

Number: CMS–10147 (OMB control number 0938–0975); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other for-profits; *Number of Respondents:* 70,000; *Number of Responses:* 49,681,292; *Total Annual Hours:* 827,690. (For questions regarding this collection, contact Trevor Rose at (410) 786 7768.)

Dated: March 22, 2021.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2021–06209 Filed 3–24–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–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 women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

DATES: Any consumer organization interested in participating in the selection of an appropriate voting or nonvoting member to represent consumer interests on an FDA advisory committee or panel may send a letter or email stating that interest to FDA (see **ADDRESSES**) by April 26, 2021, for vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA (see **ADDRESSES**) by April 26, 2021. Nominations will be accepted for current vacancies and for those that will or may occur through December 31, 2021.

ADDRESSES: All statements of interest from consumer organizations interested

in participating in the selection process should be submitted electronically to ACOMSSubmissions@fda.hhs.gov or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5122, Silver Spring, MD 20993–0002.

Consumer representative nominations should be submitted electronically by logging into the FDA Advisory Committee Membership Nomination Portal: <https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm>, or by mail to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, Rm. 5122, Silver Spring, MD 20993–0002. Additional information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's website at <https://www.fda.gov/AdvisoryCommittees/default.htm>.

FOR FURTHER INFORMATION CONTACT: For questions relating to participation in the selection process: Kimberly Hamilton, Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5122, Silver Spring, MD 20993–0002, 301–796–8220, kimberly.hamilton@fda.hhs.gov.

For questions relating to specific advisory committees or panels, contact the appropriate Contact Person listed in table 1.

TABLE 1—ADVISORY COMMITTEE CONTACTS

Contact person	Committee/panel
Rakesh Raghuwanshi, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3309, Silver Spring, MD 20993–0002, 301–796–4769, Rakesh.Raghuwanshi@fda.hhs.gov .	FDA Science Board Advisory Committee.
Christina Vert, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6268, Silver Spring, MD 20993–0002, 240–402–8054, Christina.Vert@fda.hhs.gov .	Blood Products Advisory Committee.
Jarrold Collier, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Silver Spring, MD 20993–0002, 202–906–0043, Jarrod.Collier@fda.hhs.gov .	Cellular, Tissue and Gene Therapies Advisory Committee.
Kathleen Hayes, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6307C, Silver Spring, MD 20993–0002, 301–796–7864, Kathleen.Hayes@fda.hhs.gov .	Vaccines and Related Biological Products 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 20992–0002, 301–796–2855, Latoya.Bonner@fda.hhs.gov .	Dermatologic and Ophthalmic Drugs Advisory Committee.
Yvette Waples, Center for Drugs Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2510, Silver Spring, MD 20993–0002, 301–796–9034, Yvette.Waples@fda.hhs.gov .	Gastrointestinal Drugs Advisory Committee, Pharmaceutical Science and Clinical Pharmacology Advisory Committee, Psychopharmacologic Drugs Advisory Committee.
James Swink, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5211, Silver Spring, MD 20993–0002, 301–796–6313, James.Swink@fda.hhs.gov .	Anesthesiology and Respiratory Therapy Devices Panel, Circulatory Systems Devices Panel, Dental Products Devices Panel, General Hospital and Personal Use Devices Panel, Hematology and Pathology Devices Panel, Radiological Devices Panel.

TABLE 1—ADVISORY COMMITTEE CONTACTS—Continued

Contact person	Committee/panel
Patricio Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5216, Silver Spring, MD 20993-0002, 301-796-6875, <i>Patricio.Garcia@fda.hhs.gov</i> .	Clinical Chemistry and Clinical Toxicology Devices Panel, Gastroenterology and Urology Devices Panel, General and Plastic Surgery Devices Panel, Obstetrics and Gynecology Devices Panel.
Aden Asefa, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5214, Silver Spring, MD 20993-0002, 301-796-0400, <i>Aden.Asefa@fda.hhs.gov</i> .	Immunology Devices Panel, Microbiology Devices Panel, Molecular and Clinical Genetics Devices Panel, Neurological Devices Panel.
Aden Asefa, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5214, Silver Spring, MD 20993-0002, 301-796-0400, <i>Aden.Asefa@fda.hhs.gov</i> .	National Mammography Quality Assurance Advisory Committee.
Letise Williams, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5407, Silver Spring, MD 20993-0002, 301-796-8398, <i>Letise.Williams@fda.hhs.gov</i> .	Patient Engagement 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 (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, 2021.
Cellular, Tissue and Gene Therapies Advisory Committee—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, 2021.
Vaccines and Related Biologic 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	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, 2021.
Gastrointestinal Drugs Advisory Committee—Knowledgeable in the fields of gastroenterology, endocrinology, surgery, clinical pharmacology, physiology, pathology, liver function, motility, esophagitis, and statistics.	1—Voting	July 1, 2021.
Pharmaceutical Science and Clinical Pharmacology Advisory Committee—Knowledgeable in the fields of pharmaceutical manufacturing, clinical pharmacology, pharmacokinetics, bioavailability and bioequivalence research, the design and evaluation of clinical trials, laboratory analytical techniques, pharmaceutical chemistry, physiochemistry, biochemistry, biostatistics, and related biomedical and pharmacological specialties.	1—Voting	November 1, 2021.
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	December 1, 2021.
Circulatory Systems Devices Panel—Interventional cardiologists, electrophysiologists, invasive (vascular) radiologists, vascular and cardiothoracic surgeons, and cardiologists with special interest in congestive heart failure.	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.

