4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-4099]

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in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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: 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 040747	Benzphetamine Hydrochloride (HCl) Tablets, 25 milligrams (mg) and 50 mg	Tedor Pharma, Inc., 400 Highland Corporate Dr., Cumberland, RI 02864
ANDA 062356	Gentamicin Sulfate Injection USP, Equivalent to (EQ) 10 mg base/milliliter (mL) and EQ 40 mg base/mL	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047
ANDA 074097	Isoflurane USP, 99.9%	Hospira, Inc., 275 North Field Dr., Bldg. H1, Lake Forest, IL 60045
ANDA 076484	Ciprofloxacin Injection USP, 200 mg/20 mL and 400 mg/40 mL	Fresenius Kabi USA, LLC
ANDA 080504	Epinephrine and Lidocaine HCl Injection, 0.01 mg/mL; 2% and 0.02 mg/mL; 2% Lidocaine HCl Injection, 2%	Belmora LLC, 2231 Crystal Dr., #1000, Arlington, VA 22202
ANDA 083559	Mepivacaine HCl Injection, 3%	Do.
ANDA 084315	Dexamethasone Acetate Injectable Suspension USP, EQ 8 mg base/mL	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044
ANDA 084850	Levonordefrin and Mepivacaine HCl Injection, 2%; 0.05 mg/mL	Belmora LLC
ANDA 086389	Lidocaine HCl Viscous Oral Topical Solution USP, 2%	International Medication Systems, Ltd., 1886 Santa Anita Ave., South El Monte, CA 91733
ANDA 087863	Choledyl SA (oxtriphylline) Extended-Release Tablets USP, 400 mg	Warner Chilcott Co., LLC, Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044

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: November 6, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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