



**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**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is withdrawing approval of 16 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

**DATES:** Approval is withdrawn as of **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

**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](mailto:Martha.Nguyen@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 040471	Promethazine Hydrochloride (HCl) Injection, 25 milligrams (mg)/milliliters (mL)	Mylan Institutional LLC, 4901 Hiawatha Dr., Rockford, IL 61103
ANDA 060286	Penicillin G Procaine Injection, 300,000 units/mL and 600,000 units/mL	Pfizer, Inc., 235 East 42nd St., New York, NY 10017
ANDA 065247	Cefazolin Sodium for Injection, Equivalent to (EQ) 10 grams base/vial	Hospira, Inc., 275 North Field Dr., Bldg. H1, Lake Forest, IL 60045
ANDA 065488	Azithromycin Oral Suspension, EQ 100 mg base/5 mL; EQ 200 mg base/5 mL	Lupin Pharmaceuticals, Inc., 111 South Calvert St., Harborplace Tower, 21st Floor, Baltimore, MD 21202
ANDA 076185	Dimethyl Sulfoxide Intravesical Solution, 50%	Mylan Institutional LLC
ANDA 076428	Milrinone Lactate Injection, EQ 1 mg base/mL	Do.
ANDA 076488	Mesna Injection, 100 mg/mL	Do.
ANDA 078410	Topiramate Tablets, 25 mg, 50 mg, 100 mg, and 200 mg	Lupin Pharmaceuticals, Inc.
ANDA 078957	Stavudine Capsules, 15 mg, 20 mg, 30 mg, and 40 mg	Hetero USA, Inc., 1035 Centennial Ave., Piscataway, NJ 08854
ANDA 090441	Imipramine HCl Tablets, 10 mg, 25 mg, and 50 mg	Lupin Pharmaceuticals, Inc.
ANDA 200563	Ciprofloxacin Oral Suspension, 250 mg/5 mL and 500 mg/5 mL	Do.
ANDA 205657	Chlorpheniramine Maleate, Hydrocodone Bitartrate, and Pseudoephedrine HCl Solution, 4 mg/5 mL; 5 mg/5 mL; and 60 mg/5 mL	Mayne Pharma Inc., 1240 Sugg Pkwy., Greenville, NC 27834
ANDA 205658	Hydrocodone Bitartrate and Pseudoephedrine HCl Oral Solution, 5 mg/5 mL; and 60 mg/5 mL	Do.
ANDA 200624	Metformin HCl, and Repaglinide Tablets, 500 mg/1 mg; 500 mg/2 mg	Lupin Pharmaceuticals, Inc.
ANDA 202384	Omeprazole Delayed-Release Capsules, 40 mg	Do.
ANDA 202532	Clarithromycin Extended-Release Tablets, 500 mg	Do.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Approval of each entire application is

withdrawn, including any strengths and dosage forms inadvertently missing from the table.

Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: March 2, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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