

worked to address this priority in part by performing Chemistry, Manufacturing, and Controls (CMC) reviews for CDER-regulated and CBER-regulated products. CDER or CBER may issue a product quality, or CMC, IR as a result of CMC assessments conducted in support of the application.

IRs from both CDER and CBER are expected to follow Four-Part Harmony in which reviewers are expected to communicate: (1) what was provided, (2) what is the issue or deficiency, (3) what is needed, and (4) why it is needed. This expectation can be found in CDER's Manual of Policies and Procedures (MAPP) 5016.8, "Communication Guidelines for Quality-Related Information Requests and Deficiencies." As a result of FDA's implementation of Four-Part Harmony in CMC-IRs, sponsors should understand what information FDA needs to continue their review. The PDUFA VII goals letter includes commitments for FDA to update and conduct training on existing policies and procedures (MAPPs and Standard Operating Policy and Procedure (SOPPs)), to reflect Four-Part Harmony. CDER MAPP 5016.8, "Communication Guidelines for Quality-Related Information Requests and Deficiencies" will be revised and made public. CBER SOPP 8401.1, "Issuance of and Review of Responses to Information Request Communications to Pending Applications" will also be revised.

In addition to updating the documents and conducting training, FDA is committed to contracting with an independent third party to assess current practices of CDER, CBER, and sponsors in communicating through product quality IRs during application review and effectiveness of Four-Part Harmony. This assessment will identify best practices and areas of improvement in communications between FDA review staff and sponsors through product quality IRs and is the subject of this task order.

The Statement of Work can be accessed at: [https://www.fda.gov/industry/prescription-drug-user-fee-](https://www.fda.gov/industry/prescription-drug-user-fee)

amendments/pdufa-vii-assessment-fda-and-sponsor-communications-through-product-quality-information-requests.

Dated: October 7, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-22335 Filed 10-13-22; 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 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 28, 2022, for vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA (see **ADDRESSES**) by November 28, 2022. Nominations will be accepted for current vacancies and for those that will or may occur through December 31, 2023.

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

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

FOR FURTHER INFORMATION CONTACT:

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

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

TABLE 1—ADVISORY COMMITTEE CONTACTS

Contact person	Committee/panel
Rakesh Raghuwanshi, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3309, Silver Spring, MD 20993-0002, 301-796-4769, Rakesh.Raghuwanshi@fda.hhs.gov .	FDA Science Board Advisory Committee.
Prabhakara Atreya, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 1226, Silver Spring, MD 20993-0002, 240-402-8006, Prabhakara.Atreya@fda.hhs.gov .	Allergenic Products Advisory Committee.

