4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-1336]

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in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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 holders of the applications 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 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 040252	Carisoprodol and Aspirin Tablets USP, 200 milligrams (mg)/325 mg	Oxford Pharmaceuticals, LLC, 301 Leaf Lake Pkwy., Birmingham, AL 35211
ANDA 040283	Carisoprodol, Aspirin, and Codeine Phosphate Tablets USP, 200 mg/325 mg/16 mg	Do.
ANDA 061214	Tetracycline Hydrochloride (HCl) Capsules USP, 250 mg and 500 mg	Roxane Laboratories, Inc., 1809 Wilson Rd., Columbus, OH 43228
ANDA 061682	Tetracycline HCl Tablets, 500 mg	Mylan Pharmaceuticals Inc., P.O. Box 4293, Morgantown, WV 26505
ANDA 062212	Totacillin (ampicillin/ampicillin trihydrate) Capsules, Equivalent to (EQ) 250 mg base and EQ 500 mg base	GlaxoSmithKline, Five Moore Dr., P.O. Box 13398, Research Triangle Park, NC 27709
ANDA 062654	Rocephin (ceftriaxone sodium) for Injection, EQ 500 mg base/vial, EQ 1 gram (g) base/vial, and EQ 2 g base/vial	Hoffman La-Roche, Inc., c/o Genentech, Inc., 1 DNA Way, MS 241B, South San Francisco, CA 94080
ANDA 062680	Oxacillin Sodium for Injection (Pharmacy Bulk Package)	ACS Dobfar S.p.A., c/o Interchem Corp., 120 Route 17 North, Paramus, NJ 07653
ANDA 065124	Cefotaxime for Injection USP, EQ 500 mg base/vial, EQ 1 g base/vial, and EQ 2 g base/vial	Lupin Ltd., c/o Lupin Pharmaceuticals, Inc., 111 South Calvert St., Harborplace Tower, 24th Floor, Baltimore, MD 21202
ANDA 065263	Ceftriaxone for Injection USP, EQ 10 g base/vial (Pharmacy Bulk Package)	Do.
ANDA 074845	Diltiazem HCl Extended-Release Capsules USP, 60 mg, 90 mg, and 120 mg	Biovail Corp. International, Subsidiary of Valeant Pharmaceuticals North America, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807
ANDA 077173	Ondansetron Injection USP, EQ 2 mg base/milliliter (mL)	Sun Pharmaceutical Industries Ltd., c/o Sun Pharmaceutical Industries, Inc., 2 Independence Way, Princeton, NJ 08540
ANDA 078598	Ciprofloxacin Ophthalmic Solution USP, EQ 0.3% base	Amring Pharmaceuticals, Inc., 1235 Westlakes Dr., Suite 205, Berwyn, PA 19312
ANDA 078805	Irinotecan HCl Injection, 20 mg/mL	Sun Pharma Global FZE, c/o Sun Pharmaceutical Industries, Inc., 2

Application No.	Drug	Applicant
		Independence Way, Princeton, NJ 08540
ANDA 086024	Capital and Codeine (acetaminophen and codeine phosphate) Oral Suspension USP, 120 mg/12 mg per 5 mL	Valeant Pharmaceuticals North America, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807
ANDA 091180	Dorzolamide HCl and Timolol Maleate Ophthalmic Solution, EQ 2% base/EQ 0.5% base	Zambon S.p.A., c/o Camargo Pharmaceutical Services, LLC, 9825 Kenwood Rd., Suite 203, Cincinnati, OH 45242
ANDA 203176	Nevirapine Tablets USP, 200 mg	Technology Organized, LLC, 9191 Point Replete Dr., Fort Belvoir, VA 22060
ANDA 204900	Amlodipine Besylate Tablets USP, EQ 2.5 mg base, EQ 5 mg base, and EQ 10 mg base	Sovereign Pharmaceuticals, LLC, 7590 Sand St., Fort Worth, TX 76118
ANDA 209480	Clozapine Tablets USP, 25 mg, 50 mg, 100 mg, and 200 mg	Zydus Pharmaceuticals USA, Inc., 73 Route 31 North, Pennington, NJ 08534

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: April 5, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-07440 Filed: 4/10/2018 8:45 am; Publication Date: 4/11/2018]