4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-2493]

ICU Medical, Inc., et al.; Withdrawal of Approval of 31 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 31 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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 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 020345	Aminosyn-HF (amino acids) Injection, 8%	ICU Medical, Inc., 600 North Field Dr., Lake Forest, IL 60045
ANDA 040723	Isosorbide Dinitrate Extended-Release Tablets USP, 40 milligrams (mg)	Impax Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544
ANDA 064062	Amphotericin B for Injection USP, 50 mg/vial	Teva Parenteral Medicines, Inc., 19 Hughes, Irvine, CA 92618
ANDA 064200	Cefotaxime for Injection USP, Equivalent to (EQ) 500 mg base/vial, EQ 1 gram (g) base/vial, and EQ 2 g base/vial	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047
ANDA 064201	Cefotaxime for Injection USP, EQ 10 g base/vial and EQ 20 g base/vial	Do.
ANDA 065251	Cefuroxime for Injection USP, EQ 75 g base/bag and EQ 225 g base/bag (Pharmacy Bulk Package)	Samson Medical Technologies, LLC, 2050 Springdale Rd., P.O. Box 2730, Suite 400, Cherry Hill, NJ 08034
ANDA 070892	Metoclopramide Hydrochloride (HCl) Injection, EQ 10 mg base/2 milliliters (mL)	Norbrook Laboratories, Ltd., c/o Norbrook, Inc., 9401 Indian Creek Pkwy., Suite 680, Overland Park, KS 66210
ANDA 075309	Ticlopidine HCl Tablets USP, 250 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044
ANDA 076797	Risperidone Oral Solution USP, 1 mg/mL	Precision Dose, Inc., 722 Progressive Lane, South Beloit, IL 61080
ANDA 077656	Thrive (nicotine polacrilex) Gum USP (Chewable), EQ 4 mg base	GlaxoSmithKline Consumer Healthcare, 184 Liberty Corner Rd., Suite 200, Warren, NJ 07059
ANDA 077658	Thrive (nicotine polacrilex) Gum USP (Chewable), EQ 2 mg base	Do.
ANDA 080188	Testosterone Propionate Injection USP, 25 mg/mL, 50 mg/mL, and 100 mg/mL	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 083398	Prednisolone Acetate Injectable Suspension, 25 mg/mL	Do.
ANDA 083764	Prednisolone Acetate Injectable Suspension, 50 mg/mL	Do.
ANDA 084072	Triamcinolone Diacetate Injection, 40 mg/mL	Do.
ANDA 084270	Triamcinolone Tablets USP, 4 mg	Do.
ANDA 084466	Reserpine and Hydrochlorothiazide Tablets, 0.125 mg/25 mg	Do.
ANDA 084604	Procainamide HCl Capsules, 250 mg	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 085693	Phentermine HCl Tablets USP, 8 mg	Sandoz, Inc., 4700 Sandoz Dr., Wilson, NC 27893
ANDA 085863	Theophylline Elixir, 80 mg/15 mL	Precision Dose, Inc.

Application No.	Drug	Applicant
ANDA 087185	Ergoloid Mesylates Sublingual Tablets USP, 1 mg	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 087770	Sulfinpyrazone Capsules USP, 200 mg	Do.
ANDA 088648	Methotrexate Injection USP, EQ 25 mg base/mL	Norbrook Laboratories, Ltd., c/o Norbrook, Inc.
ANDA 088928	Chlorzoxazone Tablets USP, 250 mg	Actavis Elizabeth, LLC, Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 090663	Gemcitabine for Injection USP, EQ 200 mg base/vial and EQ 1 g base/vial	Hameln RDS GmbH, c/o B&H Consulting Services, Inc., 50 Division St., Suite 206, Somerville, NJ 08876
ANDA 091469	Vancomycin HCl for Injection USP, EQ 10 g base/vial (Pharmacy Bulk Package)	Mylan Laboratories, Ltd., c/o Mylan Pharmaceuticals, Inc., 781 Chestnut Ridge Rd., P.O. Box 4310, Morgantown, WV 26504
ANDA 202390	Tramadol HCl Tablets USP, 50 mg	Accord Healthcare, Inc., 1009 Slater Rd., Suite 210-B, Durham, NC 27703
ANDA 203506	Oxymorphone HCl Extended-Release Tablets, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg	Sun Pharmaceutical Industries, Ltd., c/o Sun Pharmaceutical Industries, Inc., 2 Independence Way, Princeton, NJ 08540
ANDA 204320	Olanzapine Orally Disintegrating Tablets USP, 5 mg, 10 mg, 15 mg, and 20 mg	Ajanta Pharma, Ltd., c/o Ajanta Pharma USA, Inc., 440 U.S. Highway 22 East, One Grande Commons, Suite 150, Bridgewater, NJ 08807
ANDA 204706	Olopatadine HCl Ophthalmic Solution USP, EQ 0.1% base	Zambon S.p.A., c/o Camargo Pharmaceutical Services, LLC, 9825 Kenwood Rd., Suite 203, Cincinnati, OH 45242
ANDA 207467	Nevirapine Extended-Release Tablets, 100 mg and 400 mg	Technology Organized, LLC, 9191 Point Replete Dr., Fort Belvoir, VA 22060

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: July 23, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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