4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-1095]

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 or Agency) 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 **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**, for vacancies listed in this notice. Concurrently, nomination materials for

prospective candidates should be sent to FDA (see ADDRESSES) by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Nominations will be accepted for current vacancies and for those that will or may occur through July 31, 2018.

ADDRESSES: All statements of interest from consumer organizations interested in participating in the selection process and consumer representative nominations should be submitted electronically to ACOMSSubmissions@fda.hhs.gov, by mail or delivery service to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, 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 or delivery service to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, 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 https://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 (ACOMS), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993-0002, 301-796-8220, email: 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
Moon Hee V. Choi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2434, Silver Spring, MD 20993-0002, 301-796-2894, email: MoonHee.Choi@fda.hhs.gov	Anesthetic and Analgesic Drug Products Advisory Committee

Contact Person	Committee/Panel
Lauren Tesh, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2426, Silver Spring, MD 20993-0002, 301-796-2721, email: Lauren.Tesh@fda.hhs.gov	Antimicrobial Advisory Committee
Kalyani Bhatt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2438, Silver Spring, MD 20993-0002, 301-796-9005, email: Kalyani.Bhatt@fda.hhs.gov	Bone, Reproductive and Urological Drugs Advisory Committee
Jennifer Shepherd, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2434, Silver Spring, MD 20993-0002, 301-796-4043, email: Jennifer.Shepherd@fda.hhs.gov	Cardiovascular and Renal Drugs Advisory Committee, Medical Imaging Advisory Committee
Cindy Chee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2430, Silver Spring, MD 20993-0002, 301-796-0889, email: Cindy.Chee@fda.hhs.gov	Pulmonary-Allergy Drugs 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: Patricio.Garcia@fda.hhs.gov	Clinical Chemistry and Clinical Toxicology Devices Panel, Gastroenterology and Urology 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: Evella.Washington@fda.hhs.gov	Ear, Nose and Throat Devices Panel
Joan Adams-White, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm., 5572, Silver Spring, MD 20993-0002, 301-796-5421, email: Joannie.Adams-White@fda.hhs.gov	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: Aden.Asefa@fda.hhs.gov	Microbiology Devices Panel, Radiology 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: Sara.Anderson@fda.hhs.gov	Orthopaedic and Rehabilitation Devices Panel, Radiological 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
Anesthetic and Analgesic Drug Products Advisory Committee--Knowledgeable in the fields of anesthesiology, surgery, epidemiology or statistics, and related specialties	1--Voting	Immediately
Antimicrobial Advisory Committee--Knowledgeable in the fields of infectious disease, internal medicine, microbiology, pediatrics, epidemiology or statistics, and related specialties	1--Voting	Immediately
Bone, Reproductive and Urological Drugs Advisory Committee--Knowledgeable in the fields of obstetrics, gynecology, endocrinology, pediatrics, epidemiology or statistics and related specialties	1--Voting	Immediately
Cardiovascular and Renal Drugs Advisory Committee--Knowledgeable in the fields of cardiology, hypertension, arrhythmia, angina,	1--Voting	July 1, 2018

Committee/Panel/Areas of Expertise Needed	Type of Vacancy	Approximate Date Needed
congestive heart failure, diuresis, and biostatistics		
Medical Imaging Advisory Committee--Knowledgeable in the fields of nuclear medicine, radiology, epidemiology, statistics and related specialties	1--Voting	Immediately
Pulmonary- Allergy Drugs Advisory Committee--Knowledgeable in the fields of pulmonary medicine, allergy, clinical immunology, and epidemiology or statistics	1--Voting	Immediately
Clinical Chemistry and Clinical Toxicology Devices Panel--Doctors 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
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
Ear, Nose and Throat Devices Panel--Experts in Otologists, neurologists, audiologists	1--Non-Voting	Immediately
Medical Devices Dispute Resolution--Experts with broad, cross-cutting scientific, clinical, analytical or mediation skills	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
Orthopaedic and Rehabilitation Devices Panel--Orthopedic surgeons (joint spine, trauma, and pediatric); rheumatologists; engineers (biomedical, biomaterials, and biomechanical); experts in rehabilitation medicine, sports medicine, and connective tissue engineering; and biostatisticians	1--Non-Voting	Immediately

I. Functions and General Description of the Committee Duties

A. Anesthetic and Analgesic Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in anesthesiology and surgery.

B. Antimicrobial 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 infectious diseases and disorders.

C. Bone, Reproductive & 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 obstetrics, gynecology, and related specialties.

D. Cardiovascular and Renal 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 cardiovascular and renal disorders.

E. Medical Imaging Advisory Committee

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in diagnostic and therapeutic procedures using radioactive pharmaceuticals and contrast media used in diagnostic radiology.

F. Pulmonary-Allergy 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 pulmonary disease and diseases with allergic and/or immunologic mechanisms.

G. Certain Panels of the Medical Devices Advisory Committee

Review and evaluate data on the safety and effectiveness of marketed and investigational devices and make 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 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) understand research design, (4) discuss benefits and risks, and (5) 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 resume. Ballots must 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 section of this document), 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: April 5, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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