

§ 10.60

21 CFR Ch. I (4-1-08 Edition)

(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 is not an employee of the executive branch of the Federal Government without the agreement of the person requesting the meeting. Any person may attend by mutual consent of the person requesting the meeting and FDA.

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

(3) A person who wishes to attend a private meeting, but who is not invited to attend either by the person requesting the meeting or by FDA, or who otherwise cannot attend the meeting, may request a separate meeting with FDA to discuss the same matter or an additional matter.

(d) FDA employees have a responsibility to meet with all segments of the public to promote the objectives of the laws administered by the agency. In