DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0390]

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in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.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 060164	Nystatin Ointment	Lederle Laboratories, Division of American Cyanamid Co., P.O. Box 8299, Pearl River, NY 10965

Application No.	Drug	Applicant
ANDA 060521	Humatin (paromomycin sulfate) Capsules, Equivalent to (EQ) 250 milligrams (mg)/base	King Pharmaceuticals, 501 5th St., Bristol, TN 37620
ANDA 061034	Lincomycin Hydrochloride (HCl)	The Upjohn Co. (formerly Pharmacia and Upjohn Co.), 7000 Portage Rd., Kalamazoo, MI 49001
ANDA 061652	Oxytetracycline	Parke Davis, 201 Tabor Rd., Morris Plains, NJ 07950
ANDA 061701	Tetracycline	Wyeth Pharmaceuticals, 1211 Sherwood Ave., Richmond, VA 23220
ANDA 062032	Erypar (erythromycin stearate) Tablets, EQ 250 mg/base and EQ 500 mg/base	Parke Davis
ANDA 076490	Lithium Carbonate Extended-Release Tablets, 450 mg	Hikma Pharmaceuticals USA Inc., 1809 Wilson Rd., Columbus, OH 43228
ANDA 083001	Triamcinolone Acetonide Foam	Lederle Laboratories
ANDA 084803	Chlorpromazine HCl Tablets, 10 mg	Do.
ANDA 087635	Butalbital; Aspirin; Phenacetin; Caffeine, Tablets	Do.
ANDA 090102	Ranitidine HCl Syrup, EQ 15 mg base/milliliters	Torrent Pharma Inc., 150 Allen Rd., Suite 102, Basking Ridge, NJ 07920
ANDA 206736	Rifampin for Injection, 600 mg/vial	Watson Pharmaceuticals, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Pkwy., Building A, Parsippany, NJ 07054

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: May 5, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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