



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-2088]

Sanofi-Aventis U.S. LLC, et.al.; Withdrawal of Approval of 11 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 11 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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 061884	Rifamate (isoniazid and rifampin) Capsules, 150 milligrams (mg); 300 mg	Sanofi-Aventis U.S. LLC 55 Corporate Dr., Bridgewater, NJ 08807
ANDA 065196	Ceftazidime for Injection, 1 gram(g)/vial	Morton Grove Pharmaceuticals Inc./Wockhardt USA LLC., 6451 Main St., Morton Grove, IL 60053
ANDA 065197	Cefotaxime for Injection, Equivalent to (EQ) 1 g base/vial; EQ 2 g base/vial; EQ 500 mg base/vial	Do.
ANDA 078229	Terbinafine Hydrochloride (HCl) Tablets, EQ 250 mg base	Do.
ANDA 081134	Niacin Tablets, 500 mg	Do.
ANDA 091659	Heparin Sodium Injection, 5,000 units/milliliter (mL)	CASI Pharmaceuticals, Inc., 9620 Medical Center Dr., Suite 300, Rockville, MD 20850
ANDA 202647	Granisetron HCl Injection, EQ 0.1 mg base/mL (EQ 0.1 mg base/mL)	Yung Shin Pharmaceutical Industrial Co., Ltd./Carlsbad Technology, Inc., 5922 Farnsworth Ct., Carlsbad, CA 92008
ANDA 202648	Granisetron HCl Injection, EQ 1 mg base/mL (EQ 1 mg base/mL); EQ 4 mg base/4 mL (EQ 1 mg base/mL)	Do.
ANDA 205173	Bosentan Tablets, 62.5 mg and 125 mg	Mylan Pharmaceuticals Inc., 781 Chestnut Ridge Rd., P.O. Box 4310, Morgantown, WV 26504
ANDA 207843	Telmisartan Tablets, 20 mg, 40 mg, and 80 mg	Hisun Pharmaceutical (Hangzhou) Co., Ltd./Hisun Pharmaceuticals USA, Inc., 200 Crossing Blvd, 2nd Floor, Bridgewater, NJ 08807
ANDA 210681	Ranitidine HCl Capsules, EQ 150 mg base and EQ 300 mg base	Novitium Pharma LLC, 70 Lake Dr., East Windsor, NJ 08520

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: October 26, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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