

supporting-future-rare-disease-product-development-02242020-02242020.

Dated: January 13, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2020-N-0008]

#### Request for Nominations for Individuals and Consumer Organizations for Advisory Committees

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is requesting that any consumer organizations interested in participating in the selection of voting and/or nonvoting consumer representatives to serve on its advisory committees or panels notify FDA in writing. FDA is also requesting nominations for voting and/or nonvoting consumer representatives to serve on advisory committees and/or

panels for which vacancies currently exist or are expected to occur in the near future. Nominees recommended to serve as a voting or nonvoting consumer representative may be self-nominated or may be nominated by a consumer organization. FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

**DATES:** Any consumer organization interested in participating in the selection of an appropriate voting or nonvoting member to represent consumer interests on an FDA advisory committee or panel may send a letter or email stating that interest to FDA (see **ADDRESSES**) by February 20, 2020, for vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA (see **ADDRESSES**) by February 20, 2020. Nominations will be accepted for current vacancies and for those that will or may occur through December 31, 2020.

**ADDRESSES:** All statements of interest from consumer organizations interested in participating in the selection process should be submitted electronically to [ACOMSSubmissions@fda.hhs.gov](mailto:ACOMSSubmissions@fda.hhs.gov), by

mail to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, Rm. 5122, Silver Spring, MD 20993-0002, or by Fax: 301-847-8640.

Consumer representative nominations should be submitted electronically by logging into the FDA Advisory Committee Membership Nomination Portal: <https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm>, by mail to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, Rm. 5122, Silver Spring, MD 20993-0002, or by Fax: 301-847-8640. Additional information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's website at <http://www.fda.gov/AdvisoryCommittees/default.htm>.

**FOR FURTHER INFORMATION CONTACT:** For questions relating to participation in the selection process: Kimberly Hamilton, Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5122, Silver Spring, MD 20993-0002, 301-796-8220, email [kimberly.hamilton@fda.hhs.gov](mailto:kimberly.hamilton@fda.hhs.gov).

For questions relating to specific advisory committees or panels, contact the appropriate contact person listed in table 1.

TABLE 1—ADVISORY COMMITTEE CONTACTS

Contact person	Committee/panel
Kathleen Hayes, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6307C, Silver Spring, MD 20993-0002, 301-796-7864, email: <a href="mailto:Kathleen.Hayes@fda.hhs.gov">Kathleen.Hayes@fda.hhs.gov</a> .	Allergenic Products Advisory Committee.
Kalyani Bhatt, Center for Drugs Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2438, Silver Spring, MD 20993-0002, 301-796-9005, email: <a href="mailto:Kalyani.Bhatt@fda.hhs.gov">Kalyani.Bhatt@fda.hhs.gov</a> .	Bone, Reproductive and Urological Drugs Advisory Committee, Psychopharmacologic Drugs Advisory Committee.
LaToya Bonner, Center for Drugs Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2428, Silver Spring, MD 20993-0002, 301-796-2855, email: <a href="mailto:LaToya.Bonner@fda.hhs.gov">LaToya.Bonner@fda.hhs.gov</a> .	Dermatologic and Ophthalmic Drugs Advisory Committee.
Philip Bautista, Center for Drugs Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2430, Silver Spring, MD 20993-0002, 240-762-8729, email: <a href="mailto:Philip.Bautista@fda.hhs.gov">Philip.Bautista@fda.hhs.gov</a> .	Drug Safety and Risk Management Advisory Committee.
Patricio Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G610, Silver Spring, MD 20993-0002, 301-796-6875, email: <a href="mailto:Patricio.Garcia@fda.hhs.gov">Patricio.Garcia@fda.hhs.gov</a> .	Clinical Chemistry and Clinical Toxicology Devices Panel, Gastroenterology and Urology Devices Panel, Obstetrics and Gynecology Devices Panel.
Sara Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G616, Silver Spring, MD 20993-0002, 301-796-7047, email: <a href="mailto:Sara.Anderson@fda.hhs.gov">Sara.Anderson@fda.hhs.gov</a> .	Dental Products Devices Panel.
Evella Washington, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G640, Silver Spring, MD 20993-0002, 301-796-6683, email: <a href="mailto:Evella.Washington@fda.hhs.gov">Evella.Washington@fda.hhs.gov</a> .	Circulatory Systems Devices Panel.
Joannie Adams-White, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5519, Silver Spring, MD 20993-0002, 301-796-5421, email: <a href="mailto:Joannie.Adams-White@fda.hhs.gov">Joannie.Adams-White@fda.hhs.gov</a> .	Medical Devices Dispute Resolution Panel.
Aden Asefa, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G642, Silver Spring, MD 20993-0002, 301-796-0400, email: <a href="mailto:Aden.Asefa@fda.hhs.gov">Aden.Asefa@fda.hhs.gov</a> .	Immunology Devices Panel; Microbiology Devices Panel.

