§ 14.82 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 nonvoting members of a technical advisory committee to serve as representatives of and liaison with interested organizations. Nonvoting members—

(i) Shall be selected by the interested organizations, as provided in §14.84; technical expertise in the subject matter with which the committee is involved is not a requirement; and

(ii) May be special Government employees subject to the conflict of interest laws and regulations, except as provided in §14.84(e).

(c) A person may serve as a voting or nonvoting member on only one FDA advisory committee unless the Commissioner determines in writing that dual membership will aid the work of the committees involved and is in the public interest.

(d) Members of FDA advisory committees, and the chairman, are appointed from among those nominated under §§14.82 and 14.84 and from any other sources by the Secretary, or, by delegation of authority, by the Assistant Secretary for Health, or the Commissioner.

(e) Members appointed to an advisory committee serve for the duration of the committee, or until their terms of appointment expire, they resign, or they are removed from membership by the Commissioner.

(f) A committee member may be removed from membership for good cause. Good cause includes excessive absenteeism from committee meetings, a demonstrated bias that interferes with the ability to render objective advice, failure to abide by the procedures established in this subpart, or violation of other applicable rules and regulations, e.g., for nonvoting members, the provisions of §14.86(c).

(g) Consultants appointed under §14.31(e) are not members of advisory committees.

§ 14.84 Nominations and selection of nonvoting members of standing technical advisory committees.

(a) This section applies when the Commissioner concludes that a technical advisory committee should include nonvoting members to represent and serve as a liaison with interested individuals and organizations.

(b) Except when the Commissioner concludes otherwise, nonvoting members of a technical advisory committee are selected in accordance with paragraphs (c) and (d) of this section and are normally limited to one person selected by consumer groups and organizations and one person selected by industry groups and organizations.

(c) To select a nonvoting member to represent consumer interests, except as provided in paragraph (c)(5) of this section, the Commissioner publishes a notice in the FEDERAL REGISTER requesting nominations for each specific committee, or subcommittee, for which nonvoting members are to be appointed. A period of 30 days will be permitted for submission of nominations for that committee or subcommittee. Interested persons may nominate one or more qualified persons to represent consumer interests. Although nominations from individuals will be accepted, individuals are encouraged to submit their nominations through consumer organizations as defined in paragraph (c)(3) of this section. Nominations of qualified persons for general consideration as nonvoting members of unspecified advisory committees or subcommittees may be made at any time.

(d) Voting members serve as individuals and not as representatives of any group or organization which nominated them or with which they may be affiliated.

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