4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-0113]

Facta Farmaceutici S.p.A., et al.; Withdrawal of Approval of 23 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 23 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.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: Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993-0002, 240-402-7945, Trang.Tran@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 062117	Cephalexin for Oral Suspension USP, Equivalent to (EQ) 100 milligrams (mg) base/milliliter (mL), EQ 125 mg base/5 mL, and EQ 250 mg base/5 mL	Facta Farmaceutici S.p.A., c/o Interchem Corp., 120 Route, 17 North, Paramus, NJ 07652
ANDA 062508	Erymax (erythromycin) Topical Solution USP, 2%	Merz North America, 6501 Six Forks Rd., Raleigh, NC 27615
ANDA 075369	Enalapril Maleate Tablets USP, 10 mg and 20 mg	Krka, tovarna zdravil, d.d., Novo mesto, Slovenia, c/o KRKA USA, LLC, 4216 Cravens Point Rd., Wilmington, NC 28409
ANDA 075370	Enalapril Maleate Tablets USP, 2.5 mg and 5 mg	Do.
ANDA 077895	Ursodiol Capsules USP, 300 mg	Impax Laboratories, LLC, 30831 Huntwood Ave., Hayward, CA 94544
ANDA 078810	Oxaliplatin for Injection, 50 mg/vial and 100 mg/vial	Fresenius Kabi Oncology Plc., c/o Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047
ANDA 080420	Lidocaine Hydrochloride (HCl) Injection USP, 1%, 1.5%, and 2%	Lyphomed, Inc., 2045 North Cornell Ave., Melrose Park, IL 60160
ANDA 080421	Procaine HCl Injection USP, 1% and 2%	Do.
ANDA 083083	Lidocaine HCl Injection USP, 1% and 2%	Wyeth-Ayerst Laboratories, P.O. Box 8299, Philadelphia, PA 19101
ANDA 083744	Lidocaine HCl Injection USP, 0.5%, 1%, 1.5%, and 2%	Tera Pharmaceuticals, Inc., 6920 Stanton Ave., Buena Park, CA 90621
ANDA 083907	Lidocaine HCl With Epinephrine Injection USP	Do.
ANDA 084571	Lidocaine HCl Injection, 10 mg/20 mL and 10 mg/50 mL	Knoll Pharmaceuticals, 30 North Jefferson Rd., Whippany, NJ 07981
ANDA 084572	Lidocaine HCl Injection, 20 mg/20 mL and 20 mg/50 mL	Do.
ANDA 084720	Lidocaine HCl and Epinephrine Injection USP, 2%; 0.01 mg/mL	Naska Pharmacal Co., Inc., Riverview Rd., P.O. Box 898, Lincolnton, NC 28093
ANDA 084732	Lidocaine HCl and Epinephrine Injection USP, 2%; 0.02 mg/mL	Do.
ANDA 084947	Alphacaine (lidocaine) Ointment, 5%	Carlisle Laboratories, Inc., 404 Doughty Blvd., Inwood, NY 11696
ANDA 085037	Lidocaine HCl Injection USP, 1% and 2%	Akorn, Inc., P.O. Box 1220, Decatur, IL 62525
ANDA 085677	Cortisone Acetate Injectable Suspension USP, 25 mg/mL and 50 mg/mL	Steris Laboratories, Inc., 620 North 51st Ave., Phoenix, AZ 85043
ANDA 088051	Thalitone (chlorthalidone) Tablets USP, 25 mg	Casper Pharma LLC, 2 Tower Center Blvd., Suite 1101C, East Brunswick, NJ 08816

Application No.	Drug	Applicant
ANDA 089688	Lidocaine HCl Topical Solution USP, 4%	Paco Research, Corp., 1705 Oak St., Lakewood, NJ 08701
ANDA 091212	Lansoprazole Delayed-Release Capsules USP, 15 mg and 30 mg	Krka, tovarna zdravil, d.d., Novo mesto, c/o KRKA USA, LLC
ANDA 091377	Vancomycin HCl for Injection USP, EQ 500 mg base/vial and EQ 1gram (g) base/vial	Xellia Pharmaceuticals ApS, c/o Xellia Pharmaceuticals USA, LLC, 8841 Wadford Dr., Raleigh, NC 27616
ANDA 206243	Vancomycin HCl for Injection USP, EQ 5 g base/vial and EQ 10 g base/vial (Pharmacy Bulk Package)	Do.

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*].** 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: January 16, 2019.

Leslie Kux,

Associate Commissioner for Policy.

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