DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0008]

Request for Nominations for Voting Members for the Patient Engagement Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is requesting nominations for voting members, excluding consumer and industry representatives, to serve on the Patient Engagement Advisory Committee (the Committee) in the Center for Devices and Radiological Health. Nominations will be accepted for upcoming vacancies effective with this notice. FDA seeks to include the views of members of all gender groups, 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 May 1, 2023, will be given first consideration for membership on the Committee. Nominations received after May 1, 2023, 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 Committee Membership Nomination Portal (*https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm*) and selecting Academician/Practitioner from the dropdown menu (regardless of whether Academician/Practitioner accurately describes the nominee), 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: Letise Williams, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5407, Silver Spring, MD 20993–0002, 301–796–8398, email: *Letise.Williams@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for voting members to fill upcoming vacancies on the Patient Engagement Advisory Committee. This notice does not include consumer and industry representative nominations. The Agency will publish two separate notices announcing the vacancy of a representative of consumer interests and vacancy of representatives of interests of the device manufacturing industry.

I. General Description of the Committee Duties

The Committee provides relevant skills and perspectives to improve communication of benefits, risks and clinical outcomes, and increase integration of patient perspectives into the regulatory process for medical devices. It performs its duties by identifying new approaches, promoting innovation, recognizing unforeseen risks or barriers, and identifying unintended consequences that could result from FDA policy. The Committee provides advice on complex scientific issues related to medical devices, the regulation of devices, and their use by patients. Agency guidance and policies, clinical trial or registry design, patient preference study design, benefit-risk determinations, device labeling, unmet clinical needs, available alternatives, patient-reported outcomes, device-related quality of life measure or health status issues are among the topics that may be considered by the Committee.

II. Criteria for Voting Members

The Committee consists of a core of nine voting members, including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities who are knowledgeable in areas such as clinical research, patient or caregiver experience, healthcare needs of patient groups in the United States, or are experienced in the work of patient and health professional organizations, scientific methodologies for patient-reported outcomes and other clinical outcome assessments, scientific methodologies for eliciting patient preferences, and strategies for communicating benefits, risks, and clinical outcomes to patients and research subjects, as well as other relevant areas. Members will be invited to serve for overlapping terms of up to 4 years. Prospective members should also have an understanding of the broad spectrum of patients in a particular disease area. Almost all non-Federal members of this Committee serve as Special Government Employees, with the exception of the representatives from Industry.

III. Nomination Procedures

Any interested person may nominate one or more qualified individuals for membership on the Committee. Self-nominations are also accepted. Nominations must include a cover letter; a current, complete résumé or curriculum vitae for each nominee, including current business and/or home 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 specify the advisory committee 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 conflicts 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: February 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–04169 Filed 2–28–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0008]

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 the 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 individuals on its advisory committees regardless of their gender identification, religious affiliation, racial and ethnic identification, or disability status and, therefore, encourages nominations of appropriately qualified candidates from all 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 April 17, 2023, for vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA (see **ADDRESSES**) by April 17, 2023. Nominations will be accepted for current vacancies and for those that will or may occur through December 31, 2023.

ADDRESSES: All statements of interest from consumer organizations interested in participating in the selection process should be submitted electronically to *ACOMSSubmissions@fda.hhs.gov* or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5122, Silver Spring, MD 20993–0002.

