

provide information to a third party. The PRA requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, ACL is publishing a notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, ACL invites comments on our burden estimates or any other aspect of this collection of information, including:

(1) whether the proposed collection of information is necessary for the proper performance of ACL's functions, including whether the information will have practical utility;

(2) the accuracy of ACL's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used to determine burden estimates;

(3) ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

The Administration for Community Living (ACL) is currently engaged in an effort to better understand how ACL programs support grantees to apply CLAS Standards and related diversity, equity, and inclusion (DEI) priorities in their programming. While the previous

research effort focused on the perspective of ACL staff and national associations and advocacy organizations; this new IC will focus on a broader scope of respondents. In this IC, ACL will be reaching out to ACL-funded grantees. By capturing the perspectives of these grantees, this research aims to build on both our current knowledge of the CLAS Standards and DEI landscape at ACL, as well as to enhance our understanding of how to support the aging and disability networks to strengthen their CLAS Standards and DEI practices and priorities.

The IC, as well as analyses of available NSOAAP, Annual Performance data or other ACL data, would help address the following key research questions:

1. Who does ACL serve?

a. How do ACL clients differ by demographic characteristics and/or social determinants of health (e.g., language, culture, race/ethnicity, age, disability status)?

b. Are there any gaps in the types of people (or clients) served?

2. How are ACL program grantees meeting the needs of these diverse people (or clients)?

a. What data do they collect that would help ensure they meet diverse client needs?

b. What resources do grantee organizations need to support the cultural and linguistic needs of their clients?

Five focus groups with ACL grantees, comprised of 8–10 participants each (with each participant representing one grantee entity), would be conducted to help ACL better understand the current

service provider grantee landscape related to cultural and linguistic needs and other DEI activities. Data gathered from these focus groups would also help refine a web-based survey that would be administered to a minimum of 400 service provider grantees. The survey would allow for broader reach to help ACL understand both how provider grantees address diverse client needs and what additional resources provider grantee organizations may need to support the cultural, linguistic, and DEI needs of the people they serve. Together, these data will help ACL better understand how grantees are meeting the needs of their clients, as well as the extent of unmet CLAS/DEI needs that exist for clients and the extent to which those unmet needs may limit service access. The proposed data collection tools may be found on the ACL website for review at: <https://www.acl.gov/about-acl/public-input>.

**Estimated Program Burden:** ACL estimates the burden of this collection of information as follows:

The grantee focus groups will include no more than 50 individuals representing grantee organizations across the US. The burden for their participation is estimated at 1.5 hours per participant, for a total of 75 hours.

A minimum of 400 grantees are expected to respond to the web-based survey. The approximate burden for survey completion may be ten minutes per respondent for a total estimate of 4,000 minutes. The estimated survey completion burden includes time to review the instructions, read the questions and complete the responses.

IC BURDEN CHART

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Grantee focus groups .....	50	1	1.50	75.00
Web-based grantee survey .....	400	1	0.16	66.67
Total .....	480	1	1.66	141.67

Dated: June 27, 2022.

**Alison Barkoff,**

*Acting Administrator and Assistant Secretary for Aging.*

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**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 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 committee 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 August 15, 2022, for vacancies listed in this notice.

