

§ 14.172

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

public hearing and continuing or periodic review by the appropriate standing technical advisory committee for human prescription drugs. The Commissioner's determinations on the agenda of the committee are based upon the priorities of the various matters pending before the agency which fall within the pharmacologic class covered by that committee.

(b) High priority for such hearing and review by the appropriate standing technical advisory committee for human prescription drugs are given to the following types of human prescription drugs:

(1) Investigational drugs which are potential therapeutic advances over currently marketed products from the standpoint of safety or effectiveness, or which pose significant safety hazards, or which present narrow benefit-risk considerations requiring a close judgmental decision on approval for marketing, or which have a novel delivery system or formulation, or which are the subject of major scientific or public controversy, or which may be subject to special regulatory requirements such as a limitation on clinical trials, a patient followup requirement, postmarketing Phase IV studies, distributional controls, or boxed warnings.

(2) Marketed drugs for which an important new use has been discovered or which pose newly discovered safety hazards, or which are the subject of major scientific or public controversy, or which may be subject to important regulatory actions such as withdrawal of approval for marketing, boxed warnings, distributional controls, or newly required scientific studies.

(c) The committee may request the Commissioner for an opportunity to hold a public hearing and to review any matter involving a human prescription drug which falls within the pharmacologic class covered by the committee. The Commissioner may, after consulting with the committee on such request, grant or deny the request in light of the priorities of the other matters pending before the committee. Whenever feasible, consistent with the other work of the committee, the request will be granted.

(d) For a drug that meets any of the criteria established in paragraph (b) of this section, one or more members of or consultants to the appropriate advisory committee may be selected for more detailed monitoring of the matter and consultation with FDA on behalf of the committee. The member or consultant may be invited to attend appropriate meetings and shall assist the center in any briefing of the committee on that matter.

(e) An advisory committee may obtain advice and recommendations from other agency advisory committees, consultants, and experts which the advisory committee and the center conclude would facilitate the work of the advisory committee.

(f) Presentation of all relevant information about the matter will be made in open session unless it relates to an IND the existence of which has not previously been disclosed to the public as defined in §20.81 or is otherwise prohibited from public disclosure under part 20 and the regulations referenced therein. Sections 314.430 and 601.51 determine whether, and the extent to which, relevant information may be made available for public disclosure, summarized and discussed in open session but not otherwise made available for public disclosure, or not in any way discussed or disclosed in open session or otherwise disclosed to the public.

[44 FR 22351, Apr. 13, 1979, as amended at 54 FR 9037, Mar. 3, 1989]

§ 14.172 Utilization of an advisory committee at the request of an interested person.

Any interested person may request, under §10.30, that a specific matter relating to a particular human prescription drug be submitted to an appropriate advisory committee for a hearing and review and recommendations. The request must demonstrate the importance of the matter and the reasons why it should be submitted for a hearing at that time. The Commissioner may grant or deny the request.

§ 14.174 Advice and recommendations in writing.

Advice and recommendations given by a committee on a specific drug or a class of drugs are ordinarily in the

Food and Drug Administration, HHS

§ 15.20

form of a written report. The report may consist of the approved minutes of the meeting or a separate written report. The report responds to the specific issues or questions which the Commissioner has addressed to the advisory committee, and states the basis of the advice and recommendations of the committee.

PART 15—PUBLIC HEARING BEFORE THE COMMISSIONER

Subpart A—General Provisions

Sec.

15.1 Scope.

Subpart B—Procedures for Public Hearing Before the Commissioner

15.20 Notice of a public hearing before the Commissioner.

15.21 Notice of participation; schedule for hearing.

15.25 Written submissions.

15.30 Conduct of a public hearing before the Commissioner.

Subpart C—Records of a Public Hearing Before the Commissioner

15.40 Administrative record.

15.45 Examination of administrative record.

AUTHORITY: 5 U.S.C. 553; 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–393, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b–263n, 264.

SOURCE: 44 FR 22366, Apr. 13, 1979, unless otherwise noted.

Subpart A—General Provisions

§ 15.1 Scope.

The procedures in this part apply when:

(a) The Commissioner concludes, as a matter of discretion, that it is in the public interest to permit persons to present information and views at a public hearing on any matter pending before the Food and Drug Administration.

(b) The act or regulation specifically provides for a public hearing before the Commissioner on a matter, e.g., § 330.10(a)(8) relating to over-the-counter drugs and sections 520 (b) and (f)(1)(B), and 521 of the act relating to proposals to allow persons to order custom devices, to proposed device good manufacturing practice regulations,

and to proposed exemptions from preemption of State and local device requirements under § 808.25(e).

(c) A person who has right to an opportunity for a formal evidentiary public hearing under part 12 waives that opportunity and instead requests under § 12.32 a public hearing before the Commissioner, and the Commissioner, as a matter of discretion, accepts the request.

Subpart B—Procedures for Public Hearing Before the Commissioner

§ 15.20 Notice of a public hearing before the Commissioner.

(a) If the Commissioner determines that a public hearing should be held on a matter, the Commissioner will publish a notice of hearing in the FEDERAL REGISTER setting forth the following information:

(1) If the hearing is under § 15.1 (a) or (b), the notice will state the following:

(i) The purpose of the hearing and the subject matter to be considered. If a written document is to be the subject matter of the hearing, it will be published as part of the notice, or reference made to it if it has already been published in the FEDERAL REGISTER, or the notice will state that the document is available from an agency office identified in the notice.

(ii) The time, date, and place of the hearing, or a statement that the information will be contained in a subsequent notice.

(2) If the hearing is in lieu of a formal evidentiary public hearing under § 15.1(c), all of the information described in § 12.32(e).

(b) The scope of the hearing is determined by the notice of hearing and any regulation under which the hearing is held. If a regulation, e.g., § 330.10(a)(10), limits a hearing to review of an existing administrative record, information not already in the record may not be considered at the hearing.

(c) The notice of hearing may require participants to submit the text of their presentations in advance of the hearing if the Commissioner determines that advance submissions are necessary for the panel to formulate useful questions to be posed at the hearing under § 15.30(e). The notice may provide for