参考資料 1

Science Board to the Food and Drug Administration

Purpose

The Board shall provide advice primarily to the Commissioner and other appropriate officials on specific complex and technical issues as well as, emerging issues within the scientific community, in industry and academia. Additionally, the Board will provide advice to the Agency on keeping pace with technical and scientific evolutions in the fields of regulatory science, or formulating an appropriate research agendas; upgrading its scientific and research facilities to keep pace with these changes. It will also provide the means for critical review of Agency sponsored intramural and extramural scientific research programs.

Committee Membership

The Committee shall consist of a core of 21 voting members including a Chair and a Co-Chair. The members, Chair, and Co-Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of food safety, nutrition, chemistry, pharmacology, toxicology, clinical research or systems biology, healthcare devices, nanotechnology, medical imaging, robotics, cell and tissue based products, regenerative medicine, and combination products. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include 1 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 Committee may also include technically qualified federal members.

Contact Information

Martha Monser, Designated Federal Officer
Office of the Chief Scientist
Office of the Commissioner
WO Bldg. 32, Room 4286
10903 New Hampshire Ave.
Silver Spring, Maryland, 20993
Phone: 301-796-4627
Fax: 301-847-8617
Email: martha.monser@fda.hhs.gov

FDA Advisory Committee Information Line

1-800-741-8138
(301-443-0572 in the Washington, DC, area)
code 3014512603
Please call the Information Line for up-to-date information on meetings

http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/ScienceBoardtotheFoodandDrugAdministration/default.htm

Charter of the Science Board to the Food and Drug Administration

Authority

The Science Board was 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 (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 Science Board 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 Science Board shall provide advice primarily to the Commissioner and other appropriate officials on specific complex and technical issues, as well as, emerging issues within the scientific community. Additionally, the Science Board will provide advice to the Agency on keeping pace with technical and scientific evolutions in the fields of regulatory science; on formulating an appropriate research agenda; and on upgrading its scientific and research facilities to keep pace with these changes. It will also provide the means for critical review of Agency sponsored intramural and extramural scientific research programs.

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 Office of the Commissioner.

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 $52,986. The estimated person years of staff support required is 1.4, at an estimated annual cost of $168,010.

Designated Federal Officer

FDA will select a fulltime or permanent part-time Federal employee to serve as the Designated Federal Officer (DFO) to attend each Committee meeting and ensure that all procedures are within 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 three 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. A report will be prepared which will contain, as a minimum, a list of members and their business addresses, the Committee's functions, the dates and places of meetings, and a summary of the Committee's activities and recommendations made during the fiscal year. A copy of this report will be provided to the Department Committee Management Officer.

Duration

Continuing

Termination

Unless renewed by appropriate action prior to its expiration, the Science Board will terminate two years from the date the charter is filed.

Membership and Designation

The Committee shall consist of a core of 21 voting members including a Chair and a Co-Chair. The members, Chair, and Co-Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of food safety, nutrition, chemistry, pharmacology, toxicology, clinical research or systems biology, healthcare devices, nanotechnology, medical imaging, robotics, cell and tissue based products, regenerative medicine, and combination products. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include 1 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 Committee may also include technically qualified federal members.

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.

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

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 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.

Recordkeeping

The records of the Committee, established subcommittees, or other subgroups of the committee, shall be handled in accordance with General Records Schedule 26, Item 2 or other approved agency records disposition schedule. The records shall be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552.

Filing Date

June 30, 2010

Approved:

Date: October 5, 2011

/s/

Jill Hartzler Warner, J.D.

Associate Commissioner for

Special Medical Programs (Acting)

Roster of the Science Board to the Food and Drug Administration

Applying for Membership on FDA Advisory Committees[1]

As part of the Food and Drug Administration's (FDA's) ongoing efforts to recruit qualified experts with minimal conflicts of interest who are interested in serving on FDA advisory committees, FDA is requesting nominations for members to serve on its advisory committees.

Current Number of Vacancies: 4

Note, one or more vacancies may be in the nomination process or a final appointment may have been made.

