

COVID-19 pandemic and rapidly evolving COVID-19 vaccine development and regulatory processes. The Secretary of Health and Human Services has determined that COVID-19 is a Public Health Emergency. A notice of this ACIP meeting has also been posted on CDC's ACIP website at: <http://www.cdc.gov/vaccines/acip/index.html>. In addition, CDC has sent notice of this ACIP meeting by email to those who subscribe to receive email updates about the ACIP.

Purpose: The committee is charged with advising the Director, CDC, on the use of immunizing agents. In addition, under 42 U.S.C. 1396s, the committee is mandated to establish and periodically review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children program, along with schedules regarding dosing interval, dosage, and contraindications to administration of vaccines. Further, under provisions of the Affordable Care Act, section 2713 of the Public Health Service Act, immunization recommendations of the ACIP that have been approved by the CDC Director and appear on CDC immunization schedules must be covered by applicable health plans.

Matters To Be Considered: The agenda will include discussions on Janssen (Johnson & Johnson) COVID-19 vaccine safety. A recommendation vote is scheduled. Agenda items are subject to change as priorities dictate. For more information on the meeting agenda visit <https://www.cdc.gov/vaccines/acip/meetings/meetings-info.html>.

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on <https://www.regulations.gov>. Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail

campaign. CDC will carefully consider all comments submitted into the docket.

Written Public Comment: Written comments must be received on or before December 23, 2021.

Oral Public Comment: This meeting will include time for members of the public to make an oral comment. Oral public comment will occur before any scheduled votes including all votes relevant to the ACIP's Affordable Care Act and Vaccines for Children Program roles. Priority will be given to individuals who submit a request to make an oral public comment before the meeting according to the procedures below.

Procedure for Oral Public Comment: All persons interested in making an oral public comment at the December 16, 2021 ACIP meeting must submit a request at <http://www.cdc.gov/vaccines/acip/meetings/> no later than 8 a.m., EST, December 16, 2021, according to the instructions provided.

If the number of persons requesting to speak is greater than can be reasonably accommodated during the scheduled time, CDC will conduct a lottery to determine the speakers for the scheduled public comment session. CDC staff will notify individuals regarding their request to speak by email by December 16, 2021. To accommodate the significant interest in participation in the oral public comment session of ACIP meetings, each speaker will be limited to 3 minutes, and each speaker may only speak once per meeting.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-3926]

Request for Nominations for Voting Members on Public Advisory Panels of the Medical Devices Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on the Medical Devices Advisory Committee (MDAC) device panels in the Center for Devices and Radiological Health. This annual notice is also in accordance with the 21st Century Cures Act, which requires the Secretary of Health and Human Services (the Secretary) to provide an annual opportunity for patients, representatives of patients, and sponsors of medical devices that may be specifically the subject of a review by a classification panel to provide recommendations for individuals with appropriate expertise to fill voting member positions on classification panels. 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: Nominations received on or before February 15, 2022, will be given first consideration for membership on the Panels of the MDAC. Nominations received after February 15, 2022, will be considered for nomination to the committee as later vacancies occur.

ADDRESSES: All nominations for membership should be submitted electronically by logging into the FDA Advisory Nomination Portal at <https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm> or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993-0002. Information about becoming a member on 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: Regarding all nomination questions for membership, contact the following persons listed in table 1:

TABLE 1—PRIMARY CONTACT AND COMMITTEE OR PANEL

Primary contact person	Committee or panel
Joannie Adams-White, Office of the Center Director, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5561, Silver Spring, MD 20993, 301–796–5421, Joannie.Adams-White@fda.hhs.gov .	Medical Devices Dispute Resolution Panel.
James P. Swink, Office of Management, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66 Rm. 5211, Silver Spring, MD 20993, 301–796–6313, James.Swink@fda.hhs.gov .	Circulatory System Devices Panel, Immunology Devices Panel, Microbiology Devices Panel, Ophthalmic Devices Panel.
Akinola Awojope, Office of Management, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5216, Silver Spring, MD 20993, 301–636–0512, Akinola.Awojope@fda.hhs.gov .	Dental Products Panel, Neurological Devices Panel, Obstetrics and Gynecology Devices Panel Orthopaedic and Rehabilitation Devices Panel.
Jarrod Collier, Office of Management, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5216, Silver Spring, MD 20993, 301–796–6875, Jarrod.Collier@fda.hhs.gov .	Ear, Nose and Throat Devices Panel, General Hospital and Personal Use Devices Panel, Hematology and Pathology Devices Panel, Molecular and Clinical Genetics Panel, Radiological Devices Panel.
Candace Nalls, Office of Management, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5214, Silver Spring, MD 20993, 301–636–0510, Candace.Nalls@fda.hhs.gov .	Anesthesiology and Respiratory Therapy Devices Panel, Clinical Chemistry and Clinical Toxicology Devices Panel, General and Plastic Surgery Devices Panel.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for voting members for vacancies listed in table 2:

TABLE 2— EXPERTISE NEEDED, VACANCIES, AND APPROXIMATE DATE NEEDED

Expertise needed	Vacancies	Approximate date needed
<i>Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee</i> —Anesthesiologists, pulmonary medicine specialists, or other experts who have specialized interests in ventilator support, sleep medicine, pharmacology, physiology, or the effects and complications of anesthesia. FDA is also seeking applicants with pediatric expertise in these areas.	3	Immediately.
<i>Circulatory System Devices Panel of the Medical Devices Advisory Committee</i> —Interventional cardiologists, electrophysiologists, invasive (vascular) radiologists, vascular and cardiothoracic surgeons, and cardiologists with special interest in congestive heart failure.	1 1	Immediately. July 1, 2022.
<i>Clinical Chemistry and Clinical Toxicology Panel of the Medical Devices Advisory Committee</i> —Doctors of medicine or philosophy with experience in clinical chemistry (e.g., cardiac markers), clinical toxicology, clinical pathology, clinical laboratory medicine, and endocrinology.	1	March 1, 2022.
<i>Dental Products Panel of the Medical Devices Advisory Committee</i> —Dentists, engineers, and scientists who have expertise in the areas of dental implants, dental materials, oral and maxillofacial surgery, endodontics, periodontology, tissue engineering, snoring/sleep therapy, and dental anatomy.	3	Immediately.
<i>Ear, Nose, and Throat Devices Panel of the Medical Devices Advisory Committee</i> —Otolologists, neurotologists, and audiologists.	4	Immediately.
<i>General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee</i> —Surgeons (general, plastic, reconstructive, pediatric, thoracic, abdominal, pelvic, and endoscopic); dermatologists; experts in biomaterials, lasers, wound healing, and quality of life; and biostatisticians.	4	Immediately.
<i>General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee</i> —Internists, pediatricians, neonatologists, endocrinologists, gerontologists, nurses, biomedical engineers, human factors experts, or microbiologists/infection control practitioners or experts.	2 1	Immediately. January 1, 2022.
<i>Hematology and Pathology Devices Panel of the Medical Devices Advisory Committee</i> —Hematologists (benign and/or malignant hematology), hematopathologists (general and special hematology, coagulation and hemostasis, and hematological oncology), gynecologists with special interests in gynecological oncology, cytopathologists, and molecular pathologists with special interests in development of predictive and prognostic biomarkers, molecular oncology, cancer screening, cancer risk, digital pathology, whole slide imaging; devices utilizing artificial intelligence/machine learning.	3 1	Immediately. March 1, 2022.
<i>Immunology Devices Panel of the Medical Devices Advisory Committee</i> —Persons with experience in medical, surgical, or clinical oncology, internal medicine, clinical immunology, allergy, molecular diagnostics, or clinical laboratory medicine.	7	Immediately.
<i>Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee</i> —Experts with cross-cutting scientific, clinical, analytical or mediation skills.	1	October 1, 2022.

