Our estimated burden for the information collection reflects an overall increase of 40 hours and a corresponding increase of one response/record. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Dated: February 12, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–03459 Filed 2–20–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–6083]

Hospira, Inc., et al.; Withdrawal of Approval of 15 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 15 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of March 23, 2020.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 240–402–6980, *Martha.Nguyen@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 040372	Promethazine Hydrochloride (HCl) Injection, 25 milligrams (mg)/milliliter (mL) and 50 mg/mL.	Hospira, Inc., 275 North Field Dr., Bldg. H1, Lake Forest, IL 60045.
ANDA 062791	Cephalexin Capsules, Equivalent to (EQ) 250 mg base and 500 mg base.	Sun Pharmaceutical Industries, Inc., 2 Independence Way, Princeton, NJ 08540.
ANDA 065226	Cefazolin Sodium for Injection, EQ 500 mg base/vial and EQ 1 gram (g) base/vial.	Hospira, Inc.
ANDA 065244	Cefazolin Sodium for Injection, EQ 1 g base/vial	Do.
ANDA 065375	Cefotetan Disodium for Injection, EQ 10 g base/vial	Fresenius Kabi USA, LLC., Three Corporate Dr., Lake Zurich, IL 60047.
ANDA 065386	Piperacillin Sodium and Tazobactam Sodium for Injection, EQ 2 g base/vial; EQ 250 mg base/vial, EQ 3 g base/vial; EQ 375 mg base/vial, EQ 4 g base/vial; EQ 500 mg base/vial.	Hospira, Inc.
ANDA 065446	Piperacillin Sodium and Tazobactam Sodium for Injection, EQ 36 g base/vial; EQ 4.5 g base/vial.	Do.
ANDA 075955	Amiodarone HCl Injection, 50 mg/mL	Do.
ANDA 076124	Ranitidine HCl Syrup, EQ 15 mg base/mL	Actavis Mid Atlantic, LLC., Subsidiary of Teva Pharmaceuticals USA, Inc., 400 Interpace Pkwy., Morris Corporate Center III, Bldg. A, Third Floor, Parsippany, NJ 07054.
ANDA 076722	Ketorolac Tromethamine Injection, 15 mg/mL, 30 mg/mL, and 60 mg/mL.	INC Research, LLC., 4800 Falls of Neuse Rd., Suite 600, Raleigh, NC 27609.
ANDA 080700	Chlorpheniramine Maleate Tablets, 4 mg	Sun Pharmaceutical Industries, Inc.
ANDA 083201	Hydrocortisone Lotion, 1%	Crown Laboratories, Inc., 349 Lafe Cox Dr., Johnson City, TN 37604.
ANDA 201654	Cefazolin Sodium for Injection, EQ 1 g base/vial	Hospira, Inc.
ANDA 203950	Oxacillin Sodium for Injection, EQ 1 g base/vial and EQ 2 g base/vial.	Do.
ANDA 207731	Nystatin and Triamcinolone Acetonide Ointment, 100,000 units/g; 0.1%.	Crown Laboratories, Inc.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of March 23, 2020. 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 March 23, 2020 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: February 18, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–03512 Filed 2–20–20; 8:45 am]

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