

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]

§10.10 Summaries of administrative practices and procedures.

To encourage public participation in all agency activities, the Commissioner will prepare for public distribution summaries of FDA administrative practices and procedures in readily understandable terms.

§10.19 Waiver, suspension, or modification of procedural requirements.

The Commissioner or a presiding officer may, either voluntarily or at the request of a participant, waive, suspend, or modify any provision in parts 12 through 16 applicable to the conduct of a public hearing by announcement at the hearing or by notice in advance of the hearing if no participant will be prejudiced, the ends of justice will thereby be served, and the action is in accordance with law.

Subpart B—General Administrative Procedures

§10.20 Submission of documents to Dockets Management Branch; computation of time; availability for public disclosure.

(a) A submission to the Dockets Management Branch of a petition, comment, objection, notice, compilation of information, or any other document is to be filed in four copies except as otherwise specifically provided in a relevant FEDERAL REGISTER notice or in

another section of this chapter. The Dockets Management Branch is the agency custodian of these documents.

(b) A submission is to be signed by the person making it, or by an attorney or other authorized representative of that person. Submissions by trade associations are also subject to the requirements of §10.105(b).

(c) Information referred to or relied upon in a submission is to be included in full and may not be incorporated by reference, unless previously submitted in the same proceeding.

(1) A copy of an article or other reference or source cited must be included, except where the reference or source is:

- (i) A reported Federal court case;
- (ii) A Federal law or regulation;
- (iii) An FDA document that is routinely publicly available;
- (iv) A recognized medical or scientific textbook that is readily available to the agency; or
- (v) A designated journal listed in §510.95.

(2) If a part of the material submitted is in a foreign language, it must be accompanied by an English translation verified to be complete and accurate, together with the name, address, and a brief statement of the qualifications of the person making the translation. A translation of literature or other material in a foreign language is to be accompanied by copies of the original publication.

(3) Where relevant information is contained in a document also containing irrelevant information, the irrelevant information is to be deleted and only the relevant information is to be submitted.

(4) Under §20.63 (a) and (b), the names and other information that would identify patients or research subjects are to be deleted from any record before it is submitted to the Dockets Management Branch in order to preclude a clearly unwarranted invasion of personal privacy.

(5) Defamatory, scurrilous, or intemperate matter is to be deleted from a record before it is submitted to the Dockets Management Branch.

(6) The failure to comply with the requirements of this part or with §12.80 or §13.20 will result in rejection of the

submission for filing or, if it is filed, in exclusion from consideration of any portion that fails to comply. If a submission fails to meet any requirement of this section and the deficiency becomes known to the Dockets Management Branch, the Dockets Management Branch shall not file the submission but return it with a copy of the applicable regulations indicating those provisions not complied with. A deficient submission may be corrected or supplemented and subsequently filed. The office of the Dockets Management Branch does not make decisions regarding the confidentiality of submitted documents. Persons wishing to voluntarily submit information considered confidential shall follow the pre-submission review requirements of §20.44.

(d) The filing of a submission means only that the Dockets Management Branch has identified no technical deficiencies in the submission. The filing of a petition does not mean or imply that it meets all applicable requirements or that it contains reasonable grounds for the action requested or that the action requested is in accordance with law.

(e) All submissions to the Dockets Management Branch will be considered as submitted on the date they are post-marked or, if delivered in person during regular business hours, on the date they are delivered, unless a provision in this part, an applicable FEDERAL REGISTER notice, or an order issued by an administrative law judge specifically states that the documents must be received by a specified date, e.g., §10.33(g) relating to a petition for reconsideration, in which case they will be considered submitted on the date received.

(f) All submissions are to be mailed or delivered in person to the Dockets Management Branch, Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, except that a submission which is required to be received by the Branch by a specified date may be delivered in person to the FDA building in Washington (Room 6819, 200 C Street SW., Washington, DC 20204) and will be considered as received by the Branch on the date on which it is delivered.

(g) FDA ordinarily will not acknowledge or give receipt for documents, except:

(1) Documents delivered in person or by certified or registered mail with a return receipt requested; and

(2) Petitions for which acknowledgment of receipt of filing is provided by regulation or by customary practice, e.g., § 10.30(c) relating to a citizen petition.

(h) Saturdays, Sundays, and Federal legal holidays are included in computing the time allowed for the submission of documents, except that when the time for submission expires on a Saturday, Sunday, or Federal legal holiday, the period will be extended to include the next business day.

(i) All submissions to the Dockets Management Branch are representations that, to the best of the knowledge, information, and belief of the person making the submission, the statements made in the submission are true and accurate. All submissions are subject to the False Reports to the Government Act (18 U.S.C. 1001) under which a willfully false statement is a criminal offense.

(j) The availability for public examination and copying of submissions to the Dockets Management Branch is governed by the following rules:

(1) Except to the extent provided in paragraphs (j)(2) and (3) of this section, the following submissions, including all supporting material, will be on public display and will be available for public examination between 9 a.m. and 4 p.m., Monday through Friday. Requests for copies of submissions will be filed and handled in accordance with subpart C of part 20:

(i) Petitions.

