Dated: July 24, 2024.

Lauren K. Roth,

Associate Commissioner for Policy. [FR Doc. 2024–16617 Filed 7–26–24; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration [Docket No. FDA-2024-N-3248]

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in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

**DATES:** Approval is withdrawn as of August 28, 2024.

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## TABLE 1-ANDAS FOR WHICH APPROVAL IS WITHDRAWN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 073462	Tolmetin Sodium capsule, Equivalent to (EQ) 400 milligrams (mg) base.	Fosun Pharma USA Inc., 104 Carnegie Center, Suite 204, Princeton, NJ 08540.
ANDA 073588	Tolmetin Sodium tablet, EQ 200 mg base	Do.
ANDA 074002	Tolmetin Sodium tablet, EQ 600 mg base	Do.
ANDA 075631	Ketorolac Tromethamine injectable, 15 mg/milliliters (mL) and 30 mg/mL.	Baxter Healthcare Corp., One Baxter Parkway, Deerfield, IL 60015.
ANDA 076427	Milrinone Lactate injectable, EQ 1 mg base/mL	Do.
ANDA 076791	Haloperidol Lactate injectable, EQ 5 mg base/mL	Do.
ANDA 076828	Haloperidol Lactate injectable, EQ 5 mg base/mL	Do.
ANDA 077040	Citalopram Hydrobromide tablet, EQ 10 mg base, EQ 20 mg base, EQ 40 mg base.	Fosun Pharma USA Inc.
ANDA 077947	Fluconazole injectable, 200 mg/100 mL (2 mg/mL) and 400 mg/200 mL (2 mg/mL).	Baxter Healthcare Corp.
ANDA 078197	Granisetron Hydrochloride (HCI) injectable, EQ 0.1 mg base/ mL (EQ 0.1 mg base/mL).	Do.
ANDA 079045	Bicalutamide tablet, 50 mg	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047.
ANDA 085787	Trifluoperazine HCl concentrate, EQ 10 mg base/mL	Fosun Pharma USA Inc.
ANDA 086808	Cyproheptadine HCl tablet, 4 mg	Do.
ANDA 087774	Phenylbutazone capsule, 100 mg	Do.
ANDA 088602	Pseudoephedrine HCI; Triprolidine HCI tablet, 60 mg; 2.5.mg	Do.
ANDA 090367	Levofloxacin tablet, 250 mg, 500 mg, 750 mg	Celltrion USA, Inc., U.S. Agent for Celltrion, Inc., One Evertrust Plaza, Suite 1207, Jersey City, NJ 07302.
ANDA 091049	Ceftriaxone Sodium injectable, EQ 250 mg base/vial, EQ 500 mg base/vial, EQ 1 gram (g) base/vial, EQ 2 g base/vial.	EAS Consulting Group, LLC, U.S. Agent for Astral SteriTech Pvt. Ltd., 1700 Diagonal Rd., Suite 750, Alexandria, VA 22314.
ANDA 091436	Levofloxacin injectable, EQ 500 mg/20 mL (EQ 25 mg/mL)	Baxter Healthcare Corp.
ANDA 207032	Melphalan HCl injectable, EQ 50 mg base/vial	USWM, LLC, 4441 Springdale Rd., Louisville, KY 40241.
ANDA 207101	Sumatriptan Succinate injectable, EQ 6 mg base/0.5 mL (EQ 12 mg base/mL).	Baxter Healthcare Corp.
ANDA 211959	Clobazam tablet, 10 mg and 20 mg	Celltrion USA, Inc., U.S. Agent for Celltrion, Inc.
ANDA 212053 ANDA 215065	Chlorzoxazone tablet, 375 mg and 750 mgMethocarbamol solution, 1 g/10 mL (100 mg/mL)	AptaPharma Inc., 1533 Union Ave., Pennsauken, NJ 08110. Baxter Healthcare Corp.

Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn as of August 28, 2024. 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 August 28, 2024 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: July 24, 2024.

Lauren K. Roth,

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