

Food and Drug Administration, HHS

§ 14.122

biomedical research programs in support of FDA's drug regulatory responsibilities and its critical path initiatives related to improving the efficacy and safety of drugs and improving the efficiency of drug development.

(17) *Nonprescription Drugs Advisory Committee.*

(i) Date established: August 27, 1991.

(ii) Functions: The committee reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products for use in the treatment of a broad spectrum of human symptoms and diseases.

(18) *Pharmacy Compounding Advisory Committee.*

(i) Date established: February 12, 1998.

(ii) Function: Provides advice on scientific, technical, and medical issues concerning drug compounding by pharmacists and licensed practitioners.

(d) *Center for Devices and Radiological Health—(1) Medical Devices Advisory Committee.*

(i) Date established: October 27, 1990.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

(2) *Device Good Manufacturing Practice Advisory Committee.*

(i) Date established: May 17, 1987.

(ii) Function: Reviews proposed regulations for good manufacturing practices governing the methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of devices, and makes recommendations on the feasibility and reasonableness of the proposed regulations.

(3) *Technical Electronic Product Radiation Safety Standards Committee.*

(i) Date established: October 18, 1968.

(ii) Function: Advises on technical feasibility, reasonableness, and practicability of performance standards for electronic products to control the emission of radiation under 42 U.S.C. 263f(f)(1)(A).

(4) *National Mammography Quality Assurance Advisory Committee.*

(i) Date established: July 6, 1993.

(ii) Function: Advises on developing appropriate quality standards and reg-

ulations for the use of mammography facilities.

(e) *National Center for Toxicological Research—Science Advisory Board.*

(1) Date established: June 2, 1973.

(2) Function: Advises on establishment and implementation of a research program that will assist the Commissioner of Food and Drugs to fulfill regulatory responsibilities.

(f) *Center for Veterinary Medicine—Veterinary Medicine Advisory Committee.*

(1) Date established: April 24, 1984.

(2) Function: Reviews and evaluates available data concerning safety and effectiveness of marketed and investigational new animal drugs, feeds, and devices for use in the treatment and prevention of animal disease and increased animal production.

(g) *Center for Food Safety and Applied Nutrition—Food Advisory Committee.*

(1) Date established: December 15, 1991.

(2) Function: The committee provides advice on emerging food safety, food science, and nutrition issues that FDA considers of primary importance in the next decade.

[54 FR 9036, Mar. 3, 1989]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 14.100, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

Subpart G—Technical Electronic Products Radiation Safety Standards Committee

§ 14.120 Establishment of the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC).

The Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC), consisting of 15 members, is established in accordance with the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263f(f)(1)(A)) to provide consultation before the Commissioner prescribes any performance standard for an electronic product.

§ 14.122 Functions of TEPRSSC.

(a) In performing its function of advising the Commissioner, TEPRSSC—

§ 14.125

(1) May propose electronic product radiation safety standards to the Commissioner for consideration;

(2) Provides consultation to the Commissioner on all performance standards proposed for consideration under 42 U.S.C. 263f; and

(3) May make recommendations to the Commissioner on any other matters it deems necessary or appropriate in fulfilling the purposes of the act.

(b) Responsibility for action on performance standards under 42 U.S.C. 263f rests with the Commissioner, after receiving the advice of TEPRSSC.

§ 14.125 Procedures of TEPRSSC.

(a) When the Commissioner is considering promulgation of a performance standard for an electronic product, or an amendment of an existing standard, before issuing a proposed regulation in the FEDERAL REGISTER the Commissioner will submit to TEPRSSC the proposed standard or amendment under consideration, together with other relevant information to aid TEPRSSC in its deliberations.

(b) The agenda and other material to be considered at any meeting will be sent to members whenever possible at least 2 weeks before the meeting.

(c) Ten members constitute a quorum, provided at least three members are present from each group specified in 42 U.S.C. 263f(f)(1)(A) and in § 14.127(a), i.e., Government, industry, and the public.

(d) The chairman of TEPRSSC will ordinarily submit a report to the Commissioner of the committee's consideration of any proposed performance standard for an electronic product within 60 days after consideration. If the chairman believes that more time is needed, the chairman will inform the Director of the Center for Devices and Radiological Health in writing, in which case an additional 30 days will be allowed to make the report.

(e) Sections 14.1 through 14.7 apply to TEPRSSC, except where other provisions are specifically included in §§ 14.120 through 14.130.

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

21 CFR Ch. I (4-1-07 Edition)

§ 14.127 Membership of TEPRSSC.

(a) The Commissioner will appoint the members after consultation with public and private organizations concerned with the technical aspect of electronic product radiation safety. TEPRSSC consists of 15 members, each of whom is technically qualified by training and experienced in one or more fields of science or engineering applicable to electronic product radiation safety, as follows:

(1) Five members selected from government agencies, including State and Federal Governments.

(2) Five members selected from the affected industries after consultation with industry representatives.

(3) Five members selected from the general public, of whom at least one shall be a representative of organized labor.

(b) The Commissioner will appoint a committee member as chairman of TEPRSSC.

(c) Appointments of members are for a term of 3 years or as specified by the Commissioner.

(1) The chairman is appointed for a term concurrent with the chairman's term as a member of TEPRSSC. If the chairmanship becomes vacant without adequate notice, the executive secretary may appoint a committee member as temporary chairman pending appointment of a new chairman by the Commissioner.

(2) Members may not be reappointed for a second consecutive full term.

(d) A person otherwise qualified for membership is not eligible for selection as a member of TEPRSSC from Government agencies or the general public if the Commissioner determines that the person does not meet the requirements of the conflict of interest laws and regulations.

(e) Retention of membership is conditioned upon the following:

(1) Continued status as a member of the group from which the member was selected as specified in paragraph (a) of this section.

(2) Absence of any conflict of interest during the term of membership as specified in paragraph (d) of this section.

(3) Active participation in TEPRSSC activities.