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in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of July 15, 2019.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