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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 Division of Dockets Management 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.

Sec.
14.1 Scope.
14.5 Purpose of proceedings before an advisory committee.
14.7 Administrative remedies.
14.10 Applicability to Congress.
14.15 Committees working under a contract with FDA.

Subpart B—Meeting Procedures

14.20 Notice of hearing before an advisory committee.
14.22 Meetings of an advisory committee.
14.25 Portions of advisory committee meetings.
14.27 Determination to close portions of advisory committee meetings.
14.29 Conduct of a hearing before an advisory committee.
14.30 Chairperson of an advisory committee.
14.31 Consultation by an advisory committee with other persons.
14.33 Compilation of materials for members of an advisory committee.
14.35 Written submissions to an advisory committee.
14.39 Additional rules for a particular advisory committee.

Subpart C—Establishment of Advisory Committees

14.40 Establishment and renewal of advisory committees.
14.55 Termination of advisory committees.

Subpart D—Records of Meetings and Hearings Before Advisory Committees

14.60 Minutes and reports of advisory committee meetings.
14.61 Transcripts of advisory committee meetings.
14.65 Public inquiries and requests for advisory committee records.
14.70 Administrative record of a public hearing before an advisory committee.
14.75 Examination of administrative record and other advisory committee records.

Subpart E—Members of Advisory Committees

14.80 Qualifications for members of standing policy and technical advisory committees.
14.82 Nominations of voting members of standing advisory committees.
14.84 Nominations and selection of nonvoting members of standing technical advisory committees.
14.86 Rights and responsibilities of nonvoting members of advisory committees.
14.90 Ad hoc advisory committee members.
14.95 Compensation of advisory committee members.

Subpart F—Standing Advisory Committees

14.100 List of standing advisory committees.

Subpart G—Technical Electronic Products Radiation Safety Standards Committee

14.120 Establishment of the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC).
14.122 Functions of TEPRSSC.
14.125 Procedures of TEPRSSC.
14.127 Membership of TEPRSSC.
14.130 Conduct of TEPRSSC meetings; availability of TEPRSSC records.

Subpart H—Color Additive Advisory Committees

14.140 Establishment of a color additive advisory committee.
14.142 Functions of a color additive advisory committee.
14.145 Procedures of a color additive advisory committee.
14.147 Membership of a color additive advisory committee.

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VerDate Sep<11>2014 14:33 Jun 27, 2023 Jkt 259071 PO 00000 Frm 00278 Fmt 8010 Sfmt 8010 Q:\21\21V1.TXT PC31

14.155 Fees and compensation pertaining to a color additive advisory committee.

Subpart I—Advisory Committees for Human Prescription Drugs

14.160 Establishment of standing technical advisory committees for human prescription drugs.
14.171 Utilization of an advisory committee on the initiative of FDA.
14.172 Utilization of an advisory committee at the request of an interested person.
14.174 Advice and recommendations in writing.

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SOURCE: 44 FR 22351, Apr. 13, 1979, unless otherwise noted.

Subpart A—General Provisions

§ 14.1 Scope.

(a) This part governs 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 FD&C 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) [Reserved]

(vi) Part 860, on classification of devices;

(vii) Section 514(b)(5) of the FD&C Act on establishment, amendment, or revocation of a device performance standard;

(viii) Section 515 of the FD&C Act on review of device premarket approval applications and product development protocols; and

(ix) Section 520(f) of the FD&C 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) 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 Chairperson 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

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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

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for a particular committee, for example, TEPRSSC and advisory committees established under the Medical Device Amendments of 1976.

[44 FR 22351, Apr. 13, 1979, as amended at 54 FR 9035, Mar. 3, 1989; 78 FR 17087, Mar. 20, 2013; 81 FR 45409, July 14, 2016]

§ 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 and Human Services under 45 CFR 5.61—and 45 CFR 5.64.

[44 FR 22351, Apr. 13, 1979, as amended at 55 FR 1404, Jan. 16, 1990; 85 FR 72906, Nov. 16, 2020]

§ 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 Division of Dockets Management not less than 15 days before the meeting. The time for oral presentations and the extent to which the

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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 Division of Dockets Management 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 Designated Federal Officer 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 Designated Federal Officer at any time, unless a cutoff date has been established under § 14.35(d)(2);

(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; and

(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.

