

Commissioner exercise, in accordance with §20.82 of this chapter, the authorized discretion to disclose records related to a section 305 presentation before the consideration of criminal prosecution is closed.

(2) After consideration of criminal prosecution is closed, the records are available for public disclosure in response to a request under the Freedom of Information Act, except to the extent that the exemptions from disclosure in subpart D of part 20 of this chapter are applicable. No statements obtained through promises of confidentiality shall be available for public disclosure.

(b) Consideration of criminal prosecution based on a particular section 305 notice of opportunity for presentation of views shall be deemed to be closed within the meaning of this section and §7.85 when a final decision has been made not to recommend criminal prosecution to a United States attorney based on charges set forth in the notice and considered at the presentation, or when such a recommendation has been finally refused by the United States attorney, or when criminal prosecution has been instituted and the matter and all related appeals have been concluded, or when the statute of limitations has run.

(c) Before disclosure of any record specifically reflecting consideration of a possible recommendation for criminal prosecution of any individual, all names and other information that would identify an individual whose prosecution was considered but not recommended, or who was not prosecuted, shall be deleted, unless the Commissioner concludes that there is a compelling public interest in the disclosure of the names.

(d) Names and other information that would identify a Food and Drug Administration employee shall be deleted from records related to a section 305 presentation of views before public disclosure only under §20.32 of this chapter.

[44 FR 12168, Mar. 6, 1979]

## PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

### Subpart A—General Provisions

Sec.

- 10.1 Scope.
- 10.3 Definitions.
- 10.10 Summaries of administrative practices and procedures.
- 10.19 Waiver, suspension, or modification of procedural requirements.

### Subpart B—General Administrative Procedures

- 10.20 Submission of documents to Division of Dockets Management; computation of time; availability for public disclosure.
- 10.25 Initiation of administrative proceedings.
- 10.30 Citizen petition.
- 10.33 Administrative reconsideration of action.
- 10.35 Administrative stay of action.
- 10.40 Promulgation of regulations for the efficient enforcement of the law.
- 10.45 Court review of final administrative action; exhaustion of administrative remedies.
- 10.50 Promulgation of regulations and orders after an opportunity for a formal evidentiary public hearing.
- 10.55 Separation of functions; ex parte communications.
- 10.60 Referral by court.
- 10.65 Meetings and correspondence.
- 10.70 Documentation of significant decisions in administrative file.
- 10.75 Internal agency review of decisions.
- 10.80 Dissemination of draft Federal Register notices and regulations.
- 10.85 Advisory opinions.
- 10.90 Food and Drug Administration regulations, recommendations, and agreements.
- 10.95 Participation in outside standard-setting activities.
- 10.100 Public calendar.
- 10.105 Representation by an organization.
- 10.110 Settlement proposals.
- 10.115 Good guidance practices.

### Subpart C—Electronic Media Coverage of Public Administrative Proceedings; Guideline on Policy and Procedures

- 10.200 Scope.
- 10.203 Definitions.
- 10.204 General.
- 10.205 Electronic media coverage of public administrative proceedings.
- 10.206 Procedures for electronic media coverage of agency public administrative proceedings.

## § 10.1

## 21 CFR Ch. I (4–1–12 Edition)

AUTHORITY: 5 U.S.C. 551–558, 701–706; 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–397, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

SOURCE: 44 FR 22323, Apr. 13, 1979, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 10 appear at 68 FR 24879, May 9, 2003.

### Subpart A—General Provisions

#### § 10.1 Scope.

(a) Part 10 governs practices and procedures for petitions, hearings, and other administrative proceedings and activities conducted by the Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and other laws which the Commissioner of Food and Drugs administers.

(b) If a requirement in another part of title 21 differs from a requirement in this part, the requirements of this part apply to the extent that they do not conflict with the other requirements.

(c) References in this part and parts 12, 13, 14, 15, and 16 to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

(d) References in this part and parts 12, 13, 14, 15, and 16 to *publication*, or to the day or date of publication, or use of the phrase to *publish*, refer to publication in the FEDERAL REGISTER unless otherwise noted.

[44 FR 22323, Apr. 13, 1979, as amended at 54 FR 9034, Mar. 3, 1989; 69 FR 17290, Apr. 2, 2004]

#### § 10.3 Definitions.

(a) The following definitions apply in this part and parts 12, 13, 14, 15, 16, and 19:

*Act* means the Federal Food, Drug, and Cosmetic Act unless otherwise indicated.

*Administrative action* includes every act, including the refusal or failure to act, involved in the administration of any law by the Commissioner, except that it does not include the referral of apparent violations to U.S. attorneys for the institution of civil or criminal proceedings or an act in preparation of a referral.

*Administrative file* means the file or files containing all documents per-

taining to a particular administrative action, including internal working memoranda, and recommendations.

*Administrative record* means the documents in the administrative file of a particular administrative action on which the Commissioner relies to support the action.

*Agency* means the Food and Drug Administration.

*Chief Counsel* means the Chief Counsel of the Food and Drug Administration.

*Commissioner* means the Commissioner of Food and Drugs, Food and Drug Administration, U.S. Department of Health and Human Services, or the Commissioner's designee.

*Department* means the U.S. Department of Health and Human Services.

*Division of Dockets Management* means the Division of Dockets Management, Office of Management and Operations of the Food and Drug Administration, U.S. Department of Health and Human Services, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

*Ex parte communication* means an oral or written communication not on the public record for which reasonable prior notice to all parties is not given, but does not include requests for status reports on a matter.

*FDA* means the Food and Drug Administration.

*Food and Drug Administration employee* or *Food and Drug Administration representative* includes members of the Food and Drug Division of the office of the General Counsel of the Department of Health and Human Services.

*Formal evidentiary public hearing* means a hearing conducted under part 12.

*Interested person* or *any person who will be adversely affected* means a person who submits a petition or comment or objection or otherwise asks to participate in an informal or formal administrative proceeding or court action.

*Meeting* means any oral discussion, whether by telephone or in person.

*Office of the Commissioner* includes the offices of the Associate Commissioners but not the centers or the regional or district offices.

*Order* means the final agency disposition, other than the issuance of a regulation, in a proceeding concerning any