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in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of December 20, 2021.

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) Injection, 0.4 mg/milliliters (mL).	Hospira, Inc., 275 North Field Dr., 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 December 20, 2021. 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 December 20, 2021 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.

[FR Doc. 2021–25111 Filed 11–17–21; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, NICHD.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the Eunice Kennedy Shriver National Institute of Child Health and Human Development, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NICHD.

Date: December 3, 2021.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: A report by the Acting Scientific Director, NICHD, on the status of the NICHD