Consumer representative nominations should be submitted electronically by logging into the FDA Advisory Committee Membership Nomination Portal: *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm,* or by mail to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, Rm. 5122, Silver Spring, MD 20993–0002. 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, 301–796–8220, *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
Rakesh Raghuwanshi, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3309, Silver Spring, MD 20993–0002, 301–796–4769, *Rakesh.Raghuwanshi@fda.hhs.gov*.	FDA Science Board Advisory Committee.
Prabhakara Atreya, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 1226, Silver Spring, MD 20993–0002, 240–402–8006, *Prabhakara.Altreya@fda.hhs.gov*.	Allergenic Products Advisory Committee.
Moon Hee Choi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2434, Silver Spring, MD 20993–0002, 301–796–2894, *MoonHee.Choi@fda.hhs.gov*.	Anesthetic and Analgesic Drug Products Advisory Committee, Non-Prescription Drugs Advisory Committee.
She-Chia Jankowski, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31 Rm. 2438, Silver Spring, MD 20993–0002, 240–402–5343, *She-Chia.Jankowski@fda.hhs.gov*.	Antimicrobial Drugs Advisory Committee.
Jessica Seo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2412, Silver Spring, MD 20993–0002, 301–796–7699, *Jessica.Seo@fda.hhs.gov*.	Peripheral and Central Nervous System Drugs Advisory Committee.
Yvette Waples, Center for Drug Evaluation Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2438, Silver Spring, MD 20993–0002, 301–837–7126, *Yvette.Waples@fda.hhs.gov*.	Cardiovascular and Renal Drugs Advisory Committee, Medical Imaging Drugs Advisory Committee.
LaToya Bonner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2428, Silver Spring, MD 20993–0002, 301–796–2855, *LaToya.Bonner@fda.hhs.gov*.	Endocrinologic and Metabolic Drugs Advisory Committee.
Takyiah Stevenson, Center for Drug Evaluation Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2406, Silver Spring, MD 20993–0002, 240–402–2507, *Takyiah.Stevenson@fda.hhs.gov*.	Pharmacy Compounding Advisory Committee.
Joyce Frimpong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2426, Silver Spring, MD 20993–0002, 301–796–7973, *Joyce.Frimpong@fda.hhs.gov*.	Psychopharmacologic Drugs Advisory Committee.
Candace Nalls, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5211, Silver Spring, MD 20993–0002, 301–636–0510, *Candace.Nalls@fda.hhs.gov*.	Anesthesiology and Respiratory Therapy Devices Panel; Clinical Chemistry and Clinical Toxicology Devices Panel; Ear, Nose and Throat Devices Panel; Gastroenterology-Urology Devices Panel; General and Plastic Surgery Devices Panel.
James Swink, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5211, Silver Spring, MD 20993–0002, 301–796–6313, *James.Swink@fda.hhs.gov*.	Circulatory System Devices Panel; Microbiology Devices Panel.
Akinola Awojope, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5216, Silver Spring, MD 20993–0002, 301–636–0512, *Akinola.Awojope@fda.hhs.gov*.	Dental Products Panel; Orthopaedic and Rehabilitation Devices Panel.
Jarrod Collier, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5214, Silver Spring, MD 20993–0002, 240–672–5763, *Jarrod.Collier@fda.hhs.gov*.	General Hospital and Personal Use Devices Panel; Hematology and Pathology Devices Panel; Molecular and Clinical Genetics Panel; Ophthalmic Devices Panel; Radiological Devices Panel.

TABLE 1—ADVISORY COMMITTEE CONTACTS—Continued

Contact person	Committee/panel
James Swink, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5211, Silver Spring, MD 20993–0002, 301–796–6313, *James.Swink@fda.hhs.gov*.	National Mammography Quality Assurance Advisory Committee.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for voting and/or nonvoting consumer representatives for the vacancies listed in table 2:

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

Committee/panel/areas of expertise needed	Type of vacancy	Approximate date needed
FDA Science Board Advisory Committee—The Science Board provides advice to the Commissioner of Food and Drugs Administration (Commissioner) and other appropriate officials on specific complex scientific and technical issues important to FDA and its mission, including emerging issues within the scientific community. Additionally, the Science Board provides advice that supports the Agency in keeping pace with technical and scientific developments, including in regulatory science; and input into the Agency's research agenda, and on upgrading its scientific and research facilities and training opportunities. It also provides, where requested, expert review of Agency-sponsored intramural and extramural scientific research programs.	1—Voting	Immediately.
Allergenic Products Advisory Committee—Knowledgeable in the fields of allergy, immunology, pediatrics, internal medicine, biochemistry, and related specialties.	1—Voting	Immediately.
Anesthetic and Analgesic Drug Products Advisory Committee—Knowledgeable in the fields of anesthesiology, surgery, epidemiology or statistics, and related specialties.	1—Voting	April 1, 2023.
Non-Prescription Drugs Advisory Committee—Knowledgeable in the fields of internal medicine, family practice, clinical toxicology, clinical pharmacology, pharmacy, dentistry, and related specialties.	1—Voting	Immediately.
Antimicrobial Drugs Advisory Committee—Knowledgeable in the fields of infectious disease, internal medicine, microbiology, pediatrics, epidemiology or statistics, and related specialties.	1—Voting	May 1, 2023.
Peripheral and Central Nervous Systems Drugs Advisory Committee—Knowledgeable in the fields of neurology, neuropharmacology, neuropathology, otolaryngology, epidemiology or statistics, and related specialties.	1—Voting	February 1, 2023.
Cardiovascular and Renal Drugs Advisory Committee—Knowledgeable in the fields of cardiology, hypertension, arrhythmia, angina, congestive heart failure, diuresis, and biostatistics.	1—Voting	July 1, 2023.
Medical Imaging Drugs Advisory Committee—Knowledgeable in the fields of nuclear medicine, radiology, epidemiology, statistics, and related specialties.	1—Voting	Immediately.
Endocrinologic and Metabolic Drugs Advisory Committee—Knowledgeable in the fields of endocrinology, metabolism, epidemiology or 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	October 1, 2023.
Psychopharmacologic Drugs Advisory Committee—Knowledgeable in the fields of psychopharmacology, psychiatry, epidemiology or statistics, and related specialties.	1—Voting	Immediately.
Anesthesiology and Respiratory Therapy Devices Panel—Anesthesiologists, pulmonary medicine specialists, or other experts who have specialized interests in ventilator support, pharmacology, physiology, or the effects and complications of anesthesia.	1—Nonvoting	Immediately.
Clinical Chemistry and Clinical Toxicology Devices Panel—Doctor 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.
Ear, Nose and Throat Devices Panel—Otologists, neurotologists, audiologists	1—Nonvoting	November 1, 2023.
Gastroenterology-Urology Devices Panel—Gastroenterologists, urologists, and nephrologists	1—Nonvoting	Immediately.
General and Plastic Surgery Devices Panel—Surgeons (general, plastic, reconstructive, pediatric, thoracic, abdominal, pelvic and endoscopic); dermatologists; experts in biomaterials, lasers, wound healing, and quality of life; and biostatisticians.	1—Nonvoting	Immediately.
Circulatory System Devices Panel—Interventional cardiologists, electrophysiologists, invasive (vascular) radiologists, vascular and cardiothoracic surgeons, and cardiologists with special interest in congestive heart failure.	1—Nonvoting	Immediately.
Microbiology Devices Panel—Clinicians with an 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, and 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.
Dental Products Panel—Dentists, engineers and scientists who have expertise in the areas of dental implants, dental materials, periodontology, tissue engineering, and dental anatomy.	1—Nonvoting	Immediately.

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

Committee/panel/areas of expertise needed	Type of vacancy	Approximate date needed
Obstetrics and Gynecology Devices Panel—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; experts in labor and delivery nursing.	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.
General Hospital and Personal Use Devices Panel—Internists, pediatricians, neonatologists, endocrinologists, gerontologists, nurses, biomedical engineers, or microbiologists/infection control practitioners or experts.	1—Nonvoting	Immediately.
Hematology and Pathology Devices Panel—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 biomarkers.	1—Nonvoting	Immediately.
Molecular and Clinical Genetics Devices Panel—Experts in human genetics and in the clinical management of patients with genetic disorders, e.g., pediatricians, obstetricians, neonatologists. The Agency is also interested in considering candidates with training in inborn errors of metabolism, biochemical and/or molecular genetics, population genetics, epidemiology, and related statistical training. Additionally, individuals with experience in genetic counseling, medical ethics, as well as ancillary fields of study will be considered.	1—Nonvoting	Immediately.
Ophthalmic Devices Panel—Ophthalmists with expertise in corneal-external disease, vitreo-retinal surgery, glaucoma, ocular immunology, ocular pathology; optometrists; vision scientists; and ophthalmic professionals with expertise in clinical trial design, quality of life assessment, electrophysiology, low vision rehabilitation, and biostatistics.	1—Nonvoting	Immediately.
Radiological 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.
National Mammography Quality Assurance Advisory Committee—Physician, practitioner, or other health professional whose clinical practice, research specialization, or professional expertise includes a significant focus on mammography.	3—Voting	Immediately.

