

rooted in comparisons between new devices and predicate devices. However, the Federal Food, Drug, and Cosmetic Act (FD&C Act) does not preclude FDA from using performance criteria to facilitate this comparison. If a legally marketed device performs at certain levels relevant to its safety and effectiveness, and a new device meets those levels of performance for the same characteristics, FDA could find the new device as safe and effective as the legally marketed device. Instead of reviewing data from direct comparison testing between the two devices, FDA could support a finding of substantial equivalence with data demonstrating the new device meets the level of performance of an appropriate predicate device(s). Under this optional Safety and Performance Based Pathway, a submitter of air powered dental handpieces and air motors, or dental cement devices could satisfy the requirement to compare its device with a legally marketed device by, among other things, independently demonstrating that the device's performance meets performance criteria as established in the relevant above-listed guidance rather than using direct predicate comparison testing for some of the performance characteristics.

These guidances are being implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (see section 701(h)(1)(C) of the FD&C Act (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). FDA has determined that these guidance documents present less burdensome policies that are consistent with public health. Although these guidances are

being implemented immediately, FDA will consider all comments received and revise the guidance documents as appropriate.

These guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These guidances represent the current thinking of FDA on "Air Powered Dental Handpieces and Air Motors—Performance Criteria for Safety and Performance Based Pathway," "Dental Ceramics—Performance Criteria for Safety and Performance Based Pathway," "Dental Impression Materials—Performance Criteria for Safety and Performance Based Pathway," and "Dental Cements—Performance Criteria for Safety and Performance Based Pathway." They do not establish any rights for any person and are 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. Electronic Access**

Persons interested in obtaining a copy of the guidances may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>. These guidance documents are also available at <https://www.regulations.gov> or <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>. Persons unable to download an electronic copy of "Air Powered

Dental Handpieces and Air Motors—Performance Criteria for Safety and Performance Based Pathway," "Dental Ceramics—Performance Criteria for Safety and Performance Based Pathway," "Dental Impression Materials—Performance Criteria for Safety and Performance Based Pathway," or "Dental Cements—Performance Criteria for Safety and Performance Based Pathway" may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document number GUI00021014 for "Air Powered Dental Handpieces and Air Motors—Performance Criteria for Safety and Performance Based Pathway," document number GUI00007014 for "Dental Ceramics—Performance Criteria for Safety and Performance Based Pathway," document number GUI00007013 for "Dental Impression Materials—Performance Criteria for Safety and Performance Based Pathway," or document number GUI00021005 for "Dental Cements—Performance Criteria for Safety and Performance Based Pathway" to identify the guidance you are requesting.

**III. Paperwork Reduction Act of 1995**

While these guidances contain no new collection of information, they do refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

| 21 CFR part; guidance  | Topic   | OMB control No.        |
|--|---|------------------------|
| 807, subpart E .....<br>"Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program". | Premarket notification .....<br>Q-submissions; pre-submissions. | 0910–0120<br>0910–0756 |

Dated: September 24, 2024.  
**Lauren K. Roth,**  
*Associate Commissioner for Policy.*  
 [FR Doc. 2024–22309 Filed 9–27–24; 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 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 November 14, 2024, for vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to

FDA (see **ADDRESSES**) by November 14, 2024. Nominations will be accepted for current vacancies and for those that will or may occur through December 31, 2025.

**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 Raghuvanshi, 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.Raghuvanshi@fda.hhs.gov">Rakesh.Raghuvanshi@fda.hhs.gov</a> .           | FDA Science Board Advisory Committee.   |
| Christina Vert, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Silver Spring, MD 20993-0002, 240-402-8054, <a href="mailto:Christina.Vert@fda.hhs.gov">Christina.Vert@fda.hhs.gov</a> .                 | Blood Products Advisory Committee.  |
| Marie DeGregorio, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 1246, Silver Spring, MD 20993-0002, 240-402-4207, <a href="mailto:Marie.Degregorio@fda.hhs.gov">Marie.Degregorio@fda.hhs.gov</a> . | Cellular, Tissue and Gene Therapies Advisory Committee.   |
| Sussan Paydar, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Silver Spring, MD 20993-0002, 202-657-8533, <a href="mailto:Sussan.Paydar@fda.hhs.gov">Sussan.Paydar@fda.hhs.gov</a> .                    | Vaccines and Related Biological Products Advisory Committee.  |
| Joyce Frimpong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2438, Silver Spring, MD 20993-0002, 301-796-7973, <a href="mailto:Joyce.Frimpong@fda.hhs.gov">Joyce.Frimpong@fda.hhs.gov</a> .            | Anesthetic and Analgesic Drug Products Advisory Committee; Obstetrics, Reproductive and Urologic Drugs Advisory Committee; Psychopharmacologic Drugs Advisory Committee.  |
| Yvette Waples, Center for Drug Evaluation and 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> .               | Antimicrobial Drugs Advisory Committee, Drug Safety and Risk Management Advisory Committee; Non-Precription Drugs Advisory Committee; Oncologic Drugs Advisory Committee; Pharmaceutical Science and Clinical Pharmacology 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> .               | Cardiovascular and Renal Drugs Advisory Committee; Dermatologic and Ophthalmic Drugs Advisory Committee; Endocrinologic and Metabolic Drugs Advisory Committee.   |
| Takyiah Stevenson, Center for Drug Evaluation and 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> .   | Medical Imaging 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, <a href="mailto:Jessica.Seo@fda.hhs.gov">Jessica.Seo@fda.hhs.gov</a> .                     | Gastrointestinal Drugs Advisory Committee; Peripheral and Central Nervous System 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; General Hospital and Personal Use Devices Panel; Hematology and Pathology Devices Panel; Immunology Devices Panel; Medical Devices Dispute Resolution Panel; Microbiology Devices Panel; Molecular and Clinical Genetics Panel; Radiological Devices Panel. |