TABLE 1—ADVISORY COMMITTEE CONTACTS—Continued

Contact person	Committee/panel
Moon Hee Choi, Center for Drugs Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2434, Silver Spring, MD 20993–0002, 301–796–2894, MoonHee.Choi@fda.hhs.gov .	Anesthetic and Analgesic Drug Products Advisory Committee, Non-Prescription Drugs Advisory Committee.
She-Chia Chen, Center for Drugs Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31 Rm. 2438, Silver Spring, MD 20993–0002, 240–402–5343, She-Chia.Chen@fda.hhs.gov .	Antimicrobial Drugs Advisory Committee.
Jessica Seo, Center for Drugs Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2412, Silver Spring, MD 20993–0002, 301–796–7699, Jessica.Seo@fda.hhs.gov .	Arthritis Advisory Committee, Peripheral and Central Nervous System Drugs Advisory Committee.
Yvette Staples, Center for Drugs Evaluation Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2438, Silver Spring, MD 20993–0002, 301–837–7126, Yvette.Staples@fda.hhs.gov .	Cardiovascular and Renal Drugs Advisory Committee, Medical Imaging Drugs Advisory Committee.
LaToya Bonner, Center for Drugs Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2428, Silver Spring, MD 20993–0002, 301–796–2855, LaToya.Bonner@fda.hhs.gov .	Endocrinologic and Metabolic Drugs Advisory Committee.
Takyiah Stevenson, Center for Drugs Evaluation Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2406, Silver Spring, MD 20993–0002, 240–402–2507, Takyiah.Stevenson@fda.hhs.gov .	Pharmacy Compounding Advisory Committee.
Joyce Frimpong, Center for Drugs Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2462, Silver Spring, MD 20993–0002, 301–796–7973, Joyce.Frimpong@fda.hhs.gov .	Psychopharmacologic Drugs Advisory Committee.
Candace Nalls, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5211, Silver Spring, MD 20993–0002, 301–636–0510, Candace.Nalls@fda.hhs.gov .	Anesthesiology and Respiratory Therapy Devices Panel; Clinical Chemistry and Clinical Toxicology Devices Panel; Ear, Nose and Throat Devices Panel; Gastroenterology-Urology Devices Panel; General and Plastic Surgery Devices Panel; Circulatory System Devices Panel; Microbiology Devices Panel.
James Swink, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5211, Silver Spring, MD 20993–0002, 301–796–6313, James.Swink@fda.hhs.gov .	Dental Products Panel; Obstetrics and Gynecology Devices Panel; Orthopaedic and Rehabilitation Devices Panel.
Akinola Awojope, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5216, Silver Spring, MD 20993–0002, 301–636–0512, Akinola.Awojope@fda.hhs.gov .	General Hospital and Personal Use Devices Panel; Hematology and Pathology Devices Panel; Molecular and Clinical Genetics Panel; Ophthalmic Devices Panel; Radiological Devices Panel.
Jarrod Collier, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5211, Silver Spring, MD 20993–0002, 240–672–5763, Jarrod.Collier@fda.hhs.gov .	National Mammography Quality Assurance 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 .	

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.

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
Anesthetic and Analgesic Drug Products Advisory Committee—Knowledgeable in the fields of anesthesiology, surgery, epidemiology or statistics, and related specialties.	1—Voting	April 1, 2023.
Non-Prescription Drugs Advisory Committee—Knowledgeable in the fields of internal medicine, family practice, clinical toxicology, clinical pharmacology, pharmacy, dentistry, and related specialties.	1—Voting	Immediately.
Antimicrobial Drugs Advisory Committee—Knowledgeable in the fields of infectious disease, internal medicine, microbiology, pediatrics, epidemiology or statistics, and related specialties.	1—Voting	May 1, 2023.
Arthritis Advisory Committee—Knowledgeable in the fields of arthritis, rheumatology, orthopedics, epidemiology or statistics, analgesics, and related specialties.	1—Voting	December 1, 2023.
Peripheral and Central Nervous Systems Drugs Advisory Committee—Knowledgeable in the fields of neurology, neuropharmacology, neuropathology, otolaryngology, epidemiology or statistics, and related specialties.	1—Voting	February 1, 2023.
Cardiovascular and Renal Drugs Advisory Committee—Knowledgeable in the fields of cardiology, hypertension, arrhythmia, angina, congestive heart failure, diuresis, and biostatistics.	1—Voting	July 1, 2023.
Medical Imaging Drugs Advisory Committee—Knowledgeable in the fields of nuclear medicine, radiology, epidemiology, statistics, and related specialties.	1—Voting	Immediately.
Endocrinologic and Metabolic Drugs Advisory Committee—Knowledgeable in the fields of endocrinology, metabolism, epidemiology or statistics, and related specialties.	1—Voting	Immediately.
Pharmacy Compounding Advisory Committee—Knowledgeable in the fields of pharmaceutical compounding, pharmaceutical manufacturing, pharmacy, medicine, and other related specialties.	1—Voting	October 1, 2023.
Psychopharmacologic Drugs Advisory Committee—Knowledgeable in the fields of psychopharmacology, psychiatry, epidemiology or statistics, and related specialties.	1—Voting	Immediately.
Anesthesiology and Respiratory Therapy Devices Panel—Anesthesiologists, pulmonary medicine specialists, or other experts who have specialized interests in ventilator support, pharmacology, physiology, or the effects and complications of anesthesia.	1—Nonvoting	Immediately.
Clinical Chemistry and Clinical Toxicology Devices Panel—Doctor of Medicine or Philosophy with experience in clinical chemistry (<i>e.g.</i> , 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, <i>e.g.</i> , pulmonary disease specialists, sexually transmitted disease specialists, pediatric infectious disease specialists, experts in tropical medicine and emerging infectious diseases, mycologists; clinical microbiologists and virologists; clinical virology and microbiology laboratory directors, with expertise in clinical diagnosis and in vitro diagnostic assays, <i>e.g.</i> , hepatologists; molecular biologists.	1—Nonvoting	Immediately.
Dental Products Panel—Dentists, engineers and scientists who have expertise in the areas of dental implants, dental materials, periodontology, tissue engineering, and dental anatomy.	1—Nonvoting	Immediately.
Obstetrics and Gynecology Devices Panel—Experts in perinatology, embryology, reproductive endocrinology, pediatric gynecology, gynecological oncology, operative hysteroscopy, pelviscopy, electrosurgery, laser surgery, assisted reproductive technologies, contraception, postoperative adhesions, and cervical cancer and colposcopy; biostatisticians and engineers with experience in obstetrics/gynecology devices; urogynecologists; experts in breast care; experts in gynecology in the older patient; experts in diagnostic (optical) spectroscopy; experts in midwifery; labor and delivery nursing.	1—Nonvoting	Immediately.
Orthopaedic and Rehabilitation Devices Panel—Orthopedic surgeons (joint spine, trauma, and pediatric); rheumatologists; engineers (biomedical, biomaterials, and biomechanical); experts in rehabilitation medicine, sports medicine, and connective tissue engineering; and biostatisticians.	1—Nonvoting	Immediately.
General Hospital and Personal Use Devices Panel—Internists, pediatricians, neonatologists, endocrinologists, gerontologists, nurses, biomedical engineers, or microbiologists/infection control practitioners or experts.	1—Nonvoting	Immediately.
Hematology and Pathology Devices Panel—Hematologists (benign and/or malignant hematology), hematopathologists (general and special hematology, coagulation and hemostasis, and hematological oncology), gynecologists with special interests in gynecological oncology, cytopathologists, and molecular pathologists with special interests in development of predictive biomarkers.	1—Nonvoting	Immediately.
Molecular and Clinical Genetics Devices Panel—Experts in human genetics and in the clinical management of patients with genetic disorders, <i>e.g.</i> , pediatricians, obstetricians, neonatologists. The Agency is also interested in considering candidates with training in inborn errors of metabolism, biochemical and/or molecular genetics, population genetics, epidemiology, and related statistical training. Additionally, individuals with experience in genetic counseling, medical ethics, as well as ancillary fields of study will be considered.	1—Nonvoting	Immediately.

