than 10 days.

(3) After publication of the proposed rule, and interested person may request the Commissioner to extend the comment period for an additional specified period by submitting a written request to the Hearing Clerk stating the grounds for the request. The request is submitted under § 10.35 but should be headed "REQUEST FOR EXTENSION OF COMMENT PERIOD."

(i) A request must discuss the reason comments could not feasibly 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 the request or may grant an extension for a time period different from that requested. An extension may be limited to specific persons who have made and justified the request, but will ordinarily apply to all interested persons.

(ii) A comment time extension of 30 days or longer will be published in the **Federal Register** and will be applicable to all interested persons. A comment time extension of less than 30 days will be the subject either of a letter or memorandum filed with the Hearing Clerk or of a notice published in the **Federal Register.**

(4) A notice of proposed rulemaking will request that four copies of all comments be submitted to the Hearing Clerk, except that individuals may submit single copies. 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 their preferred alternative wording.

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

(1) The quality and persuasiveness of the comments will be the basis for the Commissioner's decision. The number or length of comments will not ordinarily be a significant factor in the decision unless the number of comments is material where the degree of public interest is a legitimate factor for consideration.

(2) The decision of the Commissioner on the matter will be based solely upon the administrative record.

(3) A final regulation published in the **Federal Register** will have a preamble stating (i) the name of the agency, (ii) the nature of the action e.g., final rule, notice, (iii) a summary first paragraph describing the substance of the document in easily understandable terms, (iv) relevant dates, e.g., the rule's effective date and comment closing date, if an opportunity for comment is provided, (v) the name, business address, and phone number of an agency contact person who can provide further information to the public about the notice, (vi) an address for the submission of written comments when they are permitted, (vii) supplementary information about the regulation in the body of the preamble that contains references to prior notices relating to the same matter and a summary of each type of comment submitted on the proposal and the Commissioner's conclusions with respect to each. The preamble is to contain a thorough and comprehensible explanation of the reasons for the Commissioner's decision on each issue.

(4) The effective date of a final regulation may not be 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; or

(ii) A regulation for which 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 will apply to interpretive rules and rules of agency practice and procedure except as provided in paragraph (e) of this section. Paragraphs (b) and (c) of this section do 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 do not apply in the following situations:

(1) When the Commissioner determines for good cause that they are impracticable, unnecessary, or contrary to the public interest. In these cases, the notice promulgating the regulation will state the reasons for the determination, and provide an opportunity for comment 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) Food additive and color additive petitions, which are subject to the provisions of § 12.20(b)(2).

(3) New animal drug regulations, which are promulgated under section 512(i) of the act.

(f) In addition to the notice and public procedure required under paragraph (b) of this section, the Commissioner may also subject a proposed or final regulation, before or after publication in the **Federal Register,** to the following additional procedures:

(1) Conferences, meetings, discussions, and correspondence under § 10.65.

(2) A hearing under Parts 12, 13, 14, or 15.

(3) A notice published in the **Federal Register** requesting information and views before the Commissioner determines whether to propose a regulation.

(4) 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 on the draft proposal may be submitted orally or in writing.

(5) A revised proposal published in the **Federal Register,** which proposal is

subject to all the provisions in this section relating to proposed regulations.

(6) A tentative final regulation or tentative revised final regulation placed on public display in 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. The Commissioner 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.

(7) A final regulation published in the **Federal Register** that provides an opportunity for the submission of further comments, in accordance with paragraph (e)(1) of this section.

(8) Any other public procedure established in this chapter and expressly applicable to the matter.

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

(1) If the regulation was initiated by a petition, the administrative record specified in § 10.30(i).

(2) If a petition for reconsideration or for a stay of action is filed, the administrative record specified in § 10.33(k) and § 10.35(h).

(3) the proposed rule published in the **Federal Register**, including all information identified or filed by the Commissioner with the Hearing Clerk on the proposal.

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

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

(6) The transcripts, minutes of meetings, reports, **Federal Register** notices, and other documents resulting from the procedures specified in paragraph (f) of this section, but not the transcript of a closed portion of a public advisory committee meeting.

(7) All documents submitted to the Hearing Clerk under § 10.65(h).

(h) The record of the administrative proceeding closes on the date of the Commissioner's decision unless some other date specified. Thereafter any interested person may submit a petition for reconsideration under § 10.33 or a petition for stay of action under § 10.35. A person who wishes to rely upon 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 under this section and § 10.50 (which list will not include regulations resulting from petitions filed and assigned a docket number under § 10.30) showing—

(1) The docket number (for a petition submitted directly to a bureau, the list also includes 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; and

(4) The disposition of the petition.

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

(a) This section applies to court review of final administrative action taken by the Commissioner, including action taken under §§ 10.25 through 10.40 and § 16.1(b), except action subject to § 10.50 and Part 12.

(b) A request that the Commissioner take or refrain from taking any form of administrative action must first be the subject of a final administrative decision based on a petition submitted under § 10.25(a) or, where applicable, a hearing under § 16.1(b) before any legal action is filed in a court complaining of the action or failure to act. If a court action is filed complaining of the action or failure to act before the submission of the decision on a petition under § 10.25(a) or, where applicable, a hearing under § 16.1(b), the Commissioner shall request dismissal of the court action or referral to the agency for an initial administrative determination on the grounds of a failure to exhaust administrative remedies, 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) A request that administrative action be stayed must first be the subject of an administrative decision based upon a petition for stay of action submitted under § 10.35 before a request is made that a court stay the action. If a court action is filed requesting a stay of administrative action before the Commissioner's decision on a petition submitted in a timely manner pursuant to § 10.35, the Commissioner shall request dismissal of the court action or referral to the agency for an initial determination on the grounds of a failure to exhaust administrative remedies, 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 a court action is filed requesting a stay of administrative action after a petition for a stay of action is denied because it was submitted after expiration of the time period provided under § 10.35, or after the time for submitting such a petition has expired, the Commissioner will request dismissal of the court action on the ground of a failure to exhaust administrative remedies.

(d) The Commissioner's final decision constitutes final agency action (reviewable in the courts under 5 U.S.C. 701 et seq. and, where appropriate, 28 U.S.C. 2201) on a petition submitted under § 10.25(a), on a petition for reconsideration submitted under § 10.33, on a petition for stay of action submitted under § 10.35, on an advisory opinion issued under § 10.85, on a guideline issued under § 10.90, on a matter involving administrative action which is the subject of an opportunity for a hearing under § 16.1(b), or on the issuance of a final regulation published in accordance with § 10.40.

(1) It is the position of FDA except as otherwise provided in paragraph (d)(2) of this section, that—

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

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

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

(2) The Commissioner shall object to judicial review of a 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; or

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

(e) An interested person may request judicial review of a 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, the person shall request a stay by the Commissioner under § 10.35 before requesting a stay by the court.

(f) The Commissioner shall take the position in an 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 must be determined solely on the basis of the administrative record specified in §§ 10.30(i), 10.33(k), 10.35(h), 10.40(g), and 16.80(c) or the administrative record applicable to any decision or action under the regulations referenced in § 16.1(b), and that additional information or views may not be considered. An interested person who wishes to rely upon information or views not included in the administrative record shall submit them to the Commissioner with a new petition to modify the action under § 10.25(a).

(g) The Commissioner requests that all petitions for judicial review of a particular matter be filed in a single U.S. District court. If petitions are filed in more than one jurisdiction, the Commissioner will 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, under 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; or

(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 under this section—

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

(i) If the Commissioner decides to proceed with the action, the court will be requested to remand the matter to the agency to reopen the administrative proceeding and record, or on the Commissioner's own initiative the administrative proceeding and record may be reopened upon receipt of the court determination. A reopened administrative proceeding will be conducted under 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, the court will be requested not to stay the matter in the interim and the Commissioner shall expedite the further administrative proceedings.

(2) If a court determines that the administrative record is adequate, but the rationale for the action must be further explained—

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

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

§ 10.50 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 under Part 12 whenever all of the following apply:

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

(2) The person requesting the hearing has a right to an opportunity for a hearing and submits adequate justification for the hearing as required by §§ 12.20 through 12.22 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 it would be in the public interest to do so.

(c) The provisions of the act, and other laws, that afford a person who would be adversely affected by administrative action an opportunity for a formal evidentiary public hearing as listed below. The list imparts no right to a hearing where the statutory section provides no opportunity for a hearing.

(1) Section 401 on definitions and standards for food.

(2) Section 403(j) on regulations for labeling of foods for special dietary uses.

(3) Section 404(a) on regulations for emergency permit control.

(4) Section 406 on tolerances for poisonous substances in food.

(5) Section 409 (c), (d), and (h) on food additive regulations.

(6) Section 501(b) on tests or methods of assay for drugs described in official compendia.

(7) Section 502(d) on regulations designating habit forming drugs.

(8) Section 502(h) on regulations designating requirements for drugs liable to deterioration.

(9) Section 502(n) on prescription drug advertising regulations.

(10) Section 506(c) on insulin regulations.

(11) Section 507(f) on regulations for antibiotic drug certification.

(12) Section 512(n)(5) on regulations for animal antibiotic drugs and certification requirements.

(13) Section 706 (b) and (c) on regulations for color additive listing and certification.

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

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

(16) Section 505 (d) and (e) on new drug applications.

(17) Section 512 (d), (e) and (m) (3) and (4) on new animal drug applications.

(18) Section 515(g) on device premarket approval applications and product development protocols.

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

§ 10.55 Separation of functions; ex parte communications.

(a) This section applies to any matter subject by statute to an opportunity for a formal evidentiary public hearing, as listed in § 10.50(c), and any matter subject to a hearing before a Public Board of Inquiry under Part 13.

(b) In the case of a matter listed in § 10.50(c) (1) through (10) and (12) through (15)—

(1) An interested person may meet or correspond with any FDA representative concerning a matter prior to publication of a notice announcing a formal evidentiary public hearing or a hearing before a Public Board of Inquiry on the matter; the provisions of § 10.65 apply to the meetings and correspondence; and

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

(i) The bureau responsible for the matter is, as a party to the hearing, 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 may not participate or advise in any decision except as witness or counsel in public proceedings. There is to be no other communication between representatives of the bureau and representatives of the office of the Commissioner concerning the matter before the decision of the Commissioner. The Commissioner may, however, designate representatives of a bureau to advise the office of the Commissioner, or designate members of that office to advise a bureau. The designation will be in writing and 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 FDA 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 FDA shall designate members of the office of General Counsel to advise and participate with the bureau in its functions in the hearing and members who are to advise the office of the Commissioner in its functions related to the hearing and the final decision. The members of the office of General Counsel designated to advise the bureau may not participate or advise in any decision of the Commissioner except as counsel in public proceedings. The designation is to be in the form of a memorandum filed with the Hearing Clerk and made a part of the administrative record in the proceeding. There may be no other communication between those members of the office of General Counsel designated to advise the office of the Commissioner and any other persons in the office of General Counsel or in the involved bureau with respect to the matter prior to the decision of the Commissioner. The Chief Counsel may assign new attorneys to advise either the bureau or the office of the Commissioner at any stage of the proceedings. The Chief Counsel will ordinarily advise and participate with the office of the Commissioner in its functions relating to the hearing and the final decision.

(iii) The office of the Commissioner is responsible for the agency review and final decision of the matter, with the advice and participation of anyone in FDA other than representatives of the involved bureau and those members of the office of General Counsel designated to assist in the bureau's functions in the hearing.

(c) In a matter listed in § 10.50(c) (11) and (16) through (19), the provisions relating to separation of functions set forth in §§ 314.200(f), 430.20(b)(7), 514.200, and 601.7(a) are applicable before publication of a notice announcing a formal evidentiary public hearing or a hearing before a Public Board of Inquiry. Following publication of the notice of hearing, the rules in paragraph (b)(2) of this section apply.

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

(1) No person outside the agency may have an ex parte communication with the presiding officer or any person representing the office of the Commissioner concerning the matter in the hearing. Neither the presiding officer nor any person representing the office of the Commissioner may have any ex parte communication with a person outside the agency concerning the matter in the hearing. All communications are to be public communications, as witness or counsel, under the applicable provisions of this part.

(2) A participant in the hearing may submit a written communication to the office of the Commissioner with respect to a proposal for settlement. These communications are to be in the form of pleadings, served on all other participants, and filed with the Hearing Clerk like any other pleading.

(3) A written communication contrary to this section must be immediately served on all other participants and filed with the Hearing Clerk by the presiding officer at the hearing, or by the Commissioner, depending on who received the communication. An oral communication contrary to this section must be immediately recorded in a written memorandum and similarly served on all other participants and filed with the Hearing Clerk. A person, including a representative of a participant in the hearing, who is involved in an oral communication contrary to this section, must, if possible, be made available for cross-examination during the hearing with respect to the substance of that conversation. Rebuttal testimony pertinent to a written or oral communication contrary to this section will be permitted. Cross-examination and rebuttal testimony will be transcribed and filed with the Hearing Clerk.

(e) The prohibitions specified in paragraph (d) of this section apply to a person who knows of a notice of hearing in advance of its publication from the time the knowledge is acquired.

(f) The making of a 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.

§ 10.60 Referral by court.

(a) This section applies when a Federal, State, or local court holds in abeyance, or refers to the Commissioner, any matter for an initial administrative determination under § 10.25(c) or § 10.45(b).

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

(c) In reviewing the matter, the Commissioner may use the following procedures:

(1) Conferences, meetings, discussions, and correspondence under § 10.65.

(2) A hearing under Parts 12, 13, 14, 15, or 16.

(3) A notice published in the Federal Register requesting information and views.

(4) Any other public procedure established in other sections of this chapter and expressly applicable to the matter under those provisions.

(d) If the Commissioner's review of the matter results in a proposed rule, the provisions of § 10.40 or § 10.50 also apply.

§ 10.65 Meetings and correspondence.

(a) In addition to public hearings and proceedings established under this part and other sections of this chapter, meetings may be held and correspondence may be exchanged between representatives of FDA and an interested person outside FDA on a matter within the jurisdiction of the laws administered by the Commissioner.

Action on meetings and correspondence does not constitute final administrative action subject to judicial review under § 10.45.

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

(1) The Commissioner shall give public notice through the public calendar described in § 10.100(a) of the time and place of the meeting and of the matters to be discussed, and may also publish notice of the meeting.

(2) The meeting will be informal, i.e., any interested person may attend and participate in the discussion without prior notice to the agency unless the notice of the meeting specifies otherwise.

(3) No official transcript or recording of the meeting will be made unless it appears to the agency that it will be useful. A written memorandum summarizing the substance of the meeting will be prepared by an FDA representative in all cases.

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

(d) Every person outside the Federal Government may request and obtain a private meeting with a representative of FDA in agency offices to discuss a matter.

(1) The person requesting a meeting may be accompanied by a reasonable number of employees, consultants, or other persons with whom there is a commercial arrangement within the meaning of § 20.81(a). Neither FDA nor any other person may require the attendance of a 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 FDA.

(2) FDA will determine which representatives of the Agency will attend the meeting. The person requesting the meeting may request but not require or preclude the attendance of a specific FDA employee.

(3) Whenever appropriate (e.g., the meeting involves a matter covered by paragraph (c) of this section or other important matter, a decision on an issue, or statements or advice or conclusions to which future reference may be desirable), a written memorandum summarizing the substance of the meeting will be prepared by an FDA representative.

(4) A person who wishes to attend a private meeting, but who either is not permitted to attend by the person requesting the meeting or by FDA or who cannot attend because the meeting is conducted by telephone, may obtain a separate meeting with FDA to discuss the same matter or an additional matter.

(e) FDA employees have a responsibility to meet with all segments of the public to promote the objectives of the laws administered by the Agency. In pursuing this responsibility the following general policy applies 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 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, but may do so where it is in the public interest and will promote the objectives of the act.

(2) The agency representative may request that the meeting be open if that would be in the public interest. The agency representative may decline to participate in a meeting held as a private meeting if that will best serve the public interest.

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

(4) A meeting, whether open or closed, is subject to paragraph (d)(3) of this section with respect to memoranda summarizing the substance of the meeting.

(f) Representatives of FDA may initiate a meeting or correspondence with any person outside the Federal Government on any matter concerning the laws administered by the Commissioner.

(1) A meeting initiated by FDA representatives which involves a small number of interested persons, for example, 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. A meeting initiated by FDA representatives which involves a large number of interested persons, for example, 10 manufacturers of an ingredient in a discussion of appropriate testing or labeling, must be held as an open conference or meeting under paragraph (b) of this section.

(2) Whenever appropriate (e.g., the meeting involves a matter covered by paragraph (c) of this section or another important matter, a decision on an issue, or statements or advice or conclusions to which future reference may be desirable), a written memorandum summarizing the substance of the meeting will be prepared by an FDA representative.

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

(h) Memoranda of meetings prepared by an FDA representative or by any other person and all correspondence which relate to a matter pending before the agency will promptly be filed in the administrative file of the proceeding.

(i) A 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 will be summarized in a written memorandum which is to be forwarded to the Food and Drug Administration, Office of Legislative Affairs. This provision does not restrict the right of an agency employee to participate in the meeting.

(j) A meeting of an advisory committee is subject to the requirements of part 14.

(k) Under 42 U.S.C. 2631(a)(8), a log or summary is to be made of all meetings between representatives of FDA and industry and other interested parties to implement the Radiation Control for Health and Safety Act of 1968.

§ 10.70 Documentation of significant decisions in administrative file.

(a) This section applies to every significant FDA decision on any matter under the laws administered by the Commissioner, whether it is raised formally, for example, by a petition or informally, for example, by correspondence.

(b) FDA employees responsible for handling a matter are responsible for insuring the completeness of the administrative file relating to it. The file must contain—

(1) Appropriate documentation of the basis for the decision, including relevant evaluations, reviews, memoranda, letters, opinions of consultants, minutes

of meetings, and other pertinent written documents; and

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

(i) The recommendations and decisions are to reveal significant controversies or differences of opinion and their resolution.

(ii) An agency employee working on a matter and, consistent with the prompt completion of other assignments, an agency employee who has worked on a matter may record individual views on that matter in a written memorandum, which is to be placed in the file.

(c) A written document placed in an administrative file must—

(1) Relate to the factual, scientific, legal or related issues under consideration;

(2) Be dated and signed by the author;

(3) Be directed to the file, to appropriate supervisory personnel, and to other appropriate employees, and show all persons to whom copies were sent;

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

(5) If it records the views, analyses, recommendations, or decisions of an agency employee in addition to the author, be given to the other employees; and

(6) Once completed (i.e., typed in final form, dated, and signed) not be altered or removed. Later additions to or revisions of the document must be made in a new document.

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

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

§ 10.75 Internal agency review of decisions.

(a) A decision of an FDA employee, other than the Commissioner, on a matter, is subject to review by the employee's supervisor under the following circumstances:

(1) At the request of the employee.

(2) On the initiative of the supervisor.

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

(4) As required by delegations of authority.

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

(c) An interested person outside the agency may request internal agency review of a decision through the established agency channels of supervision or review. Personal review of these matters by bureau directors or the office of the Commissioner will occur for any of the following purposes:

(1) To resolve an issue that cannot be resolved at lower levels within the agency (e.g., between two parts of a bureau or other component of the agency, between two bureaus or other components of the agency, or 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 delegations of authority.

(d) Internal agency review of a decision must be based on the information in the administrative file. If an interested person presents new information not in the file, the matter will be returned to the appropriate lower level in the agency for reevaluation based on the new information.

§ 10.80 Dissemination of draft FEDERAL REGISTER notices and regulations.

(a) A representative of FDA may discuss orally or in writing with an interested person ideas and recommendations for notices or regulations. FDA welcomes assistance in developing ideas for, and in gathering the information to support, notices and regulations.

(b) Notices and proposed regulations. (1) Once it is determined that a notice or proposed regulation will be prepared, the general concepts may be discussed by a representative of FDA with an interested person. Details of a draft of a notice or proposed regulation may be discussed with a person outside the executive branch only with the specific permission of the Commissioner. The permission must be in writing and filed with the Hearing Clerk.

(2) A draft of a notice or proposed regulation or its preamble, or a portion of either, may be furnished to an interested person outside the executive branch only if it is made available to all interested persons by a notice published in the **Federal Register.** A draft of a notice or proposed regulation made available in this manner may, without the prior permission of the Commissioner, be discussed with an interested person to clarify and resolve questions raised and concerns expressed about the draft.

(c) After publication of a notice or proposed regulation in the **Federal Register,** and before preparation of a draft of the final notice or regulation, a representative of FDA may discuss the proposal with an interested person as provided in paragraph (b)(2) of this section.

(d) Final notices and regulations. (1) Details of a draft of a final notice or regulation may be discussed with an interested person outside the executive branch only with the specific permission of the Commissioner. The permission must be in writing and filed with the Hearing Clerk.

(2) A draft of a final notice or regulation or its preamble, or any portion of either, may be furnished to an interested person outside the executive branch 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 made available to an interested person in this manner may, without the prior permission of the Commissioner, be discussed as provided in paragraph (b)(2) of this section.

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

(ii) If additional technical information from a person outside the executive branch is necessary to draft the final notice or regulation or its preamble, it will be requested by FDA in general terms and furnished directly to the hearing clerk to be included as part of the administrative record.

(iii) If direct discussion by FDA of a draft of a final notice or regulation or its preamble is required with a person outside the executive branch, appropriate protective procedures will be undertaken to make certain that a full and impartial administrative record is established. Such procedures may include either—

(*a*) The scheduling of an open public meeting under § 10.65(b) at which interested persons may participate in review of and comment on the draft document; or

(*b*) The preparation of a tentative final regulation or tentative revised final regulation under § 10.40(f)(9), on which interested persons will be given an additional period of time for oral and written comment.

(e) After a final regulation is published, an FDA representative may discuss any aspect of it with an interested person.

(f) In addition to the requirements of this section, the provisions of § 10.55 apply to the promulgation of a regulation subject to § 10.50 and Part 12.

(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 the regulation. Every meeting with a petitioner relating to the draft will be recorded in a written memorandum, and all memoranda and correspondence will be filed with the Hearing Clerk as part of the administrative record of the regulation under the provisions of § 10.65.

(h) In accordance with 42 U.S.C 263f, the Commissioner shall consult with interested persons 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, is being considered for an electronic product, and any draft of any proposed or final standard will be furnished to an interested person upon request and may be discussed in detail.

(i) The provisions of § 10.65 apply to meetings and correspondence relating to draft notices and regulations.

(j) The provisions of this section restricting discussion and disclosure of draft notices and regulations do not apply to situations covered by §§ 20.83 through 20.89.

§ 10.85 Advisory opinions.

(a) An interested person may request an advisory opinion from the Commissioner on a matter of general applicability.

(1) The request will be granted whenever feasible.

(2) The request may be denied if—

(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; or

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

(b) A request for an advisory opinion is to be submitted in accordance with § 10.20, is subject to the provisions of § 10.30 (c) through (l), and must 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/her 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.

(Signature) _____
(Person making request) _____
(Mailing address) _____
(Telephone number) _____

(c) The Commissioner may respond to an oral or written request to the agency as a request for an advisory opinion, in which case the request will be filed with the Hearing Clerk and be subject to this section.

(d) A statement of policy or interpretation made in the following documents, unless subsequently repudiated by the agency or overruled by a court, will 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 FDA between 1938 and 1946.

(3) Compliance policy guides issued by FDA 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 before July 1, 1975, and filed in a permanent public file for prior advisory opinions maintained by the Freedom of Information Staff (HFI–35).

(5) Guidelines issued by FDA under § 10.90(b).

(e) An advisory opinion represents the formal position of FDA on a matter and except as provided in paragraph (f) of this section, obligates the agency to follow it until it is amended or revoked. The Commissioner may not recommend legal action against a person or product with respect to an 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 before amending or revoking the opinion. This action may be taken only with the approval of the Commissioner, who may not delegate this function. Appropriate amendment or revocation of the advisory opinion involved will be expedited.

(g) An advisory opinion may be amended or revoked at any time after it has been issued. Notice of amendment or revocation will be given in the same manner as notice of the advisory opinion was originally given or in the **Federal Register**, and will 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 will 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 which has subsequently been amended or revoked is acceptable to FDA unless the Commissioner determines that substantial public interest considerations preclude continued acceptance. Whenever possible, an amended or revoked advisory opinion will state when action previously undertaken or completed does not remain acceptable, and any transition period that may be applicable.

(i) An interested person may submit written comments on an advisory opinion or modified advisory opinion. Four copies of any comments are to be sent to the Hearing Clerk for inclusion in the public file on the advisory opinion. Individuals may submit only one copy. Comments will 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 FDA employee constitutes an advisory opinion only if it is issued in writing under this section. A statement or advice given by an FDA employee orally, or given in writing but not under this section or § 10.90, 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 FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

§ 10.90 FDA regulations, guidelines, recommendations, and agreements.

(a) *Regulations.* FDA regulations are promulgated in the **Federal Register** under § 10.40 or § 10.50 and codified in the Code of Federal Regulations. Regulations may contain provisions that will be enforced as legal requirements, or which are intended only as guidelines and recommendations, or both. The dissemination of draft notices and regulations is subject to § 10.80.

(b) *Guidelines.* FDA guidelines are included in the public file of guidelines established by the Hearing Clerk, under this paragraph, unless they have been published as regulations under paragraph (a) of this section.

(1) Guidelines establish principles or practices of general applicability and do not include decisions or advice on particular situations. Guidelines relate to 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 are acceptable to FDA for a subject matter which falls within the laws administered by the Commissioner.

(i) A person may rely upon a guideline with assurance that it is acceptable to FDA, or may follow different procedures or standards. When different procedures or standards are chosen, a person may, but is not required to, discuss the matter in advance with FDA 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 FDA assures acceptance of a test as scientifically valid, if properly conducted, but does not assure approval of any ingredient or product so tested. Test results or other available information may require disapproval or additional testing.

(2) A guideline represents the formal position of FDA on a matter 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 may not recommend legal action against a person or product with respect to an action taken in conformity with a guideline issued under 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 before amending or revoking the guideline as provided in paragraph (b)(5) of this section. This action may be taken only with the approval of the Commissioner, who may not delegate that function. Amendment or revocation of the guideline involved will be expedited.

(4) A guideline will be included in the public file upon approval of the guideline by the Commissioner or relevant bureau director and publication of a notice of its availability. The notice will 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 by the Commissioner or relevant bureau director and publication of a notice of the amendment or revocation. The notice will 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 will be retained in the public file permanently so that a complete record of the development of each guideline is available.

(6) Action undertaken or completed in conformity with a guideline which has subsequently been amended or revoked will remain acceptable to FDA unless the Commissioner determines that substantial public interest considerations preclude continued acceptance. This determination may be made at the time of or after amendment or revocation of the guideline. Whenever possible, notice of an amended or revoked guideline will 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 of an amended or revoked guideline will state that an interested person may submit written comments on the guideline. Four copies of comments are to be sent to the Hearing Clerk for inclusion in the public file on the guideline. The comments will 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 a legal requirement.

(9) A statement relating to acceptable procedures or standards given by an FDA employee orally, or in writing but not under § 10.85 of 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 FDA, and does not bind or otherwise obligate the agency to the views expressed.

(10) Because of the large number of analytical methods involved in FDA activities, their length and complexity and the volume and frequency of amendment, paragraph (b)(4) of this section does not apply to analytical methods except to the extent that the Commissioner concludes that particular analytical methods should be included in the public file for a particular purpose. FDA analytical methods are available for public disclosure under Part 20.

(11) The dissemination of draft guidelines is subject to the same provisions as the dissemination of draft notices and regulations under § 10.80.

(c) *Recommendations.* In addition to the guidelines subject to paragraph (b) of this section, FDA 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 under 42 U.S.C 243 and 263d(b). These recommendations may, in the discretion of the Commissioner, be handled under the procedures established in paragraph (b) of this section, except that the recommendations will be included in a separate public file of recommendations established by the Hearing Clerk and will be separated from the guidelines in the notice of availability published in the **Federal Register**, or be published in

the **Federal Register** as regulations under paragraph (a) of this section.

(d) *Agreements.* Formal agreements, memoranda of understanding, or other similar written documents executed by FDA and another person will be included in the public file on agreements established by the Freedom of Information Staff (HFI–35) under § 20.108. A document not included in the public file is deemed to be rescinded and has no force or effect whatever.

§ 10.95 Participation in outside standard-setting activities.

(a) *General.* This section applies to participation by FDA employees in standard-setting activities outside the agency. Standard-setting activities include matters such 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. FDA encourages employee participation in outside standard-setting activities that are in the public interest.

(b) *Standard-setting activities by other Federal Government agencies.* (1) An FDA employee may participate in these activities after approval of the activity under procedures specified in the current agency Staff Manual Guide.

(2) Approval forms and all pertinent background information describing the activity will be included in the public file on standard-setting activities established in the Public Records and Documents Center.

(3) If a member of the public is invited by FDA to present views to, or to accompany, the FDA employee at a meeting, the invitations will be extended to a representative sampling of the public, including consumer groups, industry associations, professional societies, and academic institutions.

(4) An FDA employee appointed as the liaison representative to an activity shall refer all requests for information about or participation in the activity to the group or organization responsible for the 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) An FDA employee may participate in these activities after approval of the activity under procedures specified in the current agency Staff Manual Guide.

(2) Approval forms and all pertinent background information describing the activity will be included in the public file on standard-setting activities established by the Freedom of Information Staff (HFI–35).

(3) The availability for public disclosure of records relating to the activity will be governed by Part 20.

(4) If a member of the public is invited by FDA to present views to, or to accompany, the FDA employee at a meeting, the invitation will be extended to a representative sampling of the public, including consumer groups, industry associations, professional societies, and academic institutions.

(5) An FDA employee appointed as the liaison representative to an activity shall refer all requests for information about or participation in the activity to the group or organization responsible for the activity.

(d) *Standard-setting activities by private groups and organizations.* (1) an FDA employee may engage in these activities after approval of the activity under procedures specified in the current agency Staff Manual Guide. A request for official participation must be made by the group or organization in writing, must describe the scope of the activity, and must demonstrate that the minimum standards set out in paragraph (d)(5) of this section are met. Except as provided in paragraph (d)(7) of this section, a request that is granted will 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 does not connote FDA agreement with, or endorsement of, any decisions reached; and

(iii) That participation by the individual precludes service as the deciding official on the standard involved if it should later come before FDA. The deciding official is the person who signs a document ruling upon the standard.

