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; 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 January 15, 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 document announced the withdrawal of approval of 23 abbreviated new drug applications (ANDAs) from multiple applicants, withdrawn as of February 14, 2025. The document erroneously included four previously withdrawn ANDAs; ANDA 079075 for Fentanyl Citrate (fentanyl citrate) tablet, Equivalent to (EQ) 0.1 milligrams (mg) base, EQ 0.2 mg base, EQ 0.4 mg base, EQ 0.6 mg base, and EQ 0.8 mg base, held by Watson Laboratories, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Parkway, Bldg. A, Parsippany, NJ 07054; ANDA 206155 for Olanzapine (olanzapine) tablet, 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, and 20 mg, held by RegCon Solutions, LLC, U.S. Agent for Indoco Remedies Ltd., 9920 Pacific Heights Blvd., Suite 250, San Diego, CA 92121; ANDA 206204 for Piperacillin and Tazobactam (piperacillin and tazobactam) injectable, EQ 12 grams (g) base/vial and EQ 1.5 g base/vial, held by Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047; and ANDA 209708 for Mivacurium Chloride (mivacurium chloride) solution, EQ 10 mg base/5 milliliters (mL) (EQ 2 mg base/mL) and EQ

20 mg base/10 mL (EQ 2 mg base/mL), held by Woodward Pharma Services, LLC, 47220 Cartier Dr., Suite A, Wixom, MI 48393. This notice corrects that error. Because ANDAs 079075, 206155, 206204, and 209708 were withdrawn previously in the September 19, 2024 *Federal Register* notice titled "Allergan, Inc., et al.; Withdrawal of Approval of Nine Abbreviated New Drug Applications," those ANDA withdrawals still have an effective date of October 21, 2024.

Correction

In the *Federal Register* of Wednesday, January 15, 2025 (90 FR 3876), appearing on page 3876, 3877 in FR Doc. 2025-00742, the following correction is made:

On page 3876-3877, in the table, the entries for ANDAs 079075, 206155, 206204, and 209708 are removed.

Dated: July 30, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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