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Advisory Committees

Charter Medical Devices Advisory Committee

CHARTER AMENDMENT MEDICAL DEVICES ADVISORY COMMITTEE

Purpose

The Secretary, and by delegation, the Assistant Secretary for the Office of Public Health and Science and the Commissioner of Food and Drugs are charged with the administration of the Federal Food, Drug, and Cosmetic Act (FFDC Act), the Fair Packaging and Labeling Act, and various provisions of the Public Health Service Act. The Medical Devices Advisory Committee consists of 18 panels. With the exception of the Medical Devices Dispute Resolution Panel, the panels, according to their specialty area and authorization, advise the Commissioner in discharging responsibilities as they relate to assuring safety and effectiveness of medical devices, and, as required, any other product for which the Food and Drug Administration has regulatory responsibility.

Authority

15 U.S.C. 1451 et seq.; 21 U.S.C. 321, 341, 342, 343-1, 344, 345, 346, 348, 349, 350, 350a, 351, 352, 353, 353(a), 355, 360b-360l (e)(1), 360bbb-1, 371, 375, 376, 378, 379e, 381, 393, 394, 881(b); 42 U.S.C. 217a, 241, 242, 242a, 262, 263a, 264; 21 C.F.R. Part 14, 21 C.F.R. §330.10(a). The Committee and its panels are governed by the provisions of Public Law 92-463, as amended (5 U.S.C. App. 2), which sets forth standards for the formation and use of advisory committees.

Function

The Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation. The panels engage in a number of activities to fulfill the functions the FFDC Act envisions for device advisory panels. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, advises the Commissioner of Food and Drugs regarding recommended classification or reclassification of devices into one of three regulatory categories; advises on any possible risks to health associated with the use of devices; advises on formulation of product development protocols; reviews premarket approval applications for medical devices; reviews guidelines and guidance documents; recommends exemption of certain devices from the application of portions of the Act; advises on the necessity to ban a device; and responds to requests from the agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, may also make appropriate recommendations to the Commissioner of Food and Drugs on issues relating to the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices. The Committee also provides recommendations to the Commissioner or designee on complexity categorization of in vitro diagnostics under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

The Dental Products Panel also functions at times as a dental drug panel. The functions of the dental drug panel are to evaluate and recommend whether various prescription drug products should be changed to over-the-counter status and to evaluate data and make recommendations concerning the approval of new dental drug products for human use.

The Medical Devices Dispute Resolution Panel provides advice to the Commissioner on complex or contested scientific issues between the FDA and medical device sponsors, applicants, or manufacturers relating to specific products, marketing applications, regulatory decisions and actions by FDA, and Agency guidance and policies. The Panel makes recommendations on issues that are lacking resolution, are highly complex in nature, or result from challenges to regular advisory panel proceedings or Agency decisions or actions.

Structure

The Medical Devices Advisory Committee with its 18 panels shall consist of a maximum of 159 standing members. Members are selected by the Commissioner or designee from among authorities in clinical and administrative medicine, engineering, biological and physical sciences, and other related professions. A maximum of 122 members shall be standing voting members and 37 shall be nonvoting members who serve as representatives of consumer interests (18 members) and of industry interests (19 members). In addition, there

also may be alternate consumer and industry representatives.

With the exception of the Dental Products Panel and the Medical Devices Dispute Resolution Panel, as noted below, each panel consists of a maximum of seven standing voting members (including the chair) and two nonvoting members (a consumer representative and an industry representative).

The Dental Products Panel shall consist of a maximum of seven standing voting members (including the chair) and three nonvoting members. One of the nonvoting members shall be a representative of consumer interests and two shall be representatives of dental industry interests (one each to represent the medical device industry and the dental drug industry). Only one representative of industry interests may participate in the panel review of a particular matter or application unless it is a combination product (e.g., a device/drug system), then the representatives of both may participate.

The Medical Devices Dispute Resolution Panel shall consist of six voting members and two nonvoting members. Voting members shall include three standing voting members, one of whom serves as the chair, and three temporary voting members selected to provide cross-cutting scientific or clinical expertise concerning the particular issue in dispute. Nonvoting members shall include a representative of consumer interests and a representative of the interests of the device manufacturing industry.