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
Ophthalmic Devices Panel—Ophthalmists with expertise in corneal-external disease, vitreo-retinal surgery, glaucoma, ocular immunology, ocular pathology; optometrists; vision scientists; and ophthalmic professionals with expertise in clinical trial design, quality of life assessment, electrophysiology, low vision rehabilitation, and biostatistics.	1—Nonvoting	Immediately.
Radiological Devices Panel—Physicians with experience in general radiology, mammography, ultrasound, magnetic resonance, computed tomography, other radiological subspecialties, and radiation oncology; scientists with experience in diagnostic devices, radiation physics, statistical analysis, digital imaging, and image analysis.	1—Nonvoting	Immediately.
National Mammography Quality Assurance Advisory Committee—Physician, practitioner, or other health professional whose clinical practice, research specialization, or professional expertise includes a significant focus on mammography.	3—Voting	Immediately.

I. Functions and General Description of the Committee Duties

A. FDA Science Board Advisory Committee

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

B. Allergenic Products Advisory Committee

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

C. Anesthetic and Analgesic Drug Products Advisory Committee

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

D. Nonprescription Drugs Advisory Committee

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

E. Antimicrobial Drugs Advisory Committee

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

F. Arthritis Advisory Committee

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

of arthritis, rheumatism, and related diseases.

G. Peripheral and Central Nervous System Drugs Advisory Committee

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

H. Cardiovascular and Renal Drugs Advisory Committee

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

I. Medical Imaging Drugs Advisory Committee

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in diagnostic and therapeutic procedures using radioactive pharmaceuticals and contrast media used in diagnostic radiology.

