FDA will review all nominations received within the specified timeframe 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 that 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.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of July 15, 2019. Approval of each entire application is withdrawn, including any strengths or products inadvertently missing from the table.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 of 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.

BILLING CODE 4164–01–P

<table>
<thead>
<tr>
<th>Application No.</th>
<th>Drug</th>
<th>Applicant</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANDA 040664</td>
<td>A-Methapred (methylprednisolone sodium succinate) for Injection USP, Equivalent to (EQ) 40 milligrams (mg) base/vial</td>
<td>Hospira, Inc., 275 North Field Dr., Building H1, Lake Forest, IL 60045.</td>
</tr>
<tr>
<td>ANDA 040665</td>
<td>A-Methapred (methylprednisolone sodium succinate) for Injection USP, EQ 125 mg base/vial</td>
<td>Do.</td>
</tr>
<tr>
<td>ANDA 061533</td>
<td>Mycostatin (nystatin) Oral Suspension USP, 100,000 units/milliliter (mL)</td>
<td>Bristol-Myers Squibb Co., P.O. Box 4500, Princeton, NJ 08543.</td>
</tr>
<tr>
<td>ANDA 071051</td>
<td>Astramorph/PF (morphine sulfate) Injection USP, 0.5 mg/mL</td>
<td>Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047.</td>
</tr>
<tr>
<td>ANDA 071052</td>
<td>Astramorph/PF (morphine sulfate) Injection USP, 1 mg/mL</td>
<td>Do.</td>
</tr>
<tr>
<td>ANDA 071053</td>
<td>Astramorph/PF (morphine sulfate) Injection USP, 1 mg/mL</td>
<td>Do.</td>
</tr>
<tr>
<td>ANDA 078815</td>
<td>Oxaliplatin for Injection, 50 mg/vial and 100 mg/vial</td>
<td>Hospira, Inc.</td>
</tr>
<tr>
<td>ANDA 088231</td>
<td>Isoniazid Tablets USP, 100 mg</td>
<td>Do.</td>
</tr>
</tbody>
</table>

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Notice; 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 comments 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
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. 254b). Of such 12 members, at least 9 shall be chosen from among those individuals 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. 254b), 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