4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. FDA-2015-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. Nominations will be accepted for current vacancies and for those that will or may occur through December 31, 2015.

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].

ADDRESSES: All statements of interest from consumer organizations interested in participating in the selection process and consumer representative nominations should submit information electronically to kimberly.hamilton@fda.hhs.gov, or by mail to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, rm. 5103, Silver Spring, MD 20993-0002, or 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, or by mail to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, rm. 5103, Silver Spring, MD 20993-0002, or 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: Kimberly Hamilton, Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5117, Silver Spring, MD 20993-0002, 301 796-8224, email: kimberly.hamilton@fda.hhs.gov.

For questions relating to specific advisory committees or panels, contact the persons listed in Table 1:

Table 1.--Advisory Committee Contacts

Contact Person	Committee/Panel
Shanika Craig Center for Devices and Radiological Health Food and Drug Administration 10903 New Hampshire Ave. Bldg. 66, rm. 1613 Silver Spring, MD 20993-0002 Phone: 301-796-6639 Email: Shanika.Craig@fda.hhs.gov.	Anesthesiology and Respiratory Therapy Devices Panel
Dimitrus Culbreath Center for Devices and Radiological Health Food and Drug Administration 10903 New Hampshire Ave. Bldg. 31, rm. 3530 Silver Spring, MD 20993 Phone: 301-796-6872 Email: Dimitrus.Culbreath@fda.hhs.gov.	Circulatory System Devices Panel; Molecular and Clinical Genetics Panel
Sara Anderson Center for Devices and Radiological Health Food and Drug Administration 10903 New Hampshire Ave. Bldg. 66, rm. 1544 Silver Spring, MD 20993-0002 Phone: 301-796-1643 Email: Sara.Anderson@fda.hhs.gov.	Dental Products Device Panel; Hematology and Pathology Devices Panel
Yvette Waples Center for Drug Evaluation and Research Food and Drug Administration 10903 New Hampshire Ave. Bldg. 31, rm. 2510 Silver Spring, MD 20993-0002 Phone: 301-796-9034 Email: Yvette.Waples@fda.hhs.gov.	Dermatologic and Ophthalmic Drugs Advisory Committee; Pharmaceutical Science & Clinical Pharmacology Advisory Committee
Patricio Garcia Center for Devices and Radiological Health Food and Drug Administration 10903 New Hampshire Ave. Bldg. 66, rm. 1535 Silver Spring, MD 20993-0002 Phone: 301-796-6875 Email: Patricio.Garcia@fda.hhs.gov.	General and Plastic Surgery Devices Panel; Neurological Devices Panel

Natasha Facey Center for Devices and Radiological Health Food and Drug Administration 10903 New Hampshire Ave. Bldg. 66, rm. 1552 Silver Spring, MD 20993-0002 Phone: 301-796-5290 FAX: 301-874-8120 Email: Natasha.Facey@fda.hhs.gov.	General Hospital and Personal Use Devices Panel; Ophthalmic Devices Panel
Rakesh Raghuwanshi Office of the Commissioner Food and Drug Administration 10903 New Hampshire Ave. Bldg. 1, rm. 4308 Silver Spring, MD 20993-0002 Phone: 301-796-4769 Email: Rakesh.Raghuwanshi@fda.hhs.gov.	Science Advisory Board to the Food and Drug Administration
Donna Mendrick National Center for Toxicological Research Food and Drug Administration 10903 New Hampshire Ave. Bldg. 32, rm. 2208 Silver Spring, MD 20993-0002 Phone: 301-796-8892 FAX: 301-847-8600 Email: Donna.Mendrick@fda.hhs.gov.	Science Advisory Board to National Center for Toxicological Research (NCTR)
Sujata Vijh Center for Biologics Evaluation and Research Food and Drug Administration 10903 New Hampshire Ave. Bldg. 71, rm. 6128 Silver Spring, MD 20993-0002 Phone: 240-402-7107 Email: Sujata.Vijh@fda.hhs.gov.	Vaccines and Related Biological Products 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
Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee -- Anesthesiologists, pulmonary medicine specialists, or other experts who have specialized interests in ventilator support, pharmacology, physiology, or the effects and complications of anesthesia.	One Non-Voting	Immediately
Circulatory System Devices Panel of the Medical Devices Advisory Committee -- Knowledgeable in the safety and effectiveness of marked and investigational devices for use in the circulatory and vascular systems.	One Non-Voting	Immediately
Dental Products Devices Panel of the Medical Devices Advisory Committee -- Dentists, engineers and scientists who have expertise in the areas of dental implants, dental materials, periodontology, tissue engineering, and dental anatomy.	One Non-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.	One Voting	Immediately
General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee -- Knowledgeable in the fields of general, plastic, reconstructive, pediatric, thoracic, abdominal, pelvic, and endoscopic surgery; biomaterials, lasers, wound healing, and quality of life issues.	One Non-Voting	Immediately
General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee -- Internists, pediatricians, neonatologists, endocrinologists, gerontologists, nurses, biomedical engineers or microbiologists, infection control practitioners or experts.	One Non-Voting	Immediately
Hematology and Pathology Devices Panel of the Medical Devices Advisory Committee -- Knowledgeable in the fields of hematology, hematopathology, coagulation and homeostasis, hematological oncology, and gynecological oncology.	One Non-Voting	Immediately
Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee -- Experts in human genetics and in the clinical management of patients with genetic disorders, e.g., pediatricians, obstetricians, neonatologists. The Agency is also interested in considering candidates with training in inborn errors of metabolism, biochemical and/or molecular genetics, population genetics, epidemiology, and related statistical training. Additionally, individuals with experience in genetic counseling, medical ethics, as well as ancillary fields of study will be considered.	One Non-Voting	Immediately
Neurological Devices Panel of the Medical Devices Advisory Committee -- Neurosurgeons	One Non-Voting	Immediately

