IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
''De Novo Classification Process (Evaluation of Automatic Class III Designation)''.	De Novo classification process	0910–0844
''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff''.	Q-submissions	0910–0756
801 and 809	Medical Device Labeling Regulations	0910–0485
822	Postmarket Surveillance of Medical Devices	0910–0449

Dated: August 27, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–18802 Filed 8–29–19; 8:45 am]

BILLING CODE 4164–01–P

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 or Committees; Device Good Manufacturing Practice Advisory Committee and 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 Device Good Manufacturing Practice Advisory Committee (DGMPAC) and 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 October 29, 2019 will be given first consideration for membership on the DGMPAC and Panels of the MDAC. Nominations received after October 29, 2019 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: *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. 5519, Silver Spring, MD 20993, 301–796–5421, email: *Joannie.Adams-White@fda.hhs.gov*.	Medical Devices Dispute Resolution Panel.
LCDR Sara Anderson, Office of Management, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G616, Silver Spring, MD 20993, 301–796–7047, email: *Sara.Anderson@fda.hhs.gov*.	Dental Products Panel, Hematology and Pathology Devices Panel, Orthopaedic and Rehabilitation Devices Panel, Radiological Devices Panel.
Aden S. Asefa, Office of Management, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G642, Silver Spring, MD 20993, 301–796–0400, email: *Aden.Asefa@fda.hhs.gov*.	Immunology Devices Panel, Microbiology Devices Panel, Neurological Devices Panel, Ophthalmic Devices Panel, DGMPAC.
LCDR Patricio G. Garcia, Office of Management, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G610, Silver Spring, MD 20993, 301–796–6875, email: *Patricio.Garcia@fda.hhs.gov*.	Clinical Chemistry and Clinical Toxicology Devices Panel, Gastroenterology and Urology Devices Panel, General and Plastic Surgery Devices Panel, Obstetrics and Gynecology Devices Panel.

TABLE 1—PRIMARY CONTACT AND COMMITTEE OR PANEL—Continued

Primary contact person	Committee or panel
Evella F. Washington, Office of Management, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G640, Silver Spring, MD 20993 301–796–6683, email: *Evella.Washington@fda.hhs.gov*.	Anesthesiology and Respiratory Therapy Devices Panel, Circulatory System Devices Panel, General Hospital and Personal Use Devices Panel, Molecular and Clinical Genetics 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
DGMPAC—Experts in medical device quality management system requirements/current Good Manufacturing Practices, with experience in both 21 CFR part 820 and International Organization for Standardization (ISO) 13485, are needed to provide cross-cutting scientific or clinical expertise concerning the particular issue in dispute. Vacancies include a representative of the interests of the general public, government, and representatives of the interests of physicians and other health professionals.	4 1 2 1	Immediately. General Public Representative. Health Professional Representatives. Government Representative.
Anesthesiology and Respiratory Therapy Devices Panel of the MDAC—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.	1	12/1/2019.
Circulatory System Devices Panel of the MDAC—Interventional cardiologists, electrophysiologists, invasive (vascular) radiologists, vascular and cardiothoracic surgeons, and cardiologists with special interest in congestive heart failure.	1	Immediately.
Clinical Chemistry and Clinical Toxicology Panel of the MDAC—Doctors of Medicine or Philosophy with experience in clinical chemistry (*e.g.,* cardiac markers), clinical toxicology, clinical pathology, clinical laboratory medicine, and endocrinology.	1 1	Immediately. 3/1/2020.
Dental Products Panel of the MDAC—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.	1 1	Immediately. 11/1/2019.
Gastroenterology and Urology Devices Panel of the MDAC—Gastroenterologists, urologists, and nephrologists.	2	1/1/2020.
General and Plastic Surgery Devices Panel of the MDAC—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.
General Hospital and Personal Use Devices Panel of the MDAC—Internists, pediatricians, neonatologists, endocrinologists, gerontologists, nurses, biomedical engineers, human factors experts, or microbiologists/infection control practitioners or experts.	1	1/1/2020.
Hematology and Pathology Devices Panel of the MDAC—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.	2	3/1/2020.
Immunology Devices Panel of the MDAC—Persons with experience in medical, surgical, or clinical oncology, internal medicine, clinical immunology, allergy, molecular diagnostics, or clinical laboratory medicine.	3 2	Immediately. 3/1/2020.
Medical Devices Dispute Resolution Panel of the MDAC—experts with cross-cutting scientific, clinical, analytical or mediation skills.	1	10/1/2020.
Microbiology Devices Panel of the MDAC—Infectious disease (ID) clinicians (*e.g.,* pulmonary disease specialists, sexually transmitted disease specialists, pediatric ID specialists, tropical diseases specialists) and clinical microbiologists experienced in emerging IDs; 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.	2	3/1/2020.

