Government nonmember—$525, and FDA Employee—(free) Fee Waived.

Attendees are responsible for their own accommodations. Please mention SOCRA to receive the hotel room rate of $142 plus applicable taxes (available until the SOCRA room block is filled).

If you need special accommodations due to a disability, please contact SOCRA (see **FOR FURTHER INFORMATION CONTACT**) at least 21 days in advance.

Extended periods of question and answer and discussion have been included in the program schedule. SOCRA designates this education activity for a maximum of 13.3 Continuing Education (CE) Credits for SOCRA CE and Nurse CNE; SOCRA designates this live activity for a maximum of 13.3 AMA PRA Category 1 Credit(s)™. Physicians should claim only the credit commensurate with the extent of their participation. *CME for Physicians:* SOCRA is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. *CNE for Nurses:* Society of Clinical Research Associates is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

*Registration Instructions:* To register, please submit a registration form with your name, affiliation, mailing address, telephone, fax number, and email, along with a check or money order payable to ''SOCRA.'' Mail to: SOCRA (see **FOR FURTHER INFORMATION CONTACT**). To register via the Internet, go to *http://www.socra.org/html/FDAConference.htm.* Payment by major credit card is accepted (Visa/MasterCard/AMEX only). For more information on the meeting registration, or for questions on the workshop, contact SOCRA (see **FOR FURTHER INFORMATION CONTACT**).

Dated: February 9, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–02965 Filed 2–12–16; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2016–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 March 17, 2016, for vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA (see **ADDRESSES**) by March 17, 2016. Nominations will be accepted for current vacancies and for those that will or may occur through March 31, 2016.

**ADDRESSES:** All statements of interest from consumer organizations interested in participating in the selection process and consumer representative nominations should be submitted electronically to *kimberly.hamilton@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: *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. 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 appropriate Contact Person listed in table 1 in the **SUPPLEMENTARY INFORMATION** section.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

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 (see table 1 for Contact Person).

TABLE 1—ADVISORY COMMITTEE CONTACTS

| Contact person | Committee/panel |
|---|---|
| Janie Kim, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6129, Silver Spring, MD 20993–0002, Phone: 301–796–9016, Email: *Janie.Kim@fda.hhs.gov*. | Cellular, Tissue and Gene Therapies. |
| Philip Bautista, Center for Drugs Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2410, Silver Spring, MD 20993–0002, Phone: 301–796–9006, Email: *Philip.Bautista@fda.hhs.gov*. | Drug Safety and Risk Management Advisory Committee. |
| 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, Email: *Natasha.Facey@fda.hhs.gov*. | Immunology Devices Panel. |

TABLE 1—ADVISORY COMMITTEE CONTACTS—Continued

| Contact person | Committee/panel |
|---|---|
| Terri Crescenzi, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5152, Silver Spring, MD 20993–0002, Phone: 301–796–8646, Email: *Terrie.Crescenzi@fda.hhs.gov*. | Pediatrics Advisory Committee. |
| 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, Email: *Donna.Mendrick@fda.hhs.gov*. | Science Advisory Board to National Center for Toxicological Research (NCTR). |
| Bryan Emery, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6132, Silver Spring, MD 20993–0002, Phone: 240–402–8054, Email: *Bryan.Emery@fda.hhs.gov*. | Transmissible Spongiform Encephalopathies Advisory Committee. |
| 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. |

