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both. The review will ordinarily follow the established agency channels of supervision or review for that matter.

(2) A sponsor, applicant, or manufacturer of a drug or device regulated under the act or the Public Health Service Act (42 U.S.C. 262), may request review of a scientific controversy by an appropriate scientific advisory panel as described in section 505(n) of the act, or an advisory committee as described in section 515(g)(2)(B) of the act. The reason(s) for any denial of a request for such review shall be briefly set forth in writing to the requester. Persons who receive a Center denial of their request under this section may submit a request for review of the denial. The request should be sent to the Chief Mediator and Ombudsman.

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

(1) To resolve an issue that cannot be resolved at lower levels within the agency (e.g., between two parts of a center or other component of the agency, between two centers or other components of the agency, or between the agency and an interested person outside the agency).

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

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

(4) As required by delegations of authority.

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

[44 FR 22323, Apr. 13, 1979, as amended at 50 FR 8994, Mar. 6, 1985; 63 FR 63982, Nov. 18, 1998]

§ 10.80 Dissemination of draft Federal Register notices and regulations.

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

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

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

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

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

(2) A draft of a final notice or regulation or its preamble, or any portion of either, may be furnished to an interested person outside the executive branch only if it is made available to

all interested persons by a notice published in the FEDERAL REGISTER, except as otherwise provided in paragraphs (g) and (j) of this section. A draft of a final notice or regulation made available to an interested person in this manner may, without the prior permission of the Commissioner, be discussed as provided in paragraph (b)(2) of this section.

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

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

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

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

(*b*) The preparation of a tentative final regulation or tentative revised final regulation under §10.40(f)(6), on which interested persons will be given an additional period of time for oral and written comment.

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

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

(g) A draft of a final food additive color additive, or new animal drug regulation may be furnished to the petitioner for comment on the technical accuracy of the regulation. Every meeting with a petitioner relating to the draft will be recorded in a written memorandum, and all memoranda and correspondence will be filed with the Division of Dockets Management as part of the administrative record of the regulation under the provisions of §10.65.

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

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

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

[44 FR 22323, Apr. 13, 1979, as amended at 54 FR 9035, Mar. 3, 1989; 64 FR 398, Jan. 5, 1999]

§10.85 Advisory opinions.

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

(1) The request will be granted whenever feasible.

(2) The request may be denied if:

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

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

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

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

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

(b) A request for an advisory opinion is to be submitted in accordance with §10.20, is subject to the provisions of