[44 FR 22351, Apr. 13, 1979, as amended at 47 FR 26375, June 1, 1982; 54 FR 9035, Mar. 3, 1989; 66 FR 6469, Jan. 22, 2001; 66 FR 12850, Mar. 1, 2001]

§ 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 § 14.20(b)(4), an attempt is to be made to inform persons

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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, DC, 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 Science Advisory Board of the National Center for Toxicological Research will generally hold meetings in the Little Rock, AR, vicinity.

(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, DC, or Rockville, MD, or the immediate vicinity, 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 Chairperson 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.

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(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.

[44 FR 22351, Apr. 13, 1979; 48 FR 40887, Sept. 12, 1983, as amended at 54 FR 9035, Mar. 3, 1989; 78 FR 17087, Mar. 20, 2013]

§ 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 Chairperson.

(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 Designated Federal Officer 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, guidance documents 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

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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 Designated Federal Officer 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 Chairperson 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 Designated Federal Officer of the committee, a transcriber, and other regular employees of FDA (including members of the Office of the Chief Counsel) whom the Chairperson 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 Designated Federal Officer and the Chairperson, 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 paragraphs (c) (1) and (2) of this section is allowed by the Designated Federal Officer and the Chairperson to attend a closed portion of a meeting, that portion is open to attendance by any interested person.

[44 FR 22351, Apr. 13, 1979, as amended at 65 FR 56479, Sept. 19, 2000]

§ 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 Chairperson 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 Chairperson.

(b) An interested person who wishes to be assured of the right to make an

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oral presentation at a meeting shall inform the Designated Federal Officer 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 Designated Federal Officer 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 Designated Federal Officer 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 Chairperson 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 Chairperson.

(f) The Chairperson and other members may question a person concerning that person's presentation. No other person, however, may question the person. The Chairperson 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 interrupt the presentation of another participant.

§14.30 Chairperson of an advisory committee.

(a) The advisory committee Chairperson has the authority to conduct hearings and meetings, including the authority to adjourn a hearing or meeting if the Chairperson 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 Chairperson is not a full-time employee of FDA, the Designated Federal Officer 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

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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 Food and Drug Administration. 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.

[44 FR 22351, Apr. 13, 1979, as amended at 55 FR 42703, Oct. 23, 1990]

§ 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 guidance documents 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.

[44 FR 22351, Apr. 13, 1979, as amended at 65 FR 56479, Sept. 19, 2000]

§ 14.35 Written submissions to an advisory committee.

(a) Ten copies of written submissions to a committee are to be sent to the Designated Federal Officer 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 Division of Dockets Management.

(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,

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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 Designated Federal Officer 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 Designated Federal Officer 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. A notice of establishment will be published at least 15 days before the filing of the advisory committee charter under paragraph (c) of this section. A notice of renewal does not require the 15-day notice.

(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.

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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 Designated Federal Officer and alternate for every advisory committee, who are employees of FDA. The Designated Federal Officer 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.

[44 FR 22351, Apr. 13, 1979, as amended at 55 FR 42703, Oct. 23, 1990]

§ 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, as added by the Radiation Control for Health and Safety Act of 1968, transferred to the FD&C Act (21 U.S.C. 360kk(f)(1)(A)), 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 FD&C Act (21 U.S.C. 360c(b)(1)) and part 860, and the statutory medical device good manufacturing practice advisory committees established under section 520(f)(3) of the FD&C Act (21 U.S.C. 360j(f)(3)), are specifically exempted from the normal 2-year duration period.

(d) Color additive advisory committees are required to be established under the circumstances specified in sections 721(b)(5)(C) and (D) of the FD&C Act (21 U.S.C. 379e(b)(5)(C) and (D)). A color additive advisory committee is subject to the termination and renewal requirements of the Federal Advisory Committee Act and of this part.

