to their attention, the person will be required to leave the meeting immediately. This inadvertent and unauthorized attendance does not enable other unauthorized persons to attend, nor does it, of itself, constitute grounds for release of transcripts of closed portions or any other documents otherwise exempt from disclosure under §14.75 and part 20.

(4) If a person other than a person permitted to attend in accordance with paragraphs (c) (1) and (2) of this section is allowed by the Designated Federal Officer and the Chairperson to attend a closed portion of a meeting, that portion is open to attendance by any interested person.

[44 FR 22351, Apr. 13, 1979, as amended at 65 FR 56479, Sept. 19, 2000]

§14.29 Conduct of a hearing before an advisory committee.

(a) For each meeting, the open portion for public participation, which constitutes a public hearing under §14.25(a), will be at least 1 hour, unless public participation does not last that long, and may last for whatever longer time the committee Chairperson determines will facilitate the work of the committee. The FEDERAL REGISTER notice published under §14.20 will designate the time specifically reserved for the hearing, which is ordinarily the first portion of the meeting. Further public participation in any open portion of the meeting under §14.25(b) is solely at the discretion of the Chairperson.

(b) An interested person who wishes to be assured of the right to make an oral presentation at a meeting shall inform the Designated Federal Officer or other designated agency employee, orally or in writing, before the meeting.

(1) The person shall state the general nature of the presentation and the approximate time desired. Whenever possible, all written information to be discussed by that person at the meeting should be furnished in advance to the Designated Federal Officer or other designated agency employee. This material may be distributed or mailed by FDA to the committee members in advance of the meeting if time permits, and otherwise will be distributed to the members when they arrive for the meeting. The mailing or distribution may be undertaken only by FDA unless FDA grants permission to a person to mail or distribute the material

(2) Before the meeting, the Designated Federal Officer or other designated agency employee shall determine the amount of time allocated to each person for oral presentation and the time that the presentation is to begin. Each person will be so informed in writing, if time permits, or by telephone. FDA may require persons with common interests to make joint presentations.

(c) The Chairperson of the committee shall preside at the meeting in accordance with §14.30 and be accompanied by other committee members, who serve as a panel in conducting the hearing portion of the meeting.

(d) Each person may use the allotted time as desired, consistent with an orderly hearing. A person may be accompanied by additional persons, and may present any written information or views for inclusion in the record of the hearing, subject to the requirements of §14.35(c).

(e) If a person is absent at the time specified for that person's presentation, the persons following will appear in order. An attempt will be made to hear the person at the conclusion of the hearing. Interested persons attending the hearing who did not request an opportunity to make an oral presentation may be given an opportunity to do so at the discretion of the Chairperson.

(f) The Chairperson and other members may question a person concerning that person's presentation. No other person, however, may question the person. The Chairperson may allot additional time when it is in the public interest, but may not reduce the time allotted without consent of the person.

(g) Participants may question a committee member only with that member's permission and only about matters before the committee.

(h) The hearing is informal, and the rules of evidence do not apply. No motions or objections relating to the admissibility of information and views may be made or considered, but other participants may comment upon or

rebut matters presented. No participant may interrupt the presentation of another participant.

§ 14.30 Chairperson of an advisory committee.

(a) The advisory committee Chairperson has the authority to conduct hearings and meetings, including the authority to adjourn a hearing or meeting if the Chairperson determines that adjournment is in the public interest, to discontinue discussion of a matter, to conclude the open portion of a meeting, or to take any other action to further a fair and expeditious hearing or meeting.

(b) If the Chairperson is not a full-time employee of FDA, the Designated Federal Officer or other designated agency employee, or alternate, is to be the *designated Federal employee* who is assigned to the advisory committee. The designated Federal employee is also authorized to adjourn a hearing or meeting if the employee determines adjournment to be in the public interest.

§ 14.31 Consultation by an advisory committee with other persons.

(a) A committee may confer with any person who may have information or views relevant to any matter pending before the committee.

(b) An interested person may submit to the committee a written request that it confer with specific persons about any matter pending before the committee. The request is to contain adequate justification. The committee may, in its discretion, grant the request.

(c) A committee may confer with a person who is not a Federal Government executive branch employee only during the open portions of a meeting. The person may, however, submit views in writing to the committee as part of the administrative record under §14.70. The person may participate at the closed portions of a meeting only if appointed as a special Government employee by the Commissioner as provided in paragraph (e) of this section. This paragraph (c) is not intended to bar the testimony of a person during a closed portion of a meeting about matters prohibited from public disclosure under §§14.25(c) and 14.27(c).

(d) To prevent inadvertent violation of Federal conflict of interest laws and laws prohibiting disclosure of trade secrets (18 U.S.C. 208, 21 U.S.C. 331(j), 18 U.S.C. 1905), Federal executive branch employees who are not employees of the Department may not confer, testify, or otherwise participate (other than as observers) at any portion of an advisory committee meeting unless they are appointed as special Government employees by the Commissioner under paragraph (e) of this section. this paragraph does not apply to Federal executive branch employees who are appointed as members of TEPRSSC, as provided in §14.127.

(e) The Commissioner may appoint persons as special Government employees to be consultants to an advisory committee. Consultants may be appointed to provide expertise, generally concerning a highly technical matter, not readily available from the members of the committee. Consultants may be either from outside the Government or from agencies other than the Food and Drug Administration. Reports, data, information, and other written submissions made to a public advisory committee by a consultant are part of the administrative record itemized in §14.70.

[44 FR 22351, Apr. 13, 1979, as amended at 55 FR 42703, Oct. 23, 1990]

§ 14.33 Compilation of materials for members of an advisory committee.

The Commissioner shall prepare and provide to all committee members a compilation of materials bearing upon members' duties and responsibilities, including—

(a) All applicable conflict of interest laws and regulations and a summary of their principal provisions;

(b) All applicable laws and regulations relating to trade secrets and confidential commercial or financial information that may not be disclosed publicly and a summary of their principal provisions;

(c) All applicable laws, regulations, and guidance documents relating to the subject matter covered by the advisory committee and a summary of their principal provisions;

(d) All applicable laws, regulations, including the regulations in part 20 of