

above topics may be discussed in each meeting. FDA will consider all comments made at these public meetings or received through the docket (see **ADDRESSES**).

### III. Participating in the Public Meeting

**Registration:** To register for the public meetings, please visit the following website to register: <https://fdae2br3.eventbrite.com> by December 20, 2018, for the first meeting, June 14, 2019, for the second meeting, and January 17, 2020, for the third meeting. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, telephone, and method of attendance (in-person or web conference).

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending the public meetings must register by 11:59 p.m. Eastern Time on December 20, 2018, for the first meeting, June 14, 2019, for the second meeting, and January 17, 2020, for the third meeting. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public meeting/public workshop will be provided beginning at 8 a.m.

If you need special accommodations due to a disability, please contact Chenoa Conley, 301-796-0035, email: [Chenoa.Conley@fda.hhs.gov](mailto:Chenoa.Conley@fda.hhs.gov), at least 7 days before each meeting.

**Request for Oral Presentations:** During online registration you may indicate if you wish to present during the public comment session. All requests to make oral presentations must be received by the close of registration at 11:59 p.m. Eastern Time on December 20, 2018, for the first meeting, June 14, 2019, for the second meeting, and January 17, 2020, for the third meeting. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin and will select and notify participants by 11:59 p.m. Eastern Time on January 4, 2019, for the first meeting, June 26, 2019, for the second meeting, and January 30, 2020, for the third meeting. FDA will notify registered presenters of their scheduled presentation time. If

selected for presentation, any presentation materials must be emailed to [eprompt@fda.hhs.gov](mailto:eprompt@fda.hhs.gov) no later than 11:59 p.m. Eastern Time on January 18, 2019, for the first meeting, July 10, 2019, for the second meeting, and February 12, 2020, for the third meeting. Persons registered to speak should check in before the meeting and are encouraged to arrive early to ensure their designated order of presentation. Participants who are not present when called may not be permitted to speak at a later time. No commercial or promotional material will be permitted to be presented or distributed at the public meeting. An agenda will be made available at least 3 days before each public meeting at <https://www.fda.gov/Drugs/NewsEvents/ucm621215.htm>.

**Streaming Webcast of the Public Meetings and Video of the Public Meetings:** These public meetings will also be webcast; the URL will be posted at <https://www.fda.gov/Drugs/NewsEvents/ucm621215.htm> at least 1 day before each meeting. A video record of the public workshops will be available at the same website address for 1 year.

If you have never attended a Connect Pro event before, test your connection at [https://collaboration.fda.gov/common/help/en/support/meeting\\_test.htm](https://collaboration.fda.gov/common/help/en/support/meeting_test.htm). To get a quick overview of the Connect Pro program, visit [https://www.adobe.com/go/connectpro\\_overview](https://www.adobe.com/go/connectpro_overview). FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

**Transcripts:** Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm115894.htm>.

Dated: November 8, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-N-3789]

#### 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 December 17, 2018, for vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA (see **ADDRESSES**) by December 17, 2018. Nominations will be accepted for current vacancies and for those that will or may occur through December 30, 2018.

