CHARTER

Science Advisory Board to the National Center for Toxicological Research

Purpose

To assist the Commissioner of Food and Drugs in discharging his responsibilities under the Federal Food, Drug, and Cosmetic Act, the Fair Packaging and Labeling Act, and various provisions of the Public Health Service Act.

To provide a useful research resource in the accomplishment of this task, the President, on January 27, 1971, announced the establishment of the National Center for Toxicological Research (NCTR). The Center was charged with examining the biological effects of potentially toxic substances found in the environment through fundamental investigations aimed at understanding the mechanisms of action of those substances in animals and developing a better understanding of what these data in animals mean for man. The Center would be operated by the Food and Drug Administration (FDA) and utilized by other Government agencies and in cooperation with industry and the academic community.

Authority

15 USC 1451 et seq.; 21 USC 321, 341, 342, 343, 343-1, 344, 345, 346, 346a, 348, 349, 350, 350a, 351, 352, 353(f), 355, 360b, 360c-j, 371, 375, 376, 378, 379e, 381, 393, 394, 881(b); 42 USC 217a, 241, 242, 242a, 262, 264; President's announcement of January 27, 1971, establishing the National Center for Toxicological Research. The Board is governed by P.L. 92-463, as amended (5 USC App. 2), which sets forth standards for the formation and use of advisory committees.

Function

The Board advises the Director, NCTR, in establishing, implementing and evaluating the research programs that assist the Commissioner of Food and Drugs in fulfilling his regulatory responsibilities. The Board provides an extra-agency review in ensuring that the research programs at NCTR are scientifically sound and pertinent.

Structure

The Board consists of a core of nine members including the Chair. Members and the Chair are selected by the Commissioner or designee from among leading authorities in the fields related to toxicological research. One of the nine technically qualified members selected by the Commissioner or designee will be identified with consumer interests and will have been recommended by either a consortium of consumer-oriented

organizations or other interested persons.
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.

Members are invited to serve for overlapping terms of four years. A member may serve after the expiration of the member's term until a successor has taken office. Terms of more then two years are contingent upon the renewal of the Board by appropriate action prior to its expiration.

In addition, the Commissioner or designee will appoint a representative to the Board from each Center and the Office of Regulatory Affairs of the FDA and request the appointment of a liaison representative from the National Institute for Environmental Health Sciences, National Institutes of Health and the University of Arkansas for Medical Sciences.

Temporary subcommittees or site visit teams (SVTs) may be formed to make preliminary recommendations for subsequent action by the full Board. These Subcommittees or SVTs will consist of two or more Board members and additional outside members with necessary expertise to address specific scientific issues. Subcommittee members shall be selected by the Commissioner or designee and shall serve for a term of up to three years, and may be reappointed at the discretion of the Commissioner or designee. The Chairperson of the Board shall select SVT members, as well as a Board member to chair the SVT. FDA Centers and the Office of Regulatory Affairs representatives, as appropriate, will be invited to participate in SVT activities. Consultants may be used to extend the expertise of a given SVT with the approval of the Chair of the Board. The Agency Committee Management Officer shall be notified upon establishment of any 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 staff of the National Center for Toxicological Research, Food and Drug Administration.

Meetings

Meetings of the Board shall be held at least once a year at the call of the Chair with the advance approval of a Government official, who shall also approve the agenda. A Government official shall be present at all Board meetings.

Meetings of the Board shall be open to the public except as determined otherwise by the Commissioner or designee to whom the authority has been delegated. Notice of all Board meetings shall be given to the public.

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

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.

Annual Cost Estimate

The estimated annual cost for operating the Board, including compensation and travel expenses for members, but excluding staff support, is $66,825.00. The estimate of annual person-years of staff support required will be 52% of an FTE at an estimated annual cost of $52,165.00.

Reports

In the event that a portion of a meeting is closed to the public, a report shall be prepared not 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 Agency Committee Management Officer.

Termination Date

Unless renewed by the appropriate action prior to its expiration, the Science Advisory Board to the National Center for Toxicological Research will terminate on June 2, 2004.

Approved:

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Date

Linda Arey Skladany, Esq.
Associate Commissioner for External Relations