4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-1195]

Discovery Therapeutics, LLC, et al.; Withdrawal of Approval of 18 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 18 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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 040619	Methimazole Tablets, 15 milligrams (mg)	Discovery Therapeutics, LLC, 2831 Deer Hound Way, Palm Harbor, FL 34683
ANDA 070254	Naloxone Hydrochloride (HCl)	Hospira, Inc., 275 North Field Dr.,

Application No.	Drug	Applicant
	Injection, 0.4 mg/milliliters (mL)	Building H1, Lake Forest, IL 60045
ANDA 070586	Bupivacaine HCl Injection, 0.25%	Do.
ANDA 071850	Morphine Sulfate Injection, 1 mg/mL	Do.
ANDA 075220	Desmopressin Acetate Injection, 0.004 mg/mL	Do.
ANDA 076498	Tretinoin Cream, 0.05%	ZO Skin Health, Inc., 9685 Research Dr., Irvine, CA 92618
ANDA 077245	Ciprofloxacin Injection, 200 mg/20 mL (10 mg/mL) and 400 mg/40 mL (10 mg/mL)	Hospira, Inc.
ANDA 080409	Lidocaine HCl Solution, 4%	Do.
ANDA 087446	Chloroprocaine HCl Injection, 3%	Do.
ANDA 087447	Chloroprocaine HCl Injection, 2%	Do.
ANDA 201653	Levocetirizine Dihydrochloride Tablets, 5 mg	Sun Pharmaceutical Industries, Inc., U.S. Agent for Sun Pharmaceutical Industries Ltd., 270 Prospect Plains Rd., Cranbury, NJ 08512
ANDA 202524	Levetiracetam Extended Release Tablets, 500 mg and 750 mg	Rouses Point Pharmaceuticals, LLC, 11 Commerce Dr., Cranford, NJ 07016
ANDA 202857	Daptomycin Powder for Injection, 500 mg/vial	Hospira, Inc.
ANDA 203885	Amiodarone HCl Injection, 50 mg/mL	Do.
ANDA 207864	Eptifibatide Injection, 2 mg/mL and 75 mg/100 mL	The WhiteOak Group, LLC, U.S. Agent for Hybio Pharmaceutical Co., Ltd., 1629 K St. NW, Suite 300, Washington, DC 20006
ANDA 209489	Caspofungin Acetate Powder for Injection, 50 mg/vial and 70 mg/vial	Cipla USA, Inc., U.S. Agent for Cipla Limited, 10 Independence Blvd., Suite 300, Warren, NJ 07059
ANDA 210283	Clofarabine Injection, 20 mg/20 mL (1 mg/mL)	Hospira, Inc.
ANDA 210855	Sodium Nitroprusside Injection, 25 mg/mL	Cipla USA, Inc.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Approval of each entire application is withdrawn, including any strengths and dosage forms 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

[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] 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: November 12, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

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