(2) The letter requesting official FDA participation, the approval form, and the Commissioner's or bureau director's letter, together with all pertinent background information describing the activities involved, will be included in the public file on standard-setting activities established by the Freedom of Information Staff (HFI–35).

(3) The availability for public disclosure of records relating to the activities will be governed by Part 20.

(4) An FDA employee appointed as the liaison representative to an activity shall refer all requests for information about or participation in the activity to the group or organization responsible for the activity.

(5) The following minimum standards apply to an outside private standard-setting activity in which FDA employees participate:

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

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

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

(6) Membership of an FDA employee in an organization that also conducts a standard-setting activity does not invoke the provisions of this section unless the employee participates in the standard-setting activity. Participation in a standard-setting activity is subject to this section.

(7) The Commissioner may determine in writing that, because direct involvement by FDA in a particular standard-setting activity is in the public interest and will promote the objectives of the act and the agency, the participation is exempt from the requirements of paragraph (d)(1) (ii) and/or (iii) of this section. This determination will be included in the public file on standard-setting activities established by the Public Records and Documents Center and in any relevant administrative file. The activity may include the establishment and validition 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 FDA and the

associations of State and local government officials listed below in this paragraph, and the large number of agency employees who are members of or work with these associations, participation in the activities of these associations is exempt from paragraph (d) (1) through (7) of this section, except that a list of the committees and other groups of these associations will be included in the public file on standard-setting activities established by the Freedom of Information Staff (HFI–35):

(i) American Public Health Association.

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

(iii) Association of Food and Drug Officials.

(iv) Association of Official Analytical Chemists.

(v) Conference of State Sanitary Engineers.

(vi) Conference of Radiation Control Program Directors.

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

(viii) Interstate Seafood Seminar.

(ix) National Conference on Interstate Milk Shipments.

(x) National Conference on Weights and Measures.

(xi) National Environmental Health Association.

(xii) National Shellfish Sanitation Program.

§ 10.100 Public calendars.

(a) *Prospective public calendar of public proceedings.* (1) A public calendar will be prepared and made publicly available each week showing, to the extent feasible, for the following 4 weeks, the public meetings, conferences, hearings, advisory committee meetings, seminars, and other public proceedings of FDA, and other significant public events involving FDA, e.g., congressional hearings.

(2) A copy of this public calendar will be placed on public display in the following places: (i) Office of the Hearing Clerk.

(ii) Office of the Associate 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 will be prepared and made publicly available each week showing for the previous week meetings with persons outside the executive branch and other significant events involving the representatives of FDA designated under paragraph (b)(3) of this section, but telephone conversations will 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 will not be included. Meetings with members of the judiciary, representatives of Congress, or staffs of congressional committees will 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) The calendar will include all meetings, conferences, seminars, social events sponsored by the regulated industry, and speeches. The calendar will specify the date and the person and subject matter involved. When more than one FDA representative is in attendance, only the presiding or head representative will report the meeting on the public calendar. If a large number of persons is involved, the name of each need not be specified. Meetings that 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 FDA) will not be reported.

(3) The following FDA representatives and their deputies are 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) Executive and Special Assistants to the Commissioner.

(v) Executive Director for Regional Operations.

(vi) Director, National Center for Toxicological Research.

(vii) Bureau Directors.

(viii) Chief Counsel for the Food and Drug Administration, or any representative of that office attending on behalf of the Chief Counsel.

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

(i) Office of the Hearing Clerk.

(ii) Office of the Associate 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.

§ 10.105 Representation by an organization.

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

(b) A petition, comment, objection, or other representation by an organization will not abridge the right of a member to take individual action of a similar type, in the member's own name.

(c) It is requested that each organization participating in FDA administrative proceedings file annually with the Hearing Clerk a current list of all of the members of the organization.

(d) The filing by an organization of an objection or request for hearing under §§ 12.20 through 12.22 does not provide a member a legal right with respect to the objection or request for hearing that the member may individually exercise. A member of an organization wishing to file an objection or request for hearing must do so individually.

(e) In a 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. Regardless of 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 a member of the organization that the issues are precluded from further litigation by the member under the doctrines of collateral estoppel or res judicata.

§ 10.110 Settlement proposals.

At any time in the course of a proceeding subject to this part, a person may propose settlement of the issues involved. A participant in a proceeding will have an opportunity to consider a proposed settlement. Unaccepted proposals of settlement and related matters, e.g., proposed stipulations not agreed to, will not be admissible in evidence in an FDA administrative proceeding. FDA will oppose the admission in evidence of settlement information in a court proceeding or in another administrative proceeding.

PART 12—FORMAL EVIDENTIARY PUBLIC HEARING

Subpart A—General Provisions

Subpart B—Initiation of Proceedings

Subpart C—Appearance and Participation

Subpart D—Presiding Officer

Subpart E—Hearing Procedures

Subpart F—Administrative Record

Subpart G—Initial and Final Decisions

Subpart H—Judicial Review

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. 604–607 as amended (21 U.S.C. 41–50); sec. 2 et seq., Pub. L. 783, 44 Stat. 1406 as amended (15 U.S.C. 401 et seq.); sec. 1 et seq., Pub. L. 89–755, 80 Stat. 1296 as amended (15 U.S.C. 1451 et seq.).

Subpart A—General Provisions

§ 12.1 Scope.

The procedures in this part apply when—

(a) A person has a right to an opportunity for a hearing under the laws specified in § 10.50; or

(b) The Commissioner concludes that it is in the public interest to hold a formal evidentiary public hearing on any matter before FDA.

Subpart B—Initiation of Proceedings

§ 12.20 Initiation of a hearing involving the issuance, amendment, or revocation of a regulation.

(a) A proceeding under section 409(f), 502(n), 507(f), 512(n)(5), 701(e), or 706(d) of the act or section 4 or 5 of the Fair Packaging and Labeling Act may be initiated—

(1) By the Commissioner on the Commissioner's own initiative, e.g., as provided in § 170.15 for food additives; or

(2) By a petition—

(i) In the form specified elsewhere in this chapter, e.g., the form for a color additive petition in § 71.1 or for an antibiotic petition in § 431.50; or

(ii) If no form is specified, by a petition under § 10.30.

(b) If the Commissioner receives a petition under paragraph (a)(2) of this section, the Commissioner will—

(1) If it involves any matter subject to section 701(e) of the act or section 4 or 5 of the Fair Packaging and Labeling Act, and meets the requirements for filing, follow the provisions of § 10.40 (b) through (f);

(2) If it involves a color additive or food additive, and meets the requirements for filing in §§ 71.1 and 71.2, or in 171.1, 171.6, 171.7, and 171.100, publish a notice of filing of the petition within 30 days after the petition is filed instead of a notice of proposed rulemaking.

(c) The Commissioner may issue, amend, or revoke an antibiotic regulation without the requirements of notice and public procedure in § 10.40(b) or delayed effective date in § 10.40(c)(4), on the Commissioner's own initiative or as a result of a petition containing the required evidence of safety and effectiveness in the circumstances described in § 10.40(e)(1).

(d) The notice promulgating the regulation will describe how to submit objections and requests for hearing.

(e) On or before the 30th day after the date of publication of a final regulation, or of a notice withdrawing a proposal initiated by a petition under § 10.25(a), a person may submit to the Commissioner written objections and a request for a hearing. The 30-day period may not be extended except that additional information supporting an objection may be received after 30 days upon a showing of inadvertent omission and hardship, and if review of the objection and request for hearing will not thereby be impeded. If, after a final color additive regulation is published, a petition or proposal relating to the regulation is referred to an advisory committee in accordance with section 706(b)(5)(C) of the act, objections and requests for a hearing may be submitted on or before the 30th day after the date on which the order confirming or modifying the Commissioner's previous order is published.

§ 12.21 Initiation of a hearing involving the issuance, amendment, or revocation of an order.

(a) A proceeding under section 505 (d) or (e), 512 (d), (e), (m) (3) or (4), of 515(g)(1) of the act, or section 351(a) of the Public Health Service Act, may be initiated—

(1) By the Commissioner on the Commissioner's own initiative;

(2) By a petition in the form specified elsewhere in this chapter, e.g., § 314.1(c) for new drug applications, § 514.1 for new animal drug applications, § 514.2 for applications for animal feeds, or § 601.3 for licenses for biologic products; or

(3) By a petition under § 10.30.

(b) A notice of opportunity for hearing on a proposal to deny or revoke approval of all or part of an order will be published together with an

explanation of the grounds for the proposed action. The notice will describe how to submit requests for hearing. A person subject to the notice has 30 days after its issuance to request a hearing. The 30-day period may not be extended.

(c) The Commissioner may use an optional procedure specified in § 10.30(h) to consider issuing, amending, or revoking an order.

§ 12.22 Filing objections and requests for a hearing on a regulation or order.

(a) Objections and requests for a hearing under § 12.20(d) must be submitted to the Hearing Clerk and will be accepted for filing if they meet the following conditions:

(1) They are submitted within the time specified in § 12.20(e).

(2) Each objection is separately numbered.

(3) Each objection specifies with particularity the provision of the regulation or proposed order objected to.

(4) Each objection on which a hearing is requested specifically so states. Failure to request a hearing on an objection constitutes a waiver of the right to a hearing on that objection.

(5) Each objection for which a hearing is requested includes a detailed description and analysis of the factual information to be presented in support of the objection. Failure to include a description and analysis for an objection constitutes a waiver of the right to a hearing on that objection. The description and analysis may be used only for the purpose of determining whether a hearing has been justified under § 12.24, and do not limit the evidence that may be presented if a hearing is granted.

(i) A copy of any report, article, survey, or other written document relied upon must be submitted, except if the document is—

(*a*) An FDA document that is routinely publicly available;

(*b*) A recognized medical or scientific textbook that is readily available to the agency; or

(*c*) A designated journal listed in § 310.9 or § 510.95.

(ii) A summary of the nondocumentary testimony to be presented by any witnesses relied upon must be submitted.

(b) Requests for hearing submitted under § 12.21 will be submitted to the hearing clerk and will be accepted for filing if they meet the following conditions:

(1) They are submitted on or before the 30th day after the date of publication of the notice of opportunity for hearing.

(2) They comply with §§ 314.200, 514.200, or 601.7(a).

(c) If an objection or request for a public hearing fails to meet the requirements of this section and the deficiency becomes known to the Hearing Clerk, the Hearing Clerk shall return it with a copy of the applicable regulations, indicating those provisions not complied with. A deficient objection or request for a hearing may be supplemented and subsequently filed if submitted within the 30-day time period specified in § 12.20(e) or § 12.21(b).

(d) If another person objects to a regulation issued in response to a petition submitted under § 12.20(a)(2), the petitioner may submit a written reply to the Hearing Clerk.

§ 12.23 Notice of filing of objections.

As soon as practicable after the expiration of the time for filing objections to and requests for hearing on agency action involving the issuance, amendment, or revocation of a regulation under sections 502(n), 701(e), or 706(d) of the act or sections 4 or 5 of the Fair Packaging and Labeling Act, the Commissioner shall publish a notice in the **Federal Register** specifying those parts of the regulation that have been stayed by the filing of proper objections and, if no objections have been filed, stating that fact. The notice does not constitute a determination that a hearing is justified on any objections or requests for hearing that have been filed. When to do so will cause no undue delay, the notice required by this section may be combined with the notices described in §§ 12.28 and 12.35.

§ 12.24 Ruling on objections and requests for hearing.

(a) As soon as possible the Commissioner will review all objections and requests for hearing filed under § 12.22 and determine—

(1) Whether the regulation should be modified or revoked under § 12.26;

(2) Whether a hearing has been justified; and

(3) Whether, if requested, a hearing before a Public Board of Inquiry under Part 13 or before a public advisory committee under Part 14 or before the Commissioner under Part 15 has been justified.

(b) A request for a hearing will be granted if the material submitted shows the following:

(1) There is a genuine and substantial issue of fact for resolution at a hearing. A hearing will not be granted on issues of policy or law.

(2) The factual issue can be resolved by available and specifically identified reliable evidence. A hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions.

(3) The data and information submitted, if established at a hearing, would be adequate to justify resolution of the factual issue in the way sought by the person. A hearing will be denied if the Commissioner concludes that the data and information submitted are insufficient to justify the factual determination urged, even if accurate.

(4) Resolution of the factual issue in the way sought by the person is adequate to justify the action requested. A hearing will not be granted on factual issues that are not determinative with respect to the action requested, e.g., if the Commissioner concludes that the action would be the same even if the factual issue were resolved in the way sought, or if a request is made that a final regulation include a provision not reasonably encompassed by the proposal. A hearing will be granted upon proper objection and request when a food standard or other regulation is shown to have the effect of excluding or otherwise affecting a product or ingredient.

(5) The action requested is not inconsistent with any provision in the act or any regulation in this chapter particularizing statutory standards. The proper procedure in those circumstances is for the person requesting the hearing to petition for an amendment or waiver of the regulation involved.

(6) The requirements in other applicable regulations, e.g., §§ 10.20, 12.21, 12.22, 314.200, 430.20(b), 514.200, and 601.7(a), and in the notice promulgating the final regulation or the notice of opportunity for hearing are met.

(c) In making the determination in paragraph (a) of this section, the Commissioner may use any of the optional procedures specified in § 10.30(h) or in other applicable regulations, e.g., §§ 314.200, 430.20(b), 514.200, and 601.7(a).

(d) If it is uncertain whether a hearing has been justified under the principles in paragraph (b) of this section, and the Commissioner concludes that summary decision against the person requesting a hearing should be considered, the Commissioner may serve upon the person by registered mail a proposed order denying a hearing. The person has 30 days after receipt of the proposed

order to demonstrate that the submission justifies a hearing.

§ 12.26 Modification or revocation or regulation or order.

If the Commissioner determines upon review of an objection or request for hearing that the regulation or order should be modified or revoked, the Commissioner will promptly take such action by notice in the **Federal Register.** Further objections to or requests for hearing on the modification or revocation may be submitted under §§ 12.20 through 12.22 but no further issue may be taken with other provisions in the regulation or order. Objections and requests for hearing that are not affected by the modification or revocation will remain on file and be acted upon in due course.

§ 12.28 Denial of hearing in whole or in part.

If the Commissioner determines upon review of the objections or requests for hearing that a hearing is not justified, in whole or in part, a notice of the determination will be published.

(a) The notice will state whether the hearing is denied in whole or in part. If the hearing is denied in part, the notice will be combined with the notice of hearing required by § 12.35, and will specify the objections and requests for hearing that have been granted and denied.

(1) Any denial will be explained. A denial based on an analysis of the information submitted to justify a hearing will explain the inadequacy of the information.

(2) The notice will confirm or modify or stay the effective date of the regulation or order involved.

(b) The record of the administrative proceeding relating to denial of a public hearing in whole or in part on an objection or request for hearing consists of the following:

(1) If the proceeding involves a regulation—

(i) The documents specified in § 10.40(g);

(ii) The objections and requests for hearing filed by the Hearing Clerk;

(iii) If the proceeding involves a color additive regulation referred to an advisory committee in accordance with section 706(b)(5)(C) of the act, the committee's report and the record of the committee's proceeding; and

(iv) The notice denying a formal evidentiary public hearing.

(2) If the proceeding involves an order—

(i) The notice of opportunity for hearing;

(ii) The requests for hearing filed by the Hearing Clerk;

(iii) The transcripts, minutes of meetings, reports, **Federal Register** notices, and other documents constituting the record of any of the optional procedures specified in § 12.24(c) used by the Commissioner, but not the transcript of a closed portion of a public advisory committee meeting; and

(iv) The notice denying the hearing.

(c) The record specified in paragraph (b) of this section is the exclusive record for the Commissioner's decision on the complete or partial denial of a hearing. The record of the proceeding will be closed as of the date of the Commissioner's decision unless another date is specified. A person who requested and was denied a hearing may submit a petition for reconsideration under § 10.33 or a petition for stay of action under § 10.35. A person who wishes to rely upon information or views not included in the administrative record shall submit them to the Commissioner with a petition under § 10.25(a) to modify the final regulation or order.

(d) Denial of a request for a hearing in whole or in part is final agency action reviewable in the courts, under the statutory provisions governing the matter involved, as of the date of publication of the denial in the **Federal Register.**

(1) Before requesting a court for a stay of action pending review, a person shall first submit a petition for a stay of action under § 10.35.

(2) Under 28 U.S.C. 2112(a), FDA will request consolidation of all petitions on a particular matter.

(3) The time for filing a petition for judicial review of a denial of a hearing on an objection or issue begins on the date the denial is published in the **Federal Register.** (i) When an objection or issues relates to a regulation, if a hearing is denied on all objections and issues concerning a part of the proposal the effectiveness of which has not been deferred pending a hearing on other parts of the proposal; or (ii) when an issue relates to an order, if a hearing is denied on all issues relating to a particular new drug application, new animal drug application, device premarket approval application or product development protocol, or biologics license. The failure to file a petition for judicial review within the period established in the statutory provision governing the matter involved constitutes a waiver of the right to judicial review of the objection or issue, regardless whether a hearing has been granted on other objections and issues.

§ 12.30 Judicial review after waiver of hearing on a regulation.

(a) A person with a right to submit objections and a request for hearing under § 12.20(d) may submit objections and waive the right to a hearing. The waiver may be either an explicit statement, or a failure to request a hearing, as provided in 12.22(a)(4).

(b) If a person waives the right to a hearing, the Commissioner will rule upon the person's objections under §§ 12.24 through 12.28. As a matter of discretion, the Commissioner may also order a hearing on the matter under any of the provisions of this part.

(c) If the Commissioner rules adversely on a person's objection, the person may petition for judicial review in a U.S. Court of Appeals under the act.

(1) The record for judicial review is the record designated in § 12.28(b)(1).

(2) The time for filing a petition for judicial review begins as of the date of publication of the Commissioner's ruling on the objections.

§ 12.32 Request for alternative form of hearing.

(a) A person with a right to request a hearing may waive that right and request one of the following alternatives:

(1) A hearing before a Public Board of Inquiry under Part 13.

(2) A hearing before a public advisory committee under Part 14.

(3) A hearing before the Commissioner under Part 15.

(b) The request—

(1) May be on the person's own initiative or at the suggestion of the Commissioner.

(2) Must be submitted in the form of a citizen petition under § 10.30 before publication of a notice of hearing under § 12.35 or a denial of hearing under § 12.28; and

(3) Must be—

(i) In lieu of a request for a hearing under this part; or

(ii) If submitted after or with a request for hearing, in the form of a waiver of the right to request a hearing conditioned on an alternative form of hearing. Upon acceptance by the Commissioner, the waiver becomes binding and may be withdrawn only by waiving any right to any form of hearing unless the Commissioner determines otherwise.

(c) When more than one person requests and justifies a hearing under this part, an alternative form of hearing may by used only if all the persons

concur and waive their right to request a hearing under this part.

(d) The Commissioner will determine whether an alternative form of hearing should be used, and if so, which alternative is acceptable, after considering the requests submitted and the appropriateness of the alternatives for the issues raised in the objections. The Commissioner's acceptance is binding unless, for good cause, the Commissioner determines otherwise.

(e) The Commissioner will publish a notice of an alternative form of hearing setting forth the following information:

(1) The regulation or order that is the subject of the hearing.

(2) A statement specifying any part of the regulation or order that has been stayed by operation of law or in the Commissioner's discretion.

(3) The time, date, and place of the hearing, or a statment that such information will be contained in a later notice.

(4) The parties to the hearing.

(5) The issues at the hearing. The statement of issues determines the scope of the hearing.

(6) If the hearing will be conducted by a Public Board of Inquiry, the time within which—

(i) The parties should submit nominees for the Board under § 13.10(b);

(ii) A notice of participation under § 12.45 should be filed; and

(iii) Participants should submit written information under § 13.25. The notice will list the contents of the portions of the administrative record relevant to the issues at the hearing before the Board. The portions listed will be placed on public display in the office of the Hearing Clerk before the notice is published. Additional copies of material already submitted under § 13.25 need not be included with any later submissions.

(f)(1) The decision of a hearing before a Public Board of Inquiry or a public advisory committee under this section has legal status of and will be handled as an initial decision under § 12.120.

(2) The decision of a public hearing before the Commissioner under this section will be issued as a final order. The final order will have the same content as an initial decision, as specified in § 12.120 (b) and (c).

(3) Thereafter, the participants in the proceeding may pursue the administrative and court remedies specified in §§ 12.120 through 12.159.

(g) If a hearing before a public advisory committee or a hearing before the Commissioner is used as an alternative form of hearing, all submissions will be made to the Hearing Clerk, and § 10.20(j) governs their availability for public examination and copying.

(h) This section does not affect the right to an opportunity for a hearing before a public advisory committee under section 515(g)(2) of the act regarding device premarket approval applications and product development protocols. Advisory committee hearing procedures are found in part 14.

§ 12.35 Notice of hearing; stay of action.

(a) If the Commissioner determines upon review of the objections and requests for hearing that a hearing is justified on any issue, the Commissioner will publish a notice setting forth the following:

(1) The regulation or order that is the subject of the hearing.

(2) A statement specifying any part of the regulation or order that has been stayed by operation of law or in the Commissioners discretion.

(3) The parties to the hearing.

(4) The issues of fact on which a hearing has been justified.

(5) A statement of any objections or requests for hearing for which a hearing has not been justified, which are subject to § 12.28.

(6) The presiding officer, or a statement that the presiding officer will be designated in a later notice.

(7) The time within which notices of participation should be filed under § 12.45.

(8) The date, time, and place of the prehearing conference, or a statement that the date, time, and place will be announced in a later notice. The pre-hearing conference may not commence until after the time expires for filing the notice of participation required by § 12.45(a).

(9) The time within which participants should submit written information and views under § 12.85. the notice will list the contents of the portions of the administrative record relevant to the issues at the hearing. The portions listed will be placed on public display in the office of the Hearing Clerk before the notice is published. Additional copies of material already submitted under § 12.85 need not be included with any later submissions.

(b) The statement of the issues determines the scope of the hearing and the matters on which evidence may be introduced. The issues may be revised by the presiding officer. A participant may obtain interlocutory review by the Commissioner of a decision by the presiding officer to revise the issues to include an issue on which the Commissioner has not granted a hearing or to eliminate an issue on which a hearing has been granted.

(c) A hearing is deemed to begin on the date of publication of the notice of hearing.

§ 12.37 Effective date of a regulation.

(a) If no objections are filed and no hearing is requested on a regulation under § 12.20(e), the regulation is effective on the date specified in the regulation as promulgated.

(b) The Commissioner shall publish a confirmation of the effective date of the regulation. The **Federal Register** document confirming the effective date of the regulation may extend the time for compliance with the regulation.

§ 12.38 Effective date of an order.

(a) If a person who is subject to a notice of opportunity for hearing under § 12.21(b) does not request a hearing, the Commissioner will—

(1) Publish a final order denying or withdrawing approval of an NDA, NADA, device premarket approval application, or biologics license, in whole or in part, or revoking a device product development protocol or notice of completion, or declaring that such a protocol has not been completed, and stating the effective date of the order; and

(2) If the order involves withdrawal of approval of an NADA, forthwith revoke, in whole or in part, the applicable regulation, under section 512(i) of the act.

(b) If a person who is subject to a notice of opportunity for hearing under § 12.21(b) requests a hearing and others do not, the Commissioner may issue a final order covering all the drug or device products at once or may issue more than one final order covering different drug or device products at different times.

Subpart C—Appearance and Participation

§ 12.40 Appearance.

(a) A person who has filed a notice of participation under § 12.45 may appear in person or by counsel or other representative in any hearing and, subject to § 12.89, may be heard concerning all relevant issues.

(b) The presiding officer may strike a person's appearance for violation of the rules of conduct in § 12.90.

§ 12.45 Notice of participation.

(a) Within 30 days after publication of the notice of hearing under § 12.35, a person desiring to participate in a hearing is to file with the Hearing Clerk

under § 10.20 a notice of participation in the following form:

(Date)

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

Notice of Participation

Docket No. ——]

Under 21 CFR Part 12, please enter the participation of:

(Name) ——————————
(Street address) ——————————
(City and State) ——————————
(Telephone number) ——————————

Service on the above will be accepted by:

(Name) ——————————
(Street address) ——————————
(City and State) ——————————
(Telephone number) ——————————

The following statements are made as part of this notice of participation:

A. *Specific interests.* (A statement of the specific interest of the person in the proceeding, including the specific issues of fact concerning which the person desires to be heard. This part need not be completed by a party to the proceeding.)

B. *Commitment to participate.* (A statement that the person will present documentary evidence or testimony at the hearing and will comply with the requirements of 21 CFR 12.85, or, in the case of a hearing before a Public Board of Inquiry, with the requirements of 21 CFR 13.25.)

(Signed) ——————————

(b) An amendment to a notice of participation should be filed with the hearing clerk and served on all participants.

(c) No person may participate in a hearing who has not filed a written notice of participation or whose participation has been stricken under paragraph (e) of this section.

(d) The presiding officer may permit the late filing of a notice of participation upon a showing of good cause.

(e) The presiding officer may strike the participation of a person for nonparticipation in the hearing or failure to comply with any requirement of this subpart, e.g., disclosure of information as required by § 12.85 or the prehearing order issued under § 12.92. Any person whose participation is stricken may petition the Commissioner for interlocutory review.

§ 12.50 Advice on public participation in hearings.

(a) *Designated agency contact.* All inquiries from the public about scheduling, location, and general procedures should be addressed to the Associate Commissioner for Regulatory Affairs (HFC–10), Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20857, or telephone 301–443–3480. The staff of the Associate Commissioner for Regulatory affairs will attempt to respond promptly to all inquiries from members of the public, as well as to simple requests for information from participants in hearings.

(b) *Hearing schedule changes.* Requests by hearing participants for changes in the schedule of a hearing or for filing documents, briefs, or other pleadings should be made in writing directly to the Administrative Law Judge (HF–3), Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20857.

(c) *Legal advice to individuals.* FDA does not have the resources to provide legal advice to members of the public concerning participation in hearings. Furthermore, to do so would compromise the independence of the Commissioner's office and invite charges of improper interference in the hearing process. Accordingly, the Associate Commissioner for Regulatory Affairs will not answer questions about the strengths or weakesses of a party's position at a hearing, litigation strategy, or similar matters.

(d) *Role of the office of the Chief Counsel.* Under no circumstances will the office of the Chief Counsel of FDA directly provide advice about a hearing to any person who is participating or may participate in the hearing. In every hearing, certain attorneys in the office are designated to represent the bureau or bureaus whose action is the subject of the hearing. Other members of the office, including ordinarily the Chief Counsel, are designated to advise the Commissioner on a final decision in the matter. It is not compatible with these functions, nor would it be professionally responsible, for the attorneys in the office of the Chief Counsel also to advise other participants in a hearing, or for any attorney who may be called on to advise the Commissioner to respond to inquiries from other participants in the hearing, for such participants may be urging views contrary to those of the bureau involved or to what may ultimately be the final conclusions of the Commissioner. Accordingly, members of the office of the Chief Counsel, other than the attorneys responsible for representing the bureau whose action is the subject of the hearing, will not answer questions about the hearing from any participant or potential participant.

(e) *Communication between participants and attorneys.* Participants in a hearing may communicate with the attorneys responsible for representing the bureau whose action is the subject of the hearing, in the same way that they may communicate with counsel for any other party in interest about the presentation of matters at the hearing. It would be inappropriate to bar discussion of such matters as stipulations of fact, joint presentation of witnesses, or possible settlement of hearing issues. Members of the public, including participants at hearings, are advised, however, that all such communications, including those by telephone, will be recorded in memoranda that can be filed with the Hearing Clerk.

Subpart D—Presiding Officer

§ 12.60 Presiding officer.

The presiding officer in a hearing will be the Commissioner, a member of the Commissioner's office to whom the responsibility for the matter involved has been delegated, or an administrative law judge qualified under 5 U.S.C. 3105.

§ 12.62 Commencement of functions.

The functions of the presiding officer begin upon designation and end upon the filing of the initial decision.

§ 12.70 Authority of presiding officer.

The presiding officer has all powers necessary to conduct a fair, expeditious, and orderly hearing, including the power to—

(a) Specify and change the date, time, and place of oral hearings and conferences;

(b) Establish the procedures for use in developing evidentiary facts, including the procedures in § 12.92(b) and to rule on the need for oral testimony and cross-examination under § 12.87(b);

(c) Prepare statements of the areas of factual disagreement among the participants;

(d) Hold conferences to settle, simplify, or determine the issues in a hearing or to consider other matters that may expedite the hearing;

(e) Administer oaths and affirmations;

(f) Control the course of the hearing and the conduct of the participants;

(g) Examine witnesses and strike their testimony if they fail to respond fully to proper questions;

(h) Rule on, admit, exclude, or limit evidence;

(i) Set the time for filing pleadings;

(j) Rule on motions and other procedural matters;

(k) Rule on motions for summary decision under § 12.93;

(l) Conduct the hearing in stages if the number of parties is large or the issues are numerous and complex;

(m) Waive, suspend, or modify any rule in this subpart under § 10.19 if the

presiding officer determines that no party will be prejudiced, the ends of justice will be served, and the action is in accordance with law;

(n) Strike the participation of any person under § 12.45(e) or exclude any person from the hearing under § 12.90, or take other reasonable disciplinary action; and

(o) Take any action for the fair, expeditious, and orderly conduct of the hearing.

§ 12.75 Disqualification of presiding officer.

(a) A participant may request the presiding officer to disqualify himself/herself and withdraw from the proceeding. The ruling on any such request may be appealed in accordance with § 12.97(b).

(b) A presiding officer who is aware of grounds for disqualification shall withdraw from the proceeding.

§ 12.78 Unavailability of presiding officer.

(a) If the presiding officer is unable to act for any reason, the Commissioner will assign the powers and duties to another presiding officer. The substitution will not affect the hearing, except as the new presiding officer may order.

(b) Any motion based on the substitution must be made within 10 days.

