4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-2306]

TG United Inc., et al.; Withdrawal of Approval of 27 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 27 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993-0002, 240-402-6980, Martha.Nguyen@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 040083	Phentermine Hydrochloride (HCl) Capsules, 30 milligrams (mg)	TG United Inc., 16275 Aviation Loop Dr., Brooksville, FL 34604
ANDA 040451	Cyanocobalamin Injection, 1 mg/milliliters (mL)	Mylan Institutional LLC, 4901 Hiawatha Dr., Rockford, IL 61103
ANDA 040518	Bethanechol Chloride Tablets, 50 mg	Morton Grove Pharmaceuticals Inc./Wockhardt USA LLC, 6451

Application No.	Drug	Applicant
		W. Main St., Morton Grove, IL 60053
ANDA 040532	Bethanechol Chloride Tablets, 5 mg	Do.
ANDA 060347	Tetracycline HCl Capsules, 250 mg	Pharmacia & Upjohn Co., a subsidiary of Pfizer Inc., 235 East 42nd St., New York, NY 10017
ANDA 060478	Neomycin Sulfate Ophthalmic Ointment	Pfizer Inc., 235 East 42nd St., New York, NY 10017
ANDA 065266	Clarithromycin Tablets, 250 mg and 500 mg	Morton Grove Pharmaceuticals Inc./Wockhardt USA LLC
ANDA 065281	Doxycycline Hyclate Delayed Release Capsules, Equivalent to (EQ) 75 mg base; EQ 100 mg base	Bausch Health US, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807
ANDA 075208	Ranitidine HCl Tablets, EQ 150 mg base; EQ 300 mg base	Morton Grove Pharmaceuticals Inc./Wockhardt USA LLC
ANDA 075822	Loratadine Orally Disintegrating Tablets, 10 mg	GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, 184 Liberty Corner Rd., Suite 200, Warren, NJ 07059
ANDA 076760	Ranitidine HCl Tablets, EQ 75 mg base	Morton Grove Pharmaceuticals Inc./Wockhardt USA LLC
ANDA 076849	Vinorelbine Tartrate Injection, EQ 10 mg base/mL	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047
ANDA 077432	Carboplatin Injection, 50 mg/5 mL(10 mg/mL), 150 mg/15 mL (10 mg/mL), and 450 mg/45 mL (10 mg/mL)	Do.
ANDA 078500	Amlodipine Besylate Tablets, EQ 2.5 mg base; EQ 5 mg base; EQ 10 mg base	Morton Grove Pharmaceuticals Inc./Wockhardt USA LLC
ANDA 084041	Chlordiazepoxide HCl Capsules, 10 mg	Upsher-Smith Laboratories, LLC, 6701 Evenstad Dr., Maple Grove, MN 55369
ANDA 084678	Chlordiazepoxide HCl Capsules, 5 mg	Do.
ANDA 084679	Chlordiazepoxide HCl Capsules, 25 mg	Do.
ANDA 088508	Homatropine Methylbromide; Hydrocodone Bitartrate Tablets, 1.5 mg; 5 mg	King Pharmaceuticals Research and Development, LLC, 4000 Centregreen Way, Suite 300, Cary, NC 27513
ANDA 089953	Thioridazine HCl Tablets, 10 mg, 25 mg, 50 mg, and 100 mg	Sun Pharmaceutical Industries, Inc., 2 Independence Way, Princeton, NJ 08540
ANDA 090094	Didanosine Delayed Release Capsules, 125 mg, 200 mg, 250	Aurobindo Pharma USA, Inc., 279 Princeton-Hightstown Rd., East

Application No.	Drug	Applicant
	mg, and 400 mg	Windsor, NJ 08520
ANDA 090394	Iopamidol Injection, 61% and 76%	Sanochemia Corporation USA, 9201 University City Blvd., c/o Countervail Corp., Charlotte, NC 08876
ANDA 091302	Fludrocortisone Acetate Tablets, 0.1 mg	Hikma Pharmaceuticals USA Inc., 1809 Wilson Rd., Columbus, OH 43228
ANDA 203959	Temozolomide Capsules, 5 mg, 20 mg, 100 mg, 140 mg, and 250 mg	Watson Laboratories, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 425 Privet Rd., Horsham, PA 19044
ANDA 204243	Indomethacin Extended Release Capsules, 75 mg	Aurobindo Pharma USA, Inc.
ANDA 206061	Pravastatin Sodium Tablets, 20 mg, 40 mg, and 80 mg	Hisun Pharmaceuticals USA, Inc., 200 Crossing Blvd., 2nd Floor, Bridgewater, NJ 08807
ANDA 206857	Tiagabine HCl Tablets, 2 mg, 4 mg, 12 mg, and 16 mg	Wilshire Pharmaceuticals, Inc., 6 Concourse Pkwy., Suite 1800, Atlanta, GA 30328
ANDA 209076	Ibuprofen Tablets, 200 mg	Ultra Tab Laboratories, Inc., 50 Toc Dr., Highland, NY 12528

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*]. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. 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 11, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-00833 Filed: 1/14/2021 8:45 am; Publication Date: 1/15/2021]