4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-0001]

# 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 [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 November 30, 2017.

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 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 at: 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. 5103, Silver Spring, MD 20993-0002, or by FAX: 301-847-8640. Additional information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's Web site 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 (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 |
|---|---|
| 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, phone: 301-796-2721, email: Lauren.Tesh@fda.hhs.gov. | Antimicrobial Advisory Committee |

| Contact Person | Committee/Panel |
|---|---|
| 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, phone: 301-796-6875, email: Patricio.Garcio@fda.hhs.gov. | Clinical Chemistry and Clinical Toxicology Devices Panel, |
| Evella Washington, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1535, Silver Spring, MD 20993-0002, phone: 301-796-6683, email: Evella.Washington@fda.hhs.gov. | Ear, Nose and Throat Devices Panel, Immunology Devices Panel |
| Pamela Scott, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5572, Silver Spring, MD 20993-0002, phone: 301-796-5433, email: Pamela.Scott@fda.hhs.gov. | Medical Devices Dispute Resolution |
| Aden Asefa, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2648, Silver Spring, MD 20993-0002, phone: 301-796-0400, email: Aden.Asefa@fda.hhs.gov. | Neurological Devices Panel |
| LaToya Bonner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2428, Silver Spring, MD 20993-0002, phone: 301-796-2855, email: LaToya.Bonner@fda.hhs.gov. | Endocrinologic and Metabolic Drugs Advisory Committee |
| Karen Strambler, Center for Food Safety and Nutrition, Food and Drug Administration, FDA College Park, CPK1, rm. 1C008, College Park, MD 20740, phone: 240-402-2589, email: Karen.Strambler@fda.hhs.gov. | Foods Advisory Committee |
| Cindy Hong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2430, Silver Spring, MD 20993-0002, phone: 301-796-0889, email: Cindy.Hong@fda.hhs.gov. | Gastrointestinal Drugs Advisory Committee, Pulmonary-Allergy 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, phone: 301-796-4043, email: Jennifer.Shepherd@fda.hhs.gov. | Medical Imaging Advisory Committee, Pharmaceutical Science and Clinical Pharmacology |
| Sara Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1643, Silver Spring, MD 20993-0002, phone: 301-796-0889, email: Sara.Anderson@fda.hhs.gov. | National Mammography Quality Assurance Advisory Committee |
| Moon Hee Choi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2434, Silver Spring, MD 20993-0002, phone: 301-796-2894, email: MoonHee.Choi@fda.hhs.gov. | Non-Prescription Drugs Advisory Committee, Peripheral & Central Nervous Systems Advisory Committee |
| Marie ann Brill, Office of the Commissioner, Office of Medical Products and Tobacco, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5154, Silver Spring, MD 20993-0002, phone: 240-402-3838, email: Mariann.Brill@fda.hhs.gov. | Pediatrics Advisory Committee |

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 |
|---|---|---|
| Antimicrobial Advisory Committee--Knowledgeable in the fields of infectious disease, internal medicine, microbiology, pediatrics, epidemiology or statistics, and related specialties. | 1--Voting | November 30, 2017 |
| 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 | February 28, 2017 |
| Ear, Nose and Throat Devices Panel--Otologists, neurologists, audiologists. | 1--Non-Voting | Immediately |
| Immunology Devices--Persons with experience in medical, surgical, or clinical oncology, internal medicine, clinical immunology, allergy, molecular diagnostics, or clinical laboratory medicine. | 1--Non-Voting | Immediately |
| Medical Devices Dispute Resolution--Experts with broad, cross-cutting scientific, clinical, analytical, or mediation skills. | 1--Non-Voting | Immediately |
| Neurological Devices Panel--Neurosurgeons (cerebrovascular and pediatric), neurologists (stroke, pediatric, pain management, and movement disorders), interventional neuroradiologists, psychiatrists, and biostatisticians. | 1--Non-Voting | Immediately |
| Endocrinologic and Metabolic Drugs Advisory Committee--Knowledgeable in the fields of endocrinology, metabolism, epidemiology or statistics, and related specialties. | 1--Voting | June 30, 2017 |
| Foods Advisory Committee--Knowledgeable in the fields of physical sciences, biological and life sciences, food science, risk assessment, nutrition, food technology, molecular biology, and other relevant scientific and technical disciplines. | 1--Voting | June 30, 2017 |
| Gastrointestinal Drugs Advisory Committee--Knowledgeable in the fields of gastroenterology, endocrinology, surgery, clinical pharmacology, physiology, pathology, liver function, motility, esophagitis, and statistics. | 1--Voting | Immediately |
| Pulmonary-Allergy Drugs Advisory Committee--Knowledgeable in the fields of pulmonary medicine, allergy, clinical immunology, and epidemiology or statistics. | 1--Voting | May 31, 2017 |
| Medical Imaging Advisory Committee--Knowledgeable in the fields of nuclear medicine, radiology, epidemiology, statistics, and related specialties. | 1--Voting | Immediately |
| Pharmaceutical Science and Clinical Pharmacology--Knowledgeable in the fields of pharmaceutical manufacturing, clinical pharmacology, pharmacokinetics, bioavailability and bioequivalence research, the design and evaluation of clinical trials, laboratory analytical techniques, pharmaceutical chemistry, physiochemistry, biochemistry, biostatistics, and related biomedical and pharmacological specialties. | 1--Voting | Immediately |
| National Mammography Quality Assurance Advisory Committee--Physician, practitioner, or other health professional whose clinical practice, research specialization, or professional expertise includes a significant focus on mammography. | 1--Non-Voting | Immediately |
| Non-Prescription Drugs Advisory Committee--Knowledgeable in the fields of internal medicine, family practice, clinical toxicology, clinical pharmacology, pharmacy, dentistry, and related specialties. | 1--Voting | May 31, 2017 |
| Peripheral and Central Nervous System Drugs Advisory Committee--Knowledgeable in the fields of neurology, neuropharmacology, neuropathology, otolaryngology, epidemiology or statistics, and related specialties. | 1--Voting | Immediately |