Subpart E—Hearing Procedures

§ 12.80 Filing and service of submissions.

(a) Submissions, including pleadings in a hearing, are to be filed with the Hearing Clerk under § 10.20 except that only two copies need be filed. To determine compliance with filing deadlines in a hearing, a submission is considered submitted on the date it is actually received by the Hearing Clerk. When this part allows a response to a submission and prescribes a period of time for the filing of the response, an additional 3 days are allowed for the filing of the response if the submission is served by mail.

(b) The person making a submission shall serve copies of it on the other participants. Submissions of documentary data and information are not required to be served on each participant, but any accompanying transmittal letter, pleading, summary, statement of position, certification under paragraph (d) of this section, or similar document must be served on each participant.

(c) Service is accomplished by mailing a submission to the address shown in the notice of participation or by personal delivery.

(d) All submissions are to be accompanied by a certificate of service, or a statement that service is not required.

(e) No written submission or other portion of the administrative record may be held in confidence, except as provided in § 12.105.

§ 12.82 Petition to participate in forma pauperis.

(a) A participant who believes that compliance with the filing and service requirements of this section constitutes an unreasonable financial burden may submit to the Commissioner a petition to participate in forma pauperis.

(b) The petition will be in the form specified in § 10.30 except that the heading will be "Request to Participate in Forma Pauperis, Docket No. ——." Filing and service requirements for the petition are described in paragraph (c) of this section, whether or not the petition is granted. The petition must demonstrate that either (1) the person is indigent and a strong public interest justifies participation, or (2) the person's participation is in the public interest because it can be considered of primary benefit to the general public.

(c) The Commissioner may grant or deny the petition. If the petition is granted, the participant need file only one copy of each submission with the Hearing Clerk. The Hearing Clerk will make sufficient additional copies for the administrative record, and serve a copy on each other participant.

§ 12.83 Advisory opinions.

Before or during a hearing, a person may, under § 10.85, request the Commissioner for an advisory opinion on whether any regulation or order under consideration in the proceeding applies to a specific situation.

§ 12.85 Disclosure of data and information by the participants.

(a) Before the notice of hearing is published under § 12.35, the director of the bureau responsible for the matters involved in the hearing shall submit the following to the Hearing Clerk:

(1) The relevant portions of the administrative record of the proceeding. Portions of the administrative record not relevant to the issues in the hearing are not part of the administrative record.

(2) All documents in the director's files containing factual information, whether favorable or unfavorable to the director's position, which relate to the issues involved in the hearing. "Files" means the principal files in the bureau in which documents relating to the issues in the hearing are ordinarily kept, e.g., the food additive master file and the food additive petition in the case of issues concerning a food additive, or the new drug application in the case of issues concerning a new drug. Internal memoranda reflecting the deliberative process, and attorney work product and material prepared specifically for use in connection with the hearing, are not required to be submitted.

(3) All other documentary data and information relied upon.

(4) A narrative position statement on the factual issues in the notice of hearing and the type of supporting evidence the director intends to introduce.

(5) A signed statement that, to the director's best knowledge and belief, the submission complies with this section.

(b) Within 60 days of the publication of the notice of hearing or, if no participant will be prejudiced, within another period of time set by the presiding officer, each participant shall submit to the hearing clerk all data and information specified in paragraph (a)(2) through (5) of this section, and any objections that the administrative record filed under paragraph (a)(1) of this section is incomplete. With respect to the data and information specified in paragraph (a)(2) of this section, participants shall exercise reasonable diligence in identifying documents in files comparable to those described in that paragraph.

(c) Submissions required by paragraphs (a) and (b) of this section may be supplemented later in the proceeding, with the approval of the presiding officer, upon a showing that the material contained in the supplement was not reasonably known or available when the submission was made or that the relevance of the material contained in the supplement could not reasonably have been forseen.

(d) A participant's failure to comply substantially and in good faith with this section constitutes a waiver of the right to participate further in the hearing; failure of a party to comply constitutes a waiver of the right to a hearing.

(e) Participants may reference each other's submissions. To reduce duplicative submissions, participants are encouraged to exchange and consolidate lists of documentary evidence. If a particular document is bulky or in limited supply and cannot reasonably be reproduced, and it constitutes relevant evidence, the presiding officer may authorize submission of a reduced number of copies.

(f) The presiding officer will rule on questions relating to this section.

§ 12.87 Purpose; oral and written testimony; burden of proof.

(a) The objective of a formal evidentiary hearing is the fair determination of relevant facts consistent with the right of all interested persons to participate and the public interest in promptly settling controversial matters affecting the public health and welfare.

(b) Accordingly, the evidence at a hearing is to be developed to the maximum extent through written submissions, including written direct testimony, which may be in narrative or in question-and-answer form.

(1) In a hearing, the issues may have general applicability and depend on general facts that do not concern particular action of a specific party, e.g., the safety or effectiveness of a class of drug products, the safety of a food or color additive, or a definition and standard of identity for a food; or the issues may have specific applicability to past action and depend upon particular facts concerning only that party, e.g., the applicability of a grandfather clause to a particular brand of a drug or the failure of a particular manufacturer to meet required manufacturing and processing specifications or other general standards.

(i) If the proceeding involves general issues, direct testimony will be submitted in writing, except on a showing that written direct testimony is insufficient for a full and true disclosure of relevant facts and that the participant will be prejudiced if unable to present oral direct testimony. If the proceeding involves particular issues, each party may determine whether, and the extent to which, each wishes to present direct testimony orally or in writing.

(ii) Oral cross-examination of witnesses will be permitted if it appears that alternative means of developing the evidence are insufficient for a full and true disclosure of the facts and that the party requesting oral cross-examination will be prejudiced by denial of the request or that oral cross-examination is the most effective and efficient means to clarify the matters at issue.

(2) Witnesses shall give testimony under oath.

(c) Except as provided in paragraph (d) of this section, in a hearing involving issuing, amending, or revoking a regulation or order, the originator of the proposal or petition or of any significant modification will be, within the meaning of 5 U.S.C. 556(d), the proponent of the regulation or order, and will have the burden of proof. A participant who proposes to substitute a new provision for a provision objected to has the burden of proof in relation to the new provision.

(d) At a hearing involving issuing, amending, or revoking a regulation or order relating to the safety or effectiveness of a drug, antibiotic, device, food additive, or color additive, the participant who is contending that the product is safe or effective or both and who is requesting approval or contesting withdrawal of approval has the burden of proof in establishing safety or effectiveness or both and thus the right to approval. The burden of proof remains on that participant in an amendment or revocation proceeding.

§ 12.89 Participation of nonparties.

(a) A nonparty participant may—

(1) Attend all conferences (including the prehearing conference), oral proceedings, and arguments;

(2) Submit written testimony and documentary evidence for inclusion in the record;

(3) File written objections, briefs, and other pleadings; and

(4) Present oral argument.

(b) A nonparty participant may not—

(1) Submit written interrogatories; and

(2) Conduct cross-examination.

(c) A person whose petition is the subject of the hearing has the same right as a party.

(d) A nonparty participant will be permitted additional rights if the presiding officer concludes that the participant's interests would be adequately protected otherwise or that broader participation is required for a full and true disclosure of the facts, but the rights of a nonparty participant may not exceed the rights of a party.

§ 12.90 Conduct at oral hearings or conferences.

All participants in a hearing will conduct themselves with dignity and observe judicial standards of practice and ethics. They may not indulge in personal attacks, unseemly wrangling, or intemperate accusations or characterizations. Representatives of parties shall, to the extent possible, restrain clients from improprieties in connection with any proceeding. Disrespectful, disorderly, or contumacious language or conduct, refusal to comply with directions, use of dilatory tactics, or refusal to adhere to reasonable standards of orderly and ethical conduct during any hearing, constitute grounds for immediate exclusion from the proceeding by the presiding officer.

§ 12.91 Time and place of prehearing conference.

A prehearing conference will commence at the date, time, and place announced in the notice of hearing, or in a later notice, or as specified by the presiding officer in a notice modifying a prior notice. At that conference the presiding officer will establish the methods and procedures to be used in developing the evidence, determine reasonable time periods for the conduct of the hearing, and designate the times and places for the production of witnesses for direct and cross-examination if leave to conduct oral examination is granted on any issue, as far as practicable at that time.

§ 12.92 Prehearing conference procedure.

(a) Participants in a hearing are to appear at the prehearing conference prepared to discuss and resolve all matters specified in paragraph (b) of this section.

(1) To expedite the hearing, participants are encouraged to prepare in advance for the prehearing conference. Participants should cooperate with each other, and request information and begin preparation of testimony at the earliest possible time. Failure of a participant to appear at the prehearing conference or to raise matters that could reasonably be anticipated and resolved at that time will not delay the progress of the hearing, and constitutes a waiver of the rights of the participant regarding such matters as objections to the agreements reached, actions taken, or rulings issued by the presiding officer and may be grounds for striking the participation under § 12.45.

(2) Participants shall bring to the prehearing conference the following specific information, which will be filed with the Hearing Clerk under § 12.80:

(i) Any additional information to supplement the submission filed under § 12.85, which may be filed if approved under § 12.85(c)

(ii) A list of all witnesses whose testimony will be offered, orally or in writing, at the hearing, with a full curriculum vitae for each. Additional witnesses may later be identified, with the approval of the presiding officer, on a showing that the witness was not reasonably available at the time of the prehearing conference or the relevance of the witness' views could not reasonably have been foreseen at that time.

(iii) All prior written statements including articles and any written statement signed or adopted, or a recording or transcription of an oral

statement made, by persons identified as witnesses if—

(*a*) The statement is available without making request of the witness or any other person;

(*b*) The statement relates to the subject matter of the witness' testimony; and

(*c*) The statement either was made before the time the person agreed to become a witness or has been made publicly available by the person.

(b) The presiding officer will conduct a prehearing conference for the following purposes:

(1) To determine the areas of factual disagreement to be considered at the hearing. The presiding officer may hold conferences off the record in an effort to reach agreement on disputed factual questions.

(2) To identify the most appropriate techniques for developing evidence on issues in controversy and the manner and sequence in which they will be used, including, where oral examination is to be conducted, the sequence in which witnesses will be produced for, and the time and place of, oral examination. The presiding officer may consider—

(i) Submission of narrative statements of position on factual issues in controversy;

(ii) Submission of evidence or identification of previously submitted evidence to support such statements, such as affidavits, verified statements of fact, data, studies, and reports;

(iii) Exchange of written interrogatories directed to particular witnesses;

(iv) Written requests for the production of additional documentation, data, or other relevant information;

(v) Submission of written questions to be asked by the presiding officer of a specific witness; and

(vi) Identification of facts for which oral examination and/or cross-examination is appropriate.

(3) To group participants with substantially like interests for presenting evidence, making motions and objections, including motions for summary decision, filing briefs, and presenting oral argument.

(4) To hear and rule on objections to admitting into evidence information submitted under § 12.85.

(5) To obtain stipulations and admissions of facts.

(6) To take other action that may expedite the hearing.

(c) The presiding officer shall issue, orally or in writing, a prehearing order reciting the actions taken at the prehearing conference and setting forth the schedule for the hearing. The order will control the subsequent course of the hearing unless modified by the presiding officer for good cause.

§ 12.93 Summary decisions.

(a) After the hearing commences, a participant may move, with or without supporting affidavits, for a summary decision on any issue in the hearing. Any other participant may, within 10 days after service of the motion, which time may be extended for an additional 10 days for good cause, serve opposing affidavits or countermove for summary decision. The presiding officer may set the matter for argument and call for the submission of briefs.

(b) The presiding officer will grant the motion if the objections, requests for hearing, other pleadings, affidavits, and other material filed in connection with the hearing, or matters officially noticed, show that there is no genuine issue as to any material fact and that a participant is entitled to summary decision.

(c) Affidavits should set forth facts that would be admissible in evidence and show affirmatively that the affiant is competent to testify to the matters stated. When a properly supported motion for summary decision is made, a participant opposing the motion may not rest upon mere allegations or denials or general descriptions of positions and contentions; affidavits or other responses must set forth specific facts showing that there is a genuine issue of fact for the hearing.

(d) Should it appear from the affidavits of a participant opposing the motion that for sound reasons stated, facts essential to justify the opposition cannot be presented by affidavit, the presiding officer may deny the motion for summary decision, order a continuance to permit affidavits or additional evidence to be obtained, or issue other just order.

(e) If on motion under this section a summary decision is not rendered upon the whole case or for all the relief asked, and evidentiary facts need to be developed, the presiding officer will issue an order specifying the facts that appear without substantial controversy and directing further evidentiary proceedings. The facts so specified will be deemed established.

(f) A participant may obtain interlocutory review by the Commissioner of a summary decision of the presiding officer.

§ 12.94 Receipt of evidence.

(a) A hearing consists of the development of evidence and the resolution of factual issues as set forth in this subpart and in the prehearing order.

(b) All orders, transcripts, written statements of position, written direct testimony, written interrogatories and responses, and any other written material submitted in the proceeding is a part of the administrative record of the hearing, and will be promptly placed on public display in the office of the Hearing Clerk, except as provided in § 12.105.

(c) Written evidence, identified as such, is admissible unless a participant objects and the presiding officer excludes it on objection of a participant or on the presiding officer's own initiative.

(1) The presiding officer may exclude written evidence as inadmissible only if—

(i) The evidence is irrelevant, immaterial, unreliable, or repetitive;

(ii) Exclusion of part or all of the written evidence of a participant is necessary to enforce the requirements of this subpart; or

(iii) The evidence was not submitted as required by § 12.85.

(2) Items of written evidence are to be submitted as separate documents, sequentially numbered, except that a voluminous document may be submitted in the form of a cross-reference to the documents filed under § 12.85.

(3) Written evidence excluded by the presiding officer as inadmissible remains a part of the administrative record, as an offer of proof, for judicial review.

(d) Testimony, whether on direct or on cross-examination, is admissible as evidence unless a participant objects and the presiding officer excludes it.

(1) The presiding officer may exclude oral evidence as inadmissible only if—

(i) The evidence is irrelevant, immaterial, unreliable, or repetitive; or

(ii) Exclusion of part or all of the evidence is necessary to enforce the requirements of this part.

(2) If oral evidence is excluded as inadmissible, the participant may take written exception to the ruling in a brief to the Commissioner, without taking oral exception at the hearing. Upon review, the Commissioner may reopen the hearing to permit the evidence to be admitted if the Commissioner determines that its exclusion was erroneous and prejudicial.

(e) The presiding officer may schedule conferences as needed to monitor the program of the hearing, narrow and simplify the issues, and consider and rule on motions, requests, and other matters concerning the development of the evidence.

(f) The presiding officer will conduct such proceedings as are necessary for the taking of oral testimony, for the oral examination of witnesses by the presiding officer on the basis of written questions previously submitted by the parties, and for the conduct of cross-examination of witnesses by the parties. The presiding officer shall exclude irrelevant or repetitious written questions and limit oral cross-examination to prevent irrelevant or repetitious examination.

(g) The presiding officer shall order the proceedings closed for the taking of oral testimony relating to matters specified in § 10.20(j)(2)(i) (*a*) and (*b*). Such closed proceedings will be conducted in accordance with § 10.20(j)(3). Participation in closed proceedings will be limited to the witness, the witness' counsel, and Federal Government executive branch employees and special government employees. Closed proceedings will be permitted only for, and will be limited to, oral testimony directly relating to matters specified in § 10.20(j)(3).

§ 12.95 Official notice.

(a) Official notice may be taken of such matters as might be judicially noticed by the courts of the United States or of any other matter peculiarly within the general knowledge of FDA as an expert agency.

(b) If official notice is taken of a material fact not appearing in the evidence of record, a participant, on timely request, will be afforded an opportunity to show the contrary.

§ 12.96 Briefs and arguments.

(a) Promptly after the taking of evidence is completed, the presiding officer will announce a schedule for the filing of briefs. Briefs are to be filed ordinarily within 45 days of the close of the hearing. Briefs must include a statement of position on each issue, with specific and complete citations to the evidence and points of law relied on. Briefs must contain proposed findings of fact and conclusions of law.

(b) The presiding officer may, as a matter of discretion, permit oral argument after the briefs are filed.

(c) Briefs and oral argument are to refrain from disclosing specific details of written and oral testimony and documents relating to matters specified in § 10.20(j)(2)(i) (*a*) and (*b*), except as specifically authorized in a protective order issued under § 10.20(j)(3).

§ 12.97 Interlocutory appeal from ruling of presiding officer.

(a) Except as provided in paragraph (b) of this section and in §§ 12.35(b), 12.45(e), 12.93(f), and 12.99(d), when an interlocutory appeal is specifically authorized by this subpart, rulings of the presiding officer may not be appealed to the Commissioner before the Commissioner's consideration of the entire record of the hearing.

(b) A ruling of the presiding officer is subject to interlocutory appeal to the Commissioner if the presiding officer certifies on the record or in writing that immediate review is necessary to prevent exceptional delay, expense, or prejudice to any participant, or substantial harm to the public interest.

(c) When an interlocutory appeal is made to the Commissioner, a participant may file a brief with the Commissioner only if specifically authorized by the presiding officer or the Commissioner, and if such authorization is granted, within the period the Commissioner directs. If a participant is authorized to file a brief, any other participant may file a brief in opposition, within the period the Commissioner directs. If no briefs are authorized, the appeal will be presented as an oral argument to the Commissioner. The oral argument will be transcribed. If briefs are authorized, oral argument will be heard only at the discretion of the Commissioner.

§ 12.98 Official transcript.

(a) The presiding officer will arrange for a verbatim stenographic transcript of oral testimony and for necessary copies of the transcript.

(b) One copy of the transcript will be placed on public display in the office of the Hearing Clerk upon receipt.

(c) Except as provided in § 12.105, copies of the transcript may be obtained by application to the official reporter and payment of costs thereof or under Part 20.

(d) Witnesses, participants, and counsel have 30 days from the time the transcript becomes available to propose corrections in the transcript of oral testimony. Corrections are permitted only for transcription errors. The presiding officer shall promptly order justified corrections.

§ 12.99 Motions.

(a) A motion on any matter relating to the proceeding is to be filed under § 12.80, and must include a draft order, except one made in the course of an oral hearing before the presiding officer.

(b) A response may be filed within 10 days of service of a motion. The time may be shortened or extended by the presiding officer for good cause shown.

(c) The moving party has no right to reply, except as permitted by the presiding officer.

(d) The presiding officer shall rule upon the motion and may certify that ruling to the Commissioner for interlocutory review.

Subpart F—Administrative Record

§ 12.100 Administrative record of a hearing.

(a) The record of a hearing consists of—

(1) The order or regulation or notice of opportunity for hearing that gave rise to the hearing;

(2) All objections and requests for hearing filed by the Hearing Clerk under §§ 12.20 through 12.22;

(3) The notice of hearing published under § 12.35;

(4) All notices of participation filed under § 12.45;

(5) All **Federal Register** notices pertinent to the proceeding;

(6) All submissions filed under § 12.82, e.g., the submissions required by § 12.85, all other documentary evidence and written testimony, pleadings, statements of position, briefs, and other similar documents;

(7) The transcript, written order, and all other documents relating to the prehearing conference, prepared under § 12.92;

(8) All documents relating to any motion for summary decision under § 12.93;

(9) All documents of which official notice is taken under § 12.95;

(10) All pleadings filed under § 12.96;

(11) All documents relating to any interlocutory appeal under § 12.97;

(12) All transcripts prepared under § 12.98; and

(13) Any other document relating to the hearing and filed with the Hearing Clerk by the presiding officer or any participant;

(b) The record of the administrative proceeding is closed—

(1) With respect to the taking of evidence, when specified by the presiding officer; and

(2) With respect to pleadings, at the time specified in § 12.96(a) for the filing of briefs.

(c) The presiding officer may reopen the record to receive further evidence at any time before the filing of the initial decision.

§ 12.105 Examination of record.

Documents in the record will be publicly available in accordance with

§ 10.20(j). Documents available for examination or copying will be placed on public display in the office of the Hearing Clerk promptly upon receipt in that office.

Subpart G—Initial and Final Decisions

§ 12.129 Initial decision.

(a) The presiding officer shall prepare and file an initial decision as soon as possible after the filing of briefs and oral argument.

(b) The initial decision must contain—

(1) Findings of fact based issued upon relevant, material, and reliable evidence of record;

(2) Conclusions of law;

(3) A discussion of the reasons for the findings and conclusions, including a discussion of the significant contentions made by any participant;

(4) Citations to the record supporting the findings and conclusions;

(5) An appropriate regulation or order supported by substantial evidence of record and based upon the findings of fact and conclusions of law; and

(6) An effective date for the regulation or order.

(c) The initial decision must refrain from disclosing specific details of matters specified in § 10.20(j)(2)(i) (*a*) and (*b*), except as specifically authorized in a protective order issued pursuant to § 10.20(j)(3).

(d) The initial decision is to be filed with the Hearing Clerk and served upon all participants. Once the initial decision is filed with the Hearing Clerk, the presiding officer has no further jurisdiction over the matter, and any motions or requests filed with the Hearing Clerk will be decided by the Commissioner.

(e) The intital decision becomes the final decision of the Commissioner by operation of law unless a participant files exceptions with the Hearing Clerk under § 12.125(a) or the Commissioner files a notice of review under § 12.125(f).

(f) Notice that an initial decision has become the decision of the Commissioner without appeal to or review by the Commissioner will be published in the **Federal Register**, or the Commissioner may publish the decision when it is of widespread interest.

§ 12.125 Appeal from or review of initial decision.

(a) A participant may appeal an initial decision to the Commissioner by filing exceptions with the Hearing Clerk, and serving them on the other participants, within the period specified in the initial decision. The period may not exceed 30 days, unless extended by the Commissioner under paragraph (d) of this section.

(b) Exceptions must specifically identify alleged errors in the findings of fact or conclusions of law in the initial decision, and provide supporting citations to the record. Oral argument before the Commissioner may be requested in the exceptions.

(c) Any reply to the exceptions is to be filed and served within the period specified in the initial decision. The period may not exceed 30 days after the end of the period (including any extensions) for filing exceptions, unless extended by the Commissioner under paragraph (d) of this section.

(d) The Commissioner may extend the time for filing exceptions or replies to exceptions for good cause shown.

(e) If the Commissioner decides to hear oral argument, the participants will be informed of the date, time, and place, the amount of time allotted to each participant, and the issues to be addressed.

(f) Within 10 days following the expiration of the time for filing exceptions (including any extensions), the Commissioner may file with the Hearing Clerk, and serve on the participants, a notice of the Commissioner's determination to review the initial decision. The Commissioner may invite the participants to file briefs or present oral argument on the matter. The time for filing briefs or presenting oral argument will be specified in that or a later notice.

§ 12.130 Decision by Commissioner on appeal or review of initial decision.

(a) On appeal from or review of the initial decision, the Commissioner has all the powers given to make the initial decision. On the Commissioner's own initiative or on motion, the Commissioner may remand the matter to the presiding officer for any further action necessary for a proper decision.

(b) The scope of the issues on appeal is the same as the scope of the issues at the public hearing unless the Commissioner specifies otherwise.

(c) As soon as possible after the filing of briefs and any oral argument, the Commissioner will issued a final decision in the proceeding, which meets the requirements established in § 12.120 (b) and (c).

(d) The Commissioner may adopt the initial decision as the final decision.

(e) Notice of the Commissioner's decision will be published in the **Federal Register**, or the Commissioner may publish the decision when it is of widespread interest.

§ 12.139 Reconsideration and stay of action.

Following notice or publication of the final decisions, a participant may petition the Commissioner for reconsideration of any part or all of the decision under § 10.33 or may petition for a stay of the decision under § 10.35.

Subpart H—Judicial Review

§ 12.140 Review by the courts.

(a) The Commissioner's final decision constitutes final agency action from which a participant may petition for judicial review under the statutes governing the matter involved. Before requesting an order from a court for a stay of action pending review, a participant shall first submit a petition for a stay of action under § 10.35.

(b) Under 28 U.S.C. 2112(a), FDA will request consolidation of all petitions related to a particular matter.

§ 12.159 Copies of petitions for judicial review.

The Chief Counsel for FDA has been designated by the Secretary as the officer on whom copies of petitions of judicial review are to be served. This officer is responsible for filing the record on which the final decision is based. The record of the proceeding is certified by the Commissioner.

PART 13—PUBLIC HEARING BEFORE A PUBLIC BOARD OF INQUIRY

Subpart A—General Provisions

Sec.

13.1 Scope.

13.5 Notice of a hearing before a Board.

13.10 Members of a Board.

13.15 Separation of functions; ex parte communications; administrative support.

Subpart B—Hearing Procedures

13.20 Submissions to a Board.

13.25 Disclosure of date and information by the participants.

13.30 Proceedings of a Board.

Subpart C—Records of Hearing Before a Board

13.40 Administrative record of a Board.

13.45 Examination of administrative record.

13.50 Record for administrative decision.

Authority: Sec. 201 et seq., Pub. L. 717, 52 Stat. 1040 (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. 2 et seq., Pub. L. 783, 44 Stat. 1406 as amended (15 U.S.C. 401–411 notes); sec. 1 et seq., Pub. L. 89–755, 80 Stat. 1296 as amended (15 U.S.C 1451 et seq.).

Subpart A—General Provisions

§ 13.1 Scope.

The procedures in this part apply when—

(a) The Commissioner concludes, as a matter of discretion, that it is in the public interest to hold a public hearing before a Public Board of Inquiry ("Board") with respect to any matter before FDA;

(b) Under specific sections of this chapter a matter before FDA is subject to a hearing before a Board; or

(c) Under § 12.32, a person who has a right to an opportunity for a formal evidentiary public hearing waives that opportunity and requests that a Board act as an administrative law tribunal concerning the matters involved, and the Commissioner decides to accept this request.

§ 13.5 Notice of a hearing before a Board.

If the Commissioner determines that a Board should be established to conduct a hearing on any matter, a notice of hearing will be published in the **Federal Register** setting forth the following information:

(a) If the hearing is under § 13.1 (a) or (b), all applicable information described in § 12.32(e).

(1) Any written document that is to be the subject matter of the hearing will be published as a part of the notice, or the notice will refer to it if the document has already been published in the **Federal Register** or state that the document is available from the Hearing Clerk or an agency employee designated in the notice.

(2) For purposes of a hearing under § 13.1 (a) or (b), all participants who file a notice of participation under § 12.32(e)(6)(ii) are deemed to be parties and entitled to participate in selection of the Board under § 13.15(b).

(b) If the hearing is in lieu of a formal evidentiary hearing, as provided in § 13.1(c), all of the information described in § 12.32(e).

§ 13.10 Members of a Board.

(a) All members of a Board are to have medical, technical, scientific, or other qualifications relevant to the issues to be considered, are subject to the conflict of interest rules applicable to special Government employees, and are to be free from bias or prejudice concerning the issues involved. A member of a Board may be a full-time or part-time Federal Government employee or may serve on an FDA advisory committee but, except with the agreement of all parties, may not currently be a full-time or part-time employee of FDA or otherwise act as a special Government employee of FDA.

(b) Within 30 days of publication of the notice of hearing, the director of the bureau of FDA responsible for a matter before a Board, the other parties to the proceeding, and any person whose petition was granted and is the subject of the hearing, shall each submit to the Hearing Clerk the names and full curricula vitae of five nominees for members of the Board. Nominations are to state that the nominee is aware of the nomination, is interested in becoming a member of the Board, and appears to have no conflict of interest.

(1) Any two or more persons entitled to nominate members may agree upon a joint list of five qualified nominees.

(2) The lists of nominees must be submitted to the persons entitled to submit a list of nominees under this paragraph but not to all participants. Within 10 days of receipt of the lists of nominees, such persons may submit comments to the Hearing Clerk on whether the nominees of the other persons meet the criteria established in paragraph (a) of this section. A person submitting comments to the Hearing Clerk shall submit them to all persons entitled to submit a list of nominees.

(3) The lists of nominees and comments on them are to be held in confidence by the Hearing Clerk as part of the administrative record of the proceeding and are not to be made available for public disclosure, and all persons who submit or receive them shall similarly hold them in confidence. This portion of the administrative record remains confidential but is available for judicial review in the event that it becomes relevant to any issue before a court.

(c) After reviewing the lists of nominees and any comments, the Commissioner will choose three qualified persons as members of a Board. One member will be from the lists of nominees submitted by the director of the bureau and by any person whose petition was granted and is the subject of the hearing. The second will be from the lists of nominees submitted by the other parties. The Commissioner may choose the third member from any source. That member is the Chairman of the Board.

(1) If the Commissioner is unable to find a qualified person with no conflict of interest from among a list of nominees or if additional information is needed, the Commissioner will request the submission of the required additional nominees or information.

(2) If a person fails to submit a list of nominees as required by paragraph (b) of this section, the Commissioner may choose a qualified member without further consultation with that person.

(3) The Commissioner will announce the members of a board by filing a memorandum in the record of the proceeding and sending a copy to all participants.

(d) Instead of using the selection method in paragraphs (b) and (c) of this section, the director of the bureau, the other parties to the proceeding, and any person whose petition was granted and is the subject of the hearing, may, with the approval of the Commissioner, agree that a standing advisory committee listed in § 14.80 constitutes the Board for a particular proceeding, or that another procedure is to be used for selection of the members of the Board, or that the Board consists of a larger number of members.

(e) The members of a Board serve as consultants to the Commissioner and are special Government employees or Government employees. A Board functions as an administrative law tribunal in the proceeding and is not an advisory committee subject to the requirements of the Federal Advisory Committee Act or part 14.

(f) The Chairman of the Board has the authority of a presiding officer set out in § 12.70.

§ 13.15 Separation of functions; ex parte communications; administrative support.

(a) The proceeding of a Board are subject to the provisions of § 10.55 relating to separation of functions and ex parte communications. Representatives of the participants in any proceeding before a Board, including any members of the office of the Chief Counsel of FDA assigned to advise the bureau responsible for the matter, may have no contact with the members of the Board, except as participants in the proceeding, and may not participate in the deliberations of the Board.

(b) Administrative support for a Board is to be provided only by the office of the Commissioner and the office of the Chief Counsel for FDA.

