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Dated: January 8, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–00757 Filed 1–14–25; 8:45 am]

BILLING CODE 4164–01–P

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in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of February 14, 2025.

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TABLE 1—ANDAS FOR WHICH APPROVAL IS WITHDRAWN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 mg/mL and 50 mg/mL	Sandoz Inc., 100 College Rd. West, 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, Parsippany, NJ 07054.

TABLE 1—ANDAS FOR WHICH APPROVAL IS WITHDRAWN—Continued

Application No.	Drug	Applicant
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	Sciecure Pharma Inc., U.S. Agent for Beijing Sciecure 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 February 14, 2025. 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 February 14, 2025 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.

[FR Doc. 2025–00742 Filed 1–14–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–5851]

Teva Branded Pharmaceutical Products R&D, Inc., et al.; Withdrawal of Approval of 12 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 12 new drug applications (NDAs) 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 February 14, 2025.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@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—NDAS FOR WHICH APPROVAL IS WITHDRAWN

Application No.	Drug	Applicant
NDA 009388	Diamox IV (acetazolamide) Injectable, Equivalent to (EQ) 500 milligrams (mg) base per vial.	Teva Branded Pharmaceutical Products R&D, Inc., 145 Brandywine Parkway, West Chester, PA 19380.
NDA 012836	Persantine (dipyridamole) Tablets, 25mg, 50mg, and 75mg	Boehringer Ingelheim Pharmaceuticals, Inc., 900 Ridgebury Road, P.O. Box 368, Ridgefield, CT 06877.
NDA 018817	Calan (verapamil hydrochloride (HCl)) Tablets, 40 mg, 80 mg, 120 mg, and 160 mg.	Pfizer Inc., 66 Hudson Boulevard East, New York, NY 10001.
NDA 021743	Tarceva (erlotinib HCl) Tablets, EQ 25 mg base, EQ 100 mg base, and EQ 150 mg base.	OSI Pharmaceuticals, LLC, 2375 Waterview Dr., Northbrook, IL 60062.
NDA 021785	Invirase (saquinavir mesylate) Tablets, EQ 500 mg base	Hoffmann-La Roche, Inc. c/o Genentech, Inc., 1 DNA Way, South San Francisco, CA 94080.
NDA 021937	Atripla (efavirenz, emtricitabine, and tenofovir disoproxil fumarate) Tablets, 600 mg/200 mg/300 mg.	Gilead Sciences, Inc., 333 Lakeside Dr., Foster City, CA 94404.
NDA 022383	Arcapta Neohaler (indacaterol maleate) Powder for Inhalation, EQ 75 micrograms base.	Novartis Pharmaceuticals Corp., 1 Health Plaza, East Hanover, NJ 07936.
NDA 204412	Delzicol (mesalamine), Delayed-Release Capsules, 400 mg	AbbVie Inc., 1 N. Waukegan Rd., North Chicago, IL 60064.
NDA 210875	Kynmobi (apomorphine HCl) Sublingual Film, 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg.	Sumitomo Pharma America, Inc., 84 Waterford Dr., Marlborough, MA 01752.