TABLE 1—ADVISORY COMMITTEE CONTACTS—Continued

| Contact person  | Committee/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; Ophthalmic Devices Panel; Orthopaedic and Rehabilitation Devices Panel. |

**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 (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.            |
| Blood Products Advisory Committee—Knowledgeable in the fields of clinical and administrative medicine, hematology, immunology, blood banking, surgery, internal medicine, biochemistry, engineering, biological and physical sciences, biotechnology, computer technology, statistics, epidemiology, sociology/ethics, and other related professions.  | 1—Voting .....  | October 1, 2025.        |
| Cellular, Tissue and Gene Therapies—Knowledgeable in the fields of cellular therapies, tissue transplantation, gene transfer therapies and xenotransplantation (biostatistics, bioethics, hematology/oncology, human tissues and transplantation, reproductive medicine, general medicine, and various medical specialties including surgery and oncology, immunology, virology, molecular biology, cell biology, developmental biology, tumor biology, biochemistry, rDNA technology, nuclear medicine, gene therapy, infectious diseases, and cellular kinetics).  | 1—Voting .....  | April 1, 2025.          |
| Vaccines and Related Biological Products Advisory Committee—Knowledgeable in the fields of immunology, molecular biology, rDNA, virology, bacteriology, epidemiology or biostatistics, allergy, preventive medicine, infectious diseases, pediatrics, microbiology, and biochemistry.  | 1—Voting .....  | February 1, 2025.       |
| 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.            |
| Obstetrics, Reproductive and Urologic Drugs Advisory Committee—Knowledgeable in the fields of obstetrics, gynecology, urology, pediatrics, epidemiology, or statistics and related specialties.  | 1—Voting .....  | Immediately.            |
| Psychopharmacologic Drugs Advisory Committee—Knowledgeable in the fields of psychopharmacology, psychiatry, epidemiology or statistics, 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.            |
| Drug Safety and Risk Management Advisory Committee—Knowledgeable in risk communication, risk management, drug safety, medical, behavioral, and biological sciences as they apply to risk management, and drug abuse.   | 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.            |
| Oncologic Drugs Advisory Committee—Knowledgeable in the fields of general oncology, pediatric oncology, hematologic oncology, immunologic oncology, biostatistics, and other related professions.  | 1—Voting .....  | November 1, 2024.       |
| Pharmaceutical Science and Clinical Pharmacology—Knowledgeable in the fields of pharmaceutical sciences (pharmaceutical manufacturing, bioequivalence research, laboratory analytical techniques, pharmaceutical chemistry, physiochemistry, biochemistry, molecular biology, immunology, microbiology) and clinical pharmacology (dose-response, pharmacokinetics-pharmacodynamics, modeling and simulation, pharmacogenomics, clinical trial design, pediatrics and special populations and innovative methods in drug development), biostatistics, related biomedical and pharmacological specialties, current good manufacturing practices, and quality systems implementation.  | 1—Voting .....  | December 1, 2025.       |
| Cardiovascular and Renal Drugs Advisory Committee—Knowledgeable in the fields of cardiology, hypertension, arrhythmia, angina, congestive heart failure, diuresis, and biostatistics.  | 1—Voting .....  | Immediately.            |
| Dermatologic and Ophthalmic Drugs Advisory Committee—Knowledgeable in the fields of dermatology, ophthalmology, internal medicine, pathology, immunology, epidemiology or statistics, and other related professions.   | 1—Voting .....  | September 1, 2025.      |
| Endocrinologic and Metabolic Drugs Advisory Committee—Knowledgeable in the fields of endocrinology, metabolism, epidemiology or statistics, and related specialties.   | 1—Voting .....  | Immediately.            |
| Medical Imaging Drugs Advisory Committee—Knowledgeable in the fields of nuclear medicine, radiology, epidemiology, 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 |
|--|-------------------|-------------------------|
| Peripheral and Central Nervous Systems Drugs Advisory Committee—Knowledgeable in the fields of neurology, pediatric neurology, epidemiology, 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 ..... | 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.            |
| General Hospital and Personal Use Devices Panel—Internists, pediatricians, neonatologists, endocrinologists, 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 homeostasis, 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.            |
| 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.            |
| Medical Devices Dispute Resolution Panel—Experts with broad, cross-cutting scientific, clinical, analytical or mediation skills.   | 1—Nonvoting ..... | October 1, 2024.        |
| 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.            |
| 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.            |
| 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.            |
| 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.            |
| 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.            |
| 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.            |