Subpart B—Hearing Procedures

§ 13.20 Submissions to a Board.

(a) Submissions are to be filed with the Hearing Clerk under § 10.20.

(b) The person making a submission shall serve copies of it on each

participant in the proceeding, except as provided in §§ 13.10(b)(2) and 13.45. Submissions of documentary data and information need not be sent to each participant, but any accompanying transmittal letter, summary, statement of position, certification under paragraph (d) of this section, or similar document must be.

(c) A submission must be mailed to the address shown in the notice of appearance or personally delivered.

(d) All submissions are to be accompanied by a certificate of service, or a statement that service is not required.

(e) No written submission or other portion of the administrative record may be held in confidence, except as provided in §§ 13.10(b)(2) and 13.45.

(f) A participant who believes that compliance with the requirements of this section constitutes an unreasonable financial burden may submit to the Commissioner a petition to participate in forma pauperis in the form and manner specified in § 12.82.

§ 13.25 Disclosure of data and information by the participants.

(a) Before the notice of hearing is published under § 13.5, the director of the bureau responsible for the matters involved in the hearing must submit to the Hearing Clerk—

(1) The relevant portions of the existing administrative record of the proceeding. Portions of the administrative record not relevant to the issues in the hearing are not part of the administrative record;

(2) A list of all persons whose views will be presented orally or in writing at the hearing;

(3) All documents in the director's files containing factual information, whether favorable or unfavorable to the director's position, which relate to the issues involved in the hearing. "Files" means the principal files in the bureau in which documents relating to the issues in the hearing are ordinarily kept, e.g., the food additive master file and the food additive petition in the case of issues concerning a food additive, or the new drug application in the case of issues concerning a new drug. Internal memoranda reflecting the deliberative process, and attorney work product and material prepared specifically for use in connection with the hearing, are not required to be submitted.

(4) All other documentary information relied on.

(5) A signed statement that, to the best of the director's knowledge and belief, the submission complies with this section.

(b) Within the time prescribed in the notice of hearing published under § 13.5, each participant shall submit to the hearing clerk all information specified in paragraph (a)(2) through (5) of this section and any objections under the administrative record filed under paragraph (a)(1) of this section is incomplete. With respect to the information specified in paragraph (a)(3) of this section, participants are to exercise reasonable diligence in identifying documents in files comparable to those described in that paragraph.

(c) The submissions required by paragraphs (a) and (b) of this section may be supplemented later in the proceeding, with the approval of the Board, on a showing that the views of the persons or the material contained in the supplement was not known or reasonably available when the initial submission was made or that the relevance of the views of the persons or the material contained in the supplement could not reasonably have been foreseen.

(d) The failure to comply substantially and in good faith with this section in the case of a participant constitutes a waiver of the right to participate further in the hearing and in the case of a party constitutes a waiver of the right to a hearing.

(e) The Chairman rules on questions relating to this section. Any participant dissatisfied with a ruling may petition the Commissioner for interlocutory review.

§ 13.30 Proceedings of a Board.

(a) The purpose of a Board is to review medical, scientific, and technical issues fairly and expeditiously. The proceedings of a Board are conducted as a scientific inquiry rather than a legal trial.

(b) A Board may not hold its first hearing until after all participants have submitted the information required by § 13.25.

(c) The Chairman calls the first hearing of the Board. Notice of the time and location of the first hearing is to be published at least 15 days in advance and the hearing will be open to the public. All participants will have an opportunity at the first hearing to make an oral presentation of the information and views which in their opinion are pertinent to the resolution of the issues being considered by a Board. A participant's presentation may be made by more than one person. The Chairman determines the order of the presentation. Participants may not interrupt a presentation, but members of the Board may ask questions. At the conclusion of a presentation, each of the other participants may briefly comment on the presentation and may request that the Board conduct further questioning on specified matters. Members of the Board may then ask further questions. Any other participant may be permitted to ask questions if the Chairman determines that it will help resolve the issues.

(d) The hearing is informal and the rules of evidence do not apply. No motions or objections relating to the admissibility of information and views may be made or considered, but other participants may comment upon or rebut all such information and views. No participant may interrupt the presentation of another participant for any reason.

(e) Within the time specified by the Board after its first hearing, participants may submit written rebuttal information and views in accordance with § 13.20. The Chariman will then schedule a second hearing, if requested and justified by a participant. A second hearing, and any subsequent hearing, will be called only if the Chairman concludes that it is needed to fully and fairly present information that cannot otherwise adequately be considered and to properly resolve the issues. Notice of the time and location of any hearing is to be published at least 15 days in advance. The hearing is open to the public.

(f) A Board may consult with any person who it concludes may have information or views relevant to the issues.

(1) The consultation may occur only at an announced hearing of a Board. Participants have the right to suggest or, with the permission of the Chairman, ask questions of the consultant and present rebuttal information and views, as provided in paragraphs (c) and (d) of this section except that written statements may be submitted to the Board with the consent of all participants.

(2) A participant may submit a request that the Board consult with a specific person who may have information or views relevant to the issues. The request will state why the person should be consulted and why the person's views cannot be furnished to the Board by means other than having FDA arrange for the person's appearance. The Board may, in its discretion, grant or deny the request.

(g) All hearings are to be transcribed. All hearings are open to the public, except that a hearing under § 10.20(j)(3) is closed to all persons except those

persons making and participating in the presentation and Federal Government executive branch employees and special Government employees. At least a majority of Board members are to be present at every hearing. The executive sessions of a Board, during which a Board deliberates on the issues, are to be closed and are not transcribed. All members of the Board shall vote on the report of the Board.

(h) All legal questions are to be referred to the Chief counsel for FDA for resolution. The Chief Counsel's advice on any matter of procedure or legal authority is to be transmitted in writing and made a part of the record or presented in open session and transcribed.

(i) At the conclusion of all public hearings the Board will announce that the record is closed to receiving information. The Board will provide an opportunity for participants to submit written statements of their positions, with proposed findings and conclusions, and may in its discretion, provide an opportunity for participants to summarize their positions orally.

(j) The Board will prepare a decision on all issues. The decision is to include specific findings and references supporting and explaining the Board's conclusions, and a detailed statement of the reasoning on which the conclusions are based. Any member of the Board may file a separate report stating additional or dissenting views.

Subpart C—Records of a Hearing Before a Board

§ 13.40 Administrative record of a Board.

(a) The administrative record of a hearing before a Board consists of the following:

(1) All relevant **Federal Register** notices.

(2) All written submissions under § 13.20.

(3) The transcripts of all hearings of the Board.

(4) The initial decision of the Board.

(b) The record of the administrative proceeding is closed—

(1) Relevant to receiving information and data, at the time specified in § 13.30(i); and

(2) Relevant to pleadings, at the time specified in § 13.30(i) for filing a written statement of position with proposed findings and conclusions.

(c) The Board may, in its discretion, reopen the record to receive further evidence at any time before filing an initial decision.

§ 13.45 Examination of administrative record.

(a) The availability for public examination and copying of each document which is a part of the administrative record of the hearing is governed by § 10.20(j). Each document available for public examination or copying is placed on public display in the office of the Hearing Clerk promptly upon receipt in that office.

(b) Lists of nominees and comments submitted on them under § 13.10(b)(3) are not subject to disclosure unless they become an issue in a court proceeding.

§ 13.50 Record for administrative decision.

The administrative record of the hearing specified in § 13.40(a) constitutes the exclusive record for decision.

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

Subpart A—General Provisions.

Subpart B—Meeting Procedures

Subpart C—Establishment of Advisory Committees

Subpart D—Records of Meetings and Hearings Before Advisory Committees

Subpart E—Members of Advisory Committees

Subpart F—Standing Advisory Committees

Subpart G—Technical Electronic Products Radiation Safety Standards Committee

Subpart H—Color Additive Advisory Committees

Subpart I—Advisory Committees for Human Prescription Drugs

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.

89–755, 80 Stat. 1296 as amended (15 U.S.C. 1451 et seq.).

Subpart A—General Provisions

§ 14.1 Scope.

(a) This part governors the procedures when any of the following applies:

(1) The Commissioner concludes, as a matter of discretion, that it is in the public interest for a standing or ad hoc policy or technical public advisory committee ("advisory committee" or "committee") to hold a public hearing and to review and make recommendations on any matter before FDA and for interested persons to present information and views at an oral public hearing before the advisory committee.

(2) Under specific provisions in the act or other sections of this chapter, a matter is subject to a hearing before an advisory committee. The specific provisions are—

(i) Section 14.120 on review of a performance standard for an electronic product by the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC);

(ii) Section 14.140 on review of the safety of color additives;

(iii) Section 14.160 on review of the safety and effectiveness of human prescription drugs;

(iv) Section 330.10 on review of the safety and effectiveness of over-the-counter drugs;

(v) Section 601.25 on review of the safety and effectiveness of biological drugs;

(vi) Part 860, on classification of devices;

(vii) Section 514(g)(5) of the act on establishment, amendment, or revocation of a device performance standard;

(viii) Section 515 of the act on review of device premarket approval applications and product development protocols; and

(ix) Section 520(l) of the act on review of device good manufacturing practice regulations.

(3) A person who has a right to an opportunity for a formal evidentiary public hearing under Part 12 waives that opportunity and instead under § 12.32 requests a hearing before an advisory committee, and the Commissioner, as a matter of discretion, accepts the request.

(b) In determining whether a group is a "public advisory committee" as defined in § 10.3(a)(14) and thus subject to this part and to the Federal advisory Committee Act, the following guidelines will be used:

(1) An advisory committee may be a standing advisory committee or an ad hoc advisory committee. All standing advisory committees are listed in § 14.100.

(2) An advisory committee may be a policy advisory committee or a technical advisory committee. A policy advisory committee advises on broad and general matters. A technical advisory committee advises on specific technical or scientific issues, which may relate to regulatory decisions before FDA.

(3) An advisory committee includes any of its subgroups when the subgroup is working on behalf of the committee. Section 14.40(d) describes when a subgroup will be established as an advisory committee separate from the parent committee.

(4) A committee composed entirely of full-time Federal Government employees is not an advisory committee.

(5) An advisory committee ordinarily has a fixed membership, a defined purpose of providing advice to the agency on a particular subject, regular or periodic meetings, and an organizational structure, for example, a chairman and staff, and serves as a source of independent expertise and advice rather than as a representative of or advocate for any particular interest. The following groups are not advisory committees:

(i) A group of persons convened on an ad hoc basis to discuss a matter of current interest to FDA, but which has no continuing function or organization and does not involve substantial special preparation.

(ii) A group of two or more FDA consultants meeting with the agency on an ad hoc basis.

(iii) A group of experts who are employed by a private company or a trade association which has been requested by FDA to provide its views on a regulatory matter pending before FDA.

(iv) A consulting firm hired by FDA to provide advice regarding a matter.

(6) An advisory committee that is utilized by FDA is subject to this subpart even though it was not established by FDA. In general, a committee is "utilized" when FDA requests advice or recommendations from the committee on a specific matter in order to obtain an independent review and consideration of the matter, and not when FDA is merely seeking the comments of all interested persons or of persons who have a specific interest in the matter.

(i) A committee formed by an independent scientific or technical organization is utilized if FDA requests advice of that committee rather than of the parent organization, or if the circumstances show that the advice given is that of the committee and not of the parent organization. A committee formed by an independent scientific or technical organization is not utilized if FDA requests advice of the organization rather than of a committee and if the recommendations of any committee formed in response to the request are subject to substantial independent policy and factual review by the governing body of the parent organization.

(ii) A committee is not utilized by FDA if it provides only information, as contrasted with advice or opinions or recommendations.

(iii) FDA is charged with seeking out the views of all segments of the public on enforcement of the laws administered by the Commissioner. The fact that a group of individuals or a committee meets regularly with FDA, for example, a monthly meeting with consumer representatives, does not make that group or committee an advisory committee. Thus, this subpart does not apply to routine meetings, discussions, and other dealings, including exchanges of views, between FDA and any committee representing or advocating the particular interests of consumers, industry, professional organizations, or others.

(7) The inclusion of one or two FDA consultants who are special Government employees on an internal FDA committee does not make that committee an advisory committee.

(8) A Public Board of Inquiry established under Part 13, or other similar group convened by agreement between the parties to a regulatory proceeding pending before FDA to review and prepare an initial decision on the issues in lieu of a formal evidentiary public hearing, is acting as an administrative law tribunal and is not an advisory committee.

(9) An open public conference or meeting conducted under § 10.65(b) is not an advisory committee meeting.

(10) An FDA committee that primarily has operational responsibility rather than that of providing advice and recommendations is not an advisory committee, for example, the Research Involving Human Subjects Committee (RIHSC).

(c) This part applies only when a committee convenes to conduct committee business. Site visits, social gatherings, informal discussions by telephone or during meals or while traveling or at other professional

functions, or other similar activities do not constitute a meeting.

(d) An advisory committee that is utilized but not established by FDA is subject to this part only to the extent of such utilization, and not concerning any other activities of such committee.

(e) Any conference or meeting between an employee of FDA and a committee or group which is not an advisory committee shall be subject to § 10.65 or other provisions specifically applicable to the committee or group, for example, Part 13 for a Public Board of Inquiry.

(f) This part applies to all FDA advisory committees, except to the extent that specific statutes require otherwise for a particular committee, for example, TEPRSSC, the Board of Tea Experts, and advisory committees established under the Medical Device Amendments of 1976.

§ 14.5 Purpose of proceedings before an advisory committee.

(a) An advisory committee is utilized to conduct public hearings on matters of importance that come before FDA, to review the issues involved, and to provide advice and recommendations to the Commissioner.

(b) The Commissioner has sole discretion concerning action to be taken and policy to be expressed on any matter considered by an advisory committee.

§ 14.7 Administrative remedies.

A person who alleges noncompliance by the Commissioner or an advisory committee with any provision of this part or the Federal Advisory Committee Act may pursue the following administrative remedies:

(a) If the person objects to any action, including a failure to act, other than denial of access to an advisory committee document, the person shall submit a petition in the form and in accordance with the requirements of § 10.30. The provisions of § 10.45 relating to exhaustion of administrative remedies are applicable.

(1) If the person objects to past action, the person shall submit the petition within 30 days after the action objected to. If the Commissioner determines that there was noncompliance with any provision of this subpart or of the Federal Advisory Committee Act, the Commissioner will grant any appropriate relief and take appropriate steps to prevent its future recurrence.

(2) If the person objects to proposed future action, the Commissioner will expedite the review of the petition and make a reasonable effort to render a decision before the action concerned in the petition.

(3) If the person objects to action that is imminent or occurring and which could not reasonably have been anticipated, e.g., the closing of a portion of a meeting which is made known for the first time on the day of the meeting, the matter may be handled by an oral petition in lieu of a written petition.

(b) If the person objects to a denial of access to an advisory committee document, administrative review is in accordance with the procedures established by the Department of Health, Education, and Welfare under 45 CFR 5.82.

§ 14.10 Applicability to Congress.

This part applies to Congress, individual Members of Congress, and other employees or representatives of Congress in the same way that they apply to any other member of the public, except that disclosure of advisory committee records to Congress is governed by § 20.87.

§ 14.15 Committees working under a contract with FDA.

(a) FDA may enter into contracts with independent scientific or technical organizations to obtain advice and recommendations on particular matters, and these organizations may in turn undertake such work through existing or new committees. Whether a particular committee working under such a contract is an advisory committee subject to the Federal Advisory Committee Act and this subpart depends upon application of the criteria and principles in § 14.1(b).

(b) The following minimum standards apply to any committee of an independent scientific or technical organization which is working under a contract initially executed with FDA after July 1, 1975, but which is determined not to be an advisory committee:

(1) The committee shall give public notice of its meetings and agenda, and provide interested persons an opportunity to submit relevant information and views in writing at any time, and orally at specified times. The notice may be published in the **Federal Register** or disseminated by other reasonable means. It is in any event to be filed with the Hearing Clerk not less than 15 days before the meeting. The time for oral presentations and the extent to which the committee meets in open session other than for such oral presentations is in the discretion of the committee.

(2) Minutes of open sessions are to be maintained, with all written submissions attached which were made to the committee in open session. After approval, the minutes are to be forwarded to the Hearing Clerk and placed on public display. The extent to which the committee maintains minutes of closed sessions is in the discretion of the committee.

(3) In selecting the members of the committee, the organization involved is to apply the principles relating to conflicts of interest that FDA uses in establishing a public advisory committee. Those principles are set out or cross-referenced in this part and in Part 19. Upon request, FDA will assist or provide guidance to any organization in meeting this requirement.

Subpart B—Meeting Procedures

§ 14.20 Notice of hearing before an advisory committee.

(a) Before the first of each month, and at least 15 days in advance of a meeting, the Commissioner will publish a notice in the **Federal Register** of all advisory committee meetings to be held during the month. Any advisory committee meetings for that month called after the publication of the general monthly notice are to be announced in the **Federal Register** on an individual basis at least 15 days in advance. The Commissioner may authorize an exception to these notice requirements in an emergency or for other reasons requiring an immediate meeting of an advisory committee, in which case public notice will be given at the earliest time and in the most accessible form feasible including, whenever possible, publication in the **Federal Register.**

(b) The **Federal Register** notice will include—

(1) The name of the committee;

(2) The date, time, and place of the meeting;

(3) The general function of the committee;

(4) A list of all agenda items, showing whether each will be discussed in an open or closed portion of the meeting;

(5) If any portion of the meeting is closed, a statement of the time of the open and closed portions;

(6) The nature of the subjects to be discussed during, and the reasons for closing, any closed portion of the meeting;

(7) The time set aside for oral statements and other public participation;

(8) The name, address, and telephone number of the advisory committee executive secretary and any other

agency employee designated as responsible for the administrative support for the advisory committee;

(9) A statement that written submissions may be made to the advisory committee through the executive secretary at any time, unless a cutoff date has been established under § 14.35(c)(2); and

(10) When a notice is published in the **Federal Register** less than 15 days before a meeting, an explanation for the lateness of the notice.

(c) If a public hearing before an advisory committee is used in lieu of a formal evidentiary public hearing under § 14.1(a)(3), an initial notice of hearing is to be published separately in the **Federal Register** containing all the information described in § 12.32(e). This procedure may be used for any other hearing before an advisory committee when the Commissioner concludes, as a matter of discretion, that it would be informative to the public.

(d) A list of advisory committee meetings will be distributed to the press by the Associate Commissioner for Public Affairs.

(e) All advisory committee meetings are to be included on the public calendar described in § 10.100(a).

§ 14.22 Meetings of an advisory committee.

(a) No advisory committee may conduct a meeting except at the call or with the advance approval of, and with an agenda approved by, the designated Federal employee or alternate. No meeting may be held in the absence of the designated Federal employee.

(1) If any matter is added to the agenda after its publication in the **Federal Register** under § 14.5(b)(4), an attempt is to be made to inform persons known to be interested in the matter, and the change is to be announced at the beginning of the open portion of the meeting.

(2) The advisory committee meeting is to be conducted in accordance with the approved final agenda insofar as practical.

(b) Advisory committee meetings will be held at places that are reasonably accessible to the public. All advisory committee meetings will be held in Washington, D.C., or Rockville, Md., or the immediate vicinity, unless the Commissioner receives and approves a written request from the advisory committee for a different location. A different location may be approved when one or more of the following applies:

(1) The total cost of the meeting to the Government will be reduced.

(2) A substantial number of the committee members will be at the location at no expense to FDA for other reasons, e.g., for a meeting of a professional association.

(3) It is a central location more readily accessible to committee members.

(4) There is a need for increased participation available at that location.

(5) The committee wishes to review work or facilities in a specific location.

(6) The committee is concerned with matters that functionally or historically occur in some other location, e.g., the Board of Tea Experts and the Science Advisory Board of the National Center for Toxicological Research will generally hold meetings in Brooklyn, N.Y., and in the Little Rock, Ark., vicinity, respectively.

(c) Advisory committee members may, with the approval of FDA, conduct onsite visits relevant to their work.

(d) Unless the committee charter provides otherwise, a quorum for an advisory committee is a majority of the current voting members of the committee, except as provided in § 14.125(c) for TEPRSSC. Any matter before the advisory committee is to be decided by a majority vote of the voting members present at the time, except that the designated Federal official may require that any final report be voted upon by all current voting members of the committee. Any current voting member of the committee may file a separate report with additional or minority views.

(e) If space is available, any interested person may attend any portion of any advisory committee meeting which is not closed.

(f) Whenever feasible, meetings are to be held in government facilities or other facilities involving the least expense to the public. The size of the meeting room is to be reasonable, considering such factors as the size of the committee, the number of persons expected to attend a meeting, and the resources and facilities available.

(g) The Commissioner may authorize a meeting to be held by conference telephone call. For these meetings, a speaker phone will be provided in a conference room located in Washington, D.C., or Rockville, Md., to permit public participation in open portions of the meetings, as provided in §§ 14.25 and 14.29. These meetings generally will be brief, and authorized—

(1) For the purpose of taking final votes or otherwise confirming actions taken by the committee at other meetings; or

(2) Where time does not permit a meeting to be held at a central location.

(h) Any portion of a meeting will be closed by the committee chairman only when matters are to be discussed which the Commissioner has determined may be considered in closed session under § 14.27(b). If a portion of the meeting is closed, the closed portion will be held after the conclusion of the open portion whenever practicable.

(i) Any committee member may take notes during meetings and report and discuss committee deliberations after a meeting is completed and before official minutes or a report are available, within the rules and regulations adopted by FDA and by the advisory committee with the concurrence of FDA, including all of the following:

(1) There may be no attribution of individual views expressed in a closed session or revealing of numerical votes.

(2) There may be no reporting or discussion of any particular matter if the committee or FDA specifically so directs, e.g., where deliberations are incomplete or involve a sensitive regulatory decision that requires preparation or implementation.

(3) There may be no reporting or discussion of information prohibited from public disclosure under § 14.75.

(4) Notes or minutes kept or reports prepared by a committee member have no status or effect unless adopted into the official minutes or report by the committee. It is the responsibility of each committee member to make certain that the official minutes and reports are complete and accurate and fully reflect what happened at any meeting the committee member attended.

§ 14.25 Portions of advisory committee meetings.

An advisory committee meeting has the following portions:

(a) *The open public hearing.* Every committee meeting includes an open portion, which constitutes a public hearing during which interested persons may present relevant information or views orally or in writing. The hearing is conducted in accordance with § 14.29.

(b) *The open committee discussion.* A committee discusses any matter pending before it in an open portion of its meeting unless the meeting has been closed for that matter under § 14.27. To the maximum extent feasible, consistent with the policy expressed in § 14.27, a committee conducts its discussion of pending matters in an open portion. No public participation is permissible during this portion of the meeting except with the consent of the committee chairman.

(c) *The closed presentation of data.* Information prohibited from public

disclosure under Part 20 and the regulations referenced therein is presented to the committee in a closed portion of its meeting. However, if information is in the form of a summary that is not prohibited from public disclosure, the presentation is to be made in an open portion of a meeting.

(d) *The closed committee deliberations.* Deliberations about matters before an advisory committee may be held in a closed portion of a meeting only upon an appropriate determination by the Commissioner under § 14.27.

§ 14.27 Determination to close portions of advisory committee meetings.

(a) No committee meeting may be entirely closed. A portion of a meeting may be closed only in accordance with a written determination by the Commissioner under this section.

(b) The executive secretary or other designated agency employee shall prepare the initial request for a determination to close a portion of a meeting, specifying the matter(s) to be discussed during the closed portion and the reasons why the portion should be closed. The Commissioner, based upon this request and with the concurrence of the Chief Counsel, will determine whether to close a portion of a meeting. The reasons for closing a portion of a meeting will be announced in the **Federal Register** notice of the meeting under § 14.20 in accordance with the following rules:

(1) Any determination to close a portion of a meeting restricts the closing to the shortest possible time consistent with the policy in this section.

(2) A portion of a meeting may be closed only if the Commissioner determines that the closing is permitted under 5 U.S.C. 552b(c), and that the closing is necessary.

(3) Portions of meetings may ordinarily be closed if they concern the review, discussion, and evaluation of drafts or regulations, guidelines or similar preexisting internal agency documents, but only if their premature disclosure would significantly impede proposed agency action; review of trade secrets and confidential commercial or financial information; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(4) Portions of meetings ordinarily may not be closed if they concern review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs and devices; review of information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other information not exempt from public disclosure under 5 U.S.C. 552b(c); the formulation of advice and recommendations to FDA on matters that do not independently justify closing.

(5) No portion of a meeting devoted to matters other than those designated in paragraph (b) (1) through (3) of this section may be closed.

(6) A matter which is properly considered in an open portion of a meeting may instead be considered in a closed portion only if it is so inextricably intertwined with matters to be discussed in a closed portion that it is not feasible to separate them or discussion of the matter in an open portion would compromise the matters to be discussed in the closed portion.

(c) Attendance at a closed portion of a meeting is governed by the following rules:

(1) A portion of a meeting closed for the presentation or discussion of information that constitutes a trade secret or confidential commercial or financial information as defined in § 20.61 may be attended only by voting advisory committee members, nonvoting members representing consumer interests who are also special government employees as provided in § 14.80(b), the executive secretary of the advisory committee, a transcriber, consultants, and such other regular employees of FDA (including members of the Office of the Chief Counsel) as the chairman of the advisory committee may invite, and by those persons authorized to be present under § 14.25.(c), for presentation of information prohibited from public disclosure. A person making a presentation described in § 14.25(c) may be accompanied by a reasonable number of employees, consultants, or other persons in a commercial arrangement within the meaning of § 20.81(a).

(2) A portion of a meeting that has been closed for consideration of existing internal agency documents falling within § 20.62 where premature disclosure is likely to significantly impede proposed agency action; personnel, medical, and similar files, disclosure of which would be a clearly unwarranted invasion of personal privacy within the meaning of § 20.63; or investigatory records compiled for law enforcement purposes as defined in § 20.64 may be attended only by committee members (voting and nonvoting), the executive secretary of the committee, a transcriber, and other regular employees of FDA (including members of the Office of the Chief Counsel) whom the chairman of the committee may invite. Consultants, individuals performing personal service contracts, employees of other Federal agencies, and the general public may not attend such portions.

(3) If a person other than a person permitted to attend in accordance with paragraph (c) (1) and (2) of this section attempts to attend a closed portion of a meeting without the approval of the executive secretary and the chairman, and the matter is brought to their attention, the person will be required to leave the meeting immediately. This inadvertent and unauthorized attendance does not enable other unauthorized persons to attend, nor does it, of itself, constitute grounds for release of transcripts of closed portions or any other documents otherwise exempt from disclosure under § 14.75 and Part 20.

(4) If a person other than a person permitted to attend in accordance with paragraph (c) (1) and (2) of this section is allowed by the executive secretary and the chairman to attend a closed portion of a meeting, that portion is open to attendance by any interested person.

§ 14.29 Conduct of a hearing before an advisory committee.

(a) For each meeting, the open portion for public participation, which constitutes a public hearing under § 14.25(a), will be at least 1 hour, unless public participation does not last that long, and may last for whatever longer time the committee chairman determines will facilitate the work of the committee. The **Federal Register** notice published under § 14.20 will designate the time specifically reserved for the hearing, which is ordinarily the first portion of the meeting. Further public participation in any open portion of the meeting under § 14.25(b) is solely at the discretion of the chairman.

(b) An interested person who wishes to be assured of the right to make an oral presentation at a meeting shall inform the executive secretary or other designated agency employee, orally or in writing, before the meeting.

(1) The person shall state the general nature of the presentation and the approximate time desired. Whenever possible, all written information to be discussed by that person at the meeting should be furnished in advance to the executive secretary or other designated

agency employee. This material may be distributed or mailed by FDA to the committee members in advance of the meeting if time permits, and otherwise will be distributed to the members when they arrive for the meeting. The mailing or distribution may be undertaken only by FDA unless FDA grants permission to a person to mail or distribute the material

(2) Before the meeting, the executive secretary or other designated agency employee shall determine the amount of time allocated to each person for oral presentation and the time that the presentation is to begin. Each person will be so informed in writing, if time permits, or by telephone. FDA may require persons with common interests to make joint presentations.

(c) The chairman of the committee shall preside at the meeting in accordance with § 14.30 and be accompanied by other committee members, who serve as a panel in conducting the hearing portion of the meeting.

(d) Each person may use the allotted time as desired, consistent with an orderly hearing. A person may be accompanied by additional persons, and may present any written information or views for inclusion in the record of the hearing, subject to the requirements of § 14.35(c).

(e) If a person is absent at the time specified for that person's presentation, the persons following will appear in order. An attempt will be made to hear the person at the conclusion of the hearing. Interested persons attending the hearing who did not request an opportunity to make an oral presentation may be given an opportunity to do so at the discretion of the chairman.

(f) The chairman and other members may question a person concerning that person's presentation. No other person, however, may question the person. The chairman may allot additional time when it is in the public interest, but may not reduce the time allotted without consent of the person.

(g) Participants may question a committee member only with that member's permission and only about matters before the committee.

(h) The hearing is informal, and the rules of evidence do not apply. No motions or objections relating to the admissibility of information and views may be made or considered, but other participants may comment upon or rebut matters presented. No participant may interrrupt the presentation of another participant.

§ 14.30 Chairman of an advisory committee.

(a) The advisory committee chairman has the authority to conduct hearings and meetings, including the authority to adjourn a hearing or meeting if the chairman determines that adjournment is in the public interest, to discontinue discussion of a matter, to conclude the open portion of a meeting, or to take any other action to further a fair and expeditious hearing or meeting.

(b) If the chairman is not a full-time employee of FDA, the executive secretary or other designated agency employee, or alternate, is to be the "designated Federal employee" who is assigned to the advisory committee. The designated Federal employee is also authorized to adjourn a hearing or meeting if the employee determines adjournment to be in the public interest.

§ 14.31 Consultation by an advisory committee with other persons.

(a) A committee may confer with any person who may have information or views relevant to any matter pending before the committee.

(b) An interested person may submit to the committee a written request that it confer with specific persons about any matter pending before the committee. The request is to contain adequate justification. The committee may, in its discretion, grant the request.

