DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-0516]

Mylan Pharmaceuticals Inc., et.al.; Withdrawal of Approval of 11 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 11 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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 075980	Tramadol Hydrochloride (HCl) Tablets, 50 milligrams (mg)	Mylan Pharmaceuticals Inc., 3711 Collins Ferry Rd., Morgantown, WV 26505

Application No.	Drug	Applicant
ANDA 075986	Tramadol HCl Tablets, 50 mg	Do.
ANDA 201510	Pirmella 7/7/7 Tablets, 0.035 mg, 0.035 mg, 0.035 mg; 0.5 mg, 0.75 mg, 1 mg	Lupin Pharmaceuticals, Inc., U.S. Agent for Lupin Ltd., 111 South Calvert St., Harborplace Tower, 21st Floor, Baltimore, MD 21202
ANDA 201512	Pirmella 1/35 Tablets, 0.035 mg; 1 mg	Do.
ANDA 203803	Propafenone HCl, Extended-Release Capsules, 225 mg, 325 mg, and 425 mg	Mylan Pharmaceuticals Inc.
ANDA 203900	Tacrolimus Injection, Equivalent to (EQ) 5 mg base/milliliters (mL)	Hospira, A Pfizer Company, 275 North Field Dr., Lake Forest, IL 60045
ANDA 203946	Fludeoxyglucose F18 Injectable, 20-300 millicurie (mCi)/ mL	Essential Isotopes, LLC, 1513 Research Park Dr., Columbia, MO 65211
ANDA 205923	Caspofungin Acetate Powder, 50 mg/ vial, and 70 mg/ vial	Xellia Pharmaceuticals USA, LLC, U.S. Agent for Xellia Pharmaceuticals ApS, 2150 East Lake Cook Rd., Suite 1015, Buffalo Grove, IL 60089
ANDA 209571	Darifenacin Hydrobromide Extended-Release Tablets, EQ 7.5 mg/ base and EQ 15 mg/ base	Xiromed, LLC., U.S. Agent for Xiromed Pharma España, S.L., 180 Park Ave., Suite 101, Florham Park, NJ 07932
ANDA 211972	Zileuton Extended-Release Tablets, 600 mg	Lupin Pharmaceuticals, Inc.
ANDA 213222	Icatibant Acetate Injectable, EQ 30 mg base/ 3 mL (EQ 10 mg base/ mL)	Glenmark Pharmaceuticals Inc., USA, U.S. Agent for Glenmark Pharmaceuticals Ltd., 750 Corporate Dr., Mahwah, NJ 07430

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: February 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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