(e) The Tobacco Products Scientific Advisory Committee is a permanent statutory advisory committee established by section 917 of the Family Smoking Prevention and Tobacco Control Act (21 U.S.C. 387q) (Pub. L. 111–31) and is not subject to termination and renewal under paragraph (a) of this section.

[44 FR 22351, Apr. 13, 1979, as amended at 75 FR 73953, Nov. 30, 2010; 78 FR 17087, Mar. 20, 2013]

Subpart D—Records of Meetings and Hearings Before Advisory Committees

§ 14.60 Minutes and reports of advisory committee meetings.

(a) The Designated Federal Officer or other designated agency employee prepares detailed minutes of all advisory committee meetings, except that less detailed minutes may be prepared for

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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 Chairperson. 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 Designated Federal Officer 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.

[44 FR 22351, Apr. 13, 1979, as amended at 45 FR 85725, Dec. 30, 1980]

§ 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 §20.45. FDA may furnish the requested transcript or recording for copying to a private contractor who shall charge directly for the cost of copying under §20.53.

(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.

[44 FR 22351, Apr. 13, 1979, as amended at 68 FR 25285, May 12, 2003]

§ 14.65 Public inquiries and requests for advisory committee records.

(a) Public inquiries on general committee matters, except requests for

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records, are to be directed to the Committee Management Officer in the Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993.

(b) Public inquiries on matters relating to a specific committee, except requests for records, are to be directed to the Designated Federal Officer 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 Division of Freedom of Information (the Freedom of Information Staff's address is available on the agency's web site at *http://www.fda.gov*) under § 20.40 and the related provisions of part 20.

[44 FR 22351, Apr. 13, 1979, as amended at 46 FR 8456, Jan. 27, 1981; 76 FR 31469, June 1, 2011; 78 FR 17087, Mar. 20, 2013; 79 FR 68114, Nov. 14, 2014]

§ 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 Chairperson.

(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(i)(2): After they have been approved by the committee and certified by the Chairperson; and

(ii) For a matter directed to be maintained as confidential under § 14.22(i)(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

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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 Division of Dockets Management (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.

[44 FR 22351, Apr. 13, 1979, as amended at 54 FR 9035, Mar. 3, 1989]

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 subject to the conflict of interest laws and regulations either as special Government employees or as members of the uniformed services, including the Commissioned Corps of the Public Health Service (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 the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC), are subject to the conflict of interest laws and regulations either as special Government employees or as members of the uniformed services, including the Commissioned Corps of the Public Health Service.

(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 Chairperson, are appointed from among those nominated under §§14.82 and 14.84 and from any

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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.

[44 FR 22351, Apr. 13, 1979, as amended at 53 FR 50949, Dec. 19, 1988; 54 FR 9035, Mar. 3, 1989]

§ 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 nominations are to be submitted in writing to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 1503, Silver Spring, MD 20993.

(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

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any advisory committee or subcommittee. Nominations that do not comply with the requirements of this paragraph will not be considered.

(3) The Advisory Committee Oversight and Management Staff 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 governments. 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 Advisory Committee Oversight and Management Staff 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 Advisory Committee Oversight and Management Staff 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 Advisory Committee Oversight and Management Staff 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.

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(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.

[44 FR 22351, Apr. 13, 1979, as amended at 54 FR 9035, Mar. 3, 1989; 75 FR 15342, Mar. 29, 2010]

§ 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).

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§ 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)(1) Except as provided in paragraphs (a) (2) and (3) of this section, all voting advisory committee members shall, and nonvoting members may, be appointed as special Government employees and receive a consultant fee and be reimbursed for travel expenses, including per diem in lieu of subsistence, unless such compensation and reimbursement are waived.

(2) Members of the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) are not appointed as special Government employees. Any member of TEPRSSC who is not a Federal employee or member of the uniformed services, including the Commissioned Corps of the Public Health Service, shall receive a consultant fee and be reimbursed for travel expenses, including per diem in lieu of subsistence, unless such compensation and reimbursement are waived.