Concurrently, nomination materials for prospective candidates should be sent to FDA (see **ADDRESSES**) by August 15, 2022. 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](mailto: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](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
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, <a href="mailto:Rakesh.Raghuwanshi@fda.hhs.gov">Rakesh.Raghuwanshi@fda.hhs.gov</a> .	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, <a href="mailto:Prabhakara.Atreya@fda.hhs.gov">Prabhakara.Atreya@fda.hhs.gov</a> .	Allergens Products Advisory Committee.
Moon Hee Choi, Center for Drugs Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2434, Silver Spring, MD 20993-0002, 301-796-2894, <a href="mailto:MoonHee.Choi@fda.hhs.gov">MoonHee.Choi@fda.hhs.gov</a> .	Anesthetic and Analgesic Drug Advisory Committee, Non-Prescription Drugs Advisory Committee.
She-Chia Chen, Center for Dugs Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31 Rm. 2438, Silver Spring, MD 20993-0002, 240-402-5343, <a href="mailto:She-Chia.Chen@fda.hhs.gov">She-Chia.Chen@fda.hhs.gov</a> .	Antimicrobial Drugs Advisory Committee.
Jessica Seo, Center for Drugs Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2412, Silver Spring, MD 20993-0002, 301-796-7699, <a href="mailto:Jessica.Seo@fda.hhs.gov">Jessica.Seo@fda.hhs.gov</a> .	Arthritis Drugs Advisory Committee, Peripheral and Central Nervous System Drugs Advisory Committee.
Joyce Yu, Center for Drugs Evaluation Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2438, Silver Spring, MD 20993-0002, 301-837-7126, <a href="mailto:Joyce.Yu@fda.hhs.gov">Joyce.Yu@fda.hhs.gov</a> .	Cardiovascular Drugs Advisory Committee, Medical Imaging Drugs Advisory Committee.
LaToya Bonner, Center for Drugs Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2428, Silver Spring, MD 20993-0002, 301-796-2855, <a href="mailto:LaToya.Bonner@fda.hhs.gov">LaToya.Bonner@fda.hhs.gov</a> .	Endocrinologic and Metabolic Drugs Advisory Committee.
Takyiah Stevenson, Center for Drugs Evaluation Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2406, Silver Spring, MD 20993-0002, 240-402-2507, <a href="mailto:Takyiah.Stevenson@fda.hhs.gov">Takyiah.Stevenson@fda.hhs.gov</a> .	Pharmacy Compounding Drugs Advisory Committee.
Joyce Frimpong, Center for Drugs Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2462, Silver Spring, MD 20993-0002, 301-796-7973, <a href="mailto:Joyce.Frimpong@fda.hhs.gov">Joyce.Frimpong@fda.hhs.gov</a> .	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, <a href="mailto:Candace.Nalls@fda.hhs.gov">Candace.Nalls@fda.hhs.gov</a> .	Anesthesiology and Respiratory Therapy Devices Panel, Clinical Chemistry and Clinical Toxicology Devices Panel, Ear, Nose and Throat Devices Panel, Gastroenterology and 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, <a href="mailto:James.Swink@fda.hhs.gov">James.Swink@fda.hhs.gov</a> .	Circulatory System Devices Panel, Immunology 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, <a href="mailto:Akinola.Awojope@fda.hhs.gov">Akinola.Awojope@fda.hhs.gov</a> .	Dental Products Devices Panel, Obstetrics and Gynecology Devices 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. 5211, Silver Spring, MD 20993-0002, 240-672-5763, <a href="mailto:Jarrod.Collier@fda.hhs.gov">Jarrod.Collier@fda.hhs.gov</a> .	General Hospital and Personal Use Devices Panel, Hematology and Pathology Devices Panel, Molecular and Clinical Genetics Devices Panel, Ophthalmic Devices Panel, Radiology 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, <i>James.Swink@fda.hhs.gov</i> .	National Mammography Quality Assurance Advisory Committee.

**SUPPLEMENTARY INFORMATION:** FDA is or nonvoting consumer representatives requesting nominations for voting and/ 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.
Arthritis Drugs Advisory Committee—Knowledgeable in the fields of arthritis, rheumatology, orthopedics, epidemiology or statistics, analgesics, and related specialties.	1—Voting .....	December 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 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 .....	July 1, 2022.
Pharmacy Compounding Drugs 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 .....	July 1, 2022.
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 and 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.

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
Immunology Devices Panel—Persons with experience in medical, surgical, or clinical oncology, internal medicine, clinical immunology, allergy, molecular diagnostics, or clinical laboratory medicine.	1—Nonvoting .....	Immediately.
Microbiology Devices Panel—Clinicians with an expertise in infectious disease, <i>e.g.</i> , 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, <i>e.g.</i> , hepatologists; molecular biologists.	1—Nonvoting .....	Immediately.
Dental Products Devices 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.
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; 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, <i>e.g.</i> , 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—Ophthalmologists 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 Drugs 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, as well as 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 Drugs 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*

Review and evaluate 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 advise 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 will serve 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 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 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 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*

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 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. Except for 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 Devices 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.

*N. National Mammography Quality Assurance Advisory Committee*

Advise the Agency on the following: 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 exist enough 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** section of this document), 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: June 24, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022-14135 Filed 6-30-22; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. FDA-2021-E-0452; FDA-2021-E-0453]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; IMCIVREE

**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 IMCIVREE 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 the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by August 30, 2022. 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 December 28, 2022. 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 August 30, 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:

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- 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").