Chair
Martin Philbert, Ph.D.
Expertise: Toxicology
Term: 3/17/08 – 12/31/13
Dean and Professor of Toxicology
School of Public Health
The University of Michigan
1415 Washington Heights
Room 1822 SPH I
Ann Arbor, Michigan 41809-2029

Designated Federal Officer
Martha Monser
Associate Director for Program Coordination
Office of the Chief Scientist
Food and Drug Administration
White Oak 32, Room 4286
10903 New Hampshire Ave.
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Silver Spring, Maryland 20993
301-796-4627
martha.monser@fda.hhs.gov

Daniel Acosta, Jr., Ph.D
Expertise: Toxicology (cardiovascular, hepatic and *in vitro*)
Term: 1/17/12 – 12/31/15
Dean and Carl Chair
Winkle College of Pharmacy
University of Cincinnati
P.O. Box 670004
Cincinnati, Ohio 45267

Lynn R. Goldman, M.D., MPH
Expertise: Environmental Toxicology, Pediatrics
Term: 8/1/11 – 12/31/14
Dean and Professor of Environmental & Occupational Health
The George Washington University,
School of Public Health and Health Services
Ross Hall, Suite 601, 2300 Eye St., N.W.
Washington, DC 20037

Russ B. Altman, M.D., Ph.D.
Expertise: Pharmacogenomics, Bioinformatics, Datamining, and Molecular Biology
Term: 8/23/10 – 12/31/14
Professor and Chair of Bioengineering
Stanford University
318 Campus Drive, S172, MC: 5444
Stanford, CA 94305-5444

Sangtae Kim, Ph.D.
Expertise: Information Technology
Term: 01/06/09 – 12/31/12
Executive Director
Morgridge Institute for Research
P.O. Box 7365
Madison, WI 53707-7365

Jeffrey D. Bender, D.V.M. , M.S., DACVPM
Expertise: Biology and Veterinary Medicine
Term: 8/23/10 – 12/31/14
Director of Center for Animal Health and Food Safety
University of Minnesota
1354 Eckles Avenue

Frederick Kushner, M.D.
Expertise: Cardiology
Term: 5/29/09 - 12/31/13
Clinical Professor of Medicine, Tulane Medical School
ACCF/AHA Task Force for Practice Guidelines
Medical Director, Heart Clinic of Louisiana
1111 Medical Center Blvd, Suite N613

St. Paul, MN 55108

Paul R. Billings, M.D., Ph.D., FACP, FACMG
Expertise: Genomics and Molecular Medicine
Term: 8/1/11 – 12/31/14
Chief Medical Officer
Life Technologies, Inc.
850 Lincoln Drive
Foster City, CA 94404

James R. Broach, Ph.D.
Expertise: Chemistry, Molecular Biology, Genetics, Genomics
Term: 01/06/09 – 12/31/12
Associate Chair, Department of Molecular Biology
Princeton University
303 Lewis Thomas Lab
Princeton, NJ 08544

Elazer R. Edelman, M.D., Ph.D.
Expertise: Biomedical Engineering
Term: 8/1/11 – 12/31/14
Professor of Health Sciences & Technology
Harvard-MIT, Biomedical Engineering Center
77 Massachusetts Ave., Bldg. E25-438
Cambridge, MA 02139

John D. Floros, Ph.D.
Expertise: Food Science & Technology
Term: 01/06/09 – 12/31/13
Professor and Head, Department of Food Science
Pennsylvania State University
206 Food Science Building
University Park, PA 16802

Michael C. Gibbons, M.D., M.P.H.
Consumer Representative
Expertise: Urban Health expert, Physician Informatician
Term: 2/14/12 – 12/31/15
Assistant Professor and Associate Director
Johns Hopkins Urban Health Institute
School of Medicine, Center for Health Promotion
2013 E. Monument Street
Baltimore, MD 21287

Marrero, LA 70072

Suzanne P. Murphy, Ph.D., R.D.
Expertise: Nutrition
Term: 8/1/11 – 12/31/13
Professor (Researcher) and Director
Nutrition Support Shared Resource Center
1236 Lauhala St., Suite 407
Honolulu, Hawaii 96813

Joseph S. Pagano, M.D.
Expertise: Oncology, Microbiology, Immunology
Term: 01/06/09 – 12/31/12
Lineberger Professor of Cancer Research
University of North Carolina
32-000 Lineberger Cancer Center
Campus Box 7295
Chapel Hill, NC 27599

P. Hunter Peckham, Ph.D.
Expertise: Biomedical Engineering
Term: 8/1/11 – 12/31/13
Executive Director
Cleveland FES Center
MetroHealth Medical Center
2500 MetroHealth Drive
Cleveland, OH 44109

Bruce M. Psaty, M.D., Ph.D., MPH.
Expertise: Cardiology, Epidemiology, Drug Safety
Term: 8/1/11 – 12/31/14
Co-Director
Cardiovascular Health Research Unit
Metropolitan Park, East Tower
1730 Minor Avenue, Suite 1360
Seattle, WA 98101

Alan J. Russell, Ph.D.
Expertise: Regenerative Medicine
Term: 01/06/09 – 12/31/13
Director, McGowan Institute for Regenerative Medicine
University of Pittsburgh
450 Technology Drive, Suite 300
Pittsburgh, PA 15219