



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-0793]

Sun Pharmaceutical Industries, Ltd., and Sun Pharma Global FZE; Withdrawal of Approval of Four 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 March 14, 2018. The notice announced the voluntary withdrawal of approval of four abbreviated new drug applications (ANDAs) from two applicants, effective April 13, 2018. In particular, 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 076045, Lorazepam Tablets USP, 0.5 milligram (mg), 1 mg, and 2 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of this ANDA became effective, however, Sun Pharmaceutical informed FDA that it did not want approval of the ANDA withdrawn. Because Sun Pharmaceutical timely requested that approval of this ANDA not be withdrawn, the approval of ANDA 076045 is still in effect.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 Wednesday, March 14, 2018 (83 FR 11208), appearing on page 11208 in FR Doc. 2018-05120, the following correction is made:

1. On page 11208, the entry for ANDA 076045 in the table is removed.

Dated: June 26, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-14050 Filed: 6/28/2018 8:45 am; Publication Date: 6/29/2018]