(c) A committee may confer with a person who is not a Federal Government executive branch employee only during the open portions of a meeting. The person may, however, submit views in writing to the committee as part of the administrative record under § 14.70. The person may participate at the closed portions of a meeting only if appointed as a special Government employee by the Commissioner as provided in paragraph (e) of this section. This paragraph (c) is not intended to bar the testimony of a person during a closed portion of a meeting about matters prohibited from public disclosure under § 14.25(c) and § 14.27(c).

(d) To prevent inadvertent violation of Federal conflict of interest laws and laws prohibiting disclosure of trade secrets (18 U.S.C. 208, 21 U.S.C. 331(j), 18 U.S.C. 1905), Federal executive branch employees who are not employees of the Department may not confer, testify, or otherwise participate (other than as observers) at any portion of an advisory committee meeting unless they are appointed as special Government employees by the Commissioner under paragraph (e) of this section. this paragraph does not apply to Federal executive branch employees who are appointed as members of TEPRSSC, as provided in § 14.127.

(e) The Commissioner may appoint persons as special Government employees to be consultants to an advisory committee. Consultants may be appointed to provide expertise, generally concerning a highly technical matter, not readily available from the members of the committee. Consultants may be either from outside the Government or from agencies other than the Department of Health, Education, and Welfare. Reports, data, information, and other written submissions made to a public advisory committee by a consultant are part of the administrative record itemized in § 14.70.

§ 14.33 Compilation of materials for members of an advisory committee.

The Commissioner shall prepare and provide to all committee members a compilation of materials bearing upon members' duties and responsibilities, including—

(a) All applicable conflict of interest laws and regulations and a summary of their principal provisions;

(b) All applicable laws and regulations relating to trade secrets and confidential commercial or financial information that may not be disclosed publicly and a summary of their principal provisions;

(c) All applicable laws, regulations, and guidelines relating to the subject matter covered by the advisory committee and a summary of their principal provisions;

(d) All applicable laws, regulations, including the regulations in Part 20 of this chapter, advisory committee charters, **Federal Register** notices, curricula vitae, rules adopted by the advisory committee, and other material relating to the formation, composition, and operation of the advisory committee, and a summary of their principal provisions;

(e) Instructions on whom to contact when questions arise; and

(f) Other material relating to FDA and the subject matter covered by the committee which may facilitate the work of the committee.

§ 14.35 Written submissions to an advisory committee.

(a) Ten copies of written submissions to a committee are to be sent to the executive secretary unless an applicable **Federal Register** notice or other regulations in this chapter specify otherwise. Submissions are subject to the provisions of § 10.20, except that it is not necessary to send copies to the Hearing Clerk.

(b) At the request of a committee, or on the Commissioner's own initiative, the Commissioner may issue in the **Federal Register** a notice requesting the submission to the committee of written information and views pertinent to a matter being reviewed by the committee. The notice may specify the manner in which the submission should be made.

(c) At the request of a committee, or on the Commissioner's own initiative, the Commissioner may at any time request the applicant or sponsor of an application or petition about a specific product on which action is pending before FDA, and is being reviewed by an advisory committee, to present or discuss safety, effectiveness, or other data concerning the product during a regularly scheduled meeting of the committee. The request may be for an oral presentation or for a concise, well-organized written summary of pertinent information for review by the committee members before the meeting, or both. Unless specified otherwise, one copy of the written summary along with a proposed agenda outlining the topics to be covered and identifying the participating industry staff members or consultants that will present each topic is to be submitted to the executive secretary or other designated agency employee at least 3 weeks before the meeting.

(d) An interested person may submit to a committee written information or views on any matter being reviewed. Voluminous data is to be accompanied by a summary. A submission is to be made to the executive secretary and not directly to a committee member.

(1) FDA will distribute submissions to each member, either by mail or at the next meeting. Submissions will be considered by the committee in its review of the matter.

(2) A committee may establish, and give public notice of, a cutoff date after which submissions about a matter will no longer be received or considered.

(e) The Commissioner will provide the committee all information the Commissioner deems relevant. A member will, upon request, also be provided any material available to FDA which the member believes appropriate for an independent judgment on the matter, e.g., raw data underlying a summary or report, or a briefing on the legal aspects of the matter.

§ 14.39 Additional rules for a particular advisory committee.

(a) In addition to these rules, an advisory committee may, with the concurrence of the designated Federal employee, adopt additional rules which are not inconsistent with this subpart or with other legal requirements.

(b) Any additional rules will be included in the minutes of the meeting when adopted and in the materials compiled under § 14.33 and will be available for public disclosure under § 14.65(c).

Subpart C—Establishment of Advisory Committees

§ 14.40 Establishment and renewal of advisory committees.

(a) An advisory committee may be established or renewed whenever it is necessary or appropriate for the committee to hold a public hearing and to review and make recommendations on any matter pending before FDA. Except for committees established by statute, before a committee is established or renewed it must first be approved by the Department pursuant to 45 CFR Part 11 and by the General Services Administration.

(b) When an advisory committee is established or renewed, the Commissioner will issue a **Federal Register** notice certifying that the establishment or renewal is in the public interest and stating the structure, function, and purposes of the committee and, if it is a standing advisory committee, shall amend § 14.100 to add it to the list of standing advisory committees. The notice will be published at least 15 days before the filing of the advisory committee charter under paragraph (c) of this section.

(c) No committee may meet or take action until its charter is prepared and filed as required by section 9(c) of the Federal Advisory Committee Act. This requirement is to be met by an advisory committee utilized by FDA, even though it is not established by the agency, prior to utilization.

(d) The regulations of the Department cited in paragraph (a) of this section provide that the charter of a parent committee may incorporate information concerning activities of a subgroup. In such instances, a subgroup will not be established as a committee distinct from the parent committee. However, a subgroup will be established as a separate committee when the charter of the parent committee does not incorporate the activities of the subgroup, or when the subgroup includes members who are not all drawn from the parent committee.

(e) An advisory committee not required to be established by law will be established or utilized only if it is in the public interest and only if its functions cannot reasonably be performed by other existing advisory committees or by FDA.

(f) An advisory committee must meet the following standards:

(1) Its purpose is clearly defined.

(2) Its membership is balanced fairly in terms of the points of view represented in light of the functions to be performed. Although proportional representation is not required, advisory committee members are selected without regard to race, color, national origin, religion, age, or sex.

(3) It is constituted and utilizes procedures designed to assure that its advice and recommendations are the result of the advisory committee's independent judgment.

(4) Its staff is adequate. The Commissioner designates an executive secretary and alternate for every advisory committee, who are employees of FDA. The executive secretary is responsible for all staff support unless other agency employees are designated for this function.

(5) Whenever feasible, or required by statute, it includes representatives of the public interest.

§ 14.55 Termination of advisory committees.

(a) Except as provided in paragraph (c) of this section, a standing advisory committee is terminated when it is no longer needed, or not later than 2 years after its date of establishment unless it is renewed for an additional 2-year period. A committee may be renewed for as many 2-year periods as the public interest requires. The requirements for establishment of a committee under § 14.40 also apply to its renewal.

(b) FDA will issue a **Federal Register** notice announcing the reasons for terminating a committee and, if it is a standing committee, amending § 14.100 to delete it from the list.

(c) TEPRSSC is a permanent statutory advisory committee established by section 358(f)(1)(A) of the Public Health Service Act (42 U.S.C. 263f(f)(1)(A), as added by the Radiation Control for Health and Safety Act of 1968, and is not subject to termination and renewal under paragraph (a) of this section, except that a new charter is prepared and filed at the end of each 2-year period as provided in § 14.40(c). Also, the statutory medical device classification panels established under section 513(b)(1) of the act and Part 860, and the statutory medical device good manufacturing practice advisory committees established under section 520(f)(3) of the act, are specifically

exempted from the normal 2-year duration period.

(d) The Board of Tea Experts is a permanent statutory advisory committee established by the Tea Importation Act (21 U.S.C. 42) and is not subject to termination and renewal under paragraph (a) of this section, except that a new charter is prepared and filed at the end of each 2-year period as provided in § 14.40(c).

(e) Color additive advisory committees are required to be established under the circumstances specified in section 706(b)(5) (C) and (D) of the act. A color additive advisory committee is subject to the termination and renewal requirements of the Federal Advisory Committee Act and of the part.

Subpart D—Records of Meetings and Hearings Before Advisory Committees

§ 14.60 Minutes and reports of advisory committee meetings.

(a) The executive secretary or other designated agency employee prepares detailed minutes of all advisory committee meetings, except that less detailed minutes may be prepared for open portions of meetings which under § 14.61, must be transcribed or recorded by the agency. Their accuracy is approved by the committee and certified by the chairman. The approval and certification may be accomplished by mail or by telephone.

(b) The minutes include the following:

(1) The time and place of the meeting.

(2) The members, committee staff, and agency employees present, and the names and affiliations or interests of public participants.

(3) A copy of or reference to all written information made available for consideration by the committee at the proceedings.

(4) A complete and accurate description of matters discussed and conclusions reached. A description is to be kept separately for the following portions of the meeting to facilitate their public disclosure: The open portions specified in § 14.25 (a) and (b), any closed portion during which a presentation is made under § 14.25(c), and any closed deliberative portion under § 14.25(d). The minutes of a closed deliberative portion of a meeting may not refer to members by name, except upon their request, or to data or information described in § 14.75(b). Any inadvertent references that occur are to be deleted before public disclosure.

(5) A copy of or reference to all reports received, issued, or approved by the committee.

(6) The extent to which the meeting was open to the public.

(7) The extent of public participation, including a list of members of the public who presented oral or written statements.

(c) For a meeting that has a closed portion, either (1) the minutes of the closed portion are available for public disclosure under § 14.75(a)(6)(i), or (2) if under § 14.75(a)(6)(ii) they are not promptly available, the executive secretary or other designated agency employee shall prepare a brief summary of the matters considered in an informative manner to the public, consistent with 5 U.S.C. 552(b).

(d) Where a significant portion of the meeting of a committee is closed, the committee will issue a report at least annually setting forth a summary of its activities and related matters informative to the public consistent with 5 U.S.C. 552(b). This report is to be a compilation of or be prepared from the individual reports on closed portions of meeting prepared under paragraph (c) of this section.

(e) The executive secretary or other designated agency employee shall, with the approval of the committee, prepare an annual report describing its membership, functions, recommendations and other actions.

§ 14.61 Transcripts of advisory committee meetings.

(a) The agency will arrange for a transcript or recording to be made for each portion of a meeting.

(b) A transcript or recording of an open portion of a meeting made by FDA is to be included in the record of the committee proceedings.

(c) A transcript or recording of any closed portion of a meeting made by FDA will not be included in the administrative record of the committee proceedings. The transcript or recording will be retained as confidential by FDA, and will not be discarded or erased.

(d) Any transcript or recording of a meeting or portion thereof which is publicly available under this section will be available at actual cost of duplication, which will be, where applicable, the fees established in § 20.42. FDA may furnish the requested transcript or recording for copying to a private contractor who shall charge directly for the cost of copying under § 20.51.

(e) A person attending any open portion of a meeting may, consistent with the orderly conduct of the meeting, record or otherwise take a transcript of the meeting. This transcription will not be part of the administrative record.

(f) Only FDA may make a transcript or recording of a closed portion of a meeting.

§ 14.65 Public inquiries and requests for advisory committee records.

(a) Public inquiries on general committee matters, except requests for records, are to be directed to: Committee Management Officer (HFA–25), Office of the Associate Commissioner for Management and Operations, Food and Drug Administration, Department of Health, Education, and Welfare 6500 Fishers Lane, Rockville, MD 20857.

(b) Public inquiries on matters relating to a specific committee, except requests for records, are to be directed to the executive secretary or the designated agency employee listed in the **Federal Register** notices published under § 14.20.

(c) Requests for public advisory committee records, including minutes, are to be made, to FDA's Freedom of Information Staff (HFI–35) under § 20.40 and the related provisions of part 20.

§ 14.70 Administrative record of a public hearing before an advisory committee.

(a) Advice or recommendations of an advisory committee may be given only on matters covered in the administrative record of the committee's proceedings. Except as specified in other FDA regulations, the administrative record consists of all the following items relating to the matter:

(1) Any transcript or recording of an open portion of a meeting.

(2) The minutes of all portions of all meetings, after any deletions under § 14.60(b)(4).

(3) All written submissions to and information considered by the committee.

(4) All reports made by the committee.

(5) Any reports prepared by a consultant under § 14.31(e).

(b) The record of the proceeding is closed at the time the advisory committee renders its advice or recommendations or at any earlier time specified by the committee or in other sections in this chapter.

§ 14.75 Examination of administrative record and other advisory committee records.

(a) The administrative record and other committee records are available for public disclosure under Part 20, except as provided in paragraph (b) of this section, at the following times:

(1) The written information for consideration by the committee at any meeting: at the same time it is made available to the committee.

(2) The transcript or recording of any open portion of a meeting: as soon as it is available.

(3) The minutes of any open portion of a meeting: after they have been approved by the committee and certified by the chairman.

(4) The brief summary of any closed portion of a meeting prepared under § 14.60(c): as soon as it is available.

(5) All written information or views submitted to the committee at an open portion of a meeting: as soon as they are submitted.

(6) The minutes or portions thereof of a closed portion of a meeting—

(i) For a matter not directed to be maintained as confidential under § 14.22(h)(2): After they have been approved by the committee and certified by the chairman; and

(ii) For a matter directed to be maintained as confidential under § 14.22(h)(2): After the advice or report of the committee relevant to those minutes or portions thereof is acted upon by the Commissioner, or upon a determination by the Commissioner that such minutes or portions thereof may be made available for public disclosure without undue interference with agency or advisory committee operations.

(7) Formal advice or a report of the committee: After it has been acted upon, i.e., approved, disapproved, or rejected as inadequate, by the Commissioner, or upon a determination by the Commissioner that such formal advice or report may be made available for public disclosure without undue interference with agency or committee operations. Such formal advice or report may be retained as confidential while it is under active advisement.

(8) Any other committee records relating to the matter, except transcripts and recordings of closed portions of meetings: After the advice or report of the committee relevant to those records is acted upon by the Commissioner, or upon a determination by the Commissioner that the records may be made available for public disclosure without undue interference with agency or committee operations.

(b) The following information contained in the administrative record is not available for public examination or copying except as provided in § 12.32(g):

(1) Material provided to the committee by FDA that is exempt from public disclosure under Part 20 and the regulations referenced there.

(2) Material provided to the advisory committee by a person making a presentation described in § 14.25(c) and which is prohibited from public disclosure under Part 20 and the regulations referenced there.

(c) The Hearing Clerk (HFA–305) will maintain a file for each committee containing the following principal records for ready access by the public:

(1) The committee charter.

(2) A list of committee members and their curricula vitae.

(3) The minutes of committee meetings.

(4) Any formal advice or report of the committee.

Subpart E—Members of Advisory Committees

§ 14.80 Qualifications for members of standing policy and technical advisory committees.

(a) Members of a policy advisory committee—

(1) Shall have diverse interests, education, training, and experience; specific technical expertise is not a requirement;

(2) Are special Government employees subject to the conflict of interest laws and regulations (the Commissioner has determined that, because members representing particular interests, e.g., a representative of labor, industry, consumers, or agriculture, are included on advisory committees specifically for the purpose of representing these interests, any financial interest covered by 18 U.S.C. 208(a) in the class which the member represents is irrelevant to the services which the Government expects from them and thus is hereby exempted under 18 U.S.C. 208(b) as too remote and inconsequential to affect the integrity of their services); and

(3) Shall be voting members.

(b) Technical advisory committee.

(1) Voting members of technical advisory committees—

(i) Shall have expertise in the subject matter with which the committee is concerned and have diverse professional education, training, and experience so that the committee will reflect a balanced composition of sufficient scientific expertise to handle the problems that come before it; and

(ii) Except for members of TEPRSSC, are special Government employees subject to the conflict of interest laws and regulations.

(2) The Commissioner shall, when required by statute, and may when not required by statute, provide for nonvoting members of a technical advisory committee to serve as representatives of and liaison with interested organizations. Nonvoting members—

(i) Shall be selected by the interested organizations, as provided in § 14.84; technical expertise in the subject matter with which the committee is involved is not a requirement; and

(ii) May be special Government employees subject to the conflict of interest laws and regulations, except as provided in § 14.84(e).

(c) A person may serve as a voting or nonvoting member on only one FDA advisory committee unless the Commissioner determines in writing that dual membership will aid the work of the committees involved and is in the public interest.

(d) Members of FDA advisory committees, and the chairman, are appointed from among those nominated under §§ 14.82 and 14.86 and from any other sources by the Secretary, or, by delegation of authority, by the Assistant Secretary for Health, or the Commissioner.

(e) Members appointed to an advisory committee serve for the duration of the committee, or until their terms of appointment expire, they resign, or they are removed from membership by the Commissioner.

(f) A committee member may be removed from membership for good cause. Good cause includes excessive absenteeism from committee meetings, a demonstrated bias that interferes with the ability to render objective advice, failure to abide by the procedures established in this subpart, or violation of other applicable rules and regulations, e.g., for nonvoting members, the provisions of § 14.86(c).

(g) Consultants appointed under § 14.31(e) are not members of advisory committees.

§ 14.82 Nominations of voting members of standing advisory committees.

(a) The Commissioner will publish one or more notices in the **Federal Register** each year requesting nominations for voting members of all existing standing advisory committees. The notice will invite the submission of nominations for voting members from both individuals and organizations.

(b) The notice announcing the establishment of a new committee under § 14.40(b) will invite the submission of nominations for voting members.

(c) A person may nominate one or more qualified persons to an advisory committee. Nominations will specify the advisory committee for which the nominee is recommended and will include a complete curriculum vitae of the nominee. Nominations are to state that the nominee is aware of the nomination, is willing to serve as a

member of the advisory committee, and appears to have no conflict of interest that would preclude membership.

(d) Voting members serve as individuals and not as representatives of any group or organization which nominated them or with which they may be affiliated.

§ 14.84 Nominations and selection of nonvoting members of standing technical advisory committees.

(a) This section applies when the commissioner concludes that a technical advisory committee should include nonvoting members to represent and serve as a liaison with interested individuals and organizations.

(b) Except when the Commissioner concludes otherwise, nonvoting members of a technical advisory committee are selected in accordance with paragraphs (c) and (d) of this section and are normally limited to one person selected by consumer groups and organizations and one person selected by industry groups and organizations.

(c) To select a nonvoting member to represent consumer interests, except as provided in paragraph (c)(5) of this section, the Commissioner publishes a notice in the **Federal Register** requesting nominations for each specific committee, or subcommittee, for which nonvoting members are to be appointed.

(1) A period of 30 days will be permitted for submission of nominations for that committee or subcommittee. Interested persons may nominate one or more qualified persons to represent consumer interests. Although nominations from individuals will be accepted, individuals are encouraged to submit their nominations through consumer organizations as defined in paragraph (c)(3) of this section. Nominations of qualified persons for general consideration as nonvoting members of unspecified advisory committees or subcommittees may be made at any time. All noninations are to be submitted in writing to Office of Consumer Affairs (HF–7), Food and Drug Administration, Room 15B—41, 5600 Fishers Lane, Rockville, MD 20857.

(2) A complete curriculum vitae of any nominee is to be included. Nominations must state that the nominee is aware of the nomination, is willing to serve as a member of an advisory committee, and appears to have no conflict of interest. The nomination must state whether a nominee is interested only in a particular advisory committee or subcommittee, or whether the nominee is interested in becoming a member of any advisory committee or subcommittee. Nominations that do not comply with the requirements of this paragraph will not be considered.

(3) The Office of Consumer Affairs will compile a list of organizations whose objectives are to promote, encourage, and contribute to the advancement of consumer education and to the resolution of consumer problems. All organizations listed are entitled to vote upon the nominees. The list will include organizations representing the public interest, consumer advocacy groups, and consumer/health branches of Federal, State, and local govenments. Any organization that meets the criteria may be included on such list on request.

(4) The executive secretary, or other designated agency employee, will review the list of nominees and select three to five qualified nominees to be placed on a ballot. Names not selected will remain on a list of eligible nominees and be reviewed periodically by the Office of Consumer Affairs to determine continued interest. Upon selection of the nominees to be placed on the ballot, the curriculum vitae for each of the nominees will be sent to each of the organizations on the list complied under paragraph (c)(3) of this section, together with a ballot to be filled out and returned within 30 days. After the time for return of the ballots has expired, the ballots will be counted and the nominee who has received the highest number of votes will be selected as the nonvoting member representing consumer interests for that particular advisory committee or subcommittee. In the event of a tie, the Commissioner will select the winner by lot from among those tied for the highest number of votes.

(5) If a member representing consumer interests resigns or is removed before termination of the committee on which the member is serving, the following procedures will be used to appoint a replacement to serve out the term of the former member:

(i) The Commissioner will appoint the runner-up, in order of number of ballots received, on the original ballot submitted under paragraph (c)(4) of this section to fill the vacancy. If the runner-up is no longer willing to serve as a member, then the next runner-up will be appointed.

(ii) If none of the nominees on the original ballot is willing to serve, or if there was only one nominee on the original ballot, the Office of Consumer Affairs will contact by telephone eligible individuals whose names have been submitted in the past as candidates for membership as representatives of consumer interests. A list of persons who are interested in serving on an advisory committee will then be prepared. The curricula vitae of these persons, together with a ballot, will be sent to a representative number of consumer organizations that have been determined to be eligible to vote for consumer representatives in accordance with paragraph (c)(3) of this section. After 4 days have elapsed, the Office of Consumer Affairs will contact the consumer organizations by telephone and elicit their votes. The candidate who has received the highest number of votes will be selected. In the event of a tie, the Commissioner will select the winner by lot from among those tied for the highest number of votes.

(d) To select a nonvoting member to represent industry interests, the Commissioner will publish, for each committee for which the Commissioner has determined to appoint a nonvoting member, a notice requesting that, within 30 days, any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests send a letter stating that interest to the FDA employee designated in the notice. After 30 days, a letter will be sent to each organization that has expressed an interest, attaching a complete list of all such organizations, and stating that it is their responsibility to consult with each other in selecting, within 60 days after receipt of the letter, a single nonvoting member to represent industry interests for that committee. If no individual is selected within 60 days, the Commissioner will select the nonvoting member representing industry interests.

(e) The Commissioner has determined that, because nonvoting members representing consumer and industry interests are included on advisory committees specifically for the purpose of representing such interests and have no vote, any financial interest covered by 18 U.S.C. 208(a) in the class which the member represents is irrelevant to the services the Government expects from them and thus is hereby exempted under 18 U.S.C. 208(b) as too remote and inconsequential to affect the integrity of their services.

§ 14.86 Rights and responsibilities of nonvoting members of advisory committees.

(a) A nonvoting member of an advisory committee selected to represent and serve as a liaison with interested individuals, associations, and organizations has the same rights as any other committee member except that—

(1) A nonvoting member may vote only on procedural matters such as additional rules adopted under

§ 14.39(a), approval of minutes under § 14.60(a), decisions on transcripts under § 14.61(b), and future meeting dates;

(2) A nonvoting member who is a representative of industry interest may have access to data and information that constitute a trade secret or confidential commercial or financial information as defined in § 20.61 only if the person has been appointed as a special Government employee under § 14.80(b).

(b) a nonvoting member of an advisory committee is subject to, and shall abide by, all rules and regulations adopted by FDA and the committee.

(c) It is the responsibility of the nonvoting consumer and industry members of an advisory committee to represent the consumer and industry interests in all deliberations.

(1) A nonvoting member does not represent any particular organization or group, but rather represents all interested persons within the class which the member is selected to represent. Accordingly, an interested person within the class represented by that nonvoting member may, upon request, have access to all written statements or oral briefings concerning the committee prepared by the nonvoting member for distribution to any person outside the committee. When documents are prepared with non-Government funds, persons desiring copies may be required to pay a reasonable fee to cover printing and similar costs.

(2) The nonvoting member reviews all official committee minutes to assure their completeness and accuracy.

(3) The nonvoting member acts as a liaison between the committee and the interested persons whom that member represents, and transmits requests for information from the committee and relevant information and views to the committee. The nonvoting member takes the initiative in contacting interested persons whom the member represents to seek out relevant information and views and to relate the progress of the advisory committee.

(4) A nonvoting industry member represents all members of the industry, and not any particular association, company, product, or ingredient. If a matter comes before the committee that directly or indirectly affects the company employing the nonvoting industry member, the member shall so inform the committee but need not be absent during the discussion or decline to participate in the discussion. a nonvoting industry member may not discuss the company's position as such, but may discuss any matter in general terms. All presentations and discussions of scientific data and their interpretation on behalf of a company will occur in open session, except as provided in § 14.25(c).

(5) A nonvoting member of an advisory committee may not make any presentation to that advisory committee during a hearing conducted by that committee.

(6) Although a nonvoting member serves in a representative capacity, the nonvoting member shall exercise restraint in performing such functions and may not engage in unseemly advocacy or attempt to exert undue influence over the other members of the committee.

(d) A nonvoting member of an advisory committee may be removed by the Commissioner for failure to comply with this section as well as § 14.80(f).

§ 14.90 Ad hoc advisory committee members.

In selecting members of an ad hoc advisory committee, the Commissioner may use the procedures in §§ 14.82 and 14.84 or any other procedure deemed appropriate.

§ 14.95 Compensation of advisory committee members.

(a) All voting advisory committee members shall, and nonvoting members may: (1) Be appointed as special Government employees (except for members of TEPRSSC), and (2) receive a consultant fee and be reimbursed for travel expenses, including per diem in lieu of subsistence, unless such compensation and reimbursement are waived.

(b) Notwithstanding the member's primary residence, an advisory committee member, while attending meetings of the full committee or a subcommittee, will be paid whether the meetings are held in the Washington, D.C., area or elsewhere.

(c) A committee member who participates in any agency-directed assignment will be paid at an hourly rate when doing assigned work at home, a place of business, or in an FDA facility located within the member's commuting area, and at a daily rate when required to travel outside of that commuting area to perform the assignment. A committee member will not be paid for time spent on normal preparation for a committee meeting.

(1) An agency-directed assignment is an assignment that meets the following criteria:

(i) An activity that requires undertaking a definitive study. The activity must produce a tangible end product, usually a written report. Examples are (*a*) an analysis of the risks and benefits of the use of a class of drugs or a report on a specific problem generated by an IND or NDA; (*b*) the performance of similar investigations or analysis of complex industry submissions to support advisory committee deliberations other than normal meeting preparation; (*c*) the preparation of a statistical analysis leading to an estimate of toxicologically safe dose levels; and (*d*) the design or analysis of animal studies of toxicity, mutagenicity, teratogenicity, or carcinogenicity.

(ii) The performance of an IND or NDA review or similar review.

(2) A committee member who undertakes a special assignment, the end product of which does not represent the end product of the advisory committee, but rather of the committee member's own assignment, can be compensated. Should this preparatory work by members collectively result in an end product of the committee, this is to be considered normal meeting preparation and committee members are not to be compensated for this work.

(d) Salary while in travel status is authorized when a committee member's ordinary pursuits are interrupted for the substantial portion of an additional day beyond the day or days spent in performing those services, and as a consequence the committee member loses some regular compensation. This applies on weekends and holidays if the special Government employee loses income that would otherwise be earned on that day. For travel purposes, a substantial portion of a day is defined as 50 percent of the working day, and the traveler will be paid at a daily rate.

Subpart F—Standing Advisory Committees

§ 14.100 List of standing advisory committees.

Standing advisory committees and the dates of their establishment are as follows:

(a) *Office of the Commissioner, Board of Tea Experts.* (1) Date established: March 2, 1897.

(2) Function: Advises on establishment of uniform standards of purity, quality, and fitness for consumption of all tea imported into the United States under 21 U.S.C. 42.

(b) *Bureau of Biologics*—(1) Advisory review panels for biological products, and the dates of their establishment are as follows:

(i) *Allergenic Extracts Panel.* Established August 24, 1973.

(ii) *Blood and Blood Derivatives Panel.* Established August 24, 1973.

(2) Function: Review and evaluate available data on the safety and effectiveness of biological products.

(c) *Bureau of Drugs*—(1) *Anesthetic and Life Support Drugs Advisory Committee.* (i) Date established: May 1, 1978.

(ii) Function: Reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in the field of anesthesiology and surgery.

(2) *Anti-Infective and Topical Drugs Advisory Committee.* (i) Date established: April 10, 1978.

(ii) Function: Reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in infectious diseases, dermatological disorders, and ocular disease.

(3) *Arthritis Advisory Committee.* (i) Date established: April 5, 1974.

(ii) Function: Reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in arthritic conditions.

(4) *Cardiovascular and Renal Drugs Advisory Committee.* (i) Date established: August 27, 1970.

(ii) Function: Reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in cardiovascular and renal disorders.

(5) *Drug Abuse Advisory Committee.* (i) Date established: May 31, 1978.

(ii) Function: Advises on the scientific and medical evaluation of information gathered by the Department of Health, Education, and Welfare and the Department of Justice on the safety, efficacy, and abuse potential of drugs and recommends actions to be taken on the marketing, investigation, and control of such drugs.

(6) *Endocrinologic and Metabolic Drugs Advisory Committee.* (i) Date established: August 27, 1970.

(ii) Function: Reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in endocrine and metabolic disorders.

(7) *Fertility and Maternal Health Drugs Advisory Committee.* (i) Date established: March 23, 1978.

(ii) Function: Reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in the practice of obstetrics and gynecology.

(8) *Gastrointestinal Drugs Advisory Committee.* (i) Date established: March 3, 1978.

(ii) Function: Reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in gastrointestinal diseases.

(9) *Oncologic Drugs Advisory Committee.* (i) Date established: September 21, 1978.

(ii) Function: Reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in the treatment of cancer.

(10) *Peripheral and Central Nervous System Drugs Advisory Committee.* (i) Date established: June 4, 1974.

(ii) Function: Reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in neurologic disease.

(11) *Psychopharmacologic Drugs Advisory Committee.* (i) Date established: June 4, 1974.

(ii) Function: Reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in the practice of psychiatry and related fields.

(12) *Pulmonary-Allergy Drugs Advisory Committee* (i) Date established: February 17, 1972.

(ii) Function: Reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in the treatment of pulmonary disease and diseases with allergic and/or immunologic mechanisms.

