



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-5964]

Teva Pharmaceuticals USA, Inc., et al.; Withdrawal of Approval of 23 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 23 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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, 301-796-3471, Martha.Nguyen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The applicants listed in table 1 have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process 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.

Table 1.--ANDAs for Which Approval Is Withdrawn

Application No.	Drug	Applicant
ANDA 040454	Promethazine Hydrochloride (HCl) injectable, 25 milligrams (mg)/milliliters (mL) and 50 mg/mL	Teva Pharmaceuticals USA, Inc., 400 Interpace Parkway, Bldg. A, Parsippany, NJ 07054
ANDA 040593	Promethazine HCl injectable, 25	Sandoz Inc., 100 College Rd. West,

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Application No.	Drug	Applicant
	mg/mL and 50 mg/mL	Princeton, NJ 08540
ANDA 064042	Nystatin suspension, 100,000 units/mL	PAI Holdings, LLC, dba Pharmaceutical Associates, Inc., and dba PAI Pharma, 1700 Perimeter Rd., Greenville, SC 29605
ANDA 074811	Haloperidol Decanoate injectable, Equivalent to (EQ) 50 mg base/mL	Hikma Pharmaceuticals USA Inc., 2 Esterbrook Lane, Cherry Hill, NJ 08003
ANDA 076061	Pergolide Mesylate tablet, EQ 0.05 mg base, EQ 0.25 mg base, and EQ 1 mg base	Strides Pharma Inc., U.S. Agent for Strides Pharma Global Pte Ltd., 2 Tower Center Blvd., Suite 1102, East Brunswick, NJ 08816
ANDA 079075	Fentanyl Citrate tablet, EQ 0.1 mg base, EQ 0.2 mg base, EQ 0.4 mg base, EQ 0.6 mg base, and EQ 0.8 mg base	Watson Laboratories, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Parkway, Bldg. A, Parsippany NJ 07054
ANDA 079240	Sumatriptan Succinate injectable, EQ 6 mg base/0.5 mL (EQ 12 mg base/mL) and EQ 4 mg base/0.5 mL (EQ 8 mg base/mL)	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047
ANDA 084591	Promethazine HCl injectable, 25 mg/mL	Watson Laboratories, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.)
ANDA 090016	Irinotecan HCl injectable, 40 mg/2mL (20 mg/mL) and 100 mg/5 mL (20 mg/mL)	Hisun Pharmaceuticals USA Inc., U.S. Agent for Hisun Pharmaceutical (Hangzhou) Co., Ltd., 200 Crossing Blvd., 2nd Floor, Bridgewater, NJ 08807
ANDA 200536	Ranitidine HCl tablet, EQ 150 mg base	Strides Pharma Inc., U.S. Agent for Strides Pharma Global Pte Ltd.
ANDA 201745	Ranitidine HCl tablet, EQ 75 mg base	Do.
ANDA 204991	Atorvastatin Calcium tablet, EQ 10 mg base, EQ 20 mg base, EQ 40 mg base, and EQ 80 mg base	Lupin Pharmaceuticals, Inc., U.S. Agent for Lupin Ltd., Harborplace Tower, 111 South Calvert St., 21st Floor, Baltimore, MD 21202
ANDA 205512	Ranitidine HCl tablet, EQ 150 mg base and EQ 300 mg base	Strides Pharma Inc., U.S. Agent for Strides Pharma Global Pte Ltd.
ANDA 206155	Olanzapine tablet, 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, and 20 mg	RegCon Solutions, LLC, U.S. Agent for Indoco Remedies Ltd., 9920 Pacific Heights Blvd., Suite 250, San Diego, CA 92121
ANDA 206204	Piperacillin and Tazobactam injectable, EQ 12 grams (g) base/vial; EQ 1.5 g base/vial	Fresenius Kabi USA, LLC
ANDA 207338	Fentanyl Citrate tablet, EQ 0.1 mg base, EQ 0.2 mg base, EQ 0.3 mg base, EQ 0.4 mg base, EQ 0.6 mg base, and EQ 0.8 mg base	Actavis Laboratories FL, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA Inc.), 400 Interpace Parkway, Bldg. A,

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Application No.	Drug	Applicant
		Parsippany, NJ 07054
ANDA 207919	Acyclovir Sodium injectable, EQ 50 mg base/mL	Dr. Reddy's Laboratories Inc., 107 College Rd. East, Princeton, NJ 08540
ANDA 209325	Miglustat capsule, 100 mg	Breckenridge Pharmaceutical, Inc., 15 Massirio Dr., Suite 201, Berlin, CT 06037
ANDA 209708	Mivacurium Chloride solution, EQ 10 mg base/5 mL (EQ 2 mg base/mL) and EQ 20 mg base/10 mL (EQ 2 mg base/mL)	Woodward Pharma Services, LLC, 47220 Cartier Dr., Suite A, Wixom, MI 48393
ANDA 211893	Ranitidine HCl capsule, EQ 150 mg base and EQ 300 mg base	Appco Pharma LLC, 262 Old New Brunswick Rd., Suite M, N, B-1, F, Piscataway, NJ 08854
ANDA 214428	Niacin extended-release tablet, 500 mg and 1 g	Sciecare Pharma Inc., U.S. Agent for Beijing Sciecare Pharmaceutical Co., Ltd., 138 Glendale Ave., Edison, NJ 08817
ANDA 215908	Nitisinone capsule, 2 mg, 5 mg, 10 mg, and 20 mg	Torrent Pharma Inc., 106 Allen Rd., Suite 305, Basking Ridge, NJ 07920
ANDA 217094	Fluphenazine HCl tablet, 1 mg, 2.5 mg, 5 mg, and 10 mg	Torrent Pharma Inc., U.S. Agent for Torrent Pharmaceuticals Ltd., 106 Allen Rd., Suite 305, Basking Ridge, NJ 07920

Therefore, approval of the applications listed in table 1, 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 table 1. Introduction or delivery for introduction into interstate commerce of products listed in table 1 without an approved new drug application or ANDA violates sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)). Drug products that are listed in table 1 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 8, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

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