**SUPPLEMENTARY INFORMATION:** FDA is requesting nominations for voting and/or nonvoting consumer representatives for the vacancies listed in table 2:

**TABLE 2—COMMITTEE DESCRIPTIONS, TYPE OF CONSUMER REPRESENTATIVE VACANCY, AND APPROXIMATE DATE NEEDED**

Committee/panel/areas of expertise needed	Type of vacancy	Approximate date needed
Allergenic Products Advisory Committee—Knowledgeable in the fields of allergy, immunology, pediatrics, internal medicine, biochemistry, and related specialties.	1–Voting .....	August 31, 2020.
Bone, Reproductive and Urological Drugs Advisory Committee—Knowledgeable in the fields of osteoporosis and metabolic bone disease, obstetrics, gynecology, urology, pediatrics, epidemiology, or statistics and related specialties.	1–Voting .....	Immediately.
Psychopharmacologic Drugs Advisory Committee—Knowledgeable in the fields of psychopharmacology, psychiatry, epidemiology or statistics, and related specialties.	1–Voting .....	Immediately.
Dermatologic and Ophthalmic Drugs Advisory Committee—Knowledgeable in the fields of dermatology, ophthalmology, internal medicine, pathology, immunology, epidemiology or statistics, and other related professions.	1–Voting .....	August 31, 2020.
Drug Safety and Risk Management Advisory Committee—Knowledgeable in risk communication, risk management, drug safety, medical, behavioral, and biological sciences as they apply to risk management, and drug abuse.	1–Voting .....	May 31, 2020.
Clinical Chemistry and Clinical Toxicology Devices Panel—Doctor of Medicine or philosophy with experience in clinical chemistry (e.g., cardiac markers), clinical toxicology, clinical pathology, clinical laboratory medicine, and endocrinology.	1–Non-Voting .....	Immediately.
Gastroenterology and Urology Devices Panel—Gastroenterologists, urologists and nephrologists.	1–Non-Voting .....	Immediately.
Obstetrics and Gynecology Devices Panel—Experts in perinatology, embryology, reproductive endocrinology, pediatric gynecology, gynecological oncology, operative hysteroscopy, pelviscopy, electro-surgery, laser surgery, assisted reproductive technologies, contraception, postoperative adhesions, and cervical cancer and colposcopy; biostatisticians and engineers with experience in obstetrics/gynecology devices; urogynecologists; experts in breast care; experts in gynecology in the older patient; experts in diagnostic (optical) spectroscopy; experts in midwifery; labor and delivery nursing.	1–Non-Voting .....	Immediately.
Dental Products Device Panel—Dentists, engineers and scientists who have expertise in the areas of dental implants, dental materials, periodontology, tissue engineering, and dental anatomy.	1–Non-Voting .....	Immediately.
Circulatory Systems Devices Panel—Interventional cardiologists, electrophysiologists, invasive (vascular) radiologists, vascular and cardiothoracic surgeons, and cardiologists with special interest in congestive heart failure.	1–Non-Voting .....	Immediately.
Medical Devices Dispute Resolution—Experts with broad, cross-cutting scientific, clinical, analytical or mediation skills.	1–Non-Voting .....	Immediately.
Immunology Devices Panel—Persons with experience in medical, surgical, or clinical oncology, internal medicine, clinical immunology, allergy, molecular diagnostics, or clinical laboratory medicine.	1–Non-Voting .....	Immediately.
Microbiology Devices Panel—Clinicians with an expertise in infectious disease, e.g., pulmonary disease specialists, sexually transmitted disease specialists, pediatric infectious disease specialists, experts in tropical medicine and emerging infectious diseases, mycologists; clinical microbiologists and virologists; clinical virology and microbiology laboratory directors, with expertise in clinical diagnosis and in vitro diagnostic assays, e.g., hepatologists; molecular biologists.	1–Non-Voting .....	Immediately.
Radiology Devices Panel—Physicians with experience in general radiology, mammography, ultrasound, magnetic resonance, computed tomography, other radiological subspecialties and radiation oncology; scientists with experience in diagnostic devices, radiation physics, statistical analysis, digital imaging and image analysis.	1–Non-Voting .....	Immediately.

**I. Functions and General Description of the Committee Duties**

*A. Allergenic Products Advisory Committee*

Reviews and evaluates available data concerning the safety, effectiveness, and adequacy of labeling of marketed and investigational allergenic biological products or materials that are administered to humans for the diagnosis, prevention, or treatment of allergies and allergic disease as well as the affirmation or revocation of biological product licenses, on the safety, effectiveness, and labeling of the products, on clinical and laboratory studies of such products, on amendments or revisions to regulations

governing the manufacture, testing and licensing of allergenic biological products, and on the quality and relevance of FDA’s research programs.