(ii) Comments on petitions, on documents published in the FEDERAL REGISTER, and on similar public documents.

(iii) Objections and requests for hearings filed under part 12.

(iv) Material submitted at a hearing under § 12.32(a)(2) and parts 12, 13, and 15.

(v) Material placed on public display under the regulations in this chapter, e.g., agency guidelines filed under § 10.90(b).

(2)(i) Material prohibited from public disclosure under § 20.63 (clearly unwarranted invasion of personal privacy) and, except as provided in paragraph (j)(3) of this section, material submitted with objections and requests for hearing filed under part 12, or at a hearing under part 12 or part 13, or an alternative form of public hearing before a public advisory committee or a hearing under § 12.32(a) (2) or (3), of the following types will not be on public display, will not be available for public examination, and will not be available for copying or any other form of verbatim transcription unless it is otherwise available for public disclosure under part 20:

(a) Safety and effectiveness information, which includes all studies and tests of an ingredient or product on animals and humans and all studies and tests on the ingredient or product for identity, stability, purity, potency, bioavailability, performance, and usefulness.

(b) A protocol for a test or study.

(c) Manufacturing methods or processes, including quality control procedures.

(d) Production, sales distribution, and similar information, except any compilation of information aggregated and prepared in a way that does not reveal confidential information.

(e) Quantitative or semiquantitative formulas.

(f) Information on product design or construction.

(ii) Material submitted under paragraph (j)(2) of this section is to be segregated from all other submitted material and clearly so marked. A person who does not agree that a submission is properly subject to paragraph (j)(2) may request a ruling from the Associate Commissioner for Public Affairs whose decision is final, subject to judicial review under § 20.46.

(3) Material listed in paragraph (j)(2)(i) (a) and (b) of this section may be disclosed under a protective order issued by the administrative law judge or other presiding officer at a hearing referenced in paragraph (j)(2)(i). The administrative law judge or presiding officer shall permit disclosure of the data only in camera and only to the extent necessary for the proper conduct

of the hearing. The administrative law judge or presiding officer shall direct to whom the information is to be made available (e.g., to parties or participants, or only to counsel for parties or participants), and persons not specifically permitted access to the data will be excluded from the in camera part of the proceeding. The administrative law judge or other presiding officer may impose other conditions or safeguards. The limited availability of material under this paragraph does not constitute prior disclosure to the public as defined in § 20.81, and no information subject to a particular order is to be submitted to or received or considered by FDA in support of a petition or other request from any other person.

[44 FR 22323, Apr. 13, 1979, as amended at 46 FR 8455, Jan. 27, 1981; 49 FR 7363, Feb. 29, 1984; 54 FR 9034, Mar. 3, 1989; 59 FR 14363, Mar. 28, 1994]

§ 10.25 Initiation of administrative proceedings.

An administrative proceeding may be initiated in the following three ways:

(a) An interested person may petition the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action. A petition must be either: (1) In the form specified in other applicable FDA regulations, e.g., the form for a color additive petition in § 71.1, for a food additive petition in § 171.1, for a new drug application in § 314.50, for a new animal drug application in § 514.1, or (2) in the form for a citizen petition in § 10.30.

(b) The Commissioner may initiate a proceeding to issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action. FDA has primary jurisdiction to make the initial determination on issues within its statutory mandate, and will request a court to dismiss, or to hold in abeyance its determination of or refer to the agency for administrative determination, any issue which has not previously been determined by the agency or which, if it has previously been determined, the agency concluded should be reconsidered and subject to a new administrative determination. The Commissioner may utilize any of the procedures es-

tablished in this part in reviewing and making a determination on any matter initiated under this paragraph.

(c) The Commissioner will institute a proceeding to determine whether to issue, amend, or revoke a regulation or order, or take or refrain from taking any other form of administrative action whenever any court, on its own initiative, holds in abeyance or refers any matter to the agency for an administrative determination and the Commissioner concludes that an administrative determination is feasible within agency priorities and resources.

[44 FR 22323, Apr. 13, 1979, as amended at 54 FR 9034, Mar. 3, 1989]

§ 10.30 Citizen petition.

(a) This section applies to any petition submitted by a person (including a person who is not a citizen of the United States) except to the extent that other sections of this chapter apply different requirements to a particular matter.

(b) A petition (including any attachments) must be submitted in accordance with § 10.20 and in the following form:

(Date) _____

Dockets Management Branch, Food and Drug Administration, Department of Health and Human Services, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

CITIZEN PETITION

The undersigned submits this petition under _____ (relevant statutory sections, if known) of the _____ (Federal Food, Drug, and Cosmetic Act or the Public Health Service Act or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs under 21 CFR 5.10) to request the Commissioner of Food and Drugs to _____ (issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action).

A. Action requested

((1) If the petition requests the Commissioner to issue, amend, or revoke a regulation, the exact wording of the existing regulation (if any) and the proposed regulation or amendment requested.)

((2) If the petition requests the Commissioner to issue, amend, or revoke an order, a copy of the exact wording of the citation to the existing order (if any) and the exact wording requested for the proposed order.)