TABLE 2— EXPERTISE NEEDED, VACANCIES, AND APPROXIMATE DATE NEEDED—Continued

Expertise needed	Vacancies	Approximate date needed
<i>Microbiology Devices Panel of the Medical Devices Advisory Committee</i> —Infectious disease clinicians (e.g., pulmonary disease specialists, sexually transmitted disease specialists, pediatric ID specialists, tropical diseases specialists) and clinical microbiologists experienced in emerging infectious diseases; clinical microbiology laboratory directors; molecular biologists with experience in in vitro diagnostic device testing; virologists; hepatologists; or clinical oncologists experienced with tumor resistance and susceptibility.	5 2	Immediately. March 1, 2022.
<i>Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee</i> —Experts in human genetics, molecular diagnostics, and in the clinical management of patients with genetic disorders, and (e.g., pediatricians, obstetricians, neonatologists). Individuals with training in inborn errors of metabolism, biochemical and/or molecular genetics, population genetics, epidemiology and related statistical training, bioinformatics, computational genetics/genomics, variant classification, cancer genetics/genomics, molecular oncology, radiation biology, and clinical molecular genetics testing, (e.g., sequencing, whole exome sequencing, whole genome sequencing, non-invasive prenatal testing, cancer screening, circulating cell free/circulating tumor nucleic acid testing, digital PCR, genotyping, array CGH, etc.). Individuals with experience in genetics counseling, medical ethics are also desired, and individuals with experience in ancillary fields of study will be considered.	2 2	Immediately. June 1, 2022.
<i>Neurological Devices Panel of the Medical Devices Advisory Committee</i> —Neurosurgeons (cerebrovascular and pediatric), neurologists (stroke, pediatric, pain management, and movement disorders), interventional neuroradiologists, psychiatrists, and biostatisticians.	2	Immediately.
<i>Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee</i> —Experts in 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; biostatisticians and engineers with experience in obstetrics/gynecology devices; urogynecologists; experts in breast care; experts in gynecology in the older patient; experts in diagnostic (optical) spectroscopy; experts in midwifery; labor and delivery nursing.	4 1	Immediately. February 1, 2022.
<i>Ophthalmic Devices Panel of the Medical Devices Advisory Committee</i> —Ophthalmologists specializing in cataract and refractive surgery and vitreo-retinal surgery, in addition to vision scientists, optometrists, and biostatisticians practiced in ophthalmic clinical trials.	4	Immediately.
<i>Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee</i> —Orthopaedic surgeons (joint, spine, trauma, reconstruction, sports medicine, hand, foot and ankle, and pediatric orthopaedic surgeons); rheumatologists; engineers (biomedical, biomaterials, and biomechanical); experts in rehabilitation medicine, and musculoskeletal engineering; radiologists specializing musculoskeletal imaging and analyses and biostatisticians.	2 2	Immediately. September 1, 2022.
<i>Radiological Devices Panel of the Medical Devices Advisory Committee</i> —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.	3 4	Immediately. February 1, 2022.

I. General Description of the Committee Duties

The MDAC reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation. The panels engage in many activities to fulfill the functions the Federal Food, Drug, and Cosmetic Act (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, performs the following duties: (1) Advises the Commissioner regarding recommended 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 FD&C 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 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 Voting Members

The MDAC with its 18 panels shall consist of a maximum of 159 standing members. Members are selected by the Commissioner or designee from among authorities in clinical and administrative medicine, engineering, biological and physical sciences, and other related professions. Almost all non-Federal members of this committee serve as Special Government Employees. A maximum of 122 members shall be standing voting

members and 37 shall be nonvoting members who serve as representatives of consumer interests and of industry interests. FDA is publishing separate documents announcing the Request for Nominations Notification for Nonvoting Representatives on certain panels of the MDAC. Persons nominated for membership on the panels should have adequately diversified experience appropriate to the work of the panel in such fields as clinical and administrative medicine, engineering, biological and physical sciences, statistics, and other related professions. The nature of specialized training and experience necessary to qualify the nominee as an expert suitable for appointment may include experience in medical practice, teaching, and/or research relevant to the field of activity of the panel. The current needs for each panel are listed in table 2. Members will be invited to serve for terms of up to 4 years.

III. Nomination Procedures

Any interested person may nominate one or more qualified individuals for membership on one or more of the advisory panels. Self-nominations are also accepted. Nominations must include a current, complete résumé or curriculum vitae for each nominee, including current business address, telephone number, and email address if available and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Nomination Portal (see **ADDRESSES**). Nominations must also specify the advisory panel(s) for which the nominee is recommended. 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 related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest.

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: December 13, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–27376 Filed 12–16–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1425]

Agency Information Collection Activities; Proposed Collection; Comment Request; Mitigation Strategies To Protect Food Against Intentional Adulteration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on collections of information describing mitigation strategies to protect food against intentional adulteration.

DATES: Submit either electronic or written comments on the collection of information by February 15, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 15, 2022. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 15, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://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 <https://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):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, 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–2013–N–1425 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Mitigation Strategies to Protect Food Against Intentional Adulteration.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- **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 <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly