

Programming Interface (API). Instructions for navigating the report, accessing and using the API, and definitions of the report contents are

found at <https://www.fda.gov/safety/enforcement-reports/enforcement-report-information-and-definitions.com>.

We estimate the burden of the collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Activity; 21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Firm initiated recall; § 7.46 .....	2,779	1	2,779	25	69,475
Termination of recall; § 7.55 .....	2,095	1	2,095	10	20,950
Recall status reports; § 7.53 .....	2,779	13	36,127	10	361,270
<b>Total</b> .....			<b>41,001</b>		<b>451,695</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

A review of Agency data shows that 8,337 recalls were conducted during fiscal years 2017 through 2019, for an average of 2,779 recalls annually. We assume an average of 25 hours is needed to submit the requisite notification to FDA, for a total annual burden of 69,475 hours. Similarly, during the same

period, 6,287 recalls were terminated, for an average of 2,095 recall terminations annually, and we assume an average of 10 hours is needed for the corresponding information collection activity. To determine burden associated with recall status reports we divided the average number of annual

submissions (36,127) by the average number of annual respondents (2,779) and assume 10 hours is necessary for the corresponding information collection, resulting in 361,270 hours annually.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN <sup>1</sup>

Activity; 21 CFR part	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Recall communications; § 7.49.	2,779 .....	445	1,236,655 .....	0.05 (3 minutes) .....	61,832.75

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

To determine burden associated with recall communication disclosures described in § 7.49, we calculated an average of 445 disclosures per recall and attribute 3 minutes for each disclosure, resulting in 61,832.75 burden hours annually.

These estimates reflect an overall decrease in the average number of annual responses by 245,846 and a decrease in the average number of annual burden hours by 70,949.25 since our last submission for OMB review and approval of the information collection.

Dated: January 4, 2021.

**Lauren K. Roth,**  
Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-00125 Filed 1-7-21; 8:45 am]

BILLING CODE 4164-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2020-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) 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 January 29, 2021, for vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA (see **ADDRESSES**) by February 8, 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](mailto:ACOMSSubmissions@fda.hhs.gov), 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>, 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. Additional information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's website at <http://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, email: [kimberly.hamilton@fda.hhs.gov](mailto:kimberly.hamilton@fda.hhs.gov).

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

TABLE 1—ADVISORY COMMITTEE CONTACTS

Contact person	Committee/panel
Rakesh Raghuwanshi, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3309, Silver Spring, MD 20993-0002, 301-796-4769, email: <a href="mailto:Rakesh.Raghuwanshi@fda.hhs.gov">Rakesh.Raghuwanshi@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, Rm. 6268, Silver Spring, MD 20993-0002, 240-402-8054, email: <a href="mailto:Christina.Vert@fda.hhs.gov">Christina.Vert@fda.hhs.gov</a> .	Blood Products 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, email: <a href="mailto:Kathleen.Hayes@fda.hhs.gov">Kathleen.Hayes@fda.hhs.gov</a> .	Cellular, Tissue and Gene Therapies Advisory Committee, Vaccines and Related Biological Products Advisory Committee.
LaTonya 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, email: <a href="mailto:Latoya.Bonner@fda.hhs.gov">Latoya.Bonner@fda.hhs.gov</a> .	Dermatologic and Ophthalmic Drugs Advisory Committee.
Yinghua Wang, Center for Drugs Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2412, Silver Spring, MD 20992-002, 301-796-9033, email: <a href="mailto:Yinghua.Wang@fda.hhs.gov">Yinghua.Wang@fda.hhs.gov</a> .	Gastrointestinal Drugs Advisory Committee, Pharmaceutical Science and Clinical Pharmacology 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, email: <a href="mailto:Yvette.Waples@fda.hhs.gov">Yvette.Waples@fda.hhs.gov</a> .	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, email: <a href="mailto:James.Swink@fda.hhs.gov">James.Swink@fda.hhs.gov</a> .	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.
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, email: <a href="mailto:Patricio.Garcia@fda.hhs.gov">Patricio.Garcia@fda.hhs.gov</a> .	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, email: <a href="mailto:Aden.Asefa@fda.hhs.gov">Aden.Asefa@fda.hhs.gov</a> .	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, email: <a href="mailto:Aden.Asefa@fda.hhs.gov">Aden.Asefa@fda.hhs.gov</a> .	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, email: <a href="mailto:Letise.Williams@fda.hhs.gov">Letise.Williams@fda.hhs.gov</a> .	Patient Engagement Advisory Committee.

