



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[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 September 30, 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 the FDA (see ADDRESSES) by [INSERT DATE 30 DAYS AFTER 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 your 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 following persons listed in table 1 of this document:

Table 1.--Advisory Committee Contacts

Contact Person	Committee/Panel
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<p>Janie Kim, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 6129, Silver Spring, MD 20993; 301-796-9016, email: Janie.Kim@fda.hhs.gov</p>	<p>Allergenic Products Advisory Committee</p>
<p>Stephanie Begansky, Center for Drug Evaluation and Research, Division of Advisory Committee and Consultant Management, Office of Executive Programs, 10903 New Hampshire Ave., Bldg. 31, rm. 2426, Silver Spring, MD 20993-0002; 301-796-3693, FAX: 301-847-8533, email: Stephanie.Begansky@fda.hhs.gov</p>	<p>Arthritis Advisory Committee</p>
<p>Jamie Waterhouse, Center for Devices and Radiological Health, Office of Device Evaluation, 10903 New Hampshire Ave., Bldg. 66, rm. 1544, Silver Spring, MD 20993-0002; 301-796-3063, FAX: 301-847-8122, email: Jamie.Waterhouse@fda.hhs.gov</p>	<p>Circulatory System Devices Panel, Molecular and Clinical Genetics Panel</p>
<p>Yvette Waples, Center for Drug Evaluation & Research, Division of Advisory Committee and Consultant Management, Office of Executive Programs, 10993 New Hampshire Ave., Bldg. 31, rm. 2510, Silver Spring, MD 20993-0002; 301-796-9034 FAX: 301-847-8533 email: Yvette.Waples@fda.hhs.gov</p>	<p>DePrmatologic and Ophthalmic Drugs Advisory Committee</p>
<p>Patricio Garcia, Center for Devices and Radiological Health, Office of Device Evaluation, 10903 New Hampshire Ave., Bldg. 66, rm. RMG 465 HFZ-410, Silver Spring, MD 20903-0002, 301-796-6875, FAX: 301-847-8120, email: Patricio.Garcia@fda.hhs.gov</p>	<p>General and Plastic Surgery Devices Panel</p>
<p>Sara J. Anderson, Center for Devices and Radiological Health, Office of Device Evaluation, 10903 New Hampshire Ave., Bldg. 66, rm. 1544, Silver Spring, MD 20903-0002; 301-796-7047, FAX: 301-847-8122, email: Sara.Anderson@fda.hhs.gov</p>	<p>Hematology & Pathology Devices Panel, Orthopaedic and Rehabilitation Devices Panel, and National Mammography and</p>

	Quality Assurance Advisory Committee
Shanika Craig, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66 rm. 1613, Silver Spring, MD 20993-0002; 301-796-6639, FAX: 301-847-8120, email: Shanika.Craig@fda.hhs.gov	Obstetrics and Gynecology Devices Panel
Lauren Tesh, Center for Drug Evaluation and Research, , 10903 New Hampshire Ave., Bldg. 31, rm. 2426, Silver Spring, MD 20993-0002; 301-796-2721, email: Lauren.Tesh@fda.hhs.gov	Oncologic Drugs Advisory Committee
Donna Mendrick, National Center for Toxicological Research, Bldg. 32, rm, 2208, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 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, Division of Scientific Advisors and Consultants, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002; 240-402-7107, FAX: 301-595-1307, 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 Vacancy, and Approximate Date Needed

Committee/Panel/Areas of Expertise Needed	Current and Upcoming Vacancies	Approximate Date Needed

<p>Allergenic Products Advisory Committee:</p> <p>Knowledgeable in the fields of allergy, immunology, pediatrics, internal medicine, biochemistry, and related specialties.</p>	<p>One Voting</p>	<p>June 30, 2015</p>
<p>Arthritis Drugs Advisory Committee:</p> <p>Knowledgeable in the fields of arthritis, rheumatology, orthopedics, epidemiology or statistics, analgesics, and related specialties.</p>	<p>One Voting</p>	<p>September 30, 2015</p>
<p>Circulatory System Devices Panel of the Medical Devices Advisory Committee:</p> <p>Knowledgeable in the safety and effectiveness of marked and investigational devices for use in the circulatory and vascular systems.</p>	<p>One Non-Voting</p>	<p>Immediately</p>
<p>Dermatologic & Ophthalmic Drugs Advisory Committee: Knowledgeable in the fields of dermatology, ophthalmology, internal medicine, pathology, immunology, epidemiology or statistics, and other related professions.</p>	<p>One Voting</p>	<p>August 31, 2015</p>
<p>General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee:</p> <p>Knowledgeable in the fields of general, plastic, reconstructive, pediatric, thoracic, abdominal, pelvic and endoscopic surgery; biomaterials, lasers, wound healing, and quality of life issues.</p>	<p>One Non-Voting</p>	<p>Immediately</p>
<p>Hematology and Pathology Devices Panel of</p>	<p>One Non-Voting</p>	<p>Immediately</p>

<p>the Medical Devices Advisory Committee:</p> <p>Knowledgeable in the fields of hematology, hematopathology, coagulation and homeostasis, hematological oncology, gynecological oncology.</p>		
<p>Molecular & Clinical Genetics Panel of the Medical Devices Advisory Committee:</p> <p>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.</p>	<p>One Non-Voting</p>	<p>May 31, 2015</p>
<p>Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee:</p> <p>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</p>	<p>One Non-Voting</p>	<p>Immediately</p>

cervical cancer and colposcopy; obstetrics/gynecology devices; gynecology in the older patient; midwifery; labor and delivery nursing.		
Oncologic Drugs Advisory Committee: Knowledgeable in the fields of general oncology, pediatric oncology, hematologic oncology, immunologic oncology, biostatistics, and other related professions.	One Voting	Immediately
National Mammography Quality Assurance Advisory Committee: Knowledgeable in clinical practice, research specialization, or professional work that has a significant focus on mammography	Two Voting	Immediately
Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee: Knowledgeable in data concerning the safety and effectiveness of marketed and investigational orthopaedic and rehabilitation devices	Two Non-Voting	Immediately
Science Advisory Board to the NCTR: Knowledgeable in the fields related to toxicological research.	One Voting	June 30, 2015
Vaccines and Related Biological Products Advisory Committee Knowledgeable in the fields of immunology, molecular biology, rDNA, virology, bacteriology, epidemiology or biostatistics,	One Voting	Immediately

allergy, preventive medicine, infectious diseases, pediatrics, microbiology, and biochemistry.		
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I. Functions

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. Arthritis 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 arthritis, rheumatism, and related diseases.

C. 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.

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. National Mammography and Quality Assurance Advisory Committee: The committee reviews and evaluates (1) Developing appropriate quality standards and regulations for mammography facilities; (2) developing appropriate standards and regulations for bodies accrediting mammography facilities under this program; (3) developing regulations with respect to sanctions; (4) developing procedures for monitoring compliance with standards; (5) establishing a mechanism to investigate consumer complaints; (6) reporting new developments concerning breast imaging which should be considered in the oversight of mammography facilities; (7) 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; (8) determining whether there will exist a sufficient number of medical physicists after October 1, 1999; and (9) determining the costs and benefits of compliance with these requirements.

F. Oncologic 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 cancer.

G. 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.

H. 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 a 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: March 30, 2015.

Leslie Kux,

Associate Commissioner for Policy,

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