4164-01-P

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; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the *Federal Register* on July 29, 2024. The document announced the withdrawal of approval of 23 abbreviated new drug applications (ANDAs) from multiple applicants, withdrawn as of August 28, 2024. The document indicated that FDA was withdrawing approval of the ANDAs 073462 for tolmetin sodium capsules, equivalent to (EQ) 400 milligrams (mg) base; 073588 for tolmetin sodium tablets, EQ 200 mg base; 074002 for tolmetin sodium tablets, EQ 600 mg base; 077040 for citalopram hydrobromide tablets, EQ 10 mg base, EQ 20 mg base; EQ 40 mg base; 085787 for trifluoperazine hydrochloride (HCl) concentrate, EQ 10 mg base/milliliters (mL); 086808 for cyproheptadine HCl tablets, 4 mg; 087774 for phenylbutazone capsules, 100 mg; and 088602 for pseudoephedrine HCl; triprolidine HCl tablets, 60 mg/2.5.mg, held by Fosun Pharma USA Inc., 104 Carnegie Center, Suite 204, Princeton, NJ 08540. Additionally, ANDAS 075631 for ketorolac tromethamine injectable, 15 mg/mL and 30 mg/mL; 076427 for milrinone lactate injectable, EQ 1 mg base/mL; 076791 for haloperidol lactate injectable, EQ 5 mg base/mL; 076828 haloperidol lactate injectable, EQ 5 mg base/mL; 077947 for fluconazole injectable, 200 mg/100 mL (2 mg/mL) and 400 mg/200 mL (2 mg/mL); 078197 for granisetron HCl injectable, EQ 0.1 mg base/mL (EQ 0.1 mg base/mL); 091436 for levofloxacin injectable, EQ 500 mg/20 mL (EQ 25 mg/mL); 207101 for sumatriptan succinate injectable, EQ 6 mg base/0.5 mL (EQ12 mg base/mL); and 215065 for methocarbamol solution, 1gram /10 mL (100 mg/mL), held by

Baxter Healthcare Corp., One Baxter Parkway, Deerfield, IL 60015; and the ANDAs 090367 for levofloxacin tablets, 250 mg, 500 mg, 750 mg; and 211959 for clobazam tablets, 10 mg and 20 mg, held by Celltrion USA, Inc., U.S. Agent for Celltrion, Inc., One Evertrust Plaza, Suite 1207, Jersey City, NJ 07302; and the ANDA 212053 for chlorzoxazone tablet, 375 mg and 750 mg, held by i3 Pharmaceuticals LLC, 200 Park Ave., Warminster, PA 18974. Before FDA withdrew the approval of these ANDAs, Fosun Pharma USA Inc.; Baxter Healthcare Corp.; Celltrion USA, Inc., U.S. Agent for Celltrion, Inc.; and i3 Pharmaceuticals LLC, 200 Park Ave., Warminster, PA 18974, informed FDA that they did not want the approval of the ANDAs withdrawn. Because Fosun Pharma USA Inc.; Baxter Healthcare Corp.; Celltrion USA, Inc., U.S. Agent for Celltrion, Inc.; and i3 Pharmaceuticals, LLC, timely requested that approval of their respective ANDAs not be withdrawn, the approvals are still in effect. This notice corrects these errors.

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: In the *Federal Register* of Monday, July 29, 2024 (89 FR 60902), appearing on page 60902 in FR Doc. 2024-16627, the following correction is made:

On page 60902, in the table, the entries for ANDA 073462, ANDA 073588, ANDA 074002, ANDA 075631, ANDA 076427, ANDA 076791, ANDA 076828, ANDA 077040, ANDA 077947, ANDA 078197, ANDA 085787, ANDA 086808, ANDA 087774, ANDA 088602, ANDA 090367, ANDA 091436 ANDA 207101, ANDA 211959, ANDA 212053, and ANDA 215065 are removed.

Dated: December 20, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

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