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. 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document announced the withdrawal of approval of 23 abbreviated new drug applications (ANDAs) from multiple applicants, withdrawn as of February 14, 2025.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 indicated that FDA was withdrawing approval of the ANDA 209325 for miglustat capsule, 100 milligrams, held by Breckenridge Pharmaceutical, Inc., 15 Massirio Dr., Suite 201, Berlin, CT 06037. Before FDA withdrew the approval of this ANDA, Breckenridge Pharmaceutical, Inc. informed FDA that they did not want the approval of the ANDA withdrawn. Because Breckenridge Pharmaceutical, Inc., timely requested that approval of ANDA 209325 not be withdrawn, the approval is still in effect. This notice corrects this error.

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:

Correction

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

On page 3877, in the table, the entry for ANDA 209325 is removed.

Dated: March 31, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

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