C H A R T E R

Nonprescription Drugs Advisory Committee

Authority

The Nonprescription Drugs Advisory Committee established under 15 U.S.C. 1451 et seq.; 21 U.S.C. 321, 341, 342, 343, 343-1, 344, 345, 346, 348, 349, 350, 350a, 351, 352, 353(f), 355, 360b, 360c-j, 371, 375, 376, 378, 379e, 381, 393, 394, 881(b); 42 U.S.C. 217a, 241, 242, 242a, 262, 264; 21 CFR Part 14, 330.10(a), Pub. L. 92-463 as amended, (5 U.S.C. App.), the Federal Advisory Committee Act, which sets forth standards for the formation and use of advisory committees.

Objectives and Scope of Activities

The Nonprescription Drugs Advisory Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which the Food and Drug Administration has regulatory responsibility.

Description of Duties

The Committee reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products, or any other FDA-regulated product, for use in the treatment of a broad spectrum of human symptoms and diseases and advises the Commissioner either on the promulgation of monographs establishing conditions under which these drugs are generally recognized as safe and effective and not misbranded or on the approval of new drug applications for such drugs. The Committee serves as a forum for the exchange of views regarding the prescription and nonprescription status, including switches from one status to another, of these various drug products and combinations thereof. The Committee may also conduct peer review of agency sponsored intramural and extramural scientific biomedical programs in support of FDA's mission and regulatory responsibilities.

Agency or Official to Whom the Committee Reports

The Committee provides advice to the Commissioner of Food and Drugs.

Support

Management and support services shall be provided by the Center for Drug Evaluation and Research.

Estimated Annual Operating Costs and Staff Years

The estimated annual cost for operating the Committee, including compensation and travel expenses for members but excluding staff support, is $101,260. The estimated person years of staff support required is 1.10, at an estimated annual cost of $150,036.

Designated Federal Officer

FDA will select a full-time or permanent part-time Federal employee to serve as the Designated Federal Officer (DFO) to attend each Committee meeting and ensure that the committee conducts its business in accordance with all applicable statutory, regulatory, and HHS General Administration Manual directives. The DFO will approve and prepare all meeting agendas, call all of the Committee and subcommittee meetings, adjourn any meeting when the DFO determines adjournment to be in the public interest and chair meetings when directed to do so by the official to whom the Committee reports. The DFO shall be present at all meetings of the full committee and subcommittees.

Estimated Number and Frequency of Meetings

Meetings shall be held approximately 4 times a year. 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.

Duration

Continuing

Termination

Unless renewed by appropriate action the Nonprescription Drugs Advisory Committee will terminate two years from the date the charter is filed.

Membership and Designation

The Committee shall consist of a core of 10 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of internal medicine, family practice, clinical toxicology, clinical pharmacology, pharmacy, dentistry, and related specialties. Members will be invited to serve for overlapping terms of up to four years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests.

The Commissioner or designee shall have the authority to select members of other scientific and technical FDA advisory committees (normally not to exceed 10 members) to serve temporarily as voting members and to designate consultants to serve temporarily as voting members when: (1) expertise is required that is not available among current voting standing members of the Committee (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. Because of the size of the Committee and the variety in the types of issues that it will consider, 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 CFR §14.22(d)) authorize a committee charter to specify quorum requirements.

If functioning as a medical device panel, a non-voting representative of consumer interests and a non-voting representative of industry interests will be included in addition to the voting members.

Subcommittee

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.

Subcommittees make preliminary recommendations and/or reports regarding specific issues for the full Committee's consideration. 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.

Recordkeeping

Meetings of the Committee and its subcommittees will be conducted according to the Federal Advisory Committee Act, other applicable laws and Departmental policies. Committee and subcommittee records will be handled in accordance with General Records Schedule 6.2, Federal Advisory Committee Records or other approved agency records disposition schedule. These records will be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552.

Filing Date

August 27, 2017

Approved:

Date

Rachel E. Sherman, M.D.
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Office of the Commissioner, FDA