**SUPPLEMENTARY INFORMATION:** FDA is requesting nominations for voting and/or nonvoting consumer representatives 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 shall provide advice to the 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 will provide 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 will also provide, where requested, expert review of Agency sponsored intramural and extramural scientific research programs	1—Voting .....	January 1, 2021.

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
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 .....	September 1, 2021.
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, physicochemistry, 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
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—Non-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—Non-Voting	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—Non-Voting	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—Non-Voting	Immediately.
General Hospital and Personal Use Devices Panel—Internists, pediatricians, neonatologists, endocrinologists, gerontologists, nurses, biomedical engineers, or microbiologists/infection control practitioners, or experts	1—Non-Voting	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—Non-Voting	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—Non-Voting	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—Non-Voting	Immediately.
Gastroenterology and Urology Devices Panel—Gastroenterologists, urologists and nephrologists	1—Non-Voting	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—Non-Voting	Immediately.
Obstetrics and Gynecology Devices Panel—Experts in perinatology, embryology, reproductive endocrinology, pediatric gynecology, gynecological oncology, operative hysteroscopy, pelviscopy, electro-surgery, 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—Non-Voting	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—Non-Voting	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—Non-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
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—Non-Voting	June 1, 2021.
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—Non-Voting	Immediately.
Neurological Devices Panel—Neurosurgeons (cerebrovascular and pediatric), neurologists (stroke, pediatric, pain management, and movement disorders), interventional neuroradiologists, psychiatrists, and biostatisticians	1—Non-Voting	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 .....	2—Immediately 2—February 1, 2021.
Patient Engagement Advisory Committee—Experts who are knowledgeable in areas such as clinical research, primary care patient experience, and health care 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 shall provide advice to the 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 will provide 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 will also provide, 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 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 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 Biologic Products Advisory Committee

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. 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

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

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 the 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

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

Reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, advises on the classification or reclassification of devices into one of three regulatory categories; advises on

any possible risks to health associated with the use of devices; advises on formulation of product development protocols; reviews premarket approval applications for medical devices; reviews guidelines and guidance documents; recommends exemption of certain devices from the application of portions of the Federal Food, Drug, and Cosmetic Act; advises on the necessity to ban a device; and 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 of Food and Drugs 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*

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; reporting new developments concerning breast imaging which should be considered in the oversight of mammography facilities. As well as 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*

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, in order to improve communication of benefits, risks, clinical outcomes, and increase integration of patient perspectives into the regulatory process for medical devices. It 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 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 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: January 4, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021-00124 Filed 1-7-21; 8:45 am]

BILLING CODE 4164-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-N-3240]

#### List of Bulk Drug Substances for Which There Is a Clinical Need Under Section 503B of the Federal Food, Drug, and Cosmetic Act; Reopening of the Comment Period

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

**ACTION:** Notice; reopening of the comment period.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is reopening the comment period for a notice that appeared in the **Federal Register** of July 31, 2020, in which FDA identified certain bulk drug substances (active pharmaceutical ingredients) that FDA has considered and proposes to include or not include on the list of bulk drug substances for which there is a clinical need (the 503B Bulks List). The Agency is taking this action in response to a request received during the initial comment period, which asked the Agency to allow interested persons additional time to submit comments.

**DATES:** FDA is reopening the comment period on the notice published on July 31, 2020 (85 FR 46126). Submit either electronic or written comments by February 8, 2021.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 8, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 8, 2021.

Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### Electronic Submissions

Submit electronic comments in the following way:

- **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>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

**Instructions:** All submissions received must include the Docket No. FDA-2018-N-3240 for "List of Bulk Drug Substances for Which There is a Clinical Need Under Section 503B of the Federal Food, Drug, and Cosmetic Act." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

**FOR FURTHER INFORMATION CONTACT:** Dominic Markwordt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5104, Silver Spring, MD 20993, 301-796-9349.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of July 31, 2020 (85 FR 46126), FDA published a notice that identified four bulk drug substances that FDA considered and proposed to include on the 503B Bulks List: diphenylcyclopropenone (DPCP), glycolic acid, squaric acid dibutyl ester (SADBE), and trichloroacetic acid (TCA). The July 31, 2020, notice also identified 19 bulk drug substances that FDA considered and proposed not to include on the 503B Bulks List: Diazepam, dobutamine hydrochloride