(13) *Radiopharmaceutical Drugs Advisory Committee.* (i) Date established: August 30, 1967.

(ii) Function: Reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in the practice of nuclear medicine.

(14) *Advisory review panels for over-the-counter (OTC) drugs.* (i) Dates established—*(a) Antimicrobial Panel.* Established March 16, 1972;

(*b*) *Oral Cavity Panel.* Established July 16, 1973;

(*c*) *Miscellaneous Internal Drug Products Panel.* Established July 16, 1973; and

(*d*) *Miscellaneous External Drug Products Panel.* Established July 16, 1973.

(ii) Function: Review and evaluate available data on the safety and effectiveness of nonprescription drug products.

(d) *Bureau of Medical Devices.* (1) Advisory panels for medical devices, and the dates of their establishment are as follows:

(i) *Circulatory Systems Devices Panel.* Established April 28, 1978.

(ii) *Clinical Chemistry and Hematology Devices Panel.* Established April 28, 1978.

(iii) *General Medical Devices Panel.* Established April 28, 1978.

(iv) *Immunology and Microbiology Devices Panel.* Established April 28, 1978.

(v) *Obstetrics-Gynecology and Radiologic Devices Panel.* Established April 28, 1978.

(vi) *Ophthalmic; Ear, Nose, and Throat; and Dental Devices Panel.* Established April 28, 1978.

(vii) *Respiratory and Nervous System Devices Panel.* Established April 28, 1978.

(viii) *Surgical and Rehabilitation Devices Panel.* Established April 28, 1978.

(2) Function: Review and evaluate available data on the safety and effectiveness of devices currently in use and make recommendations for their regulation.

(3) *Device Good Manufacturing Practice Advisory Committee.* (i) Date established: August 12, 1976.

(ii) Function: Reviews proposed regulations for good manufacturing practices governing the methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of devices, and makes recommendations on the feasibility and reasonableness of the proposed regulations.

(e) *Bureau of Radiological Health*—(1) *Medical Radiation Advisory Committee.* (i) Date established: October 31, 1963.

(ii) Function: Advises on the formulation of policy and development of a coordinated program for the application of ionizing radiation in the healing arts.

(2) *Technical Electronic Product Radiation Safety Standards Committee.* (i) Date established: October 18, 1968.

(ii) Function: Advises on technical feasibility, reasonableness, and practicability of performance standards for electronic products to control the emission of radiation under 42 U.S.C. 263f(f)(1)(A).

(f) *National Center for Toxicological Research, Science Advisory Board.* (i) Date established: June 2, 1973.

(2) Function: Advises on establishment and implementation of a research program that will assist the

Commissioner of Food and Drugs and the Administrator, Environmental Protection Agency, in fulfilling their regulatory responsibilities.

Subpart G—Technical Electronic Products Radiation Safety Standards Committee

§ 14.120 Establishment of the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC).

The Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC), consisting of 15 members, is established in accordance with the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263f(f)(1)(A)) to provide consultation before the Commissioner prescribes any performance standard for an electronic product.

§ 14.122 Functions of TEPRSSC.

(a) In performing its function of advising the Commissioner, TEPRSSC—

(1) May propose electronic product radiation safety standards to the Commissioner for consideration;

(2) Provides consultation to the Commissioner on all performance standards proposed for consideration under 42 U.S.C. 263f; and

(3) May make recommendations to the Commissioner on any other matters it deems necessary or appropriate in fulfilling the purposes of the act.

(b) Responsibility for action on performance standards under 42 U.S.C. 263f rests with the Commissioner, after receiving the advice of TEPRSSC.

§ 14.125 Procedures of TEPRSSC.

(a) When the Commissioner is considering promulgation of a performance standard for an electronic product, or an amendment of an existing standard, before issuing a proposed regulation in the **Federal Register** the Commissioner will submit to TEPRSSC the proposed standard or amendment under consideration, together with other relevant information to aid TEPRSSC in its deliberations.

(b) The agenda and other material to be considered at any meeting will be sent to members whenever possible at least 2 weeks before the meeting.

(c) Ten members constitute a quorum, provided at least three members are present from each group specified in 42 U.S.C. 263f(f)(1)(A) and in § 14.127(a), i.e., Government, industry, and the public.

(d) The chairman of TEPRSSC will ordinarily submit a report to the Commissioner of the committee's consideration of any proposed performance standard for an electronic product within 60 days after consideration. If the chairman believes that more time is needed, the chairman will inform the Director of the Bureau of Radiological Health in writing, in which case an additional 30 days will be allowed to make the report.

(e) Sections 14.1 through 14.7 apply to TEPRSSC, except where other provisions are specifically included in §§ 14.120 through 14.130.

§ 14.127 Membership of TEPRSSC.

(a) The Commissioner will appoint the members after consultation with public and private organizations concerned with the technical aspect of electronic product radiation safety. TEPRSSC consists of 15 members, each of whom is technically qualified by training and experienced in one or more fields of science or engineering applicable to electronic product radiation safety, as follows:

(1) Five members selected from government agencies, including State and Federal Governments.

(2) Five members selected from the affected industries after consultation with industry representatives.

(3) Five members selected from the general public, of whom at least one shall be a representative of organized labor.

(b) The Commissioner will appoint a committee member as chairman of TEPRSSC.

(c) Appointments of members are for a term of 3 years or as specified by the Commissioner.

(1) The chairman is appointed for a term concurrent with the chairman's term as a member of TEPRSSC. If the chairmanship becomes vacant without adequate notice, the executive secretary may appoint a committee member as temporary chairman pending appointment of a new chairman by the Commissioner.

(2) Members may not be reappointed for a second consecutive full term.

(d) A person otherwise qualified for membership is not eligible for selection as a member of TEPRSSC from Government agencies or the general public if the Commissioner determines that the person does not meet the requirements of the conflict of interest laws and regulations.

(e) Retention of membership is conditioned upon the following:

(1) Continued status as a member of the group from which the member was selected as specified in paragraph (a) of this section.

(2) Absence of any conflict of interest during the term of membership as specified in paragraph (d) of this section.

(3) Active participation in TEPRSSC activities.

(f) Appointment as a member of TEPRSSC is conditioned on certification that the prospective member:

(1) Agrees to the procedures and criteria specified in this subpart.

(2) Has no conflict of interest as specified in paragraph (d) of this section.

(3) Will notify the executive secretary of TEPRSSC before any change in representative status on TEPRSSC which may be contrary to the conditions of the appointment.

(g) Members of TEPRSSC who are not full-time officers or employees of the United States receive compensation under § 14.95, in accordance with 42 U.S.C. 210(c).

§ 14.130 Conduct of TEPRSSC meeting; availability of TEPRSSC records.

(a) In accordance with 42 U.S.C. 263f(f)(1)(B), all proceedings of TEPRSSC are recorded, and the record of each proceeding is available for public inspection.

(b) All proceedings of TEPRSSC are open except when the Commissioner has determined, under § 14.27, that a portion of a meeting may be closed.

Subpart H—Color Additive Advisory Committees

§ 14.140 Establishment of a color additive advisory committee.

The Commissioner will establish a color additive advisory committee under the following circumstances:

(a) The Commissioner concludes, as a matter of discretion, that it would be in the public interest for a color additive advisory committee to review and make recommendations about the safety of a color additive on which important issues are pending before FDA and for interested persons to present information and views at an oral public hearing before a color additive advisory committee.

(b) There is an issue arising under section 706(b)(5)(B) of the act concerning the safety of a color additive, including its potential or actual carcinogenicity, that requires the exercise of scientific judgment and a person who would be adversely affected by the issuance, amendment, or repeal of a regulation listing a color additive requests that the matter, or the Commissioner as a matter of discretion determines that the matter should, be referred to a color additive advisory committee.

(1) Paragraph (b) does not apply to any issue arising under the transitional provisions in section 203 of the Color Additive Amendments of 1960 relating to provisional listing of commercially established colors. A color additive advisory committee to consider any such matter will be established under paragraph (a) of this section.

(2) A request for establishment of a color additive advisory committee is to be made in accordance with § 10.30. The Commissioner may deny any petition if inadequate grounds are stated for establishing a color additive advisory committee. A request for establishment of a color additive advisory committee may not rest on mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires scientific judgment and justifies a hearing before a color additive advisory committee. When it conclusively appears from the request for a color additive advisory committee that the matter is premature or that it does not involve an issue arising under section 706(b)(5)(B) of the act or that there is no genuine and substantial issue of fact requiring scientific judgment, or for any other reason a color additive advisory committee is not justified, the Commissioner may deny the establishment of a color additive advisory committee.

(3) Establishment of a color additive advisory committee on the request of an interested person is conditioned upon receipt of the application fee specified in § 14.155.

(4) Any person adversely affected may request referral of the matter to a color additive advisory committee at any time before, or within 30 days after, publication of an order of the Commissioner acting upon a color additive petition or proposal.

§ 14.142 Functions of a color additive advisory committee.

(a) A color additive advisory committee reviews all available information relating to the matter referred to it, including all information contained in any pertinent color additive petition and in FDA files. All information reviewed is placed on public display and is available for review at the office of the Hearing Clerk.

(b) The Commissioner specifies to the color additive advisory committee, in writing, the issues on which review and recommendations are requested.

(c) The date of the first meeting of a color additive advisory committee, following receipt of the administrative record by each of the committee members, is designated as the beginning of the period allowed for consideration of the matter by the committee. Within 60 days after the first meeting, unless the time is extended as provided in paragraph (d) of this section, the chairman of the committee shall certify to the Commissioner the report containing the recommendations of the committee, including any minority report. The report states the recommendations of the committee and the reasons or basis for them. The report includes copies of all material considered by the committee in addition to the administrative record furnished to it.

(d) If the chairman concludes that the color additive advisory committee needs additional time, the chairman shall so inform the Commissioner in writing and may certify the report of the committee to the Commissioner within 90 days instead of 60 days.

(e) More than one matter may be handled concurrently by a color additive advisory committee.

§ 14.145 Procedures of a color additive advisory committee.

(a) A color additive advisory committee is subject to all the requirements of the Federal Advisory Committee Act and this part.

(b) All interested persons have a right to consult with the color additive advisory committee reviewing a matter and to submit information and views to a color additive advisory committee, in accordance with the procedures in this part.

§ 14.147 Membership of a color additive advisory committee.

(a) The members of a color additive advisory committee are selected in the following manner:

(1) If a color additive advisory committee is established for purposes that do not include review of an issue arising under section 706(b)(5)(B) of the act, or is established on the initiative of the Commissioner, the Commissioner may use the procedure in paragraph (a)(2) of this section to select the members or may use an existing standing advisory committee listed in § 14.100, or may establish a new advisory committee under this subpart. Once the Commissioner has established a color additive advisory committee under this paragraph and has referred to it a matter relating to a color additive, no interested person may subsequently request that an additional or different color additive advisory committee be established to review and make recommendations about that color additive.

(2) If the Commissioner established a color additive advisory committee to review an issue arising under section 706(b)(5)(B) of the act on the request of an interested person, it shall be established under the following requirements:

(i) Except as provided in paragraph (a)(2) (ii) and (iii) of this section, the Commissioner will request the National Academy of Sciences to select the members of a color additive advisory committee from among experts qualified in the subject matter to be reviewed by the committee, and of adequately diversified professional backgrounds. The Commissioner will appoint one of the members as the chairman.

(ii) If the National Academy of Sciences is unable or refuses to select the members of a color additive advisory committee, the Commissioner will select the members.

(iii) If the Commissioner and the requesting party agree, section 706(b)(5)(D) of the act may be waived and the matter may be referred to any standing advisory committee listed in § 14.100 or to any advisory committee established under any other procedure that is mutually agreeable. Once the Commissioner has established a color additive advisory committee and has referred to it a matter relating to a color additive, no interested person may subsequently request that an additional or different color additive advisory committee be established to review and make recommendations about that color additive.

(b) Members of a color additive advisory committee are subject to the requirements of the Federal Advisory Committee Act and this subpart, except that no member of a color additive advisory committee may by reason of such membership alone be a special government employee or be subject to the conflict of interest laws and regulations.

§ 14.155 Fees and compensation pertaining to a color additive advisory committee.

(a) When a matter is referred to a color additive advisory committee, all related costs, including personal compensation of committee members, travel, materials, and other costs, are borne by the person requesting the referral, such costs to be assessed on the basis of actual cost to the government. The compensation of such costs includes personal compensation of committee members at a rate not to exceed $128.80 per member per day.

(b) In the case of a request for referral to a color additive advisory committee a special advance deposit is to be made in the amount of $2,500. Where required, further advances in increments of $2,500 each are to be made upon request of the Commissioner. All deposits for referrals to a color additive advisory committee in excess of actual expenses will be refunded to the depositor.

(c) All deposits and fees required by this section are to be paid by money order, bank draft, or certified check drawn to the order of the Food and Drug Administration, collectable at par in Washington, DC. All deposits and fees are to be forwarded to the Associate Commissioner for Management and Operations, Food and Drug Administration, 5600 Fishers Lane Rockville, MD 20857, and after appropriate record of them is made, they will be transmitted to the Treasurer of the United States for deposit in the special account "Salaries and Expenses, Certification, Inspection, and Other Services, Food and Drug Administration."

(d) The Commissioner may waive or refund such fees in whole or in part when, in the Commissioner's judgment, such action will promote the public interest. Any person who believes that payment of these fees will be a hardship may petition the Commissioner under § 10.30 to waive or refund the fees.

Subpart I—Advisory Committees for Human Prescription Drugs

§ 14.160 Establishment of standing technical advisory committees for human prescription drugs.

The standing technical advisory committees for human prescription drugs are established to advise the Commissioner:

(a) Generally on the safety and effectiveness, including the labeling and advertising, and regulatory control of the human prescription drugs falling within the pharmacologic class covered by the advisory committee and on the scientific standards appropriate for a determination of safety and effectiveness in that class of drugs.

(b) Specifically on any particular matter involving a human prescription drug pending before FDA, including whether the available information is adequate to support a determination that—

(1) A particular IND study may properly be conducted;

(2) A particular drug meets the statutory standard for proof of safety and effectiveness necessary for approval or continued approval for marketing; or

(3) A particular drug is properly classified as a new drug, an old drug, or a banned drug.

§ 14.171 Utilization of an advisory committee on the initiative of FDA.

(a) Any matter involving a human prescription drug under review within the agency may, in the discretion of the Commissioner, be the subject of a public hearing and continuing or periodic review by the appropriate standing technical advisory committee for human prescription drugs. The Commissioner's determinations on the agenda of the committee are based upon the priorities of the various matters pending before the agency which fall within the pharmacologic class covered by that committee.

(b) High priority for such hearing and review by the appropriate standing technical advisory committee for human prescription drugs are given to the following types of human prescription drugs:

(1) Investigational drugs which are potential therapeutic advances over currently marketed products from the standpoint of safety or effectiveness, or which pose significant safety hazards, or which present narrow benefit-risk considerations requiring a close judgmental decision on approval for marketing, or which have a novel delivery system or formulation, or which are the subject of major scientific or public controversy, or which may be subject to special regulatory requirements such as a limitation on clinical trials, a patient followup requirement, postmarketing Phase IV studies, distributional controls, or boxed warnings.

(2) Marketed drugs for which an important new use has been discovered or which pose newly discovered safety hazards, or which are the subject of major scientific or public controversy, or which may be subject to important regulatory actions such as withdrawal of approval for marketing, boxed warnings, distributional controls, or newly required scientific studies.

(c) The committee may request the Commissioner for an opportunity to hold a public hearing and to review any matter involving a human prescription drug which falls within the pharmacologic class covered by the committee. The Commissioner may, after consulting with the committtee on such request, grant or deny the request in light of the priorities of the other matters pending before the committee. Whenever feasible, consistent with the other work of the committee, the request will be granted.

(d) For a drug that meets any of the criteria established in paragraph (b) of this section, one or more members of or consultants to the appropriate advisory committee may be selected for more detailed monitoring of the matter and consultation with FDA on behalf of the committee. The member or consultant may be invited to attend appropriate meetings and shall assist the bureau in any briefing of the committee on that matter.

(e) An advisory committee may obtain advice and recommendations from other agency advisory committees, consultants, and experts which the advisory committee and the bureau conclude would facilitate the work of the advisory committee.

(f) Presentation of all relevant information about the matter will be made in open session unless it relates to an IND the existence of which has not previously been disclosed to the public as defined in § 20.81 or is otherwise prohibited from public disclosure under part 20 and the regulations referenced therein. Sections 314.14, 431.71, and 601.51 determine whether, and the extent to which, relevant information may be made available for public disclosure, summarized and discussed in open session but not otherwise made available for public disclosure, or not in any way discussed or disclosed in open session or otherwise disclosed to the public.

§ 14.172 Utilization of an advisory committee at the request of an interested person.

Any interested person may request, under § 10.30, that a specific matter relating to a particular human prescription drug be submitted to an appropriate advisory committee for a hearing and review and recommendations. The request must demonstrate the importance of the matter and the reasons why it should be submitted for a hearing at that time. The Commissioner may grant or deny the request.

§ 14.174 Advice and recommendations in writing.

Advice and recommendations given by a committee on a specific drug or a class of drugs are ordinarily in the form of a written report. The report may consist of the approved minutes of the meeting or a separate written report. The report responds to the specific issues or questions which the Commissioner has addressed to the advisory committee, and states the basis

of the advice and recommendations of the committee.

PART 15—PUBLIC HEARING BEFORE THE COMMISSIONER

Subpart A—General Provisions

Subpart B—Procedures for Public Hearing Before the Commissioner

Subpart C—Records of a Public Hearing Before the Commissioner

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. 604–607 as amended (21 U.S.C. 41–50); sec. 2 et seq., Pub. L. 783, 44 Stat. 1406 as amended (15 U.S.C. 401 et seq.); sec. 1 et seq., Pub. L. 89–755, 80 Stat. 1296 as amended (15 U.S.C. 1451 et seq.).

Subpart A—General Provisions

§ 15.1 Scope.

The procedures in this part apply when:

(a) The Commissioner concludes, as a matter of discretion, that it is in the public interest to permit persons to present information and views at a public hearing on any matter pending before the Food and Drug Administation.

(b) The act or regulation specifically provides for a public hearing before the Commissioner on a matter, e.g., § 330.10(a)(8) relating to over-the-counter drugs and sections 520 (b) and (f)(1)(B), and 521 of the act relating to proposals to allow persons to order custom devices, to proposed device good manufacturing practice regulations, and to proposed exemptions from preemption of State and local device requirements under § 808.25(e).

(c) A person who has right to an opportunity for a formal evidentiary public hearing under Part 12 waives that opportunity and instead requests under § 12.32 a public hearing before the Commissioner, and the Commissioner, as a matter of discretion, accepts the request.

Subpart B—Procedures for Public Hearing Before the Commissioner

§ 15.20 Notice of a public hearing before the Commissioner.

(a) If the Commissioner determines that a public hearing should be held on a matter, the Commissioner will publish a notice of hearing in the **Federal Register** setting forth the following information:

(1) If the hearing is under § 15.1 (a) or (b), the notice will state the following:

(i) The purpose of the hearing and the subject matter to be considered. If a written document is to be the subject matter of the hearing, it will be published as part of the notice, or reference made to it if it has already been published in the **Federal Register**, or the notice will state that the document is available from an agency office identified in the notice.

(ii) The time, date, and place of the hearing, or a statement that the information will be contained in a subsequent notice.

(2) If the hearing is in lieu of a formal evidentiary public hearing under § 15.1(c), all of the information described in § 12.32(e).

(b) The scope of the hearing is determined by the notice of hearing and any regulation under which the hearing is held. If a regulation, e.g., § 330.10(a)(10), limits a hearing to review of an existing administrative record, information not already in the record may not be considered at the hearing.

(c) The notice of hearing may require participants to submit the text of their presentations in advance of the hearing if the Commissioner determines that advance submissions are necessary for the panel to formulate useful questions to be posed at the hearing under § 15.30(e). The notice may provide for the submission of a comprehensive outline as an alternative to the submission of the text if the Commissioner determines that submission of an outline will be sufficient.

§ 15.21 Notice of participation; schedule for hearing.

(a) The notice of hearing will provide persons an opportunity to file a written notice of participation with the Hearing Clerk within a specified period of time containing the information specified in the notice, e.g., name of participant, address, phone number, affiliation, if any, topic of presentation and approximate amount of time requested for the presentation. If the public interest requires, e.g., a hearing is to be conducted within a short period of time or is to be primarily attended by individuals without an organizational affiliation, the notice may name a specific FDA employee and telephone number to whom an oral notice of participation may be given or provide for submitting notices of participation at the time of the hearing. A written or oral notice of participation must be received by the designated person by the close of business of the day specified in the notice.

(b) Promptly after expiration of the time for filing a notice, the Commissioner will determine the amount of time allotted to each person and the approximate time that oral presentation is scheduled to begin. If more than one hearing is held on the same subject, a person will ordinarily be allotted time for a presentation at only one hearing.

(c) Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and to request time for a joint presentation. The Commissioner may require joint presentations by persons with common interests.

(d) The Commissioner will prepare a hearing schedule showing the persons making oral presentations and the time alloted to each person, which will be filed with the Hearing Clerk and mailed or telephoned before the hearing to each participant.

(e) The hearing schedule will state whether participants must be present by a specified time to be sure to be heard in case the absence of participants advances the schedule.

§ 15.25 Written submissions.

A person may submit information or views on the subject of the hearing in writing to the Hearing Clerk, under § 10.20. The record of the hearing will remain open for 15 days after the hearing is held for any additional written submissions, unless the notice of the hearing specifies otherwise or the presiding officer rules otherwise.

§ 15.30 Conduct of a public hearing before the Commissioner.

(a) The Commissioner or a designee may perside at the hearing, except where a regulation provides that the Commissioner will preside personally. The presiding officer may be accompanied by other FDA employees or other Federal Government employees designated by the Commissioner, who

may serve as a panel in conducting the hearing.

(b) The hearing will be transcribed.

(c) Persons may use their alloted time in whatever way they wish, consistent with a reasonable and orderly hearing. A person may be accompanied by any number of additional persons, and may present any written information or views for inclusion in the record of the hearing, subject to the requirements of § 15.25. The presiding officer may allot additional time to any person when the officer concludes that it is in the public interest, but may not reduce the time alloted for any person without the consent of the person.

(d) If a person is not present at the time specified for the presentation, the persons following will appear in order, with adjustments for those appearing at their scheduled time. An attempt will be made to hear any person who is late at the conclusion of the hearing. Other interested persons attending the hearing who did not request an opportunity to make an oral presentation will be given an opportunity to make an oral presentation at the conclusion of the hearing, in the discretion of the presiding officer, to the extent that time permits.

(e) The presiding officer and any other persons serving on a panel may question any person during or at the conclusion of the presentation. No other person attending the hearing may question a person making a presentation. The presiding officer may, as a matter of discretion, permit questions to be submitted to the presiding officer or panel for response by them or by persons attending the hearing.

(f) The hearing is informal in nature, and the rules of evidence do not apply. No motions or objections relating to the admissibility of information and views may be made or considered, but other participants may comment upon or rebut all such information and views. No participant may interrupt the presentation of another participant at any hearing for any reason.

(g) The hearing may end early only if all persons scheduled for a later presentation have already appeared or it is past the time specified in the hearing schedule, under § 15.21(e), by which participants must be present.

(h) The Commissioner or the presiding officer may, under § 10.19, suspend, modify, or waive any provision of this part.

Subpart C—Records of a Public Hearing Before the Commissioner

§ 15.40 Administrative record.

(a) The administrative record of a public hearing before the Commissioner consists of the following:

(1) All relevant **Federal Register** notices, including any documents to which they refer.

(2) All written submissions under § 15.25.

(3) The transcript of the oral hearing.

(b) the record of the administrative proceeding will be closed at the time specified in § 15.25.

§ 15.45 Examination of administrative record.

Section 10.20(j) governs the availability for public examination and copying of each document in the administrative record of the hearing.

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

Subpart A—General Provisions

Sec.
16.1 Scope.
16.5 Inapplicability and limited applicability.

Subpart B—Initiation of Proceedings

16.22 Initiation of regulatory hearing.
16.24 Regulatory hearing required by the act or a regulation.

Subpart C—Commissioner and Presiding Officer

16.40 Commissioner.
16.42 Presiding officer.
16.44 Communication to presiding officer and Commissioner.

Subpart D—Procedures for Regulatory Hearing

16.60 Hearing procedure.
16.62 Right to counsel.

Subpart E—Administrative Record and Decision

16.80 Administrative record of a regulatory hearing.
16.85 Examination of administrative record.
16.95 Administrative decision and record for decision.

Subpart F—Reconsideration and Stay

16.119 Reconsideration and stay of action.

Subpart G—Judicial Review

16.120 Judicial review.

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. 604–607 as amended (21 U.S.C. 41–50); sec. 2 et seq., Pub. L. 783, 44 Stat. 1406 as amended (15 U.S.C. 401 et seq.); sec. 1 et seq., Pub. L. 89–755, 80 Stat. 1296 as amended (15 U.S.C. 1451 et seq.).

Subpart A—General Provisions

§ 16.1 Scope.

The procedures in this part apply when:

(a) The Commissioner is considering any regulatory action, including a refusal to act, and concludes, as a matter of discretion, on the Commissioner's initiative or at the suggestion of any person, to offer an opportunity for a regulatory hearing to obtain additional information before making a decision or taking action.

(b) The act or a regulation provides a person with an opportunity for a hearing on a regulatory action, including proposed action, and the act or a regulation either specifically provides an opportunity for a regulatory hearing under this part or provides an opportunity for a hearing for which no procedures are specified by regulation. Listed below are the statutory and regulatory provisions under which regulatory hearings are available:

(1) Statutory provisions:

Section 304(g) of the act relating to the administrative detention of devices (see § 800.55(g)).

Section 514(g)(4)(B) of the act relating to an action to make a device performance standard effective upon publication.

Section 515(e)(1) of the act relating to the proposed withdrawal of approval of a device premarket approval application.

Section 515(f)(6) of the act relating to a proposed order revoking a device product development protocol or declaring a protocol not completed.

Section 515(f)(7) of the act relating to revocation of a notice of completion of a product development protocol.

Section 516 of the act relating to a proposed banned device regulation (see § 895.21(d)).

Section 518(b) of the act relating to a determination that a device is subject to a repair, replacement, or refund order or that a correction plan, or revised correction plan, submitted by a manufacturer, importer, or distributor is inadequate.

Section 520(g) (4) and (5) of the act relating to disapproval and withdrawal of approval of an application for an investigational device exemption (see §§ 813.30(d) and 813.35(c)).

Section 520(1)(2) of the act relating to approval or denial of a petition to reclassify a class III device that FDA previously had regarded as a new drug (see § 860.136).

(2) Regulatory provisions:

§ 71.37(a), relating to use of food containing a color additive.

§ 80.31(b), relating to refusal to certify a batch of a color additive.

§ 80.34(b), relating to suspension of certification service for a color additive.

§ 130.17(1), relating to a temporary permit to vary from a food standard.

§ 170.17(b), relating to use of food containing an investigational food additive.

§ 202.1(j)(5), relating to approval of prescription drug advertisements.

§ 312.1(c)(1), relating to whether an investigator is entitled to receive investigational new drugs.

§ 312.1(c) (4) and (d), relating to termination of an IND for a sponsor.

§ 312.9(c), relating to termination of an IND for tests in vitro and in laboratory research animals for a sponsor.

§ 429.50, relating to suspension of certification service for an insulin drug.

§ 431.52, relating to suspension of certification service for an antibiotic drug.

§ 433.2(d), relating to exemption from certification for an antibiotic drug.

§ 433.12(b)(5), relating to an exemption from labeling for a certifiable antibiotic drug.

§ 433.13(b), relating to an exemption from manufacturing use for a certifiable antibiotic drug.

§ 433.14(b), relating to an exemption for storage for a certifiable antibiotic drug.

§ 433.15(b), relating to an exemption for processing for a certifiable antibiotic drug.

§ 433.16(b), relating to an exemption for repacking for a certifiable antibiotic drug.

§ 511.1(b)(5), relating to use of food containing an investigational new animal drug.

§ 511.1(c)(1), relating to termination of an INAD for an investigator.

§ 511.1(c) (4) and (d), relating to termination of an INAD for a sponsor.

§ 514.210, relating to suspension of certification service for a veterinary antibiotic drug.

§ 1003.11(a)(3), relating to the failure of an electronic product to comply with an applicable standard or to a defect in an electronic product.

§ 1003.31(d), relating to denial of an exemption from notification requirements for an electronic product which fails to comply with an applicable standard or has a defect.

§ 1004.6, relating to plan for repurchase, repair, or replacement of an electronic product.

§ 1210.30, relating to denial, suspension, or revocation of a permit under the Federal Import Milk Act.

§ 16.5 Inapplicability and limited applicability.

(a) This part does not apply to the following:

(1) Informal presentation of views before reporting a criminal violation under section 305 of the act and section 5 of the Federal Import Milk Act and § 1210.31.

(2) A hearing on a refusal of admission of a food, drug, device, or cosmetic under section 801(a) of the act and § 1.94, or of an electronic product under section 360(a) of the Public Health Service Act and § 1005.20.

(3) Factory inspections, recalls, regulatory letters, and similar compliance activities related to law enforcement.

(b) If a regulation provides a person with an opportunity for hearing and specifies some procedures for the hearing but not a comprehensive set of procedures, the procedures in this part apply to the extent that they are supplementary and not in conflict with the other procedures specified for the hearing. Thus, the procedures in subpart A of Part 108 relating to emergency permit control are supplemented by the nonconflicting procedures in this part, e.g., the right to counsel, public notice of the hearing, reconsideration and stay, and judicial review.

Subpart B—Initiation of Proceedings

§ 16.22 Initiation of regulatory hearing.

(a) A regulatory hearing is initiated by a notice of opportunity for hearing from FDA. The notice will—

(1) Be sent by mail, telegram, telex, personal delivery, or any other mode of written communication;

(2) Specify the facts and the action that are the subject of the opportunity for a hearing;

(3) State that the notice of opportunity for hearing and the hearing are governed by this part; and

(4) State the time within which a hearing may be requested, and state the name, address, and telephone number of the FDA employee to whom any request for hearing is to be addressed.

