4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-0163]

Hospira, Inc., et al.; Withdrawal of Approval of 12 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* of February 12, 2019. The document announced the withdrawal of approval of 12 abbreviated new drug applications (ANDAs) from multiple applicants. The document erroneously included ANDA 077736 for Polyethylene Glycol 3350 Powder for Oral Solution, 17 grams/scoopful, held by Breckenridge Pharmaceutical, Inc. (Breckenridge). This document corrects that error.

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.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of February 12, 2019 (84 FR 3467), in FR Doc. 2019-02032, the following correction is made:

1. On page 3467, in the table, the entry for ANDA 077736 is removed. The approval of ANDA 077736 was withdrawn effective November 2, 2018.

In the *Federal Register* of April 2, 2018 (83 FR 13994), FDA denied a hearing and issued an order withdrawing approval of multiple ANDAs for polyethylene glycol 3350, effective May

2, 2018. Breckenridge's ANDA 077736 was included in the April 2018 notice. In the *Federal Register* of July 30, 2018 (83 FR 36604), FDA subsequently published a notice granting a temporary stay of the effective date of the April 2018 notice, extending the withdrawal of approval of the ANDAs to November 2, 2018. Thus, the approval of ANDA 077736 was withdrawn effective November 2, 2018.

Dated: June 12, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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