DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–2256]

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 July 15, 2019, for vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA (see **ADDRESSES**) by July 15, 2019. Nominations will be accepted for current vacancies and for those that will or may occur through December 31, 2019.

ADDRESSES: All statements of interest from consumer organizations interested in participating in the selection process should be submitted electronically to *ACOMSSubmissions@fda.hhs.gov,* by mail to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, Rm. 5122, Silver Spring, MD 20993–0002, or by Fax: 301–847–8640.

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, 10903 New Hampshire Ave., Bldg. 32, Rm. 5122, Silver Spring, MD 20993–0002, or by Fax: 301–847–8640. 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, email: *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
Yinghua Wang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 31, Rm. 2412, Silver Spring, MD 20993–0002, 301–796–9033, email: *Yinghua.Wang@fda.hhs.gov*.	Arthritis Advisory Committee.
Kalyani Bhatt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2438, Silver Spring, MD 20993–0002, 301–796–9005, email: *Kalyani.Bhatt@fda.hhs.gov*.	Bone, Reproductive and Urological Drugs Advisory Committee; Psychopharmacologic Drugs Advisory Committee.
Jennifer Shepherd, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2434, Silver Spring, MD 20993–0002, 301–796–4043, email: *Jennifer.Shepherd@fda.hhs.gov*.	Medical Imaging Drugs Advisory Committee.
Lauren Hotaki, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2426, Silver Spring, MD 20993–0002, 301–796–2721, email: *Lauren.Hotaki@fda.hhs.gov*.	Oncologic Drugs Advisory Committee.
Cindy Chee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2430, Silver Spring, MD 20993–0002, 301–796–0889, email: *Cindy.Chee@fda.hhs.gov*.	Pharmacy Compounding Advisory Committee.
Patricio Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G610, Silver Spring, MD 20993–0002, 301–796–6875, email: *Patricio.Garcia@fda.hhs.gov*.	Clinical Chemistry and Clinical Toxicology Devices Panel; Gastroenterology and Urology Devices Panel; Obstetrics and Gynecology Devices Panel.
Sara Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G616, Silver Spring, MD 20993–0002, 301–796–7047, email: *Sara.Anderson@fda.hhs.gov*.	Dental Products Devices Panel; National Mammography Advisory Committee; Orthopaedic and Rehabilitation Devices Panel.
Evella Washington, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G640, Silver Spring, MD 20993–0002, 301–796–6683, email: *Evella.Washington@fda.hhs.gov*.	Circulatory Systems Devices Panel.
Joannie Adams-White, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5519, Silver Spring, MD 20993–0002, 301–796–5421, email: *Joannie.Adams-White@fda.hhs.gov*.	Medical Devices Dispute Resolution Panel.
Aden Asefa, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G642, Silver Spring, MD 20993–0002, 301–796–0400, email: *Aden.Asefa@fda.hhs.gov*.	Immunology Devices Panel; Microbiology Devices Panel; Radiological Devices Panel.

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
Arthritis Advisory Committee—Knowledgeable in the fields of arthritis, rheumatology, orthopedics, epidemiology or statistics, analgesics, and related specialties.	1—Voting	September 30, 2019.
Bone, Reproductive and Urological Drugs Advisory Committee—Knowledgeable in the fields of obstetrics, gynecology, endocrinology, pediatrics, epidemiology or statistics, and related specialties.	1—Voting	Immediately.
Psychopharmacologic Drugs Advisory Committee—Knowledgeable in the fields of psychopharmacology, psychiatry, epidemiology or statistics, and related specialties.	1—Voting	June 30, 2019.
Medical Imaging Drugs Advisory Committee—Knowledgeable in the fields of nuclear medicine, radiology, epidemiology, statistics, and related specialties.	1—Voting	Immediately.
Oncologic Drugs Advisory Committee—Knowledgeable in the fields of general oncology, pediatric oncology, hematologic oncology, immunologic oncology, biostatistics, and other related professions.	1—Voting	June 30, 2019.
Pharmacy Compounding Advisory Committee—Knowledgeable in the fields of pharmaceutical compounding, pharmaceutical manufacturing, pharmacy, medicine, and other related specialties.	1—Voting	Immediately.
Clinical Chemistry and Clinical Toxicology Devices Panel—Doctors 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.
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.
Dental Products Device 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	October 30, 2019.
National Mammography Advisory Committee—Physician, practitioner, or other health professional whose clinical practice, research specialization, or professional expertise includes a significant focus on mammography.	1—Non-Voting	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—Non-Voting	Immediately.
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.
Medical Devices Dispute Resolution—Experts with broad, cross-cutting scientific, clinical, analytical, or mediation skills.	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.
Radiology 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.

I. Functions and General Description of the Committee Duties

A. 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.

B. Bone, Reproductive and Urologic Drugs Advisory Committee

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

C. 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.

D. 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.

E. Oncologic Drugs Advisory Committee

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

F. Pharmacy Compounding Advisory Committee

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

G. 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.

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: June 10, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–12566 Filed 6–13–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0163]

Hospira, Inc., et al.; Withdrawal of Approval of 12 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 12 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of July 15, 2019.

FOR FURTHER INFORMATION CONTACT: Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993–0002, 240–402–7945, *Trang.Tran@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 040664	A-Methapred (methylprednisolone sodium succinate) for Injection USP, Equivalent to (EQ) 40 milligrams (mg) base/vial.	Hospira, Inc., 275 North Field Dr., Building H1, Lake Forest, IL 60045.
ANDA 040665	A-Methapred (methylprednisolone sodium succinate) for Injection USP, EQ 125 mg base/vial.	Do.
ANDA 060462	Garamycin (gentamicin sulfate) Cream USP, EQ 0.1% base.	Schering Corp., 2000 Galloping Hill Rd., Kenilworth, NJ 07033.
ANDA 061533	Mycostatin (nystatin) Oral Suspension USP, 100,000 units/milliliter (mL).	Bristol-Myers Squibb Co., P.O. Box 4500, Princeton, NJ 08543.
ANDA 071051	Astramorph/PF (morphine sulfate) Injection USP, 0.5 mg/mL.	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047.
ANDA 071052	Astramorph/PF (morphine sulfate) Injection USP, 1 mg/mL	Do.
ANDA 071053	Astramorph/PF (morphine sulfate) Injection USP, 1 mg/mL	Do.
ANDA 075656	Morphine Sulfate Extended-Release Tablets, 100 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 078815	Oxaliplatin for Injection, 50 mg/vial and 100 mg/vial	Hospira, Inc.
ANDA 088119	Isoniazid Tablets USP, 300 mg	Duramed Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 400 Interpace Pky., Morris Corporate Center III, Parsippany, NJ 07054.
ANDA 088231	Isoniazid Tablets USP, 100 mg	Do.
ANDA 091597	Gemcitabine for Injection USP, EQ 200 mg base/vial and EQ 1 gram base/vial.	Sagent Pharmaceuticals, Inc., 1901 North Roselle Rd., Suite 450, Schaumburg, IL 60195.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of July 15, 2019. Approval of each entire application is withdrawn, including any strengths or products inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on July 15, 2019, may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: June 10, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–12560 Filed 6–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–2224]

Arthritis Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a