

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

(a) The Commissioner shall promulgate regulations and orders after an opportunity for a formal evidentiary public hearing under part 12 whenever all of the following apply:

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

(2) The person requesting the hearing has a right to an opportunity for a hearing and submits adequate justification for the hearing as required by §§ 12.20 through 12.22 and other applicable provisions in this chapter, e.g., §§ 314.200, 514.200, and 601.7(a).

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

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

(1) Section 401 on any action for the amendment or repeal of any definition and standard of identity for any dairy product (including products regulated under parts 131, 133, and 135 of this chapter) or maple sirup (regulated under § 168.140 of this chapter).

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

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

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

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

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

(7) [Reserved]

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

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

(10)–(11) [Reserved]

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

(13) Section 721 (b) and (c) on regulations for color additive listing and certification.

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

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

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

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

(18) Section 515(g) on device pre-market approval applications and product development protocols.

(19) Section 351(a) of the Public Health Service Act on a biologics license for a biological product.

(20) Section 306 on debarment, debarment period and considerations, termination of debarment under section 306(d)(3), suspension, and termination of suspension.

[44 FR 22323, Apr. 13, 1979, as amended at 54 FR 9034, Mar. 3, 1989; 58 FR 49190, Sept. 22, 1993; 60 FR 38626, July 27, 1995; 63 FR 26697, May 13, 1998; 64 FR 398, Jan. 5, 1999; 64 FR 56448, Oct. 20, 1999; 67 FR 4906, Feb. 1, 2002]

§ 10.55 Separation of functions; ex parte communications.

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

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

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

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

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(i) The center responsible for the matter is, as a party to the hearing, responsible for all investigative functions and for presentation of the position of the center at the hearing and in any pleading or oral argument before the Commissioner. Representatives of the center may not participate or advise in any decision except as witness or counsel in public proceedings. There is to be no other communication between representatives of the center and representatives of the office of the Commissioner concerning the matter before the decision of the Commissioner. The Commissioner may, however, designate representatives of a center to advise the office of the Commissioner, or designate members of that office to advise a center. The designation will be in writing and filed with the Division of Dockets Management no later than the time specified in paragraph (b)(2) of this section for the application of separation of functions. All members of FDA other than representatives of the involved center (except those specifically designated otherwise) shall be available to advise and participate with the office of the Commissioner in its functions relating to the hearing and the final decision.

(ii) The Chief Counsel for FDA shall designate members of the office of General Counsel to advise and participate with the center in its functions in the hearing and members who are to advise the office of the Commissioner in its functions related to the hearing and the final decision. The members of the office of General Counsel designated to advise the center may not participate or advise in any decision of the Commissioner except as counsel in public proceedings. The designation is to be in the form of a memorandum filed with the Division of Dockets Management and made a part of the administrative record in the proceeding. There may be no other communication between those members of the office of General Counsel designated to advise the office of the Commissioner and any other persons in the office of General Counsel or in the involved center with respect to the matter prior to the decision of the Commissioner. The Chief Counsel may assign new attorneys to advise either the center or the office of the Commis-

sioner at any stage of the proceedings. The Chief Counsel will ordinarily advise and participate with the office of the Commissioner in its functions relating to the hearing and the final decision.

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

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

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

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

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

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

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

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

[44 FR 22323, Apr. 13, 1979, as amended at 50 FR 8994, Mar. 6, 1985; 54 FR 9035, Mar. 3, 1989; 64 FR 398, Jan. 5, 1999]

§ 10.60 Referral by court.

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

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

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

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

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

(3) A notice published in the FEDERAL REGISTER requesting information and views.

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

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

§ 10.65 Meetings and correspondence.

(a) In addition to public hearings and proceedings established under this part and other sections of this chapter, meetings may be held and correspondence may be exchanged between representatives of FDA and an interested person outside FDA on a matter within the jurisdiction of the laws administered by the Commissioner. Action on meetings and correspondence does not constitute final administrative action subject to judicial review under § 10.45.

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

(1) The Commissioner shall inform the public of the time and place of the meeting and of the matters to be discussed.

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

(c) Every person outside the Federal Government may request a private meeting with a representative of FDA in agency offices to discuss a matter. FDA will make reasonable efforts to accommodate such requests.

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