

most informative design is a randomized, double-blind clinical trial that includes a concurrent control group (approved drug or placebo).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Inborn Errors of Metabolism That Use Dietary Management: Considerations for Optimizing and Standardizing Diet in Clinical Trials for Drug Product Development." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 have been approved under OMB Control No. 0910–0014.

## III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: July 6, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023–14691 Filed 7–11–23; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2023–N–2727]

#### Request for Nominations for Individuals and Consumer Organizations for Advisory Committees

**AGENCY:** Food and Drug Administration, Department of Health and Human Services (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 28, 2023, for vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA (see **ADDRESSES**) by August 28, 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](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> .	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, <a href="mailto:MoonHee.Choi@fda.hhs.gov">MoonHee.Choi@fda.hhs.gov</a> .	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, <a href="mailto:She-Chia.Jankowski@fda.hhs.gov">She-Chia.Jankowski@fda.hhs.gov</a> .	Antimicrobial Drugs Advisory Committee.

TABLE 1—ADVISORY COMMITTEE CONTACTS—Continued

Contact person	Committee/panel
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, <a href="mailto:Jessica.Seo@fda.hhs.gov">Jessica.Seo@fda.hhs.gov</a> .	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. 2510, Silver Spring, MD 20993–0002, 301–796–9034, <a href="mailto:Yvette.Waples@fda.hhs.gov">Yvette.Waples@fda.hhs.gov</a> .	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, <a href="mailto:LaToya.Bonner@fda.hhs.gov">LaToya.Bonner@fda.hhs.gov</a> .	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, <a href="mailto:Takyiah.Stevenson@fda.hhs.gov">Takyiah.Stevenson@fda.hhs.gov</a> .	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, <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-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; 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 Panel; Orthopaedic and Rehabilitation Devices Panel.
Jarrod Collier, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 1333, 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 Panel; Ophthalmic Devices Panel; Radiological 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> .	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, analgesics (such as: abuse deterrent opioids, novel analgesics, and issues related to opioid abuse), epidemiology or statistics, and related specialties.	1—Voting .....	Immediately.
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 .....	Immediately.
Peripheral and Central Nervous Systems Drugs Advisory Committee—Knowledgeable in the fields of neurology, neuropsychopharmacology, neuropathology, otolaryngology, epidemiology or statistics, and related specialties.	1—Voting .....	Immediately.
Cardiovascular and Renal Drugs Advisory Committee—Knowledgeable in the fields of cardiology, hypertension, arrhythmia, angina, congestive heart failure, diuresis, and biostatistics.	1—Voting .....	Immediately.
Medical Imaging 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.

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
Pharmacy Compounding Advisory Committee—Knowledgeable in the fields of pharmaceutical compounding, pharmaceutical manufacturing, pharmacy, medicine, and 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—Otolologists, 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, 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.
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—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 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 including analgesics, *e.g.*, abuse-deterrent opioids, novel analgesics, and issues related to opioid abuse, and those for use in anesthesiology and makes appropriate recommendations to the Commissioner.

*D. Non-Prescription Drugs Advisory Committee*

Reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (non-prescription) 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 non-prescription 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 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 under sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353a and 353b), and, as required, any other product for which FDA has regulatory responsibility.

*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 FD&C 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 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; 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: July 6, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023-14690 Filed 7-11-23; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2021-D-1149]

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Emergency Use Authorization of Medical Products and Related Authorities

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments (including recommendations) on the collection of information by August 11, 2023.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting "Currently under Review—Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0595. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

### Emergency Use Authorization of Medical Products and Related Authorities

*OMB Control Number 0910-0595—Revision*

This information collection helps support FDA's implementation of sections 564, 564A, and 564B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-3, 360bbb-3a, and 360bbb-3b), which govern the authorization of medical products for use in emergencies. The statutes authorize FDA to permit the introduction into interstate commerce a *drug, device, or biological product intended for use in an actual or potential emergency*. The purpose of these provisions is to sustain and strengthen national preparedness for public health, military, and domestic emergencies involving chemical, biological, radiological, and nuclear agents, including emerging infectious disease threats.

We are revising the information collection to discuss the guidance document entitled, "Transition Plan for Medical Devices Issued Emergency Use