*B. Bone, Reproductive and Urologic Drugs Advisory Committee*

Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the practice of osteoporosis and metabolic bone disease, obstetrics, gynecology, urology, and related specialties.

*C. Psychopharmacologic Drugs Advisory Committee*

Reviews and evaluates data concerning the safety and effectiveness

of marketed and investigational human drug products for use in the practice of psychiatry and related fields.

*D. Dermatologic and Ophthalmic Drugs Advisory Committee*

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of dermatologic and ophthalmic disorders.

*E. Drug Safety and Risk Management Advisory Committee*

Risk management, risk communication, and quantitative evaluation of spontaneous reports for drugs for human use and for any other

product for which the FDA has regulatory responsibility. Scientific and medical evaluation of all information gathered by the Department of Health and Human Services (DHHS) and the Department of Justice with regard to safety, efficacy, and abuse potential of drugs or other substances, and recommends actions to be taken by the DHHS with regard to the marketing, investigation, and control of such drugs or other substances.

#### *F. Certain Panels of the Medical Devices Advisory Committee*

Reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, advises on the classification or reclassification of devices into one of three regulatory categories; advises on any possible risks to health associated with the use of devices; advises on formulation of product development protocols; reviews premarket approval applications for medical devices; reviews guidelines and guidance documents; recommends exemption of certain devices from the application of portions of the Federal Food, Drug, and Cosmetic Act; advises on the necessity to ban a device; and responds to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, may also make appropriate recommendations to the Commissioner of Food and Drugs (the Commissioner) on issues relating to the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

The Dental Products Panel also functions at times as a dental drug panel. The functions of the dental drug panel are to evaluate and recommend whether various prescription drug products should be changed to over-the-counter status and to evaluate data and make recommendations concerning the approval of new dental drug products for human use.

The Medical Devices Dispute Resolution Panel provides advice to the Commissioner on complex or contested scientific issues between FDA and medical device sponsors, applicants, or manufacturers relating to specific products, marketing applications, regulatory decisions and actions by FDA, and Agency guidance and policies. The Panel makes

recommendations on issues that are lacking resolution, are highly complex in nature, or result from challenges to regular advisory panel proceedings or Agency decisions or actions.

#### **II. Criteria for Members**

Persons nominated for membership as consumer representatives on committees or panels should meet the following criteria: (1) Demonstrate an affiliation with and/or active participation in consumer or community-based organizations, (2) be able to analyze technical data, (3) be able to understand research design, (4) be able to discuss benefits and risks, and (5) be able to evaluate the safety and efficacy of products under review. The consumer representative should be able to represent the consumer perspective on issues and actions before the advisory committee; serve as a liaison between the committee and interested consumers, associations, coalitions, and consumer organizations; and facilitate dialogue with the advisory committees on scientific issues that affect consumers.

#### **III. Selection Procedures**

Selection of members representing consumer interests is conducted through procedures that include the use of organizations representing the public interest and public advocacy groups. These organizations recommend nominees for the Agency's selection. Representatives from the consumer health branches of Federal, State, and local governments also may participate in the selection process. Any consumer organization interested in participating in the selection of an appropriate voting or nonvoting member to represent consumer interests should send a letter stating that interest to FDA (see **ADDRESSES**) within 30 days of publication of this document.

Within the subsequent 30 days, FDA will compile a list of consumer organizations that will participate in the selection process and will forward to each such organization a ballot listing at least two qualified nominees selected by the Agency based on the nominations received, together with each nominee's current curriculum vitae or résumé. Ballots are to be filled out and returned to FDA within 30 days. The nominee receiving the highest number of votes ordinarily will be selected to serve as the member representing consumer interests for that particular advisory committee or panel.

#### **IV. Nomination Procedures**

Any interested person or organization may nominate one or more qualified

persons to represent consumer interests on the Agency's advisory committees or panels. Self-nominations are also accepted. Nominations must include a current, complete résumé or curriculum vitae for each nominee and a signed copy of the *Acknowledgement and Consent* form available at the FDA Advisory Nomination Portal (see **ADDRESSES**), and a list of consumer or community-based organizations for which the candidate can demonstrate active participation.

Nominations must also specify the advisory committee(s) or panel(s) for which the nominee is recommended. In addition, nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest. Members will be invited to serve for terms up to 4 years.

FDA will review all nominations received within the specified timeframes and prepare a ballot containing the names of qualified nominees. Names not selected will remain on a list of eligible nominees and be reviewed periodically by FDA to determine continued interest. Upon selecting qualified nominees for the ballot, FDA will provide those consumer organizations that are participating in the selection process with the opportunity to vote on the listed nominees. Only organizations vote in the selection process. Persons who nominate themselves to serve as voting or nonvoting consumer representatives will not participate in the selection process.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: January 14, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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