4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1227]

Roerig Division of Pfizer Inc., et.al.; Withdrawal of Approval of 10 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 10 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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 060709	Oleandomycin Injection	Roerig Division of Pfizer Inc., 235 East 42nd St., New York, NY 10017
ANDA 061087	Benzocaine, Oxytetracycline Hydrochloride (HCl), and Polymyxin B Sulfate Otic Solution	Pfizer Laboratories, Division of Pfizer Inc., 235 East 42nd St., New York, NY 10017
ANDA 061725	Tetracycline HCl Capsules, 250 milligrams (mg) and 500 mg	Warner Chilcott Division of Warner Lambert-Pfizer, Inc., 235 East 42nd St., New York, NY 10017
ANDA 061943	Chloramphenicol Ophthalmic Solution, 0.5%	Lederle Laboratories, Division of American Cyanamid Co., 1 Cyanamid Plaza, Wayne, NJ 07470
ANDA 062175	Tetracycline HCl Capsules, 250 mg	Warner Chilcott Division of Warner Lambert-Pfizer, Inc.
ANDA 062215	Oxytetracycline HCl Capsules	Lederle Laboratories, Division of American Cyanamid Co.
ANDA 076203	Ribavirin Capsules, 200 mg	Kadmon Pharmaceuticals, LLC, 119 Commonwealth Dr., Warrendale, PA 15086
ANDA 077456	Ribavirin Tablets, 200 mg, 400 mg, and 600 mg	Do.
ANDA 084669	Chlorpropamide Tablets, 250 mg	Sandoz Inc., 2555 W. Midway Blvd., Broomfield, CO 80038
ANDA 201750	Articaine HCI and Epinephrine Bitartrate for Injection, 4%; Equivalent to (EQ) 0.017 mg base/1.7 milliliters (mL); (4%; EQ 0.01 mg base/mL)	Hansamed Ltd., 4761 Tara Ct., West Bloomfield, MI 48323

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: July 15, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020-15727 Filed: 7/20/2020 8:45 am; Publication Date: 7/21/2020]