

§ 14.65

FDA, and will not be discarded or erased.

(d) Any transcript or recording of a meeting or portion thereof which is publicly available under this section will be available at actual cost of duplication, which will be, where applicable, the fees established in § 20.45. FDA may furnish the requested transcript or recording for copying to a private contractor who shall charge directly for the cost of copying under § 20.53.

(e) A person attending any open portion of a meeting may, consistent with the orderly conduct of the meeting, record or otherwise take a transcript of the meeting. This transcription will not be part of the administrative record.

(f) Only FDA may make a transcript or recording of a closed portion of a meeting.

[44 FR 22351, Apr. 13, 1979, as amended at 68 FR 25285, May 12, 2003]

§ 14.65 Public inquiries and requests for advisory committee records.

(a) Public inquiries on general committee matters, except requests for records, are to be directed to: Committee Management Officer (HFA-306), Office of Management and Operations, Food and Drug Administration, Department of Health and Human Services, 5600 Fishers Lane, Rockville, MD 20857.

(b) Public inquiries on matters relating to a specific committee, except requests for records, are to be directed to the executive secretary or the designated agency employee listed in the FEDERAL REGISTER notices published under § 14.20.

(c) Requests for public advisory committee records, including minutes, are to be made, to FDA's Freedom of Information Staff (HFI-35) under § 20.40 and the related provisions of part 20.

[44 FR 22351, Apr. 13, 1979, as amended at 46 FR 8456, Jan. 27, 1981]

§ 14.70 Administrative record of a public hearing before an advisory committee.

(a) Advice or recommendations of an advisory committee may be given only on matters covered in the administrative record of the committee's proceedings. Except as specified in other

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FDA regulations, the administrative record consists of all the following items relating to the matter:

(1) Any transcript or recording of an open portion of a meeting.

(2) The minutes of all portions of all meetings, after any deletions under § 14.60(b)(4).

(3) All written submissions to and information considered by the committee.

(4) All reports made by the committee.

(5) Any reports prepared by a consultant under § 14.31(e).

(b) The record of the proceeding is closed at the time the advisory committee renders its advice or recommendations or at any earlier time specified by the committee or in other sections in this chapter.

§ 14.75 Examination of administrative record and other advisory committee records.

(a) The administrative record and other committee records are available for public disclosure under part 20, except as provided in paragraph (b) of this section, at the following times:

(1) The written information for consideration by the committee at any meeting; at the same time it is made available to the committee.

(2) The transcript or recording of any open portion of a meeting; as soon as it is available.

(3) The minutes of any open portion of a meeting; after they have been approved by the committee and certified by the chairman.

(4) The brief summary of any closed portion of a meeting prepared under § 14.60(c); as soon as it is available.

(5) All written information or views submitted to the committee at an open portion of a meeting; as soon as they are submitted.

(6) The minutes or portions thereof of a closed portion of a meeting—

(i) For a matter not directed to be maintained as confidential under § 14.22(i)(2): After they have been approved by the committee and certified by the chairman; and

(ii) For a matter directed to be maintained as confidential under § 14.22(i)(2): After the advice or report of the committee relevant to those minutes or

portions thereof is acted upon by the Commissioner, or upon a determination by the Commissioner that such minutes or portions thereof may be made available for public disclosure without undue interference with agency or advisory committee operations.

(7) Formal advice or a report of the committee: After it has been acted upon, i.e., approved, disapproved, or rejected as inadequate, by the Commissioner, or upon a determination by the Commissioner that such formal advice or report may be made available for public disclosure without undue interference with agency or committee operations. Such formal advice or report may be retained as confidential while it is under active advisement.

(8) Any other committee records relating to the matter, except transcripts and recordings of closed portions of meetings: After the advice or report of the committee relevant to those records is acted upon by the Commissioner, or upon a determination by the Commissioner that the records may be made available for public disclosure without undue interference with agency or committee operations.

(b) The following information contained in the administrative record is not available for public examination or copying except as provided in § 12.32(g):

(1) Material provided to the committee by FDA that is exempt from public disclosure under part 20 and the regulations referenced there.

(2) Material provided to the advisory committee by a person making a presentation described in § 14.25(c) and which is prohibited from public disclosure under part 20 and the regulations referenced there.

(c) The Division of Dockets Management (HFA-305) will maintain a file for each committee containing the following principal records for ready access by the public:

(1) The committee charter.

(2) A list of committee members and their curricula vitae.

(3) The minutes of committee meetings.

(4) Any formal advice or report of the committee.

[44 FR 22351, Apr. 13, 1979, as amended at 54 FR 9035, Mar. 3, 1989]

Subpart E—Members of Advisory Committees

§ 14.80 Qualifications for members of standing policy and technical advisory committees.

(a) Members of a policy advisory committee—

(1) Shall have diverse interests, education, training, and experience; specific technical expertise is not a requirement;

(2) Are subject to the conflict of interest laws and regulations either as special Government employees or as members of the uniformed services, including the Commissioned Corps of the Public Health Service (the Commissioner has determined that, because members representing particular interests, e.g., a representative of labor, industry, consumers, or agriculture, are included on advisory committees specifically for the purpose of representing these interests, any financial interest covered by 18 U.S.C. 208(a) in the class which the member represents is irrelevant to the services which the Government expects from them and thus is hereby exempted under 18 U.S.C. 208(b) as too remote and inconsequential to affect the integrity of their services); and

(3) Shall be voting members.

(b) *Technical advisory committee.*(1) Voting members of technical advisory committees—

(i) Shall have expertise in the subject matter with which the committee is concerned and have diverse professional education, training, and experience so that the committee will reflect a balanced composition of sufficient scientific expertise to handle the problems that come before it; and

(ii) Except for members of the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC), are subject to the conflict of interest laws and regulations either as special Government employees or as members of the uniformed services, including the Commissioned Corps of the Public Health Service.

(2) The Commissioner shall, when required by statute, and may when not required by statute, provide for non-voting members of a technical advisory committee to serve as representatives