| Committee/Panel/Areas of Expertise Needed | Type of Vacancy | Approximate Date Needed |
|---|---|---|
| Pediatrics Advisory Committee--Knowledgeable in pediatric research, pediatric subspecialties, statistics, and/or biomedical ethics. The core of voting members shall also include one representative from a pediatric health organization and one representative from a relevant patient or patient-family organization and 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. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests. | 1--Voting | Immediately |

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

### A. 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.

### B. 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: (1) Advises on the classification or reclassification of devices into one of three regulatory categories; (2) advises on any possible risks to health associated with the use of devices; (3) advises on formulation of product development protocols; (4) reviews premarket approval applications for medical devices; (5) reviews guidelines and guidance documents; (6) recommends exemption of certain devices from the application of portions of the Federal Food, Drug, and Cosmetic Act; (7) advises on the necessity to ban a device; and (8) 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.

C. Endocrinologic and Metabolic Drugs Advisory Committee

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

D. Food Advisory Committee

Make recommendations on emerging food safety, food science, nutrition, and other food-related health issues that FDA considers of primary importance for its food and cosmetics programs. Reviewing and evaluating available data and making recommendations on matters such as those relating to: (1) Broad scientific and technical food or cosmetic related issues; (2) the safety of new foods and food ingredients; (3) labeling of foods and cosmetics; (4) nutrient needs and nutritional adequacy; and (5) safe exposure limits for food contaminants. The

Committee may also be asked to provide advice and make recommendations on ways of communicating to the public the potential risks associated with these issues and on approaches that might be considered for addressing the issues.

E. Gastrointestinal 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 gastrointestinal diseases.

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. Medical Imaging Drugs 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.

H. Pharmaceutical Science and Clinical Pharmacology Advisory Committee

Provide advice on scientific and technical issues concerning the safety, and effectiveness of human generic drug products for use in the treatment of a broad spectrum of human diseases, and as required, any other product for which FDA has regulatory responsibility. The committee may also review Agency sponsored intramural and extramural biomedical research programs in support of FDA's generic drug regulatory responsibilities.

I. National Mammography Quality Assurance Advisory Committee

Advise the Agency on the following development of appropriate quality standards and regulations for mammography facilities; standards and regulations for bodies accrediting

mammography facilities under this program; regulations with respect to sanctions; procedures for monitoring compliance with standards; establishing a mechanism to investigate consumer complaints; reporting new developments concerning breast imaging which should be considered in the oversight of mammography facilities. As well as determining whether there exists a shortage of mammography facilities in rural and health professional shortage areas and determining the effects of personnel on access to the services of such facilities in such areas; determining whether there will exist a sufficient number of medical physicists after October 1, 1999; and determining the costs and benefits of compliance with these requirements.

J. Non-Prescription Drugs Advisory Committee

Review and evaluate available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products, or any other FDA-regulated product, for use in the treatment of a broad spectrum of human symptoms and diseases and advise the Commissioner either on the promulgation of monographs establishing conditions under which these drugs are generally recognized as safe and effective and not misbranded or on the approval of new drug applications for such drugs. The Committee will serve as a forum for the exchange of views regarding the prescription and nonprescription status, including switches from one status to another, of these various drug products and combinations thereof. The Committee may also conduct peer review of Agency sponsored intramural and extramural scientific biomedical programs in support of FDA's mission and regulatory responsibilities.

K. Peripheral and Central Nervous System Advisory Committee

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of neurologic diseases.

## L. Pediatrics Advisory Committee

The Committee advises and makes recommendations to the Commissioner of Food and Drugs regarding: (1) Pediatric research; (2) identification of research priorities related to pediatric therapeutics and the need for additional treatments of specific pediatric diseases or conditions, (3) the ethics, design, and analysis of clinical trials related to pediatric therapeutics, (4) pediatric labeling disputes, (5) pediatric labeling changes, (6) adverse event reports for drugs granted pediatric exclusivity and any safety issues that may occur, (7) any other pediatric issue or pediatric labeling dispute involving FDA regulated products, (8) research involving children as subjects, and (9) any other matter involving pediatrics for which FDA has regulatory responsibility. The Committee also advises and makes recommendations to the Secretary directly or to the Secretary through the Commissioner on research involving children as subjects that is conducted or supported by the Department of Health and Human Services.

## 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 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 should include a cover letter and current curriculum vitae or résumé for each nominee, including a current business and/or home address, telephone number, and email address if available, and a list of consumer or community-based organizations for which the candidate can demonstrate active participation.

Nominations should also specify the advisory committee(s) or panel(s) for which the nominee is recommended. In addition, nominations should include confirmation 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: June 9, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation and Analysis.

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