**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. Blood Products Advisory Committee*

Reviews and evaluates available data concerning the safety, effectiveness, and appropriate use of blood products derived from blood and serum or biotechnology which are intended for use in the diagnosis, prevention, or treatment of human diseases as well as the safety, effectiveness, and labeling of the products, on clinical and laboratory studies involving such products, on the affirmation or revocation of biological product licenses, and on the quality and relevance of FDA’s research program

which provides the scientific support for regulating these products.

#### *C. Cellular, Tissue, and Gene Therapies*

Reviews and evaluates available data relating to the safety, effectiveness, and appropriate use of human cells, human tissues, gene transfer therapies, and xenotransplantation products which are intended for transplantation, implantation, infusion, and transfer in the prevention and treatment of a broad spectrum of human diseases and in the reconstruction, repair or replacement of tissues for various conditions, as well as considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products.

#### *D. Vaccines and Related Biological Products*

Reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines and related biological products which are intended for use in the prevention, treatment, or diagnosis of human diseases, as well as considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products.

#### *E. 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.

#### *F. Obstetrics, Reproductive and Urologic Products Advisory Committee*

Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drug products for use in the practice of obstetrics, gynecology, urology, and related specialties.

#### *G. 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.

#### *H. 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.

#### *I. Drug Safety and Risk Management Advisory Committee*

Reviews and evaluates information on risk management, risk communication, and quantitative evaluation of spontaneous reports for drugs for human use and for any other product for which FDA has regulatory responsibility. Advises on the scientific and medical evaluation of all information gathered by the Department of Health and Human Services (HHS) and the Department of Justice with regard to safety, efficacy, and abuse potential of drugs or other substances, and recommends actions to be taken by HHS with regard to the marketing, investigation, and control of such drugs or other substances.

#### *J. 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.

#### *K. Oncologic 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 cancer.

#### *L. Pharmaceutical Science and Clinical Pharmacology*

Reviews and evaluates scientific, clinical, and technical issues related to the safety and effectiveness of drug products for use in the treatment of a broad spectrum of human diseases, the quality characteristics which such drugs purport or are represented to have, and as required, any other product for which FDA has regulatory responsibility, and make appropriate recommendations to the Commissioner. The Committee may also review Agency-sponsored

intramural and extramural biomedical research programs in support of FDA's drug regulatory responsibilities and its critical path initiatives related to improving the efficacy and safety of drugs and improving the efficiency of drug development.

#### *M. 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.

#### *N. Dermatologic and Ophthalmic Drugs*

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

#### *O. 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.

#### *P. 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.

#### *Q. Gastrointestinal 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 gastrointestinal diseases.

#### *R. 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.

#### *S. 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.

## 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 45 days of the end of this 30-day period, 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 resume. 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: September 24, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Statement of Organization, Functions, and Delegations of Authority

**AGENCY:** Food and Drug Administration, Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration's (FDA), Center for Veterinary Medicine's (CVM), Office of Management (OM) and Office of New Animal Drug Evaluation (ONADE) have modified their organizational structures. The new organizational structures were approved by the Secretary of Health and Human Services on July 22, 2024.

**FOR FURTHER INFORMATION CONTACT:** Yashika Rahaman, Director, Office of Planning, Evaluation, and Risk Management, Office of Finance, Budget, Acquisitions, and Planning, Food and Drug Administration, 4041 Powder Mill Rd., Beltsville, MD 20705-4304, 301-796-3843.

#### I. Introduction

Part D, Chapter D-B, (Food and Drug Administration), the Statement of Organization, Functions and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, 60 FR 56606, November 9, 1995,