



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-0601]

Mylan Institutional LLC et al.; Withdrawal of Approval of 16 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 9, 2020. The document announced the withdrawal of approval (as of April 8, 2020) of 16 abbreviated new drug applications (ANDAs) from multiple applicants. The document indicated that FDA was withdrawing approval of the following four ANDAs after receiving a withdrawal request from Lupin Pharmaceuticals, Inc., 111 South Calvert St., Harborplace Tower, 21st Floor, Baltimore, MD 21202: ANDA 065488, Azithromycin Oral Suspension, Equivalent to (EQ) 100 milligrams (mg) base/5 milliliters (mL); EQ 200 mg base/5 mL; ANDA 078410, Topiramate Tablets, 25 mg, 50 mg, 100 mg, and 200 mg; ANDA 090441, Imipramine Hydrochloride Tablets, 10 mg, 25 mg, and 50 mg; and ANDA 200563, Ciprofloxacin Oral Suspension, 250 mg/5 mL and 500 mg/5 mL. Before FDA withdrew the approval of these ANDAs, Lupin Pharmaceuticals, Inc., informed FDA that it did not want the approval of the ANDAs withdrawn. Because Lupin Pharmaceuticals, Inc., timely requested that approval of these ANDAs not be withdrawn, the approval of ANDAs 065488, 078410, 090441, and 200563 is still in effect.

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, 240-402-6980, Martha.Nguyen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of Monday, March 9, 2020 (85 FR 13661), in FR Doc. 2020-04691, the following correction is made:

On page 13661, in the table, the entries for ANDAs 065488, 078410, 090441, and 200563 are removed.

Dated: June 12, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020-13070 Filed: 6/16/2020 8:45 am; Publication Date: 6/17/2020]