

**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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

**DATES:** Approval is withdrawn as of April 8, 2020.

**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 April 8, 2020. 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 April 8, 2020 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.*

[FR Doc. 2020-04691 Filed 3-6-20; 8:45 am]

**BILLING CODE 4164-01-P****DEPARTMENT OF HEALTH AND HUMAN SERVICES****Health Resources and Services Administration****Meeting of the Advisory Committee on Organ Transplantation**

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** In accordance with the Federal Advisory Committee Act, this notice announces that the Secretary's

Advisory Committee on Organ Transplantation (ACOT) has scheduled a public meeting. Information about ACOT and the agenda for this meeting can be found on the ACOT website at <https://www.organdonor.gov/about-dot/acot.html>.

**DATES:** April 7, 2020, 8:00 a.m.–4:00 p.m. Eastern Time (ET).

**ADDRESSES:** This meeting will be held in-person. The address for the meeting is 5600 Fishers Lane, Rockville, Maryland 20857, Room 5A03.

**FOR FURTHER INFORMATION CONTACT:** Robert Walsh, Designated Federal Official, (DFO), at Healthcare Systems Bureau, Division of Transplantation, HRSA, 5600 Fishers Lane, 8W60, Rockville, Maryland 20857; 301-443-6839; or [RWalsh@hrsa.gov](mailto:RWalsh@hrsa.gov).

**SUPPLEMENTARY INFORMATION:** ACOT provides advice and recommendations to the Secretary of HHS (Secretary) on