I. Functions and General Description of the Committee Duties

A. FDA Science Board Advisory Committee

The Science Board Advisory Committee (Science Board) provides advice to the Commissioner of Food and Drugs (Commissioner) and other appropriate officials on specific complex scientific and technical issues important to FDA and its mission, including emerging issues within the scientific community. Additionally, the Science Board provides advice that supports the Agency in keeping pace with technical and scientific developments, including in regulatory science, and input into the Agency's research agenda and on upgrading its scientific and research facilities and training opportunities. It also provides, where requested, expert review of Agency-sponsored intramural and extramural scientific research programs.

B. Allergenic Products Advisory Committee

Reviews and evaluates available data concerning the safety, effectiveness, and adequacy of labeling of marketed and investigational allergenic biological products or materials that are administered to humans for the diagnosis, prevention, or treatment of allergies and allergic disease, and makes appropriate recommendations to the Commissioner regarding the affirmation or revocation of biological product licenses; on the safety, effectiveness, and labeling of the products; on clinical and laboratory studies of such products; on amendments or revisions to regulations governing the manufacture, testing, and licensing of allergenic biological products; and on the quality and relevance of FDA's research programs.

C. Anesthetic and Analgesic Drug Products Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in anesthesiology and surgery.

D. Nonprescription Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products, or any other FDA-regulated product, for use in the treatment of a broad spectrum of human symptoms and diseases, and advises the Commissioner either on the promulgation of monographs establishing conditions under which these drugs are generally recognized as safe and effective and not misbranded or on the approval of new drug applications for such drugs. The Committee serves as a forum for the exchange of views regarding the prescription and nonprescription status, including switches from one status to another, of these various drug products and combinations thereof. The Committee may also conduct peer review of Agency-sponsored intramural

and extramural scientific biomedical programs in support of FDA's mission and regulatory responsibilities.

E. Antimicrobial 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 infectious diseases and disorders.

F. Arthritis Advisory Committee

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of arthritis, rheumatism, and related diseases.

G. Peripheral and Central Nervous System Drugs Advisory Committee

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of neurologic diseases.

H. 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.

I. Medical Imaging Drugs 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.

J. Endocrinologic and Metabolic Drugs Advisory Committee

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of endocrine and metabolic disorders.

K. Pharmacy Compounding Advisory Committee

Provides advice on scientific, technical, and medical issues concerning drug compounding by pharmacists and licensed practitioners.

L. Psychopharmacologic Drugs Advisory Committee

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the practice of psychiatry and related fields.

M. Medical Devices Advisory Committee Panels

The Medical Devices Advisory Committee has established certain panels to review and evaluate data on the safety and effectiveness of marketed and investigational devices and make recommendations for their regulation. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area: (1) advises on the classification or reclassification of devices into one of three regulatory categories and advises on any possible risks to health associated with the use of devices; (2) advises on formulation of product development protocols; (3) reviews premarket approval applications for medical devices; (4) reviews guidelines and guidance documents; (5) recommends exemption of certain devices from the application of portions of the Federal Food, Drug, and Cosmetic Act; (6) advises on the necessity to ban a device; and (7) 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 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.

N. National Mammography Quality Assurance Advisory Committee

Advises the Agency on the development of appropriate quality standards and regulations for mammography facilities; standards and regulations for bodies accrediting mammography facilities under this program; regulations with respect to sanctions; procedures for monitoring compliance with standards; establishing a mechanism to investigate consumer complaints; and reporting new developments concerning breast imaging that should be considered in the oversight of mammography facilities. The Committee also advises on determining whether there exists a shortage of mammography facilities in rural and health professional shortage areas and determining the effects of personnel on access to the services of such facilities in such areas; determining whether there will be a sufficient number of medical physicists after October 1, 1999; and determining the costs and benefits of compliance with these requirements.

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 45 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 résumé. 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 of 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. After 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 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–04170 Filed 2–28–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2018–E–4422, FDA–2018–E–4827, and FDA–2018–E–4427]

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

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 VYZULTA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications 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 drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by May 1, 2023. 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 August 28, 2023. 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. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 1, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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 Nos. FDA–2018–E–4422, FDA–2018–E–4827, and FDA–2018–E–4427 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; VYZULTA.'' 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