(3) Voting and nonvoting advisory committee members who are members of the uniformed services, including the Commissioned Corps of the Public Health Service, provide service on Food and Drug Administration advisory committees as part of their assigned functions, are not appointed as special government employees, but are reimbursed by the Food and Drug Administration for travel expenses.

(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, DC, 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.

[44 FR 22351, Apr. 13, 1979, as amended at 53 FR 50949, Dec. 19, 1988]

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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—*

(1) *Board of Tea Experts.*

(i) Date established: March 2, 1897.

(ii) 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.

(2) *Science Board to the Food and Drug Administration.*

(i) Date established: June 26, 1992.

(ii) Function: The board shall provide advice primarily to the agency's Senior Science Advisor and, as needed, to the Commissioner and other appropriate officials on specific complex and technical issues as well as emerging issues within the scientific community in industry and academia. Additionally, the board will provide advice to the agency on keeping pace with technical and scientific evolutions in the fields of regulatory science; on formulating an appropriate research agenda; and on upgrading its scientific and research facilities to keep pace with these changes. It will also provide the means for critical review of agency sponsored intramural and extramural scientific research programs.

(3) *Pediatric Advisory Committee.*

(i) Date established: June 18, 2004.

(ii) Function: Advises on pediatric therapeutics, pediatric research, and other matters involving pediatrics for which the Food and Drug Administration has regulatory responsibility.

(4) *Risk Communication Advisory Committee.*

(i) Date rechartered: July 9, 2009.

(ii) Function: The committee reviews and evaluates strategies and programs designed to communicate with the public about the risks and benefits of FDA-regulated products so as to facilitate optimal use of these products. The committee also reviews and evaluates research relevant to such communication to the public by both FDA and other entities. It also facilitates interactively sharing risk and benefit information with the public to enable people to make informed independent judgments about use of FDA-regulated products.

(5) *Tobacco Products Scientific Advisory Committee.*

(i) Date Established: August 12, 2009.

(ii) Function: The committee reviews and evaluates safety, dependence, and health issues relating to tobacco products and provides appropriate advice, information, and recommendations to the Commissioner of Food and Drugs. Specifically, the committee will submit reports and recommendations on tobacco-related topics, including: The impact of the use of menthol in cigarettes on the public health, including such use among children, African Americans, Hispanics and other racial and ethnic minorities; the nature and impact of the use of dissolvable tobacco products on the public health, including such use on children; the effects of the alteration of nicotine yields from tobacco products and whether there is a threshold level below which nicotine yields do not produce dependence on the tobacco product involved; and any application submitted by a manufacturer for a modified risk tobacco product. The committee may provide recommendations to the Secretary of Health and Human Services regarding any regulations to be issued under the Federal Food, Drug, and Cosmetic Act and may review any applications for new tobacco products or petitions for exemption under section 906(e) of the Family Smoking Prevention and Tobacco Control Act. The committee may consider and provide recommendations on any other matter as provided in the Family Smoking Prevention and Tobacco Control Act.

(b) *Center for Biologics Evaluation and Research—*

(1) *Allergenic Products Advisory Committee.*

(i) Date established: July 9, 1984.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of allergenic biological products intended for use in the diagnosis, prevention, or treatment of human disease.

(2) *Cellular, Tissue and Gene Therapies Advisory Committee.*

(i) Date established: October 28, 1988.

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(ii) Function: Reviews and evaluates available data relating to the safety, effectiveness, and appropriate use of human cells, human tissues, gene transfer therapies and xenotransplantation products which are intended for transplantation, implantation, infusion, and transfer in the prevention and treatment of a broad spectrum of human diseases and in the reconstruction, repair or replacement of tissues for various conditions. The Committee also considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products, and makes appropriate recommendations to the Commissioner of Food and Drugs.

(3) *Blood Products Advisory Committee.*

(i) Date established: May 13, 1980.

(ii) Function: Reviews and evaluates data on the safety and effectiveness, and appropriate use of blood products intended for use in the diagnosis, prevention, or treatment of human diseases.

(4) *Vaccines and Related Biological Products Advisory Committee—*

(i) Date established: December 31, 1979.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of vaccines intended for use in the diagnosis, prevention, or treatment of human diseases.