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
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	March 1, 2021.
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.
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.
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.
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.
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, 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	June 1, 2021.
Neurological Devices Panel—Neurosurgeons (cerebrovascular and pediatric), neurologists (stroke, pediatric, pain management, and movement disorders), interventional neuroradiologists, psychiatrists, and biostatisticians.	1—Nonvoting	December 1, 2021.
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.	4—Voting	Immediately.
Patient Engagement Advisory Committee—Experts who are knowledgeable in areas such as clinical research, primary care patient experience, and healthcare needs of patient groups in the United States. Selected Committee members may also be experienced in the work of patient and health professional organizations; methodologies for eliciting patient preferences; and strategies for communicating benefits, risks, and clinical outcomes to patients and research subjects.	1—Voting	May 1, 2021.

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

The 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 is

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 that provides the scientific support for regulating these products.

C. Cellular, Tissue, and Gene Therapies Advisory Committee

The Cellular, Tissue, and Gene Therapies Advisory Committee reviews and evaluates available data relating to the safety, effectiveness, and appropriate use of human cells, human tissues, gene transfer therapies and xenotransplantation products that 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. The Committee also considers the quality and relevance of FDA's research program that provides scientific support for the regulation of these products.

D. Vaccines and Related Biologic Products Advisory Committee

The Vaccines and Related Biologic Products Advisory Committee reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines and related biological products that 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 that provides scientific support for the regulation of these products.

E. Dermatologic and Ophthalmic Drugs Advisory Committee

The Dermatologic and Ophthalmic 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 dermatologic and ophthalmic disorders.

F. Gastrointestinal Drugs Advisory Committee

The 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.

G. Pharmaceutical Science and Clinical Pharmacology Advisory Committee

The Pharmaceutical Science and Clinical Pharmacology Advisory Committee provides advice on scientific and technical issues concerning the safety and effectiveness of human generic drug products for use in the treatment of a broad spectrum of human diseases and, as required, any other product for which FDA has regulatory responsibility. The Committee may also review Agency-sponsored intramural and extramural biomedical research programs in support of FDA's generic drug regulatory responsibilities.

H. Psychopharmacologic Drugs Advisory Committee

The Psychopharmacologic Drugs Advisory Committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human products for use in the practice of psychiatry and related fields.

I. Certain Panels of the Medical Devices Advisory Committee

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 Dental Products Panel also functions at times as a dental drug panel. The functions of the dental drug

panel are to evaluate and recommend whether various prescription drug products should be changed to over-the-counter status and to evaluate data and make recommendations concerning the approval of new dental drug products for human use.

The Medical Devices Dispute Resolution Panel provides advice to the Commissioner on complex or contested scientific issues between FDA and medical device sponsors, applicants, or manufacturers relating to specific products, marketing applications, regulatory decisions and actions by FDA, and Agency guidance and policies. The Panel makes recommendations on issues that are lacking resolution, are highly complex in nature, or result from challenges to regular advisory panel proceedings or Agency decisions or actions.

J. National Mammography Quality Assurance Advisory Committee

The National Mammography Quality Assurance Advisory Committee advises 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 the Agency 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 a sufficient number of medical physicists after October 1, 1999; and determining the costs and benefits of compliance with these requirements.

K. Patient Engagement Advisory Committee

The Patient Engagement Advisory Committee advises the Agency on complex issues relating to medical devices, the regulation of devices, and their use by patients. The Committee may consider topics such as Agency guidance and policies, clinical trial or registry design, patient preference study design, benefit-risk determinations, device labeling, unmet clinical needs, available alternatives, patient reported outcomes and device-related quality of life or health status issues, and other

patient-related topics. The Committee will provide relevant skills and perspectives to improve communication of benefits, risks, and clinical outcomes and increase integration of patient perspectives into the regulatory process for medical devices. The Committee will perform its duties by discussing and providing advice and recommendation in ways such as identifying new approaches, promoting innovation, recognizing unforeseen risks or barriers, and identifying unintended consequences that could result from FDA policy.

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 30 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. Upon 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 who 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: March 22, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-06206 Filed 3-24-21; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-D-0369]

Product-Specific Guidances; Draft and Revised Draft Guidances for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of additional draft and revised draft product-specific guidances. The guidances provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled "Bioequivalence Recommendations for Specific Products" that explained the process that would be used to make product-specific guidances available to the public on FDA's website. The guidances identified in this notice were developed using the process described in that guidance.

DATES: Submit either electronic or written comments on the draft guidances by May 24, 2021 to ensure that the Agency considers your comment on these draft guidances before it begins work on the final versions of the guidances.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.