4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-1524]

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in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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 040524	Promethazine Hydrochloride (HCl) Injection USP, 25 milligrams (mg)/milliliter (mL) and 50 mg/mL	Bedford Laboratories, 300 Northfield Rd., Bedford, OH 44146
ANDA 070857	Trazodone HCl Tablets USP, 50 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044
ANDA 070987	Diazepam Tablets USP, 2 mg	Halsey Drug Co., Inc., 1827 Pacific St., Brooklyn, NY 11233
ANDA 070996	Diazepam Tablets USP, 5 mg	Do.
ANDA 071717	Flurazepam HCl Capsules USP, 15 mg and 30 mg	Aurolife Pharma, LLC, 279 Princeton Hightstown Rd., East Windsor, NJ 08520
ANDA 071751	Methyldopa Tablets USP, 125 mg	Halsey Drug Co., Inc.
ANDA 071752	Methyldopa Tablets USP, 250 mg	Do.
ANDA 077190	Milrinone Lactate Injection, EQ 1 mg base/mL	Gland Pharma, Ltd., c/o INC Research, LLC, 4800 Falls of Neuse Rd., Suite 600, Raleigh, NC 27609
ANDA 077703	Pamidronate Disodium for Injection USP, 30 mg/vial and 90 mg/vial	Sun Pharma Global FZE, c/o Sun Pharmaceutical Industries, Inc., 270 Prospect Plains Rd., Cranbury, NJ 08512
ANDA 080300	Prednisone Tablets USP, 5 mg	Halsey Drug Co., Inc.
ANDA 080961	Chlorpheniramine Maleate Tablets USP, 4 mg	Aurolife Pharma, LLC
ANDA 083453	Niacin Tablets USP, 500 mg	Halsey Drug Co., Inc.
ANDA 083629	Kloromin (chlorpheniramine maleate) Tablets USP, 4 mg	Do.
ANDA 083930	Dextroamphetamine Sulfate Tablets USP, 10 mg	Do.
ANDA 084676	Secobarbital Sodium Capsules USP, 100 mg	Do.
ANDA 085088	Hydralazine HCl Tablets USP, 50 mg	Upsher-Smith Laboratories, LLC, 6701 Evenstad Dr., Maple Grove, MN 55369
ANDA 085219	Hydrochlorothiazide Tablets, 50 mg	Aurolife Pharma, LLC
ANDA 085923	Amitriptyline HCl Tablets USP, 10 mg	Halsey Drug Co., Inc.
ANDA 087279	Butalbital, Aspirin, and Caffeine Tablets	Sandoz, Inc., 227-15 North Conduit Ave., Laurelton, NY 11413
ANDA 088116	Myfed (pseudoephedrine HCl and triprolidine HCl) Syrup, 30 mg/5 mL and 1.25 mg/5 mL	USL Pharma, LLC, 301 South Cherokee St., Denver, CO 80223
ANDA 088725	Chlorpropamide Tablets USP, 100 mg	Aurolife Pharma, LLC
ANDA 089130	Hydralazine HCl Tablets USP, 25 mg	Halsey Drug Co., Inc.
ANDA 089178	Hydralazine HCl Tablets USP, 100 mg	Do.
ANDA 201484	Levofloxacin Tablets, 250 mg, 500 mg, and 750 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.

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 or products 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: May 20, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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