



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA- 2026-N-0008]

Advisory Committee; Science Board to the Food and Drug Administration; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Science Board to the Food and Drug Administration by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Science Board to the Food and Drug Administration for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the June 26, 2028, expiration date.

DATES: The Science Board to the Food and Drug Administration will expire on June 26, 2026, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Advisory Committee Oversight and Management Staff, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3215, Silver Spring, MD 20993-0002, (301) 796-8220, ACOMSSubmissions@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102-3.65 and approval by the Department of Health and Human Services and by the General Services Administration, FDA is announcing the renewal of the Science Board to the Food and Drug Administration (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The 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 FDA has regulatory responsibility.

The Committee reviews and evaluates data concerning specific complex scientific and technical issues important to FDA and its mission, including emerging issues within the scientific community, and makes appropriate recommendations to the Commissioner.

The Committee shall consist of a core of at least 15 voting members including the Chair. Subject to legal and regulatory requirements, members and the Chair are selected by and serve at the discretion of the Commissioner or designee. Each member, including the Chair, will be selected from among authorities knowledgeable in the fields of food science (safety and nutrition); clinical research; veterinary medicine; pharmacology; toxicology; biostatistics; medical devices; public health and epidemiology; product manufacturing and quality; and other scientific areas relevant to FDA regulated products such as systems biology, informatics, nanotechnology, and combination products.

Members may be invited to serve for terms of up to four years, or for less time in the discretion of the Commissioner or designee. Non-Federal members of this committee will serve as Special Government Employees or representatives. Federal members will serve as Regular Government Employees or ExOfficios. 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 Commissioner or designee shall have the authority to select members of other scientific and technical FDA advisory committees to serve temporarily as voting members and to designate Special Government Employees 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.

A quorum for the Committee is a majority of the current voting members present at the time, provided that FDA may specify a quorum that is less than a majority of the current voting members because of the size of the Committee and the variety in the types of issues that it will consider, or other reason determined appropriate in accordance with legal and regulatory requirements. 21 CFR §14.22(d).

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

Members appointed to an advisory committee serve for the duration of the committee, or until their terms expire, they resign, or they are removed from membership by the Commissioner or designee. Committee members' terms may be ended prior to their date of expiration, for reasons determined to be good cause. Good cause includes excessive absenteeism from committee meetings, a demonstrated bias that interferes with the ability to render objective advice, failure to abide by established procedures, or violation of other applicable rules and regulations.

Further information regarding the most recent charter and other information can be found at <https://www.fda.gov/advisory-committees/science-board-food-and-drug-administration/charter-science-board-food-and-drug-administration> or by contacting the Advisory Committee Oversight and Management Staff (see FOR FURTHER INFORMATION CONTACT). Because the

committee's name and description of duties remain unchanged, 21 CFR 14.100 will not be amended.

Renewal Requirements and Justification: The Commissioner has determined that renewal of the Science Board to the Food and Drug Administration is in the public interest. This determination is based on the Committee's essential role in providing independent expert advice concerning specific complex scientific and technical issues important to FDA and its mission, including emerging issues within the scientific community, the continued need for specialized expertise in this area, and the Committee's demonstrated value in supporting FDA's regulatory mission. The following information supports this determination in accordance with applicable legal and regulatory requirements.

Public Interest Determination

Pursuant to 41 CFR § 102-3.60(a), to establish, renew, reestablish, or merge a discretionary (agency discretion) advisory committee, an agency must first consult with the General Services Administration's Committee Management Secretariat (the Secretariat) and, as part of the consultation, provide a written public interest determination approved by the head of the agency to the Secretariat with a copy to the Office of Management and Budget. In addition, pursuant to 41 CFR § 102-3.35, an agency shall follow the same consultation process and document in writing the same determination of need before creating a subcommittee under a discretionary committee that is not made up entirely of members of a parent advisory committee. Information on the following factors for the committee is provided to the Secretariat to demonstrate that renewing the committee is in the public interest:

- 1. Annual budget**

The overall annual budget for this committee is \$97,121.

- a. Federal personnel on a full-time equivalent (FTE) basis

The estimated person years of Federal staff support required is 0.20 at an estimated annual cost of \$51,087.

- b. Other Federal internal costs

The anticipated total value in USD of other internal costs, such as cost associated with IT and supplies for meetings, is \$16,822

- c. Proposed payments to members

The estimated annual payment to members is \$11,170.

- d. Proposed number of members

The anticipated number of members is 15.