(b) A person offered an opportunity for a hearing has the amount of time specified in the notice, which may not be less than 3 working days after receipt of the notice, within which to request a hearing. The request may be filed by mail, telegram, telex, personal delivery, or any other mode of written communication, addressed to the designated FDA employee. If no response is filed within that time, the offer is deemed to have been refused and no hearing will be held.

(c) If a hearing is requested, the Commissioner will designate a presiding officer, and the hearing will take place at a time and location agreed upon by the party requesting the hearing, the FDA, and the presiding officer or, if agreement cannot be reached, at a reasonable time and location designated by the presiding officer.

(d) A notice of opportunity for hearing under this section will not operate to delay or stay any administrative action, including enforcement action by the agency unless the Commissioner, as a matter of discretion, determines that delay or a stay is in the public interest.

§ 16.24 Regulatory hearing required by the act or a regulation.

(a) A regulatory hearing required by the act or a regulation under § 16.1(b) will be initiated in the same manner as other regulatory hearings subject to the additional procedures in this section.

(b) The notice will state whether any action concerning the matter that is the subject of the opportunity for hearing is or is not being taken pending the hearing under paragraph (c) of this section.

(c) The Commissioner may take such action pending a hearing under this section as the Commissioner concludes is necessary to protect the public health, except where expressly prohibited by statute or regulation. A hearing to consider action already taken, and not stayed by the Commissioner, will be conducted on an expedited basis.

(d) The hearing may not be required to be held at a time less than 2 working days after receipt of the request for hearing.

(e) Before the hearing, FDA will give to the party requesting the hearing reasonable notice of the matters to be considered at the hearing, including a comprehensive statement of the basis for the decision or action taken or proposed that is the subject of the hearing and a general summary of the information that will be presented by FDA at the hearing in support of the decision or action. This information may be given orally or in writing, in the discretion of FDA.

(f) FDA and the party requesting the hearing will, if feasible, at least 1 day before the hearing provide to each other written notice of any published articles or written information to be presented at or relied on at the hearing. A copy will also be provided in advance if the other participant could not reasonably be expected to have or be able to obtain a copy. If written notice or a copy is not provided, the presiding officer may, if time permits, allow the party who did not receive the notice or copy additional time after the close of the hearing to make a submission concerning the article or information.

Subpart C—Commissioner and Presiding Officer

§ 16.40 Commissioner.

Whenever the Commissioner has delegated authority under part 5 on a matter for which a regulatory hearing is available under this part, the functions

of the Commissioner under this part may be performed by any of the officials to whom the authority has been delegated, e.g., a bureau director.

§ 16.42 Presiding officer.

(a) An FDA employee to whom the Commissioner delegates such authority, or any other agency employee designated by an employee to whom such authority is delegated, may serve as the presiding officer and conduct a regulatory hearing under this part.

(b) In a regulatory hearing required by the act or a regulation, the presiding officer is to be free from bias or prejudice and may not have participated in the investigation or action that is the subject of the hearing or be subordinate to a person, other than the Commissioner, who has participated in such investigation or action.

(c)(1) The Commissioner or the delegate under § 16.40 is not precluded by this section from prior participation in the investigation or action that is the subject of the hearing. If there has been prior participation, the Commissioner or the delegate should, if feasible, designate a presiding officer for the hearing who is not a subordinate. Thus, if the Commissioner's authority to make a final decision has been delegated to a bureau director, the presiding officer may be an official in another bureau or the office of the Commissioner. The exercise of general supervisory responsibility, or the designation of the presiding officer, does not constitute prior participation in the investigation or action that is the subject of the hearing so as to preclude the Commissioner or delegate from designating a subordinate as the presiding officer.

(2) The party requesting a hearing may make a written request to have the Commissioner or the delegate under § 16.40 be the presiding officer, notwithstanding paragraph (c)(1) of this section. If accepted, as a matter of discretion, by the Commissioner or the delegate, the request is binding upon the party making the request.

(3) A different presiding officer may be substituted for the one originally designated under § 16.22 without notice to the parties.

§ 16.44 Communications to presiding officer and Commissioner.

(a) Regulatory hearings are not subject to the separation of functions rules in § 10.55.

(b) Those persons who are directly involved in the investigation or presentation of the position of FDA or any party at a regulatory hearing that is required by the act or a regulation should avoid any off-the-record communication on the matter to the presiding officer or the Commissioner or their advisors if the communication is inconsistent with the requirement of § 16.95(b)(1) that the administrative record be the exclusive record for decision. If any communication of this type occurs, it is to be reduced to writing and made part of the record, and the other party provided an opportunity to respond.

(c) A copy of any letter or memorandum of meeting between a participant in the hearing and the presiding officer or the Commissioner, e.g., a response by the presiding officer to a request for a change in the time of the hearing, is to be sent to all participants by the person writing the letter or the memorandum.

Subpart D—Procedures for Regulatory Hearing

§ 16.60 Hearing procedure.

(a) A regulatory hearing is public, except when the Commissioner determines that all or part of a hearing should be closed to prevent a clearly unwarranted invasion of personal privacy; to prevent the disclosure of a trade secret or confidential commercial or financial information that is not available for public disclosure under § 20.61; or to protect investigatory records complied for law enforcement purposes that are not available for public disclosure under § 20.64.

(1) The Commissioner may determine that a regulatory hearing is closed either on the Commissioner's initiative or on a request by the party asking for a regulatory hearing, in the request for the hearing.

(2) If the hearing is a private hearing, no persons other than the party requesting the hearing, counsel and witnesses, and an employee or consultant or other person subject to a commercial arrangement as defined in § 20.81(a) and FDA representatives with a direct professional interest in the subject matter of the proceeding are entitled to attend.

(3) If the hearing is a public hearing, it will be announced on the public calendar described in § 10.100(a) whenever feasible, and any interested person who attends the hearing may participate to the extent of presenting relevant information.

(b) A regulatory hearing will be conducted by a presiding officer. Employees of FDA will first give a full and complete statement of the action which is the subject of the hearing, together with the information and reasons supporting it, and may present any oral or written information relevant to the hearing. The party requesting the hearing may then present any oral or written information relevant to the hearing. All parties may confront and conduct reasonable cross-examination of any person (except for the presiding officer and counsel for the parties) who makes any statement on the matter at the hearing.

(c) The hearing is informal in nature, and the rules of evidence do not apply. No motions or objections relating to the admissibility of information and views will be made or considered, but any other party may comment upon or rebut all such data, information, and views.

(d) The presiding officer may order the hearing to be transcribed. The party requesting the hearing may have the hearing transcribed, at the party's expense, in which case a copy of the transcript is to be furnished to FDA. Any transcript of the hearing will be included with the presiding officer's report of the hearing.

(e) The presiding officer shall prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. Whenever time permits, the parties to the hearing will be given the opportunity to review and comment on the presiding officer's report of the hearing.

(f) The presiding officer shall include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and shall include a recommended decision, with a statement of reasons, unless the Commissioner directs otherwise.

(g) The presiding officer has the power to take such actions and make such rulings as are necessary or appropriate to maintain order and to conduct a fair, expeditious, and impartial hearing, and to enforce the requirements of this part concerning the conduct of hearings. The presiding officer may direct that the hearing be conducted in any suitable manner permitted by law and these regulations.

(h) The Commissioner or the presiding officer has the power under § 10.19 to suspend, modify, or waive any provision of this part.

§ 16.62 Right to counsel.

Any party to a hearing under this part has the right at all times to be advised and accompanied by counsel.

Subpart E—Administrative Record and Decision

§ 16.80 Administrative record of a regulatory hearing.

(a) The administrative record of the regulatory hearing consists of the following:

(1) The notice of opportunity for hearing and the response.

(2) All written information and views submitted to the presiding officer at the hearing or after if specifically permitted by the presiding officer.

(3) Any transcript of the hearing.

(4) The presiding officer's report of the hearing and comments on the report under §-16.60(e).

(5) All letters and memoranda of meetings or communications between participants and the presiding officer or the Commissioner referred to in § 16.44(c).

(b) The record of the regulatory hearing is closed to the submission of information and views, at the close of the hearing, unless the presiding officer specifically permits additional time for a further submission.

§ 16.85 Examination of administrative record.

Part 20 governs the availability for public disclosure of each document that is a part of the administrative record of a regulatory hearing.

§ 16.95 Administrative decision and record for decision.

(a) With respect to a regulatory hearing at the Commissioner's initiative under § 16.1(a), the Commissioner shall consider the administrative record of the hearing specified in § 16.80(a) together with all other relevant information and views available to FDA in determining whether regulatory action should be taken and, if so, in what form.

(b) With respect to a regulatory hearing required by the act or a regulation under § 16.1(b)—

(1) The administrative record of the hearing specified in § 16.80(a) constitutes the exclusive record for decision;

(2) On the basis of the administrative record of the hearing, the Commissioner shall issue a written decision stating the reasons for the Commissioner's administrative action and the basis in the record; and

(3) For purposes of judicial review under § 10.45, the record of the administrative proceeding consists of the record of the hearing and the Commissioner's decision.

Subpart F—Reconsideration and Stay

§ 16.119 Reconsideration and stay of action.

After any final administrative action that is the subject of a hearing under this part, any party may petition the Commissioner for reconsideration of any part or all of the decision or action under § 10.33 or may petition for a stay of the decision or action under § 10.39.

Subpart G—Judicial Review

§ 16.120 Judicial review.

Section 10.45 governs the availability of judicial review concerning any regulatory action which is the subject of a hearing under this part.

Interested persons may, on or before January 8, 1978, submit to the hearing clerk (HFA–305), Food and Drug Administration, Room 4–65, 5600 Fishers Lane, Rockville, MD. 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the Hearing Clerk, Food and Drug Administration.

Effective date. This regulation is effective May 14, 1979.

Dated: April 6, 1979.

Joseph P. Hile,
Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–0286]
[FR Doc. 79–11402 Filed 4–12–79; 8:45 am]
BILLING CODE 4110–03–M

federal register

Friday
April 13, 1979

Part V

Department of the Interior

Office of the Secretary

Nondiscrimination on the Basis of Handicap

DEPARTMENT OF THE INTERIOR

43 CFR Part 17

Nondiscrimination on the Basis of Handicap

AGENCY: Department of the Interior.

ACTION: Notice of Intent; final rule.

SUMMARY: This rule will implement the requirements of Section 504 of the Rehabilitation Act of 1973, as amended, which provides that "no otherwise qualified handicapped individual in the United States * * * shall, solely by reason of his handicap, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance," with regard to programs of the Department of the Interior. In many respects, this rule is similar to the Department of Health, Education and Welfare's final rule of May 4, 1977, implementing Executive Order 11914, "Nondiscrimination with Respect to the Handicapped in Federally-Assisted Programs" which was published in the **Federal Register** on April 28, 1976 at 41 FR 17871. Comments are requested.

DATE: Comments must be received on or before June 12, 1979.

ADDRESS: Comments should be sent to: Director, Office for Equal Opportunity, Department of the Interior, 18th and C Streets, NW, Washington, D.C. 20240.

FOR FURTHER INFOMATION CONTACT: Melvin Fowler (202) 343–6335.

SUPPLEMENTARY INFORMATION: All comments from interested parties on the regulations are invited and will assist the Department in developing final standards and guidelines under Section 504. Comments would be particularly helpful with regard to achieving program accessibility in historic properties where structural changes will alter significant architectural or historical features of a facility.

The Department also particularly invites your comments on achieving the greatest program accessibility in the most integrated setting possible in recreational facilities where complete accessibility is difficult to achieve, such as wilderness and river areas.

The Department has determined that this is a significant rule, in accordance with 43 CFR 14.3(c). In order to aid the Department in assessing the economic effects of this proposed rule, in accordance with Executive Order 12044 (43 FR 22573), and 43 CFR Part 14, comments are particularly sought in the following areas:

I. Cost of compliance.

A. Indicate personnel required by state and local governments.

B. Indicate costs of providing accessibility in:

1. Programs and facilities financed by the Land and Water Conservation Fund.

2. Programs and facilities financed by Historic Preservation Grants.

3. Indian Schools and Johnson O' Malley grants to public schools.

4. Programs and facilities financed by Dingell-Johnson and Pitman-Robertson Funds.

5. Indian Financing Act loans and loan guarantees.

6. Fish and Wildlife recreation grants under the Reclamation Small Loans Act.

C. Funds for planning, inspection and supervision other than salaries.

II. Assessment of the benefits of compliance.

Assess the number of persons who may benefit from the programs set forth in the regulations, or otherwise assess handicap usage of facilities covered.

III. Assessment of cost effective compliance.

Assess in terms of cost the various methods of offering the services of parks, historic properties, natural areas, and recreational facilities in accordance with these regulations.

Comments with regard to the possible beneficial and/or adverse environmental impact of the proposed regulations are also requested.

The primary author of this document is: A. G. Hancock, Attorney, Solicitor's Office, Equal Opportunity Compliance. Mr. Hancock may be reached at (202) 343–6346.

Dated: April 4, 1979.

James A. Joseph,
Under Secretary of the Interior.

Accordingly, 43 CFR Part 17 is retitled Nondiscrimination in Federally-Assisted Programs of the Department of the Interior; 43 CFR Section 17.1 through 17.19 are redesignated Subpart A and retitled Effectuation of Title VI of the Civil Rights Act of 1964; and a new Subpart B is added to read as follows:

Subpart B—Nondiscrimination on the Basis of Handicap.

Sec.

Authority: Sec. 504, Rehabilitation Act of 1973, Pub. L. 93–112, 87 Stat. 394 (29 USC 794); Sec. 111(a), Rehabilitation Act Amendments of 1974, Pub. L. 93–516, 88 Stat. 1619 (29 USC 706); Executive Order 11914, 41 FR 1781. Department of Health, Education, and Welfare, Implementation of Executive Order 11914, 45 FR 2132; Sec. 606, Education of the Handicapped Act (20 USC 1405), as amended by Pub. L. 94–142, 89 Stat. 795; Sec. 321, Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970, 84 Stat. 182 (42 USC 4581), as amended; sec. 407, Drug Abuse Office and Treatment Act of 1972, 86 Stat. 78 (21 USC 1174), as amended.

Subpart B—General Provisions

§ 17.20 Purpose.

This subpart contains the regulations of the Department of the Interior implementing Executive Order 11914, regarding nondiscrimination on the basis of handicap in Federally-assisted programs.

§ 17.21 Application.

This subpart applies to each recipient of Federal assistance from the Department of the Interior and to each program or activity that receives or benefits from such assistance.

§ 17.22 Definitions.

As used in this part, the term:

(a) "The Act" means the Rehabilitation Act of 1973, Public Law 93–112, as amended by the Rehabilitation Act Amendments of 1974, Public Law 93–516, 29 U.S.C. 794.

(b) "Section 504" means section 504 of the Act.

(c) "Education of the Handicapped Act" means that statute as amended by the Education for all Handicapped Children Act of 1975, Public Law 94–142, 20 U.S.C. 1401 et seq.

(d) "Department" means the Department of the Interior.

(e) "Director" means the Director of the Office for Equal Opportunity of the Department.

(f) "Recipient" means any state or its political subdivision, any instrumentality of a state or its political subdivision, any public or private agency, institution, organization, or other entity, or any person to which Federal financial assistance is extended directly or through another recipient, including any successor, assignee, or transferee of a recipient, but excluding the ultimate beneficiary of the assistance.

(g) "Applicant for assistance" means one who submits an application, request, or plan required to be approved by a Department official or by a recipient as a condition to becoming a recipient.

(h) "Federal financial assistance" means any grant, loan, contract (other than a procurement contract or a contract of insurance or guaranty), or any other arrangement by which the Department provides or otherwise makes available assistance in the form of

(1) Funds;

(2) Services of Federal personnel; or

(3) Real and personal property or any interest in or use of such property, including:

(i) Transfers or leases of such property for less than fair market value or for reduced consideration; and

(ii) Proceeds from a subsequent transfer or lease of such property if the Federal share of its fair market value is not returned to the Federal Government.

(i) "Facility" means all or any portion of buildings, structures, equipment, roads, walks, parking lots, or other real or personal property or interest in such property.

(j) "Handicapped person." (1) Handicapped person means any person who (i) has a physical or mental impairment which substantially limits one or more major life activity, (ii) has a record of such an impairment, or (iii) is regarded as having such an impairment.

(2) As used in paragraph (j)(i) of this section, the phrase:

(i) "Physical or mental impairment" means (A) any physiological disorder or condition, cosmetic disfigurement, or anatomical loss affecting one or more of the following body systems: Neurological; musculoskeletal; special sense organs; respiratory, including speech organs; cardiovascular; reproductive; digestive; genito-urinary; hemic and lymphatic; skin; and endocrine; or (B) any mental or physiological disorder, such as mental retardation, organic brain syndrome, emotional or mental illness, and specific learning disabilities. The term "physical or mental impairment" includes, but is not limited to, such diseases and conditions as orthopedic, visual, speech, and hearing impairments, cerebral palsy, epilepsy, muscular dystrophy, multiple sclerosis, cancer, heart disease, diabetes, mental retardation, emotional illness, drug addiction, and alcoholism.

(ii) "Major life activities" means functions such as caring for one's self, performing manual tasks, walking, seeing, hearing, speaking, breathing, learning, and working.

(iii) "Has a record of such an impairment" means has a history of, or has been misclassified as having, a mental or physical impairment that substantially limits one or more major life activities.

(iv) "Is regarded as having an impairment" means (A) has a physical or mental impairment that does not substantially limit major life activities but that is treated by a recipient as constituting such a limitation; (B) has a physical or mental impairment that substantially limits major life activities only as a result of the attitudes of others toward such impairment or (C) has none of the impairments defined in paragraph (j)(2)(i) of this section but is treated by a recipient as having such an impairment.

(k) "Qualified handicapped person" means:

(1) With respect to employment, a handicapped person who, with reasonable accommodation, can perform the essential functions of the job in question;

(2) With respect to public preschool, elementary, secondary, or adult education services, a handicapped person (i) of an age during which nonhandicapped persons are provided such services, (ii) of any age during which it is mandatory under state law to provide such services to handicapped persons, or (iii) to whom a state is required to provide a free appropriate public education under § 612 of the Education of the Handicapped Act; and

(3) With respect to postsecondary and vocational education services, a handicapped person who meets the academic and technical standards requisite to admission or participation in the recipient's education program or activity.

(4) With respect to other services, a handicapped person who meets the essential eligibility requirements for the receipt of such services.

(l) "Handicap" means any condition or characteristic that renders a person a handicapped person as defined in paragraph (i) of this section.

(m) "Historic Properties" means those properties listed in the National Register of Historic Places or properties designated as historic under a statute of the appropriate state of local governmental body.

§ 17.23 Discrimination prohibited.

(a) *General.* No qualified handicapped person shall, on the basis of handicap, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any program or activity which receives or benefits from Federal financial assistance.

(b) *Discriminatory actions prohibited.* (1) a recipient, in providing any aid, benefit, or service, may not, directly or through contractual, licensing, or other arrangements, on the basis of handicap:

(i) Deny a qualified handicapped person the opportunity to participate in or benefit from the aid, benefit, or service;

(ii) Afford a qualified handicapped person an opportunity to participate in or benefit from the aid, benefit, or services that is not equal to that afforded others;

(iii) Provide a qualified handicapped person with an aid, benefit, or service that is not as effective as that provided to others;

(iv) Provide different or separate aid, benefits or services to handicapped persons or to any class of handicapped persons unless such action is necessary to provide qualified handicapped persons with aid, benefits, or services that are as effective as those provided to others;

(v) Aid or perpetuate discrimination against a qualified handicapped person by providing significant assistance to an agency, organization, or person that discriminates on the basis of handicap in providing any aid, benefit, or services to beneficiaries of the recipient's program;

(vi) Deny a qualified handicapped person the opportunity to participate as a member of planning or advisory boards; or

(vii) Otherwise limit a qualified handicapped person in the enjoyment of any right, privilege, advantage, or opportunity enjoyed by others receiving an aid, benefit, or service.

(2) For purposes of this subpart, aids, benefits, and services, to be equally effective, are not required to produce the identical result or level of achievement for handicapped and nonhandicapped persons, but must afford handicapped persons equal opportunity to obtain the same result, to gain the same benefit, or to reach the same level of achievement, in the most integrated setting appropriate to the person's needs.

(3) Despite the existence of separate or different programs or activities provided in accordance with this part, a recipient may not deny a qualified handicapped person the opportunity to participate in all programs or activities covered by this part that are not separate or different.

(4) A recipient may not, directly or through contractual or other arrangements, utilize criteria or methods of administration (i) that have the effect of subjecting qualified handicapped persons to discrimination on the basis of handicap, (ii) that have the purpose or effect of defeating or substantially impairing accomplishment of the objectives of the recipient's program with respect to handicapped persons, or (iii) that perpetuate the discrimination of another recipient if both recipients are subject to common administrative control or are agencies of the same state.

(5) In determining the site or location of a facility, an applicant for assistance or a recipient may not make selections (i) that have the effect of excluding handicapped persons from, denying them the benefits of, or otherwise subjecting them to discrimination under any program or activity that receives or benefits from Federal financial assistance or (ii) that have the purpose or effect of defeating or substantially impairing the accomplishment of the objectives of the program or activity with respect to handicapped persons.

(6) As used in this section, the aid, benefit, or service provided under a program or activity receiving or benefiting from Federal financial assistance includes any aid, benefit, or service provided in or through a facility that has been constructed, expanded, altered, leased or rented, or otherwise acquired, in whole or in part, with Federal financial assistance.

(c) *Programs limited by Federal law.* The exclusion of nonhandicapped persons from the benefits of a program limited by Federal statute or executive order to handicapped persons or the exclusion of a specific class of handicapped persons from a program limited by Federal statute or Executive Order to a different class of handicapped persons is not prohibited by this subpart.

§ 17.24 Assurances required.

(a) *Assurances.* An applicant for Federal financial assistance for a program or activity to which this part applies shall submit an assurance, on a form specified by the Director, that the program will be operated in compliance with this subpart. An applicant may incorporate these assurances by reference in subsequent applications to the Department.

(b) *Duration of obligation.* (1) In the case of Federal financial assistance extended in the form of real property or to provide real property or structures on the property, the assurance will obligate the recipient or, in the case of a subsequent transfer, the transferee, for the period during which the real property or structures are used for the purpose for which Federal financial assistance is extended or for another purpose involving the provision of similar services or benefits.

(2) In the case of Federal financial assistance extended to provide personal property, the assurance will obligate the recipient for the period during which it retains ownership or possession of the property.

(3) In all other cases the assurance will obligate the recipient for the period during which Federal financial assistance is extended.

(c) *Covenants.* (1) Where Federal financial assistance is provided in the form of real property or interest in the property from the Department, the instrument effecting or recording this transfer shall contain a covenant running with the land to assure nondiscrimination for the period during which the real property is used for a purpose for which the Federal financial assistance is extended or for another purpose involving the provision of similar services or benefits.

(2) Where no transfer of property is involved but property is purchased or improved with Federal financial assistance, the recipient shall agree to include the covenant described in paragraph (c)(1) of this section in the instrument effecting or recording any subsequent transfer of the property.

(3) Where Federal financial assistance is provided in the form of real property or interest in the property from the Department, the covenant shall unless prohibited by the conveyance authority, also include a condition coupled with a right to be reserved by the Department to revert title to the property in the event of a breach of the covenant. If a transferee of real property proposes to mortgage or otherwise encumber the real property as security for financing construction of new, or improvement of existing, facilities on the property for the purposes for which the property was transferred, the director may, upon request of the transferee and if necessary to accomplish such financing and upon such conditions as he or she deems appropriate, agree to forebear the exercise of such right to revert title for so long as the lien of such mortgage or other encumbrance remains effective.

§ 17.25 Remedial action, voluntary action, and self-evaluation.

(a) *Remedial action.* (1) If the Director finds that a recipient has discriminated against persons on the basis of handicap in violation of section 504 or this part, the recipient shall take such remedial action as the Director deems necessary to overcome the effects of the discrimination.

(2) Where a recipient is found to have discriminated against persons on the basis of handicap in violation of section 504 or this part and where another recipient exercises control over the recipient that has discriminated, the Director, where appropriate, may require either or both recipients to take remedial action.

(3) The director may, where necessary to overcome the effects of discrimination in violation of section 504 or this part, require a recipient to take remedial action (i) with respect to handicapped persons who are no longer participants in the recipient's program but who were participants in the program when such discrimination occurred or (ii) with respect to

handicapped persons who would have been participants in the program had the discrimination not occurred.

(b) *Voluntary action.* A recipient may take steps, in addition to any action that is required by this part, to overcome the effects of conditions that resulted in limited participation in the recipient's program or activity by qualified handicapped persons.

(c) *Self-evaluation.* (1) A recipient shall, within one year of the effective date of this subpart:

(i) Evaluate, with the assistance of interested persons, including handicapped persons or organizations representing handicapped persons, its current policies and practices and the effects thereof that do not or may not meet the requirements of this part;

(ii) Modify, after consultation with interested persons, including handicapped persons or organizations representing handicapped persons, any policies and practices that do not meet the requirements of this subpart; and

(iii) Take, after consultation with interested persons, including handicapped persons or organizations representing handicapped persons, appropriate remedial steps to eliminate the effects of any discrimination that resulted from adherence to these policies and practices.

(2) A recipient that employs fifteen or more persons shall, for at least three years following completion of the evaluation required under paragraph (c)(1) of this section, maintain on file, make available for public inspection, and provide to the director upon request: (i) a list of the interested persons consulted, (ii) a description of areas examined and any problems identified, and (iii) a description of any modifications made and of any remedial steps taken.

§ 17.26 Designation of responsible employee and adoption of grievance procedures.

(a) *Designation of responsible employee.* A recipient that employs fifteen or more persons shall designate at least one person to coordinate its efforts to comply with this subpart.

(b) *Adoption of grievance procedures.* A recipient that employs fifteen or more persons shall adopt grievance procedures that incorporate appropriate due process standards and that provide for the prompt and equitable resolution of complaints alleging any action prohibited by this part. Such procedures need not be established with respect to complaints from applicants for employment.

§ 17.27 Notification.

(a) A recipient that employs fifteen or more persons shall take appropriate initial and continuing steps to notify participants, beneficiaries, applicants, and employees, including those with impaired vision or hearing, and unions or professional organizations holding collective bargaining or professional agreements with the recipient, that it does not discriminate on the basis of handicap in violation of section 504 and this subpart. The notification shall state, where appropriate, that the recipient does not discriminate in admission or access to, or treatment or employment in, its programs and activities. The notification shall also include an identification of the responsible employee designated pursuant to § 17.26(a). A recipient shall make the initial notification required by this paragraph within 90 days of the effective date of this subpart. Methods of initial and continuing notification may include the posting of notices, publications in newspapers and magazines, placement of notices in recipients' publications, and distribution of memoranda or other written communications.

(b) If a recipient publishes or uses recruitment materials or publications containing general information that it makes available to participants, beneficiaries, applicants, or employees, it shall include in those materials or publications a statement of the policy described in paragraph (a) of this section. A recipient may meet the requirement of this paragraph either by including appropriate inserts in existing materials and publications or by revising and reprinting the materials and publications.

§ 17.28 Administrative requirements for small recipients.

The Director may require any recipient with fewer than fifteen employees, or any class of such recipients, to comply with §§ 17.26, and 17.27, in whole or in part, when the Director finds a violation of this subpart or finds that such compliance will not significantly impair the ability of the recipient or class of recipients to provide benefits or services.

§ 17.29 Effect of state or local law or other requirements and effect of employment opportunities.

(a) The obligation to comply with this subpart is not obviated or alleviated by the existence of any state or local law or other requirement that, on the basis of handicap, imposes prohibitions or limits upon the eligibility of qualified handicapped persons to receive services or to practice any occupation or profession.

(b) The obligation to comply with this part is not obviated or alleviated because employment opportunities in any occupation or profession are or may be more limited for handicapped persons than for nonhandicapped persons.

§ 17.30 Employment practices.

(a) *General.* (1) No qualified handicapped person shall, on the basis of handicap, be subjected to discrimination in employment under any program or activity to which this subpart applies.

(2) A recipient that receives assistance under the Education of the Handicapped Act shall take positive steps to employ and advance in employment qualified handicapped persons in programs assisted under the Act.

(3) A recipient shall make all decisions concerning employment under any program or activity to which this subpart applies in a manner which ensures that discrimination on the basis of handicap does not occur, and may not limit, segregate, or classify applicants or employees in any way that adversely affects their opportunities or status because of handicap.

(4) A recipient may not participate in a contractual or other relationship that has the effect of subjecting qualified handicapped applicants or employees to discrimination prohibited by this subpart. The relationships referred to in this subparagraph include relationships with employment and referral agencies, with labor unions with organizations providing or administering fringe benefits to employees of the recipient, and with organizations providing training and apprenticeship programs.

(b) *Specific activities.* The provisions of this subpart apply to:

(1) Recruitment, advertising, and the processing of applications for employment;

(2) Hiring, upgrading, promotion, award of tenure, demotion, transfer, layoff, termination, right of return from layoff, and rehiring;

(3) Rates of pay or any other form of compensation and changes in compensation;

(4) Job assignments, job classifications, organizational structures, position descriptions, lines of progressions, and seniority lists;

(5) Leaves of absence, sick leave, or any other leave;

(6) Fringe benefits available by virtue or employment, whether or not administered by the recipient;

(7) Selection and financial support for training, including apprenticeship, professional meetings, conferences, and other related activities, and selection for leaves of absence to pursue training;

(8) Employer-sponsored activities, including social or recreational programs; and

(9) Any other term, condition, or privilege of employment.

(c) A recipient's obligation to comply with this subpart is not affected by any inconsistent term of any collective bargaining agreement to which it is a party.

§ 17.31 Reasonable accommodations.

(a) A recipient shall make reasonable accommodations to the known physical or mental limitations of an otherwise qualified handicapped applicant or employee unless the recipient can demonstrate that the accommodations would impose an undue hardship on the operation of its program.

