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]

BILLING CODE 4164–01–P

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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of July 15, 2019.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

forthcoming public advisory committee meeting of the Arthritis Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on July 25, 2019, from 8:30 a.m. to 5 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2019–N–2224. The docket will close on July 24, 2019. Submit either electronic or written comments on this public meeting by July 24, 2019. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 24, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 24, 2019. 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.

Comments received on or before July 11, 2019, will be provided to the committee. Comments received after that date will be taken into consideration by FDA.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- 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–2019–N–2224 for ''Arthritis Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' Received comments, those filed in a timely manner (see the **ADDRESSES** section), 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.

- 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.'' FDA 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 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 the 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.gpo.gov/fdsys/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.

FOR FURTHER INFORMATION CONTACT: Yinghua S. Wang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, email: *AAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The committee will discuss supplemental new drug application (sNDA) 205832 for nintedanib capsules (drug name OFEV), sponsored by Boehringer Ingelheim, for the treatment of systemic sclerosis-associated interstitial lung disease (SSc-ILD). The focus of the discussion will be whether the application provides substantial evidence of efficacy for the proposed indication.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is

available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before July 2, 2019. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by July 3, 2019.

Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Yinghua Wang (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 10, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–12559 Filed 6–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Solicitation of Nominations for Membership To Serve on the National Advisory Council on Migrant Health

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Request for nominations.

SUMMARY: HRSA is seeking nominations of qualified candidates to be considered for appointment as members of the National Advisory Council on Migrant Health (NACMH/Council). The NACMH consults with and makes recommendations to the HHS Secretary concerning the organization, operation, selection, and funding of migrant health centers (MHC) and other entities, under grants and contracts under the Public Health Service (PHS) Act. HRSA is seeking nominations to fill up to five positions on the NACMH with individuals served by nominating health centers.

DATES: HRSA will receive written nominations for NACMH membership on a continuous basis.

ADDRESSES: Nomination packages must be submitted in hardcopy to the Designated Federal Official (DFO), NACMH, Strategic Initiatives and Planning Division, Office of Policy and Program Development, Bureau of Primary Health Care, HRSA, 16N38B, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: All requests for information regarding NACMH nominations should be sent to Esther Paul, DFO, NACMH, HRSA, in one of three ways: (1) Send a request to the following address: Esther Paul, Strategic Initiatives and Planning Division, Office of Policy and Program Development, Bureau of Primary Health Care, HRSA, 16N38B, 5600 Fishers Lane, Rockville, Maryland 20857; (2) call 301–594–4300; or (3) send an email to *epaul@hrsa.gov.* A copy of the NACMH charter and list of the current membership are available on the NACMH website at *https://bphc.hrsa.gov/qualityimprovement/strategicpartnerships/nacmh/index.html.*

SUPPLEMENTARY INFORMATION: NACMH was established and authorized under section 217 of the PHS Act, as amended (42 U.S.C. 218), to consult with and make recommendations to the HHS Secretary concerning the organization, operation, selection, and funding of MHCs, and other entities under grants and contracts under section 330 of the PHS Act (42 U.S.C. 254b). The NACMH meets twice each calendar year, or at the discretion of the DFO in consultation with the NACMH Chair.

Authority: NACMH is authorized under section 217 of the PHS Act, as amended (42 U.S.C. 218), and established by the Secretary. The NACMH is governed by the Federal Advisory Committee Act (5 U.S.C. Appendix 2) (FACA), which sets forth standards for the formation and use of advisory committees.

Nominations: HRSA requests nominations for voting members to serve as Special Government Employees (SGEs) on the NACMH. The nominations are to fill five open positions with MHC governing board members who are served by the nominating MHC and who are familiar with the delivery of health care to migratory and seasonal agricultural workers. The Secretary appoints NACMH members with the expertise needed to fulfill the duties of the Advisory Committee. The membership requirements set forth in section 217 of the PHS Act, as amended (42 U.S.C. 218), require that the Council consist of 15 members, at least 12 of whom shall be members of the governing boards of MHCs or other entities assisted under section 330 of the PHS Act (42 U.S.C. 254b). Of such 12 members, at least 9 shall be chosen from among those members served by such health centers and familiar with the delivery of health care to migratory and seasonal agricultural workers. The remaining three Council members shall be individuals qualified by training and experience in the medical sciences or in the administration of health programs. New members filling a vacancy that occurred prior to the expiration of a term may serve only for the remainder of such term. Members may serve after the expiration of their terms until their successors have taken office, but no longer than 120 days. Nominees must reside in the United States, and international travel cannot be funded.

Individuals selected for appointment to NACMH will be invited to serve for up to 4 years as SGEs. Members appointed as SGEs receive a stipend and reimbursement for per diem and travel expenses incurred for attending NACMH meetings, as authorized by 5 U.S.C. 5703 of the FACA for persons employed intermittently in government service.

A complete nomination package should include the following information for each nominee: (1) A