**ADDRESSES:** All statements of interest from consumer organizations interested in participating in the selection process should be submitted electronically to [ACOMSSubmissions@fda.hhs.gov](mailto:ACOMSSubmissions@fda.hhs.gov), by mail to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, Rm. 5122, 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. 5122, 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, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5122, Silver Spring, MD 20993-0002, Phone: 301-796-6319, [kimberly.hamilton@fda.hhs.gov](mailto: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, <a href="mailto:Lauren.Tesh@fda.hhs.gov">Lauren.Tesh@fda.hhs.gov</a> .	Antimicrobial Advisory Committee.
Kalyani Bhatt, Center for Drugs Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2438, Silver Spring, MD 20993-0002, Phone: 301-796-9005, <a href="mailto:Kalyani.Bhatt@fda.hhs.gov">Kalyani.Bhatt@fda.hhs.gov</a> .	Bone Reproductive and Urological Drugs Advisory Committee.
Jennifer Shepherd, Center for Drugs Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2434, Silver Spring, MD 20993-0002, Phone: 301-796-4043, <a href="mailto:Jennifer.Shepherd@fda.hhs.gov">Jennifer.Shepherd@fda.hhs.gov</a> .	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, Phone: 301-796-0889, <a href="mailto:Cindy.Chee@fda.hhs.gov">Cindy.Chee@fda.hhs.gov</a> .	Pharmacy Compounding 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, Phone: 301-796-6875, <a href="mailto:Patricio.Garcia@fda.hhs.gov">Patricio.Garcia@fda.hhs.gov</a> .	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, Phone: 301-796-6683, <a href="mailto:Evella.Washington@fda.hhs.gov">Evella.Washington@fda.hhs.gov</a> .	Ear, Nose and Throat Devices Panel.
Pamela Scott, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2647, Silver Spring, MD 20993-0002, Phone: 301-796-5433, <a href="mailto:Pamela.Scott@fda.hhs.gov">Pamela.Scott@fda.hhs.gov</a> .	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, Phone: 301-796-0400, <a href="mailto:Aden.Asefa@fda.hhs.gov">Aden.Asefa@fda.hhs.gov</a> .	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. G616m Silver Spring, MD 20993-0002, Phone: 301-796-7047, <a href="mailto:Sara.Anderson@fda.hhs.gov">Sara.Anderson@fda.hhs.gov</a> .	Orthopaedic and Rehabilitation 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/area 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 .....	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, congestive heart failure, diuresis, and biostatistics.	1—Voting .....	Immediately.
Medical Imaging Advisory Committee—Knowledgeable in the fields of nuclear medicine, radiology, epidemiology, statistics, and related specialties.	1—Voting .....	Immediately.
Pharmacy Compounding Advisory Committee—Knowledgeable in the fields of pharmaceutical compounding, pharmaceutical manufacturing pharmacy, medicine, and other related specialties.	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—Nonvoting .....	Immediately.

TABLE 2—COMMITTEE DESCRIPTIONS, TYPE OF CONSUMER REPRESENTATIVE VACANCY, AND APPROXIMATE DATE NEEDED—Continued

Committee/panel/area of expertise needed	Type of vacancy	Approximate date needed
Gastroenterology and Urology Devices Panel—Gastroenterologists, urologists and nephrologists.	1—Nonvoting .....	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—Nonvoting .....	Immediately.
Ear, Nose and Throat Devices Panel—Experts in otology, neurology, and audiology.	1—Nonvoting .....	Immediately.
Medical Devices Dispute Resolution—Experts with broad, cross-cutting scientific, clinical, analytical, or mediation skills.	1—Nonvoting .....	Immediately.
Microbiology Devices Panel—Clinicians with 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—Nonvoting .....	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—Nonvoting .....	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. Bone, Reproductive, and Urological 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.

*C. 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.

*D. 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.

*E. Pharmacy Compounding Advisory Committee*

Provides advice on scientific, technical, and medical issues

concerning drug compounding by pharmacists and licensed practitioners.

*F. 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, 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 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 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**), 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: November 13, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### **Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: MCH Jurisdictional Survey Instrument for the Title V MCH Block Grant Program, OMB No. 0906-XXXX, New**

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, or any other aspect of the ICR related to the Maternal and Child Health (MCH) Jurisdictional Survey that is to be

administered in the U.S. territories and jurisdictions (excluding the District of Columbia) for purposes of collecting information related to the well-being of all mothers, children, and their families.

**DATES:** Comments on this ICR must be received no later than January 15, 2019.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443-1984.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the information request collection title for reference.

*Information Collection Request Title:* MCH Jurisdictional Survey Instrument for the Title V MCH Block Grant Program, OMB No. 0906-XXXX New.

*Abstract:* The purpose of the Title V MCH Block Grant is to improve the health of the nation's mothers, infants, children, including children with special health care needs, and their families by creating federal/state partnerships that provide each state/jurisdiction with needed flexibility to respond to its individual MCH population needs. Unique to the MCH Block Grant is a commitment to performance accountability, while assuring state flexibility. Utilizing a three-tiered national performance measure framework, which includes National Outcome Measures (NOMs), National Performance Measures (NPMs), and Evidence-Based and Evidence-Informed Strategy Measures, State Title V programs report annually on their performance relative to the selected national performance and outcome measures. Such reporting enables the state and federal program offices to assess the progress achieved in key MCH priority areas and to document Title V program accomplishments.

By legislation (Section 505(a) of Title V of the Social Security Act), the MCH Block Grant Application/Annual Report must be developed by, or in consultation with, the State MCH Health agency. In establishing state reporting requirements, HRSA's Maternal and Child Health Bureau (MCHB) considers the availability of national data from other federal agencies. Data for the national performance and outcome measures are pre-populated for states in