(c) *Center for Drug Evaluation and Research—*

(1) *Anesthetic and Analgesic Drug Products Advisory Committee.*

(i) Date established: May 1, 1978.

(ii) *Function:* Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products including analgesics, *e.g.,* abuse-deterrent opioids, novel analgesics, and issues related to opioid abuse, and those for use in anesthesiology.

(2) *Antimicrobial Drugs Advisory Committee.*

(i) Date established: October 7, 1980.

(ii) Function: Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of infectious diseases and disorders.

(3) *Arthritis Advisory Committee.*

(i) Date established: April 5, 1974.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in arthritic conditions.

(4) *Cardiovascular and Renal Drugs Advisory Committee.*

(i) Date established: August 27, 1970.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in cardiovascular and renal disorders.

(5) *Dermatologic and Ophthalmic Drugs Advisory Committee.*

(i) Date established: October 7, 1980.

(ii) Function: Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of dermatologic and ophthalmic disorders.

(6) *Drug Safety and Risk Management Advisory Committee.*

(i) Date established: May 31, 1978.

(ii) Function: Reviews and evaluates data on risk management plans, provides active surveillance methodologies, trademark studies, methodologies for risk management communication, and related issues.

(7) *Endocrinologic and Metabolic Drugs Advisory Committee.*

(i) Date established: August 27, 1970.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in endocrine and metabolic disorders.

(8) *Obstetrics, Reproductive and Urologic Drugs Advisory Committee.*

(i) Date established: March 23, 1978.

(ii) Function: The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drug products for use in the practice of obstetrics, gynecology, urology and related specialties, and makes appropriate recommendations to the Commissioner of Food and Drugs.

(9) *Gastrointestinal Drugs Advisory Committee.*

(i) Date established: March 3, 1978.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in gastrointestinal diseases.

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(10) *Oncologic Drugs Advisory Committee.*

(i) Date established: September 1, 1978.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in treatment of cancer.

(11) *Peripheral and Central Nervous System Drugs Advisory Committee.*

(i) Date established: June 4, 1974.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in neurological disease.

(12) *Psychopharmacologic Drugs Advisory Committee.*

(i) Date established: June 4, 1974.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the practice of psychiatry and related fields.

(13) *Pulmonary-Allergy Drugs Advisory Committee.*

(i) Date established: February 17, 1972.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the treatment of pulmonary disease and diseases with allergic and/or immunologic mechanisms.

(14) *Medical Imaging Drugs Advisory Committee.*

(i) Date established: May 18, 2011.

(ii) Function: Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in diagnostic and therapeutic procedures using radioactive pharmaceuticals and contrast media used in diagnostic radiology.

(15) *Pharmaceutical Science and Clinical Pharmacology Advisory Committee.*

(i) Date established: January 22, 1990.

(ii) Function: The committee shall provide advice on scientific, clinical and technical issues related to safety and effectiveness of drug products for use in the treatment of a broad spectrum of human diseases, the quality characteristics which such drugs purport or are represented to have and as required, any other product for which the Food and Drug Administration has regulatory responsibility, and make appropriate recommendations to the Commissioner of Food and Drugs. The Committee may also review agency sponsored intramural and extramural biomedical research programs in support of FDA's drug regulatory responsibilities and its critical path initiatives related to improving the efficacy and safety of drugs and improving the efficiency of drug development.

(16) *Nonprescription Drugs Advisory Committee.*

(i) Date established: August 27, 1991.

(ii) Functions: The committee reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products for use in the treatment of a broad spectrum of human symptoms and diseases.

(17) *Pharmacy Compounding Advisory Committee.*

(i) Date re-established: April 25, 2012.

(ii) Function: Provides advice on scientific, technical, and medical issues concerning drug compounding under sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act and, as required, any other product for which the Food and Drug Administration has regulatory responsibility, and makes appropriate recommendations to the Commissioner of Food and Drugs.

(d) *Center for Devices and Radiological Health—*

(1) *Medical Devices Advisory Committee.*

(i) *Date established:* October 27, 1990.

