

Food and Drug Administration, HHS

§ 14.75

meeting prepared under paragraph (c) of this section.

[44 FR 22351, Apr. 13, 1979, as amended at 45 FR 85725, Dec. 30, 1980]

§ 14.61 Transcripts of advisory committee meetings.

(a) The agency will arrange for a transcript or recording to be made for each portion of a meeting.

(b) A transcript or recording of an open portion of a meeting made by FDA is to be included in the record of the committee proceedings.

(c) A transcript or recording of any closed portion of a meeting made by FDA will not be included in the administrative record of the committee proceedings. The transcript or recording will be retained as confidential by 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 § 20.42. FDA may furnish the requested transcript or recording for copying to a private contractor who shall charge directly for the cost of copying under § 20.51.

(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.

§ 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 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.