



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-3569]

GlaxoSmithKline, LLC, et al.; Withdrawal of Approval of 24 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 24 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.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 061336	Bactocill (oxacillin sodium) Capsules, Equivalent to (EQ) 250 milligrams (mg) base and EQ 500 mg base	GlaxoSmithKline, LLC, Five Moore Dr., P.O. Box 13398, Research Triangle Park, NC 27709
ANDA 061773	Kefzol (cefazolin) for Injection USP, EQ 250 mg base/vial, EQ 500 mg base/vial, EQ 1 gram (g) base/vial, EQ 10 g base/vial, and EQ 20 g base/vial	ACS Dobfar S.p.A., c/o Interchem Corp., 120 Rte. 17 North, Paramus, NJ 07652
ANDA 062615	Nystatin Vaginal Inserts USP, 100,000 units	Odyssey Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044
ANDA 063304	Clindamycin Phosphate Topical Solution USP, EQ 1% base	Wockhardt Bio AG, c/o Morton Grove Pharmaceuticals, Inc., 6451 Main St., Morton Grove, IL 60053
ANDA 065001	Cefuroxime for Injection USP, EQ 750mg base/vial and EQ 1.5 g base/vial	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047
ANDA 065002	Cefuroxime for Injection USP, EQ 7.5 g base/vial (Pharmacy Bulk Package)	Do.
ANDA 070736	Ibuprofen Tablets USP, 300 mg, 400 mg, and 600 mg	Aurolife Pharma, LLC, 279 Princeton Hightstown Rd., East Windsor, NJ 08520
ANDA 071202	Sensorcaine--MPF Spinal (bupivacaine hydrochloride (HCl)) in Dextrose Injection 8.25% USP, 0.75%	Fresenius Kabi USA, LLC
ANDA 071846	Nitroglycerin in Dextrose 5% Injection, 10 mg/100 milliliter (mL)	Hospira, Inc., 275 North Field Dr., Bldg. H1, Lake Forest, IL 60045
ANDA 071847	Nitroglycerin in Dextrose 5% Injection, 20 mg/100 mL	Do.
ANDA 071848	Nitroglycerin in Dextrose 5% Injection, 40 mg/100 mL	Do.
ANDA 072629	Albuterol Tablets USP, EQ 2 mg base	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA Inc., 425 Privet Rd., Horsham, PA 19044
ANDA 074991	Loperamide HCl Oral Solution, 1 mg/5 mL	Duramed Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044
ANDA 077312	Fentanyl Citrate Troche/Lozenge, EQ 0.2 mg base, EQ 0.4 mg base, EQ 0.6 mg base, EQ 0.8 mg base, EQ 1.2 mg, and EQ 1.6 mg base	Par Pharmaceutical, Inc., One Ram Ridge Rd., Chestnut Ridge, NY 10977

Application No.	Drug	Applicant
ANDA 077853	Metformin HCl Tablets USP, 500 mg, 850 mg, and 1 g	Provident Pharmaceutical, Inc., c/o Vintage Pharmaceuticals, LLC, 1400 Atwater Dr., Malvern, PA 19355
ANDA 080355	Hydrocortisone Tablets USP, 20 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., Morris Corporate Center III, 400 Interpace Pkwy., Parsippany, NJ 07054
ANDA 080377	Lidocaine HCl with Epinephrine Injection, 1%; 0.01 mg/mL and 2%; 0.01 mg/mL	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044
ANDA 087100	Chlorthalidone Tablets USP, 25 mg	Do.
ANDA 087211	Methocarbamol and Aspirin Tablets, 400 mg/325 mg	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044
ANDA 090184	Podofilox Topical Solution, 0.5%	Bausch & Lomb, Inc., Subsidiary of Valeant Pharmaceuticals North America, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807
ANDA 202002	Imiquimod Cream, 5%	Strides Pharma Global Pte Ltd., c/o Strides Pharma, Inc., 2 Tower Center Blvd., Suite 1102, East Brunswick, NJ 08816
ANDA 203247	Sodium Fluoride F-18 Injection, 10-200 millicurie (mCi)/mL	University of Texas MD Anderson Cancer Center, Cyclotron Radiochemistry Facility, 1881 East Rd., Unit 1903, Houston, TX 77054
ANDA 203933	Ammonia N-13 Injection, 3.75-37.5 mCi/mL	Do.
ANDA 205072	Cefadroxil Capsules USP, EQ 500 mg base	CSPC Ouyi Pharmaceutical Co., Ltd., c/o Megalith Pharmaceuticals, Inc., 9625 Hillside Rd., Rancho Cucamonga, CA 91737

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: September 25, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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