(b) Reasonable accommodations may include: (1) making facilities used by employees readily accessible to and usable by handicapped persons, and (2) job restructuring, part-time or modified work schedules, acquisition or modification of equipment or devices, the provision of readers or interpreters, and other similar actions. This list is neither all-inclusive not meant to suggest that employers must follow all the actions listed.

(c) In determining pursuant to paragraph (a) of this section whether an accommodation would impose an undue hardship on the operation of a recipient's program, factors to be considered include:

(1) The overall size of the recipient's program with respect to number of employees, number and type of facilities, and size of budget;

(2) The type of the recipient's operations, including the composition and structure of the recipient's workforce; and

(3) The nature and cost of the accommodation needed.

(d) A recipient may not deny any employment opportunity to a qualified handicapped employee or applicant if the basis for denial is the need to make reasonable accommodation to the physical or mental limitations of the employee or applicant.

§ 17.32 Employment criteria.

(a) A recipient may not make use of any employment test or other selection criterion that screens out or tends to screen out handicapped persons or any class of handicapped persons unless: the (1) test score or other selection criterion, as used by the recipient, is shown to be job-related for the position in question, and (2) alternative job-related tests or criteria that do not screen out or tend to screen out as many handicapped persons are unavailable.

(b) A recipient shall select and administer tests concerning employment so as best to ensure that, when administered to an applicant or employee who has a handicap that impairs sensory, manual, or speaking skills, the test results accurately reflect the applicant's or employee's job skills, aptitude, or whatever other factor the test purports to measure, rather than reflecting the applicant's or employee's impaired sensory, manual, or speaking skills (except where those skills are the factors that the test purports to measure).

§ 17.33 Pre-employment inquiries.

(a) Except as provided in paragraphs (b) and (c) of this section, a recipient may not conduct a pre-employment medical examination or may not make pre-employment inquiry of an applicant as to whether the applicant is a handicapped person or as to the nature or severity of a handicap. A recipient may, however, make pre-employment inquiry into an applicant's ability to perform job-related functions.

(b) When a recipient is taking remedial action to correct the effects of past discrimination pursuant to § 17.25(a), when a recipient is taking voluntary action to overcome the effects of conditions that resulted in limited participation in its federally assisted program or activity pursuant to § 17.25(b), or when a recipient is taking affirmative action pursuant to section 503 of the Act, the recipient may invite applicants for employment to indicate whether and to what extent they are handicapped, provided that:

(1) The recipient states clearly on any written questionnaire used for this purpose or makes clear orally if no written questionnaire is used that the information requested is intended for use solely in connection with its remedial action obligations or its voluntary or affirmative action efforts; and

(2) The recipient states clearly that the information is being requested on a voluntary basis, that it will be kept confidential as provided in paragraph (d) of this section, that refusal to provide it will not subject the applicant or employee to any adverse treatment, and that it will be used only in accordance with this subpart.

(c) Nothing in this section shall prohibit a recipient from conditioning an offer of employment on the results of a medical examination conducted prior to the employee's entrance on duty, provided that: (1) All entering employees are subjected to such an examination regardless of handicap, and (2) the results of such an examination are used only in accordance with the requirements of this subpart.

(d) Information obtained in accordance with this section as to the medical condition or history of the applicant shall be collected and maintained on separate forms that shall be accorded confidentiality as medical records, except that:

(1) Supervisors and managers may be informed regarding restrictions on the work or duties of handicapped persons and regarding necessary accommodations;

(2) First aid and safety personnel may be informed, where appropriate, if the condition might require emergency treatment; and

(3) Government officials investigating compliance with the Act shall be provided relevant information upon request.

§§ 17.34–17.35 [Reserved]

§ 17.36 Program accessibility.

No qualified handicapped person shall, because a recipient's facilities are inaccessible to or unusable by handicapped persons, be denied the benefits of, be excluded from participation in, or otherwise be subjected to discrimination under any program or activity to which this subpart applies.

§ 17.37 Existing facilities.

(a) *Program accessibility.* A recipient shall operate each program or activity to which this subpart applies so that the program or activity, when viewed in its entirety, is readily accessible to handicapped persons. This paragraph does not require a recipient to make each of its existing facilities or every part of a facility accessible to and usable by handicapped persons.

(b) *Methods.* A recipient may comply with the requirements of paragraph (a) of this section through such means as redesigning of equipment, reassignment of classes or other services to accessible buildings, assignment of aides to beneficiaries, delivery of services at alternate accessible sites, alteration of existing facilities and construction of new facilities in conformance with the

requirements of § 17.38, or any other methods that result in making its program or activity accessible to handicapped persons. A recipient is not required to make structural changes in existing facilities where other methods are effective in achieving compliance with paragraph (a) of this section. In choosing among available methods for meeting the requirement of paragraph (a) of this section, a recipient shall give priority to those methods that offer programs and activities to handicapped persons in the most integrated setting appropriate.

(c) *Small recipients.* If a recipient with fewer than fifteen employees that provides services finds, after consultation with a handicapped person seeking its services, that there is no method of complying with paragraph (a) of this section other than making a significant alteration in its existing facilities, the recipient may, as an alternative, refer the handicapped person to other providers of those services whose facilities are accessible.

(d) *Time period.* A recipient shall comply with the requirement of paragraph (a) of this section within sixty days of the effective date of this subpart except that where structural changes in facilities are necessary, such changes shall be made within three years of the effective date of this subpart, but in any event as expeditiously as possible.

(e) *Transition plan.* In the event that structural changes to facilities are necessary to meet the requirement of paragraph (a) of this section a recipient shall develop, within six months of the effective date of this subpart, a transition plan setting forth the steps necessary to complete such changes. The plan shall be developed with the assistance of interested persons, including handicapped persons or organizations representing handicapped persons. A copy of the transition plan shall be made available for public inspection. The plan shall, at a minimum:

(1) Identify physical obstacles in the recipient's facilities that limit the accessibility of its program or activity to handicapped persons;

(2) Describe in detail the methods that will be used to make the facilities accessible;

(3) Specify the schedule for taking the steps necessary to achieve full program accessibility and, if the time period of the transition plan is longer than one year, identify steps that will be taken during each year of the transition period; and

(4) Indicate the person responsible for implementation of the plan.

(f) *Notice.* The recipient shall adopt and implement procedures to ensure that interested persons, including persons with impaired vision or hearing, can obtain information as to the existence and location of services, activities, and facilities that are accessible to and usable by handicapped persons.

§ 17.38 New construction.

(a) *Design and construction.* Each facility or part of a facility constructed by, on behalf of, or for the use of a recipient shall be designated and constructed in such manner that the facility or part of the facility is readily accessible to and usable by handicapped persons, if the construction was commenced after the effective date of this subpart.

(b) *Alteration.* Each facility or part of a facility which is altered by, on behalf of, or for the use of a recipient after the effective date of this subpart, in a manner that affects or could affect the usability of the facility or part of the facility, shall, to the maximum extent feasible, be altered in such manner that the altered portion of the facility is readily accessible to and usable by handicapped persons.

(c) *American National Standards Institute accessibility standards.* Design, construction, or alteration of facilities in conformance with the "American National Standard Specifications for Making Buildings and Facilities Accessible to, and Usable by, the Physically Handicapped," published by the American National Standards Institute, Inc. (ANSI A117.1–1961 (R1971)), which is incorporated by reference in this subpart, shall constitute compliance with paragraphs (a) and (b) of this section. Departures from particular requirements of those standards, by the use of other methods, shall be permitted when it is clearly evident the equivalent access to the facility or part of the facility is thereby provided.

§§ 17.39–17.41 [Reserved]

§ 17.42 Preschool, elementary, and secondary education.

This subpart applies to preschool, elementary, secondary, and adult education programs and activities that receive or benefit from federal financial assistance, and to recipients that operate, or that receive or benefit from the federal financial assistance for the operation of such programs or activities.

§ 17.43 Location and notification.

A recipient that operates a public elementary or secondary education program shall annually:

(a) Undertake to identify and locate every qualified handicapped person residing in the recipient's jurisdiction who is not receiving a public education; and

(b) Take appropriate steps to notify handicapped persons and their parents or guardians of the recipient's duty under this subpart.

§ 17.44 Free appropriate public education.

(a) *General.* A recipient that operates a public elementary or secondary education program shall provide a free appropriate public education to each qualified handicapped person who is in the recipient's jurisdiction, regardless of the nature of the person's handicap.

(b) *Appropriate education.* (1) For the purpose of this subpart, the provision of an appropriate education is the provision of regular or special education and related aids and services that (i) are designed to meet individual educational needs of handicapped persons as adequately as the needs of non-handicapped persons are met and (ii) are based upon adherence to procedures that satisfy the requirements of §§ 17.45, 17.46, and 17.47.

(2) Implementation of an individualized education program developed in accordance with the Education of the Handicapped Act is one means of meeting the standard established in paragraph (b)(1)(i) of this section.

(3) A recipient may place a handicapped person in or refer such person to a program other than the one that it operates as its means of carrying out the requirements of this subpart. If so, the recipient remains responsible for ensuring that the requirements of this subpart are met with respect to any handicapped person so placed or referred.

(c) *Free education.* (1) *General.* For the purpose of this section, the provision of a free education is the provision of educational and related services without cost to the handicapped person or to his or her parents or guardian, except for those fees that are imposed on nonhandicapped persons or their parents or guardian. It may consist either of the provision of free services or, if a recipient places a handicapped person in or refers such person to a program not operated by the recipient as its means of carrying out the requirements of this subpart, of payment for the costs of the program. Funds available from any public or private

agency may be used to meet the requirements of this subpart. Nothing in this section shall be construed to relieve an insurer or similar third party from an otherwise valid obligation to provide or pay for services provided to a handicapped person.

(2) *Transportation.* If a recipient places a handicapped person in or refers such person to a program not operated by the recipient as its means of carrying out the requirements of this subpart, the recipient shall ensure that adequate transportation to and from the program is provided at no greater cost than would be incurred by the person or his or her parents or guardian if the person were placed in the program operated by the recipient.

(3) *Residential placement.* If placement in a public or private residential program is necessary to provide a free appropriate public education to a handicapped person because of his or her handicap, the program, including nonmedical care and room and board, shall be provided at no cost to the person or his or her parents or guardian.

(4) *Placement of handicapped persons by parents.* If a recipient has made available, in conformance with the requirements of this section and § 17.45, a free appropriate public education to a handicapped person, and the person's parents or guardian choose to place the person in a private school, the recipient is not required to pay for the person's education in the private school. Disagreements between a parent or guardian and a recipient regarding whether the recipient has made such a program available, or otherwise regarding the question of financial responsibility, are subject to the due process procedures of § 17.47.

(d) *Compliance.* A recipient may not exclude any qualified handicapped person from a public elementary or secondary education after the effective date of this subpart. A recipient that is not, on the effective date of this regulation, in full compliance with the other requirements of the preceding paragraphs of this section shall meet such requirements at the earliest practicable time and in no event later than 1 year after the effective date of this subpart.

§ 17.45 Educational setting.

(a) *Academic setting.* A recipient to which this subpart applies shall educate, or shall provide for the education of, each qualified handicapped person in its jurisdiction with persons who are not handicapped to the maximum extent appropriate to the needs of the handicapped person. A recipient shall place a handicapped person in the regular educational environment operated by the recipient unless it is demonstrated by the recipient that the education of the person in the regular environment with the use of supplementary aids and services cannot be achieved satisfactorily. Whenever a recipient places a person in a setting other than the regular educational environment pursuant to this paragraph, it shall take into account the proximity of the alternate setting to the person's home.

(b) *Nonacademic settings.* In providing or arranging for the provision of nonacademic and extracurricular services and activities, including meals, recess periods, and the services and activities set forth in § 17.48(a)(2), a recipient shall ensure that handicapped persons participate with nonhandicapped persons in such activities and services to the maximum extent appropriate to the needs of the handicapped person in question.

(c) *Comparable facilities.* If a recipient, in compliance with paragraph (a) of this section, operates a facility that is identifiable as being for handicapped persons, the recipient shall ensure that the facility and the services and activities provided therein are comparable to the other facilities, services, and activities of the recipient.

§ 17.46 Evaluation and placement.

(a) *Preplacement evaluation.* A recipient that operates a public elementary or secondary education program shall conduct an evaluation in accordance with the requirements of paragraph (b) of this section of any person who, because of handicap, needs or is believed to need special education or related services before taking any action with respect to the initial placement of the person in a regular or special education program and any subsequent significant change in placement.

(b) *Evaluation procedures.* A recipient to which this subpart applies shall establish standards and procedures for the evaluation and placement of persons who, because of handicap, need or are believed to need special education or related services which ensure that:

(1) Tests and other evaluation materials have been validated for the specific purpose for which they are used and are administered by trained personnel in conformance with the instructions provided by their producer;

(2) Tests and other evaluation materials include those tailored to assess specific areas of educational need and not merely those which are designed to provide a single general intelligence quotient; and

(3) Tests are selected and administered so as best to ensure that, when a test is administered to a student with impaired sensory, manual, or speaking skills, the test results accurately reflect the student's aptitude or achievement level or whatever other factor the test purports to measure, rather than reflecting the student's impaired sensory, manual, or speaking skills (except where those skills are the factors that the test purports to measure).

(c) *Placement procedures.* In interpreting evaluation data and in making placement decisions, a recipient shall (1) draw upon information from a variety of sources, including aptitude and achievement tests, teacher recommendations, physical condition, social or cultural background, and adaptive behavior, (2) establish procedures to ensure that information obtained from all such sources is documented and carefully considered, (3) ensure that the placement decision is made by a group of persons, including persons knowledgeable about the child, the meaning of the evaluation data, and the placement options, and (4) ensure that the placement decision is made in conformity with § 17.45.

(d) *Reevaluation.* A recipient to which this section applies shall establish procedures, in accordance with paragraph (b) of this section, for periodic reevaluation of students who have been provided special education and related services. A reevaluation procedure consistent with the Education for the Handicapped Act is one means of meeting this requirement.

§ 17.47 Procedural safeguards.

A recipient that operates a public elementary or secondary education program shall establish and implement, with respect to actions regarding the identification, evaluation, or educational placement of persons who, because of handicap, need or are believed to need special instruction or related services, a system of procedural safeguards that includes notice, an opportunity for the parents or guardian of the person to examine relevant records, an impartial hearing with opportunity for participation by the person's parents or guardian and representation by counsel, and a review procedure. Compliance with the procedural safeguards of section 615 of the Education of the Handicapped Act is one means of meeting this requirement.

§ 17.48 Nonacademic services.

(a) *General.* (1) A recipient to which this subpart applies shall provide nonacademic and extracurricular services and activities in such manner as is necessary to afford handicapped students an equal opportunity for participation in such services and activities.

(2) Nonacademic and extracurricular services and activities may include counseling services, physical recreational athletics, transportation, health services, recreational activities, special interest groups or clubs sponsored by the recipient, referrals to agencies which provide assistance to handicapped persons, and employment of students, including both employment by the recipient and assistance in making available outside employment.

(b) *Counseling services.* A recipient to which this subpart applies that provides personal, academic, or vocational counseling, guidance, or placement services to its students shall provide these services without discrimination on the basis of handicap. The recipient shall ensure that qualified handicapped students are not counseled toward more restrictive career objectives than are nonhandicapped students with similar interests and abilities.

(c) *Physical education and athletics.* (1) In providing physical education courses and athletics and similar programs and activities to any of its students, a recipient to which this subpart applies may not discriminate on the basis of handicap. A recipient that offers physical education courses or that operates or sponsors interscholastic, club, or intramural athletics shall provide to qualified handicapped students an equal opportunity for participation in these activities.

(2) A recipient may offer to handicapped students physical education and athletic activities that are separate or different from those offered to nonhandicapped students only if separation or differentiation is consistent with the requirements of § 17.45, and only if no qualified handicapped student is denied the opportunity to compete for means or to participate in courses that are not separate or different.

§ 17.49 Preschool and adult education programs.

A recipient to which this subpart applies that operates a preschool education or day care program or activity or an adult education program or activity may not, on the basis of handicap, exclude qualified handicapped persons from the program or activity, and shall take into account the needs of such persons in determining the aid, benefits, or services to be provided under the program or activity.

§ 17.50 Private education programs.

(a) A recipient that operates a private elementary or secondary education program may not, on the basis of handicap, exclude a qualified handicapped person from such program if the person can be provided an appropriate education, as defined in § 17.44(b)(1), within the recipient's program.

(b) A recipient to which this section applies may not charge more for the provision of an appropriate education to handicapped persons than to nonhandicapped persons except to the extent that any additional charge is justified by a substantial increase in cost to the recipient.

(c) A recipient to which this section applies that operates special education programs shall operate such programs in accordance with the provisions of § 17.46 and § 17.47. Each recipient to which this section applies is subject to the provisions of §§ 17.45, 17.48, and 17.49.

§ 17.51 [Reserved]

§ 17.52 Application.

This subpart applies to postsecondary education programs and activities, including postsecondary vocational education programs and activities, that receive or benefit from Federal financial assistance and to recipients that operate, or that receive or benefit from Federal financial assistance for the operation of such programs or activities.

§ 17.53 Admissions and recruitment.

(a) *General.* Qualified handicapped persons may not, on the basis of handicap, be denied admission or be subjected to discrimination in admission or recruitment by a recipient to which this subpart applies.

(b) *Admissions.* In administering its admission policies, a recipient to which this subpart applies:

(1) May not apply limitations upon the number or proportion of handicapped persons who may be admitted

(2) May not make use of any test or criterion for admission that has a disproportionate adverse effect on handicapped persons or any class of handicapped persons unless (i) the test or criterion, as used by the recipient, has been validated as a predictor of success in the education program or activity in question and (ii) alternate tests or criteria that have a less disproportionate adverse effect are not shown by the Director to be available;

(3) Shall assure itself that (i) admissions tests are selected and administered so as best to ensure that, when a test is administered to an applicant who has a handicap that impairs sensory, manual, or speaking skills, the test results accurately reflect the applicant's aptitude or achievement level or whatever other factor the test purports to measure, rather than reflecting the applicant's impaired sensory, manual, or speaking skills (except where those skills are the factors that the test purports to measure); (ii) admissions tests that are designed for persons with impaired sensory, manual, or speaking skills are offered as often and in as timely a manner as are other admissions tests; and (iii) admissions tests are administered in facilities that, on the whole, are accessible to handicapped persons; and

(4) Except as provided in paragraph (c) of this section, may not make preadmission inquiry as to whether an applicant for admission is a handicapped person but, after admission, may make inquiries on a confidential basis as to handicaps that may require accommodation.

(c) *Preadmission inquiry exception.* When a recipient is taking remedial action to correct the effect of past discrimination pursuant to § 17.25(a) or when a recipient is taking voluntary action to overcome the effects of conditions that resulted in limited participation in its federally assisted program or activity pursuant to § 17.25(b), the recipient may invite applicants for admission to indicate whether and to what extent they are handicapped, provided, that:

(1) The recipient states clearly on any written questionnaire used for this purpose, or makes clear orally if no written questionnaire is used, that the information requested is intended for use solely in connection with its remedial action obligations or its voluntary action efforts; and

(2) The recipient states clearly that the information is being requested on a voluntary basis, that it will be kept confidential, that refusal to provide it will not subject the applicant to any adverse treatment, and that it will be used only in accordance with this subpart.

(d) *Validity studies.* For the purpose of paragraph (b)(2) of this section, a recipient may base prediction equations on first year grades, but shall conduct periodic validity studies against the criterion of overall success in the

education program or activity in question in order to monitor the general validity of the test scores.

§ 17.54 Treatment of students.

(a) No qualified handicapped student shall, on the basis of handicap, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any academic, research, occupational training, housing, health, insurance, counseling, financial aid, physical education, athletics, recreation, transportation, other extracurricular, or other postsecondary education program or activity to which this subpart applies.

(b) A recipient to which this subpart applies that considers participation by students in education programs or activities not operated wholly by the recipient as part of, or equivalent to, an education program or activity operated by the recipient shall assure itself that the other education program or activity, as a whole, provides an equal opportunity for the participation of qualified handicapped persons.

(c) A recipient to which this subpart applies may not, on the basis of handicap, exclude any qualified handicapped student from any course, course of study, or other part of its education program or activity.

(d) A recipient to which this subpart applies shall operate its programs and activities in the most integrated setting appropriate.

§ 17.55 Academic adjustments.

(a) *Academic requirements.* A recipient to which this subpart applies shall make such modifications to its academic requirements as are necessary to ensure that such requirements do not discriminate or have the effect of discriminating, on the basis of handicap, against a qualified handicapped applicant or student. Academic requirements that the recipient can demonstrate are essential to the program of instruction being pursued by such student, or to any directly related licensing requirement, will not be regarded as discriminatory within the meaning of this section. Modifications may include changes in the length of time permitted for the completion of degree requirements, substitution of specific courses required for the completion of degree requirements, and adaptation of the manner in which specific courses are conducted.

(b) *Other rules.* A recipient to which this subpart applies may not impose upon handicapped students other rules, such as the prohibition of tape recorders in classrooms or of guide dogs in campus buildings, that have the effect of limiting the participation of handicapped students in the recipient's education program or activity.

(c) *Course examinations.* In its course examinations or other procedures for evaluating students' academic achievement in its program, a recipient to which this subpart applies shall provide such methods for evaluating the achievement of students who have a handicap that impairs sensory, manual, or speaking skills as will best ensure that the results of the evaluation represent the student's achievement in the course, rather than reflecting the student's impaired sensory, manual, or speaking skills (except where such skills are the factors that the test purports to measure).

(d) *Auxiliary aids.* (1) A recipient to which this subpart applies shall take such steps as are necessary to ensure that no handicapped student is denied the benefits of, excluded from participation in, or otherwise subjected to discrimination under the education program or activity operated by the recipient because of the absence of educational auxiliary aids for students with impaired sensory, manual, or speaking skills.

(2) Auxiliary aids may include taped texts, interpreters or other effective methods of making orally delivered materials available to students with hearing impairments, readers in libraries for students with visual impairments, classroom equipment adapted for use by students with manual impairments, and other similar services and actions. Recipients need not provide attendants, individually prescribed devices, readers for personal use of study, or other devices or services of a personal nature.

§ 17.56 Housing.

(a) *Housing provided by the recipient.* A recipient that provides housing to its nonhandicapped students shall provide comparable, convenient, and accessible housing to handicapped students at the same cost as to others. At the end of the transition period provided for in Subpart D, such housing shall be available in sufficient quantity and variety so that the scope of handicapped students' choice of living accommodations is, as a whole, comparable to that of nonhandicapped students.

(b) *Other housing.* A recipient that assists any agency, organization, or person in making housing available to any of its students shall take such action as may be necessary to assure itself that such housing is, as a whole, made available in a manner that does not result in discrimination on the basis of handicap.

§ 17.57 Financial and employment assistance to students.

(a) *Provisions of financial assistance.* (1) In providing financial assistance to qualified handicapped persons, a recipient to which this subpart applies may not (i), on the basis of handicap, provide less assistance than is provided to nonhandicapped persons, limit eligibility for assistance, or otherwise discriminate or (ii) assist any entity or person that provides assistance to any of the recipient's students in a manner that discriminates against qualified handicapped persons on the basis of handicap.

(2) A recipient may administer or assist in the administration of scholarships, fellowships, or other forms of financial assistance established under wills, trusts, bequests, or similar legal instruments that require awards to be made on the basis of factors that discriminate or have the effect of discriminating on the basis of handicap only if the overall effect of the award of scholarships, fellowships, and other forms of financial assistance is not discriminatory on the basis of handicap.

(b) *Assistance in making available outside employment.* A recipient that assists any agency, organization, or person in providing employment opportunities to any of its students shall assure itself that such employment opportunities, as a whole, are made available in a manner that would not violate this subpart if they were provided by the recipient.

(c) *Employment of students by recipients.* A recipient that employs any of its students may not do so in a manner that violates this subpart.

§ 17.58 Nonacademic services.

(a) *Physical education and athletics.* (1) In providing physical education courses and athletics and similar programs and activities to any of its students, a recipient to which this subpart applies may not discriminate on the basis of handicap. A recipient that offers physical education courses or that operates or sponsors intercollegiate, club, or intramural athletics shall provide to qualified handicapped students an equal opportunity for participation in these activities.

(2) A recipient may offer to handicapped students physical education and athletic activities that are separate or different only if separation or differentiation is consistent with the requirements of § 17.54(d) and only if no qualified handicapped student is denied

the opportunity to compete for teams or to participate in courses that are not separate or different.

(b) *Counseling and placement services.* A recipient to which this subpart applies that provides personal, academic, or vocational counseling, guidance, or placement services to its students shall provide these services without discrimination on the basis of handicap. The recipient shall ensure that qualifed handicapped students are not counseled toward more restrictive career objectives than are nonhandicapped students with similar interests and abilities. This requirement does not preclude a recipient from providing factual information about licensing and certification requirements that may present obstacles to handicapped persons in their pursuit of particular careers.

(c) *Social organizations.* A recipient that provides significant assistance to fraternities, sororities, or similar organizations shall assure itself that the membership practices of such organizations do not permit discrimination otherwise prohibited by this subpart.

§ 17.59—17.60 [Reserved]

§ 17.61 Health, welfare, and social services.

This subpart applies to health, welfare, and other social service programs and activities that receive or benefit from federal financial assistance and to recipients that operate, or that receive or benefit from federal financial assistance for the operation of such programs or activities.

(a) *General.* In providing health, welfare, or other social services or benefits, a recipient may not, on the basis of handicap:

(1) Deny a qualified handicapped person these benefits or services;

(2) Afford a qualified handicapped person an opportunity to receive benefits or services that is not equal to that offered nonhandicapped persons;

(3) Provide a qualified handicapped person with benefits or services that are not as effective (as defined in § 17.23(b)) as the benefits or services provided to others;

(4) Provide benefits or services in a manner that limits or has the effect of limiting the participation of qualified handicapped persons; or

(5) Provide different or separate benefits or services to handicapped persons except where necessary to provide qualified handicapped persons with benefits and services that are as effective as those provided to others.

(b) *Notice.* A recipient that provides notice concerning benefits or services, or written material concerning waivers of rights or consent to treatment, shall take such steps as are necessary to ensure that qualified handicapped persons, including those with impaired sensory or speaking skills, are not denied effective notice because of their handicap.

(c) *Emergency treatment for the hearing impaired.* A recipient hospital that provides health services or benefits shall establish a procedure for effective communication with persons with impaired hearing for the purpose of providing emergency health care.

(d) *Auxiliary aids.* (1) A recipient that employs fifteen or more persons shall provide appropriate auxiliary aids to persons with impaired sensory, manual, or speaking skills, where necessary to afford such persons an equal opportunity to benefit from the service in question.

(2) The Director may require recipients with fewer than fifteen employees to provide auxiliary aids where the provision of aids would not significantly impair the ability of the recipient to provide its benefits or services.

(3) For the purpose of this paragraph, auxiliary aids may include brailled and taped material, interpreters, visual aids, and other aids for persons with impaired hearing or vision.

§ 17.62 Drug and alcohol addicts.

A recipient that operates a general hospital or outpatient facility may not discriminate in admission or treatment against a drug or alcohol abuser or addict who is suffering from a medical condition, because of the person's drug or alcohol abuse or addiction.

§ 17.63 Education of institutionalized persons.

A recipient that operates or supervises a program or activity for persons who are institutionalized because of handicap shall ensure that each qualified handicapped person, as defined in § 17.22(k)(2), in its program or activity is provided an appropriate education, as defined in § 17.44(b). Nothing in this section shall be interpreted as altering in any way the obligations of recipients under § 17.36.

§ 17.64 Programs Involving Historic Properties.

This subpart applies to programs involving historic properties that receive or benefit from federal financial assistance and to recipients that operate or that receive or benefit from federal financial assistance provided for the operation of such programs.

(a) *Accessibility in existing historic properties.* In the case of existing historic properties, accessibility of programs or activities shall mean accessibility of historic programs or activities when viewed in their entirety as provided at § 17.37. In providing accessibility in historic properties, the fullest accessibility will be provided to the handicapped as is possible consistent with the principles of programs involving historic properties, to preserve historical features of these facilities. When it is not reasonable to make building alterations or structural changes to historic properties, other methods of providing accessibility may include, but are not limited to:

(1) construction of new facilities in conformance with the requirements of § 17.38.

(2) Reassigning programs to accessible locations.

(3) Delivering programs or activities at alternative accessible sites operated by or available for such use by the recipient.

(4) Assignment of aides to beneficiaries.

(5) Other methods that result in making the program or activity accessible to handicapped persons.

(b) *To the maximum extent possible, alterations and structural changes necessary to achieve accessibility shall be undertaken so as not to alter or destroy architecturally significant elements or features of the properties.* Accessibility must, to the extent possible, be achieved in accordance with the intent of the "Secretary of the Interior's Standards for Rehabilitation" (36 CFR 67.7).

§ 17.65 [Reserved]

§ 17.66 Recreational Programs.

This subpart applies to recreational programs that receive or benefit from federal financial assistance and to recipients that operate, or that receive or benefit from federal financial assistance for the operation of such programs or activities.

(a) *Accessibility in existing recreational facilities.* In the case of existing recreational facilities, accessibility of programs or activities shall mean accessibility of programs or activities when viewed in their entirety as provided at § 17.37. When it is not reasonable to alter natural features, the following other methods of achieving accessibility may include, but are not limited to:

(1) Construction of new facilities in conformance with the requirements of § 17.38.

(2) Reassigning programs to accessible locations.

(3) Delivering programs or activities at alternative accessible sites operated by or available for such use by the recipient.

(4) Assignments of aides to beneficiaries.

(5) Other methods that result in making the program or activity accessible to handicapped persons.

§ 17.67 [Reserved]

§ 17.68 Enforcement procedures.

The compliance and enforcement provisions applicable to title VI of the Civil Rights Act of 1964 apply to this subpart. These procedures are found in 43 CFR Part 17, Subpart A, §§ 17.5–17.11.

§ 17.69—§ 17.75 [Reserved]

[FR Doc 79-11481 Filed 4-12-79; 8:45 am]
BILLING CODE 4310-10-M