

any matter concerning the laws administered by the Commissioner. Unless otherwise required by law, meetings may be public or private at FDA's discretion.

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

[66 FR 6468, Jan. 22, 2001]

§ 10.70 Documentation of significant decisions in administrative file.

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

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

(1) Appropriate documentation of the basis for the decision, including relevant evaluations, reviews, memoranda, letters, opinions of consultants, minutes of meetings, and other pertinent written documents; and

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

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

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

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

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

(2) Be dated and signed by the author;

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

(4) Avoid defamatory language, intemperate remarks, undocumented

charges, or irrelevant matters (e.g., personnel complaints);

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

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

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

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

§ 10.75 Internal agency review of decisions.

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

(1) At the request of the employee.

(2) On the initiative of the supervisor.

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

(4) As required by delegations of authority.

(b)(1) The review will be made by consultation between the employee and the supervisor or by review of the administrative file on the matter, or both. The review will ordinarily follow the established agency channels of supervision or review for that matter.

(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

§ 10.80

21 CFR Ch. I (4-1-04 Edition)

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.