DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

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 actions of those substances in animals and developing a better understanding of what this data in animals means 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 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); the Committee is 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 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. 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.

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 shall be invited to serve for overlapping four-year terms. Terms of more then two years are contingent upon the renewal of the Committee by appropriate action prior to its expiration.

In addition, the Commissioner or his 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 Medical Sciences.

The Site Visit Subcommittee (SVS) consisting of two or more Board members may be established, as needed, to address specific issues within their respective areas of expertise. The Chairperson of the Board shall select these individuals, as well as selecting a Board member to Chair the SVS. FDA Centers and the Office of Regulatory Affairs representatives, as appropriate, will be invited to participate in SVS activities. Consultants may be used to extend the expertise of a given SVS with the approval of the Chair of the Board. The SVS makes preliminary recommendations regarding specific scientific issues for subsequent action by the full Board.

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 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 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 Designated Federal officer, who shall also approve the agenda. A Designated Federal officer shall be present at all Board meetings.

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 regulation (21 CFR §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 (5U.S.C. 552b (c)) and the Federal Advisory Committee Act. Notice of all 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 committee, including compensation and travel expenses for members, but excluding staff support, is $45,925. The estimate of annual person-years of staff support required will be .50 of an FTE, at an estimated annual cost of $61,146.

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 (5U.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 as a minimum the function of the Committee, a list of members and their business addresses, the dates and place 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

Unless renewed by appropriate action prior to its expiration, the Science Advisory Board to the National Center for Toxicological Research will terminate on June 2, 2010.

Approved:

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Date

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