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

Expertise needed	Vacancies	Approximate date needed
Molecular and Clinical Genetics Panel of the MDAC—Experts in human genetics, molecular diagnostics, and in the clinical management of patients with genetic disorders, *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 polymerase chain reaction, genotyping, array comparative genomic hybridization, etc.). Individuals with experience in genetics counseling and medical ethics are also desired, and individuals with experience in ancillary fields of study will be considered.	2 1	Immediately. 6/1/2020.
Neurological Devices Panel of the MDAC—Neurosurgeons (cerebrovascular and pediatric), neurologists (stroke, pediatric, pain management, and movement disorders), interventional neuroradiologists, psychiatrists, and biostatisticians.	1 2	Immediately. 12/1/2019.
Obstetrics and Gynecology Devices Panel of the MDAC—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.	2 1	Immediately. 2/1/2020.
Ophthalmic Devices Panel of the MDAC—Ophthalmologists specializing in cataract and refractive surgery and vitreo-retinal surgery, in addition to vision scientists, optometrists, and biostatisticians practiced in ophthalmic clinical trials.	3	Immediately.
Orthopaedic and Rehabilitation Devices Panel of the MDAC—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. 9/1/2020.
Radiological Devices Panel of the MDAC—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	2/1/2020.

I. General Description of the Committees' Duties

A. DGMPAC

The DGMPAC reviews regulations proposed for promulgation regarding good manufacturing practices governing the methods used in, and the facilities and controls used for, the manufacture, packing, storage and installation of devices, and makes recommendations to the Commissioner of Food and Drugs (the Commissioner) regarding the feasibility and reasonableness of those proposed regulations. The DGMPAC also advises the Commissioner on any petition submitted by a manufacturer for an exemption or variance from good manufacturing practice regulations that is referred to the committee.

B. MDAC

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

A. DGMPAC

The DGMPAC consists of a core of nine members including the Chair. Members and the Chair are selected by the Secretary. Persons nominated for membership as a health professional or officer or employee of any Federal, State, or local government should have knowledge of or expertise in any one or more of the following areas: Quality assurance concerning the design, manufacture, and use of medical devices in accordance with 21 CFR part 820 and/or ISO 13485. To be eligible for selection as a representative of the general public, nominees should possess appropriate qualifications to understand and contribute to the DGMPAC's work. Three of the members shall be officers or employees of any State or local government or of the Federal Government; two shall be representative of the interests of the device manufacturing industry; two shall be representatives of the interests of physicians and other health professionals; and two shall be representatives of the interests of the general public. Almost all non-Federal members of this committee serve as Special Government Employees. Members are invited to serve for overlapping terms of 4 years. The current needs for the DGMPAC are listed in table 2.

B. Panels of the MDAC

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 Non-Voting 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 or advisory committees. 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 committee(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: August 26, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–18766 Filed 8–29–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–E–0189]

Determination of Regulatory Review Period for Purposes of Patent Extension; MACI

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for MACI and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by October 29, 2019. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by February 26, 2020. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

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 October 29, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 29, 2019. 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