CHARTER

Device Good Manufacturing Practice Advisory Committee

Purpose

The Secretary and, by delegation, the Assistant Secretary for Health and the Commissioner of Food and Drugs are charged with the administration of the Federal Food, Drug, and Cosmetic Act. The Device Good Manufacturing Practice Advisory Committee advises the Commissioner in discharging his responsibilities as they relate to assuring safe and effective use of medical devices.

Authority

21 USC 360c-j; the committee is governed by the provisions of the Federal Advisory Committee Act (PL 92-463) which sets forth standards for the formation and use of advisory committees.

Function

The committee reviews regulations proposed for promulgation regarding 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 to the Commissioner of Food and Drugs regarding the feasibility and reasonableness of those proposed regulations. The committee also advises the Commissioner with regard to any petition submitted by a manufacturer for an exemption or variance from good manufacturing practice regulations that is referred to the committee.

Structure

The committee consists of nine members including the Chair. Members and the Chair are selected by the Secretary. Three of the members shall be officers or employees of any State or local government or of the Federal Government; two shall be representative of the interests of the device manufacturing industry; two shall be representative of the interests of physicians and other heal th professionals; and two shall be representative of the interests of the general public.

Members are invited to serve for overlapping terms of 4 years. Personnel actions are initiated for annual reappointment as required by regulation.

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

Meetings

The committee meets approximately once a year or as required. All meetings are held at the call of the Chair with the advance approval of a Government official who also shall approve the agenda. A Government official shall be present at all meetings.

Meetings are open to the public except as determined otherwise by the Commissioner. Notice of all meetings is given to the public.

Meetings are conducted and records of the proceedings kept as required by applicable laws and Department regulations.

Compensation

Members who are not full-time Federal employees will be paid at the rate of $128.80 per day for time spent at meetings plus travel and per diem expenses in accordance with Standard Government Travel Regulations.

Annual Cost Estimate

The estimated annual cost of operating the committee in FY 1986, including compensation and travel expenses for members but excluding staff support, was $18,271.

The estimated manyears of staff support required was .15 at an estimated annual cost of $5,217. Cost figures for subsequent years will be shown in the Annual Report as required by PL 92-463.

Report

In the event that a portion of a meeting is closed to the public, a report shall be prepared no later than November 1 of each year which contains as 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 21 USC 360(b)(1).

This charter will remain in effect until amended or terminated by the Commissioner.

5/17/87
Date

Frank E. Young
Commissioner of Food and Drugs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administratio
Rockville MD 20857

CHARTER AMENDMENT

The citation from the Public Health Service Act (42 USC 217a, 241) is hereby inserted in the Authority paragraph of the charters for the following Food and Drug Administration advisory committees:

Anesthesiology and Respiratory Therapy Devices Panel
Circulatory System Devices Panel
Clinical Chemistry and Clinical Toxicology Devices Panel
Dental Devices Panel
Ear, Nose, and Throat Devices Panel
Gastroenterology-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
Neurological Devices Panel
Obstetrics-Gynecology Devices Panel
Ophthalmic Devices Panel
Orthopedic and Rehabilitation Devices Panel
Radiologic Devices Panel
→ Device Good Manufacturing Practice Advisory Committee

07 APR 1982
Date

Frank E. Young
Commissioner of Food and Drugs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SECOND CHARTER AMENDMENT

COMPENSATION

Members who are not full-time Federal employees shall be paid at the rate of the General Schedule 15, step 10, per day for time spent at meetings plus per diem and travel expenses in accordance with Standard Government Travel Regulations.

This Amendment is applicable to the following Food and Drug Administration advisory committees:

Device Good Manufacturing Practice Advisory Committee
Medical Devices Advisory Committee

11/16/99
Date

Linda Suydam
Linda Suydam, D.P.A.
Senior Associate Commissioner