(ii) *Function:* Reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

(2) *Device Good Manufacturing Practice Advisory Committee.*

(i) Date established: May 17, 1987.

(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.

(3) *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

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electronic products to control the emission of radiation under 42 U.S.C. 263f(f)(1)(A).

(4) *National Mammography Quality Assurance Advisory Committee.*

(i) Date established: July 6, 1993.

(ii) Function: Advises on developing appropriate quality standards and regulations for the use of mammography facilities.

(5) *Patient Engagement Advisory Committee.*

(i) Date Established: October 6, 2015.

(ii) Function: Provides advice to the Commissioner on complex issues relating to medical devices, the regulation of devices, and their use by patients. Agency guidance and policies, clinical trial or registry design, patient preference study design, benefit-risk determinations, device labeling, unmet clinical needs, available alternatives, patient reported outcomes, and device-related quality of life or health status issues are among the topics that may be considered by the Committee. The Committee provides relevant skills and perspectives in order to improve communication of benefits, risks, and clinical outcomes, and increase integration of patient perspectives into the regulatory process for medical devices. It performs its duties by identifying new approaches, promoting innovation, recognizing unforeseen risks or barriers, and identifying unintended consequences that could result from FDA policy.

(e) *National Center for Toxicological Research—Science Advisory Board.*

(1) 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 to fulfill regulatory responsibilities.

[54 FR 9036, Mar. 3, 1989]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §14.100, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

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 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360kk(f)(1)(A)) to provide consultation before the Commissioner prescribes any performance standard for an electronic product.

[44 FR 22351, Apr. 13, 1979, as amended at 78 FR 17087, Mar. 20, 2013]

§ 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 21 U.S.C. 360kk; 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 21 U.S.C. 360kk rests with the Commissioner, after receiving the advice of TEPRSSC.

[44 FR 22351, Apr. 13, 1979, as amended at 78 FR 17087, Mar. 20, 2013]

§ 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.

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(c) Ten members constitute a quorum, provided at least three members are present from each group specified in 21 U.S.C. 360kk(f)(1)(A) and in §14.127(a), i.e., Government, industry, and the public.

(d) The Chairperson 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 Chairperson believes that more time is needed, the Chairperson will inform the Director of the Center for Devices and 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.

[44 FR 22351, Apr. 13, 1979, as amended at 54 FR 9037, Mar. 3, 1989; 78 FR 17087, Mar. 20, 2013]

§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 Chairperson of TEPRSSC.

(c) Appointments of members are for a term of 3 years or as specified by the Commissioner.

(1) The Chairperson is appointed for a term concurrent with the Chairperson's term as a member of TEPRSSC. If the Chairpersonship becomes vacant without adequate notice, the Designated Federal Officer may appoint a committee member as temporary Chairperson pending appointment of a new Chairperson 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 Designated Federal Officer 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 21 U.S.C. 360kk(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.

[44 FR 22351, Apr. 13, 1979, as amended at 78 FR 17087, Mar. 20, 2013]

Subpart

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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 721(b)(5)(B) of the FD&C 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 721(b)(5)(B) of the FD&C 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 Division of Dockets Management.

(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 Chairperson 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

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considered by the committee in addition to the administrative record furnished to it.

(d) If the Chairperson concludes that the color additive advisory committee needs additional time, the Chairperson 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 721(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 721(b)(5)(B) of the FD&C 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 Chairperson.

(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 721(b)(5)(D) of the FD&C 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.

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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, collectible 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)

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portant 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 committee 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 center 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 center 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 314.430 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.

[44 FR 22351, Apr. 13, 1979, as amended at 54 FR 9037, Mar. 3, 1989]

§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

Sec.

15.1 Scope.

Subpart B—Procedures for Public Hearing Before the Commissioner

15.20 Notice of a public hearing before the Commissioner.
15.21 Notice of participation; schedule for hearing.
15.25 Written submissions.
15.30 Conduct of a public hearing before the Commissioner.

Subpart C—Records of a Public Hearing Before the Commissioner

15.40 Administrative record.
15.45 Examination of administrative record.

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