J. Endocrinologic and Metabolic Drugs Advisory Committee

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

K. Pharmacy Compounding Advisory Committee

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

L. Psychopharmacologic Drugs Advisory Committee

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human

drug products for use in the practice of psychiatry and related fields.

M. Medical Devices Advisory Committee Panels

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

The Dental Products Panel reviews and evaluates data concerning the safety and effectiveness of marketed and investigational products for use in dentistry, endodontics or bone physiology relative to the oral and maxillofacial area.

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: October 6, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–22305 Filed 10–13–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–1026]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Text Analysis of Proprietary Drug Name Interpretations

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 November 14, 2022.

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 title of this information collection is “Text Analysis of Proprietary Drug Name Interpretations.” 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.

For copies of the questionnaire: Office of Prescription Drug Promotion (OPDP) Research Team, DTCresearch@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.

Text Analysis of Proprietary Drug Name Interpretations

OMB Control Number 0910—NEW

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(d)(2)(C)) authorizes FDA to conduct research relating to drugs and other FDA-regulated products in carrying out the provisions of the FD&C Act.

The Office of Prescription Drug Promotion’s (OPDP) mission is to protect the public health by helping to ensure that prescription drug promotion is truthful, balanced, and accurately communicated. OPDP’s research program provides scientific evidence to help ensure that our policies related to prescription drug promotion will have the greatest benefit to public health. Toward that end, we have consistently conducted research to evaluate the aspects of prescription drug promotion that are most central to our mission. Our research focuses in particular on three main topic areas: advertising features, including content and format; target populations; and research quality. Through the evaluation of advertising features, we assess how elements such as graphics, format, and disease and product characteristics impact the communication and understanding of prescription drug risks and benefits. Focusing on target populations allows us to evaluate how understanding of prescription drug risks and benefits may vary as a function of audience, and our focus on research quality aims at maximizing the quality of research data through analytical methodology development and investigation of sampling and response issues. This study will inform all three topic areas.

Because we recognize the strength of data and the confidence in the robust nature of the findings are improved through the results of multiple converging studies, we continue to develop evidence to inform our thinking. We evaluate the results from our studies within the broader context of research and findings from other sources, and this larger body of knowledge collectively informs our policies as well as our research program. Our research is documented on our home page, which can be found at <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-prescription-drug-promotion-opdp-research>. The website includes links to the latest **Federal Register**

notices and peer-reviewed publications produced by our office.

As part of the prescription drug regulatory review process, sponsors propose proprietary names for their products. These names undergo a proprietary name review that involves the Office of Surveillance and Epidemiology, the relevant medical office, and OPDP. OPDP reviews names to assess for alignment with the FD&C Act, which provides, among other things, that labeling can misbrand a product if false or misleading representations are made (see 21 U.S.C. 321(n) and 352(a)). A proprietary name that appears in labeling could result in such misbranding if it is false or misleading. OPDP reviews, among other things, whether names: (1) overstate the efficacy or safety of the drug, (2) suggest drug indications that are not accurate, (3) suggest superiority without substantiation, or (4) are of a fanciful nature that misleadingly implies unique effectiveness or composition. It would be helpful in OPDP’s review of promotional implications of proprietary names for data on consumer and prescriber interpretations of proposed proprietary names to be more readily available for consideration. The proposed research will use text analysis (e.g., topic modeling and sentiment analysis) to learn how consumer and primary care physician (PCP) populations interpret prescription drug names, which will assist OPDP’s consideration of promotional implications.

This proposed research builds upon and extends OPDP’s research entitled “Empirical Study of Promotional Implications of Proprietary Prescription Drug Names” (86 FR 14440; March 16, 2021). That research involves an experimental design intended to assess names that potentially overstate the efficacy of a product. In contrast, the proposed research involves a survey design that comprises primarily open-ended questions intended to generate text for analysis, an approach that is unrestricted in its ability to assess text with different types of promotional implications (e.g., minimization of risk and unsubstantiated claims of superiority, in addition to overstatement of efficacy). The proposed research will add to the depth and breadth of knowledge we can draw from during the review of proposed proprietary drug names.

The key objectives of the proposed research are as follows:

1. To apply new techniques such as topic modeling and sentiment analysis (forms of text analysis) to answer OPDP’s research questions about