With the exception of the Medical Devices Dispute Resolution Panel, the panels shall be organized according to medical device specialty areas as follows: Anesthesiology and Respiratory Therapy Devices Panel; Circulatory System Devices Panel; Clinical Chemistry and Clinical Toxicology Devices Panel; Dental Products Panel; Ear, Nose, and Throat Devices Panel; Gastroenterology and Urology Devices Panel; General and Plastic Surgery Devices Panel; General Hospital and Personal Use Devices Panel; Hematology and Pathology Devices Panel; Immunology Devices Panel; Microbiology Devices Panel; Molecular and Clinical Genetics Panel; Neurological Devices Panel; Obstetrics and Gynecology Devices Panel; Ophthalmic Devices Panel; Orthopaedic and Rehabilitation Devices Panel; and Radiological Devices Panel.

The Commissioner or designee shall have the authority to select members of other scientific and technical FDA advisory panels or committees (normally not to exceed an additional 10 members) to serve temporarily as voting members and to designate consultants to serve temporarily as voting members on the panels when, (1) expertise is required that is not available among the current voting standing members of the panels (when additional voting members are added to the Committee to provide needed expertise, a quorum will be based on the combined total of regular and added members), or (2) to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking.

Standing members for each panel are invited to serve for overlapping four-year terms. A member may serve after expiration of the member's term until a successor has taken office. A member may serve after expiration of the member's term only if selection for replacement is still pending with the Commissioner or designee.

Temporary subcommittees consisting of two or more committee members may be established by the Commissioner or designee as needed to address specific issues within their respective areas of expertise. One of the voting members will be designated as the chair.

Subcommittees make preliminary recommendations regarding specific issues for subsequent action by the full committee. The Department Committee Management Officer shall be notified upon establishment of each subcommittee, and shall be provided information on its name, membership, function, and estimated frequency of meetings.

Management and support services shall be provided by the Center for Devices and Radiological Health, Food and Drug Administration.

Meetings

Meetings of the full committee or advisory panel chairpersons are called by the Food and Drug Administration as necessary. Each of the 18 panels shall meet at a minimum of once a year or as necessary at the call of the Designated Federal officer, who shall also approve the agenda. A Designated Federal officer shall be present at all meetings.

Because of the size of the Committee and the variety in the types of issues that it will consider, the FDA may, in connection with a particular committee meeting, specify a quorum that is less than a majority of the current-voting members. The Agency's regulations (21 C.F.R. § 14.22(d)) authorize a committee charter to specify quorum requirements.

Meetings shall be open to the public except as determined otherwise by the Commissioner or designee in accordance with the Government in the Sunshine Act (5 U.S.C. 552b (c)) and the Federal Advisory Committee Act. Notice of all meetings shall be given to the public.

Meetings shall be conducted and records of the proceedings kept as required by applicable laws and the Departmental regulations.

Compensation

Members who are not full-time Federal employees shall be paid at the rate of the General Schedule Grade 15,

step 10, per day for time spent at meetings plus per diem and travel expenses in accordance with Standard Government Travel Regulations.

Annual Cost Estimate

The estimated annual cost of operating the committee in FY 08, including compensation and travel expenses for members but excluding staff support, will be \$1,324,365. The estimated person years of staff support required in FY 08 will be 14.95 at an estimated annual cost of \$1,560,880. Cost figures for subsequent years will be shown in the Annual Report as required by PL 92-463.

Reports

In the event that the Commissioner or designee determines that a portion of a meeting is closed to the public in accordance with the Government in the Sunshine Act (5 U.S.C. 552b (c)) and the Federal Advisory Committee Act, a report shall be prepared not later than November 1 of each year which contains at a minimum the function of the committee, a list of members and their business addresses, the dates and places of meetings, and a summary of the committee's activities and recommendations during the preceding year. A copy of the report shall be provided to the Department Committee Management Officer.

Termination Date

Sec. 14 of the Federal Advisory Committee Act does not apply to the duration of this committee, as stated in 2 U.S.C. 360c(b)(1).

This charter will remain in effect until amended or terminated by the Commissioner of Food and Drugs or designee.

_ 7/15/08____

Date

_____/S/_____

Randall W. Lutter, Ph.D. Deputy Commissioner for Policy

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