(cerebrovascular and pediatric), neurologists (stroke, pediatric, pain management, and movement disorders), interventional neuroradiologists, psychiatrists, and biostatisticians.		
Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee -- Knowledgeable in the fields of perinatology, embryology, reproductive endocrinology, pediatric gynecology, gynecological oncology, operative hysteroscopy, pelviscopy, electrosurgery, laser surgery, assisted reproductive technologies, contraception, postoperative adhesions, and cervical cancer and colposcopy; obstetrics/gynecology devices; gynecology in the older patient; midwifery; and labor and delivery nursing.	One Non-Voting	Immediately
Ophthalmic Devices Panel of the Medical Devices Advisory Committee -- Ophthalmologists with expertise in corneal-external disease, vitreo-retinal surgery, glaucoma, ocular immunology, ocular pathology; optometrists; vision scientists; and ophthalmic professionals with expertise in clinical trial design, quality of life assessment, electrophysiology, low vision rehabilitation, and biostatistics.	One Non-Voting	Immediately
Pharmaceutical Science and Clinical Pharmacology Advisory Committee -- 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.	One Voting	Immediately
Science Board Advisory Committee for the Food and Drug Administration -- Knowledgeable in the fields of food science, safety, and nutrition; chemistry; pharmacology; translational and clinical medicine and research; toxicology; biostatistics; medical devices; imaging; robotics; cell and tissue based products; regenerative medicine; public health and epidemiology; international health and regulation; product safety; product manufacturing sciences and quality; and other scientific areas relevant to FDA regulated products such as systems biology, informatics, nanotechnology, and combination products.	One Voting	Immediately
Science Advisory Board to the NCTR -- Knowledgeable in the fields related to toxicological research.	One Voting	Immediately
Vaccines and Related Biological Products -- Knowledgeable in the fields of immunology, molecular biology, rDNA, virology, bacteriology, epidemiology or biostatistics, allergy, preventive medicine, infectious diseases, pediatrics, microbiology, and biochemistry.	One Voting	Immediately

I. Functions and General Description of the Committee Duties

A. Certain Panels of the Medical Devices Advisory Committee

The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation. The panels engage in a number of activities to fulfill the functions the Federal Food, Drug, and Cosmetic Act (the FD&C Act) envisions for device advisory panels. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, advises the Commissioner of Food and Drugs (the Commissioner) regarding recommended 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 FD&C 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 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.

B. 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.

C. 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 the 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.

D. Science Board

Provides advice primarily to the Commissioner of Food and Drugs and other appropriate officials on specific complex and technical issues as well as emerging issues in the scientific community, 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, 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.

E. Science Advisory Board to the National Center for Toxicological Research

Reviews and advises the Agency on the establishment, implementation, and evaluation of the research programs and regulatory responsibilities as it relates to NCTR. The Board will also provide an extra-Agency review in ensuring that the research programs at NCTR are scientifically sound and pertinent.

F. Vaccines and Related Biological Products Advisory Committee

Reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines and related biological products which are intended for use in the prevention, treatment, or diagnosis of human diseases, as well as considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products.

II. Criteria for Members

Persons nominated for membership as consumer representatives on committees or panels should meet the following criteria: (1) Demonstrate ties to consumer and 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 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 resume 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. 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.

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.

Dated: September 25, 2015.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

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