- e. Reimbursable costs

The estimated annual reimbursable costs, including travel and related expenses for members is \$10,760

- 2. If applicable, the total dollar value of grants expected to be recommended during the fiscal year

N/A

- 3. Criteria for selecting members to ensure the committee has the necessary expertise and fairly balanced membership

Ensuring Necessary Expertise:

Members must have background, education, and experience commensurate with the committee's function of advising FDA on specific complex scientific and technical issues important to FDA and its mission, including emerging issues within the scientific community. Additionally, the Committee will provide advice that supports the Agency in keeping pace with technical and scientific developments, including regulatory science;

and input into the Agency's research agenda; and on upgrading its scientific and research facilities and training opportunities. Members will be selected from among authorities knowledgeable in the fields of food science (safety and nutrition); clinical research; veterinary medicine; pharmacology; toxicology; biostatistics; medical devices; public health and epidemiology; product manufacturing and quality; and other scientific areas relevant to FDA regulated products such as systems biology, informatics, nanotechnology, and combination products.

Ensuring Fair Balance:

Appointments are made without discrimination. The committee is reviewed in totality for balance, characterized by inclusion of necessary knowledge, insight, and scientific perspective from the relevant community or expertise area. Nominations are sought from all geographic locations within the United States and its territories, and from diverse sources including professional and scientific societies, academia, government agencies, industry and trade associations, consumer and patient organizations, and current Agency staff.

4. List of all other Federal advisory committees of the agency

FDA maintains the following Federal advisory committees:

Anesthetic and Analgesic Drug Products Advisory Committee

Antimicrobial Drugs Advisory Committee

Blood Products Advisory Committee

Cardiovascular and Renal Drugs Advisory Committee

Cellular Tissue and Gene Therapies Advisory Committee

Dermatologic and Ophthalmic Drugs Advisory Committee

Device Good Manufacturing Practice Advisory Committee

Digital Health Advisory Committee

Drug Safety and Risk Management Advisory Committee

Endocrinologic and Metabolic Drugs Advisory Committee

Gastrointestinal Drugs Advisory Committee

Genetic and Metabolic Disease Advisory Committee

Medical Devices Advisory Committee

National Mammography Quality Assurance Advisory Committee (Administratively Inactive)

Nonprescription Drugs Advisory Committee

Oncologic Drugs Advisory Committee

Patient Engagement Advisory Committee

Pediatrics Advisory Committee

Peripheral and Central Nervous System Advisory Committee

Pharmacy Compounding Advisory Committee

Psychopharmacologic Drugs Advisory Committee

Pulmonary-Allergy Drugs Advisory Committee

Risk Communication Advisory Committee (Administratively Inactive)

Technical Electronic Product Radiation Safety Standards Committee

Tobacco Products Advisory Committee

5. Justification that the information or advice provided by the Federal advisory committee or subcommittee is not available from another Federal advisory committee, another Federal Government source, or any other more cost-effective and less burdensome source
- The Committee advises and informs the Commissioner or designee(s) in discharging responsibilities as they relate to helping ensure safe and effective drugs and biologic products for human use, and as required, any other product for which the FDA has regulatory responsibility.

The topics considered by the Science Board require specialized expertise in specific complex scientific and technical issues that is not within the primary scope of other FDA advisory committees. As such, these issues cannot be appropriately addressed by another standing committee without diminishing the depth and relevance of the expert input provided to the Agency. The Science Board is currently FDA's only advisory committee that has the requisite expertise to address issues associated with food, cosmetic, or veterinary products, and its continuation is necessary to allow the FDA to receive outside expert scientific advice in those areas.

6. If the consultation is a committee renewal, a summary of the previous accomplishments of the committee and the reasons it needs to continue

Summary of Previous Accomplishments:

The Science Board serves the public interest by providing scientific support for the regulation of certain products and making appropriate recommendations to the Commissioner.

On October 7, 2024, the Science Board met to receive an update from the New Alternative Methods subcommittee and hear details about the FDA's reorganization scheduled for implementation on October 1, 2024, that included significant updates to the Office of the Chief Scientist and the creation of a unified Human Foods Program.

Impact: This meeting's impact was to transmit formal Science Board recommendations on New Approach Methodologies (NAMs) that later fed into FDA's NAMs roadmap and related guidance activity.

7. Explanation of why the committee/subcommittee is essential to the conduct of agency business

The Science Board is currently FDA's only advisory committee that has the requisite expertise to address issues associated with food, cosmetic, or veterinary products, and its continuation is necessary to allow the FDA to receive outside expert scientific advice in those areas. The Science Board also has a unique role in providing guidance on complex scientific and regulatory issues, and this role cannot be fulfilled by any other FDA advisory committee.

In conclusion, this public interest determination documents that renewing the committee is in the public interest, essential to the conduct of agency business, and that the information to be obtained is not already available through another advisory committee or source within the Federal Government.

This notice is issued under the Federal Advisory Committee Act as amended (5 U.S.C. 1001 et seq.). For general information related to FDA advisory committees, please visit us at <http://www.fda.gov/AdvisoryCommittees/default.htm>.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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