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 |
|---|---|---|
| Cellular, Tissue and Gene Therapies Advisory Committee—Knowledgeable in the fields of cellular therapies, tissue transplantation, gene transfer therapies and xenotransplantation (biostatistics, bioethics, hematology/oncology, human tissues and transplantation, reproductive medicine, general medicine and various medical specialties including surgery and oncology, immunology, virology, molecular biology, cell biology, developmental biology, tumor biology, biochemistry, rDNA technology, nuclear medicine, gene therapy, infectious diseases, and cellular kinetics. | 1-Voting ..... | 3/31/2016. |
| 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 ..... | 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 .... | 2/28/2016. |
| 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. |
| Science Advisory Board to the NCTR—Knowledgeable in the fields related to toxicological research ..... | 1-Voting ..... | Immediately. |
| Transmissible Spongiform Encephalopathies Advisory Committee—Knowledgeable in the fields of clinical and administrative medicine, hematology, virology, neurovirology, neurology, infectious diseases, immunology, transfusion medicine, surgery, internal medicine, biochemistry, biostatistics, epidemiology, biological and physical sciences, sociology/ethics, and other related professions. | 1-Voting ..... | Immediately. |
| Vaccines and Related Biological Products Advisory Committee—Knowledgeable in the fields of immunology, molecular biology, rDNA, virology, bacteriology, epidemiology or biostatistics, allergy, preventive medicine, infectious diseases, pediatrics, microbiology, and biochemistry. | 1-Voting ..... | Immediately. |

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

### *A. Cellular, Tissue, and Gene Therapies Advisory Committee*

Reviews and evaluates available data relating to the safety, effectiveness, and appropriate use of human cells, human tissues, gene transfer therapies and xenotransplantation products which are intended for transplantation, implantation, infusion and transfer in the prevention and treatment of a broad spectrum of human diseases and in the reconstruction, repair or replacement of tissues for various conditions, as well as considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products.

### *B. 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 Service (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 DHHS with regard to the marketing, investigation, and control of such drugs or other substances.

### *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 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 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.

*D. 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 DHHS.

*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. Transmissible Spongiform Encephalopathies Advisory Committee*

Reviews and evaluates available scientific data concerning the safety of products which may be at risk for transmission of spongiform encephalopathies having an impact on the public health, as well as considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products.

*G. 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.

**III. 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.

**IV. 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.

**V. 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: February 8, 2016.

**Jill Hartzler Warner,**

*Associate Commissioner for Special Medical Programs.*

[FR Doc. 2016–03010 Filed 2–12–16; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2016–N–0382]**

### Building the National Evaluation System for Medical Devices: Using Real-World Evidence To Improve Device Safety and Effectiveness; Public Workshop; Request for Comments

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

**ACTION:** Notice of public workshop; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA), in collaboration with the University of Maryland Center of Excellence in Regulatory Science and Innovation, is announcing a public workshop titled ''Building the National Evaluation System for Medical Devices: Using Real-World Evidence to Improve Device Safety and Effectiveness.'' The objective of the workshop is to discuss the scientific progress being made in harnessing evidence generated from the real-world use of medical devices to improve device safety and effectiveness. A national evaluation system for medical devices, which leverages real-world evidence, can help FDA more efficiently strike the right balance between premarket and postmarket data collection, facilitate access to medical devices, and more quickly and robustly identify safety signals that may arise in the postmarket period. The promise of using real-world evidence to promote the safety and effectiveness of medical devices can only be achieved through robust public-private partnerships and new approaches to informatics, epidemiology, biostatistics, and healthcare data systems integration.

**DATES:** The public workshop will be held on March 24, 2016, from 8:30 a.m. to 4:30 p.m.

**ADDRESSES:** The public workshop will be held at the University of Maryland, Pharmacy Hall, 20 North Pine St., Baltimore, MD 21201. For additional travel and hotel information, please refer to *www.pharmacy.umaryland.edu/DeviceEval.* (FDA has verified the Web site addresses throughout this notice, but FDA is not responsible for subsequent changes to the Web sites after this document publishes in the **Federal Register**).

You may submit comments as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

*Instructions:* All submissions received must include the Docket No. FDA–2016–N–0382 for ''Building the National Evaluation System for Medical Devices: Using Real-World Evidence to Improve Device Safety and Effectiveness; Public Workshop; Request for Comments''. Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Ann Anonsen, University of Maryland, Fischell Department of Bioengineering, 2207 Jeong H. Kim Bldg., College Park, MD 20742, 301–405–0285, FAX: 304–405–9953, *aanonsen@umd.edu;* or Audrey Thomas, Office of Regulatory Science and Innovation, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4220, Silver Spring,