

## § 10.1

## 21 CFR Ch. I (4–1–04 Edition)

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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 that the Commissioner of Food and Drugs administers under § 5.10.

(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]

#### § 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 pertaining 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.

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*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 matter and includes action on a new drug application, new animal drug application, or biological license.

*Participant* means any person participating in any proceeding, including each party and any other interested person.

*Party* means the center of the Food and Drug Administration responsible for a matter involved and every person who either has exercised a right to request or has been granted the right by the Commissioner to have a hearing under part 12 or part 16 or who has waived the right to a hearing to obtain the establishment of a Public Board of Inquiry under part 13 and as a result of whose action a hearing or a Public Board of Inquiry has been established.

*Person* includes an individual, partnership, corporation, association, or other legal entity.

*Petition* means a petition, application, or other document requesting the Commissioner to establish, amend, or revoke a regulation or order, or to take or not to take any other form of administrative action, under the laws administered by the Food and Drug Administration.

*Presiding officer* means the Commissioner or the Commissioner's designee or an administrative law judge appointed as provided in 5 U.S.C. 3105.

*Proceeding and administrative proceeding* means any undertaking to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action.

*Public advisory committee or advisory committee* means any committee, board, commission, council, conference, panel, task force, or other similar group, or

any subcommittee or other subgroup of an advisory committee, that is not composed wholly of full-time employees of the Federal Government and is established or utilized by the Food and Drug Administration to obtain advice or recommendations.

*Public Board of Inquiry or Board* means an administrative law tribunal constituted under part 13.

*Public hearing before a public advisory committee* means a hearing conducted under part 14.

*Public hearing before a Public Board of Inquiry* means a hearing conducted under part 13.

*Public hearing before the Commissioner* means a hearing conducted under part 15.

*Regulations* means an agency rule of general or particular applicability and future effect issued under a law administered by the Commissioner or relating to administrative practices and procedures. In accordance with §10.90(a), each agency regulation will be published in the FEDERAL REGISTER and codified in the Code of Federal Regulations.

*Regulatory hearing before the Food and Drug Administration* means a hearing conducted under part 16.

*Secretary* means the Secretary of Health and Human Services.

*The laws administered by the Commissioner or the laws administered by the Food and Drug Administration* means all the laws that the Commissioner is authorized to administer under §5.10.

(b) A term that is defined in section 201 of the Federal Food, Drug, and Cosmetic Act or part 1 has the same definition in this part.

(c) Words in the singular form include the plural, words in the masculine form include the feminine, and vice versa.

(d) Whenever a reference is made in this part to a person in FDA, e.g., the director of a center, the reference includes all persons to whom that person has delegated the specific function involved.

[44 FR 22323, Apr. 13, 1979, as amended at 46 FR 8455, Jan. 27, 1981; 50 FR 8994, Mar. 6, 1985; 54 FR 6886, Feb. 15, 1989; 54 FR 9034, Mar. 3, 1989; 59 FR 14363, Mar. 28, 1994]