4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-0478]

Sebela Ireland, Ltd. et al.; Withdrawal of Approval of 24 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 February 23, 2018. The notice announced the voluntary withdrawal of approval of 24 abbreviated new drug applications (ANDAs) from multiple applicants, effective March 26, 2018. The notice indicated that FDA was withdrawing approval of the following ANDA after receiving a withdrawal request from Sun Pharmaceutical Industries, Ltd., c/o Sun Pharmaceutical Industries, Inc. (Sun Pharmaceutical), 2 Independence Way, Princeton, NJ 08540: ANDA 077483, Benazepril Hydrochloride and Hydrochlorothiazide Tablets, 5 milligrams (mg)/6.25 mg, 10 mg/12.5 mg, 20 mg/12.5 mg, and 20 mg/25 mg. Before withdrawal of this ANDA became effective, however, Sun Pharmaceutical informed FDA that it did not want approval of the ANDA withdrawn. Because Sun Pharmaceutical timely requested that approval of this ANDA not be withdrawn, the approval of ANDA 077483 is still in effect.

FOR FURTHER INFORMATION CONTACT: Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993-0002, 240-402-7945.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of Friday, February 23, 2018 (83 FR 8089), appearing on page 8089 in FR Doc. 2018-03700, the following correction is made:

1. On page 8090, the entry for ANDA 077483 in the table is removed.

Dated: June 1, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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