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in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of April 8, 2020.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

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.*

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

policy, program development, and other matters of significance concerning the activities under 42 U.S.C. Section 217a, Section 222 of the Public Health Service Act, as amended, and 42 CFR 121.12. ACOT advises the Secretary, through the HRSA Administrator, on all aspects of organ donation, procurement, allocation, and transplantation, and on such other matters that the Secretary determines; advises the Secretary on federal efforts to maximize the number of deceased donor organs made available for transplantation and to support the safety of living organ donation; at the request of the Secretary, reviews significant proposed Organ Procurement and Transplantation Network policies submitted for the Secretary's approval to recommend whether they should be made enforceable; and provides expert input on the latest advances in the science of transplantation.

During the April 7, 2020, meeting, ACOT will discuss issues related to the recent HHS National Survey of Organ Donation Attitudes and Behaviors and efforts to increase organ transplantation. Agenda items are subject to change as priorities dictate. Refer to the ACOT website for any updated information concerning the meeting.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to ACOT should be sent to Robert Walsh, DFO, using the contact information above at least 3 business days prior to the meeting.

Individuals who plan to attend and need special assistance or another reasonable accommodation should notify Robert Walsh at the address and phone number listed above at least 10 business days prior to the meeting. Since this meeting occurs in a federal government building, attendees must go through a security check to enter the building. Non-U.S. Citizen attendees must notify HRSA of their planned attendance at least 20 business days prior to the meeting in order to facilitate their entry into the building. All attendees are required to present government-issued identification prior to entry.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020–04744 Filed 3–6–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: Application and Other Forms Used by the National Health Service Corps (NHSC) Scholarship Program (SP), the NHSC Students to Service Loan Repayment Program (S2S LRP), and the Native Hawaiian Health Scholarship Program (NHHSP), OMB No. 0915–0146—Revision

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

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than May 8, 2020.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Application and Other Forms Used by NHSC Scholarship Program (SP), the NHSC Students to Service Loan Repayment Program, and the Native Hawaiian Health Scholarship Program.

OMB No. 0915–0146—Revision

Abstract: Administered by HRSA's Bureau of Health Workforce, the NHSC SP, NHSC S2S LRP, and the NHHSP provide scholarships or loan repayment to qualified students who are pursuing primary care health professions education and training. In return, students agree to provide primary health care services in medically underserved communities located in federally designated Health Professional Shortage Areas once they are fully trained and licensed health professionals. Awards are made to applicants who demonstrate the greatest potential for successful completion of their education and training as well as commitment to provide primary health care services to communities of greatest need. The information from program applications, forms, and supporting documentation is used to select the best qualified candidates for these competitive awards, and to monitor program participants' enrollment in school, postgraduate training, and compliance with program requirements.

Although some program forms vary from program to program (see program-specific burden charts below), required forms generally include: A program application, academic and non-academic letters of recommendation, the authorization to release information, and the acceptance/verification of good standing report. Additional forms for the NHSC SP include the data collection worksheet, which is completed by the educational institutions of program participants; the post-graduate training verification form (applicable for NHSC S2S LRP participants), which is completed by program participants and their residency director; and the enrollment verification form, which is completed by program participants and the educational institution for each academic term. For this ICR, the NHHSP program proposes to add 3 new forms including the scholar enrollment verification, change in program curriculum and graduation documentation forms. These forms will be completed by the grantee on behalf of the participant and the educational institution to verify the participant's enrollment status for each academic term, to provide notice of any change in the participant's program curriculum, and to verify that NHHSP has met its financial obligation to pay tuition and related fees or to hold additional funds to cover any tuition balance or fees on the participant's student account.

Need and Proposed Use of the Information: The NHSC SP, S2S LRP, and NHHSP applications, forms, and supporting documentation are used to collect necessary information from applicants that enable HRSA to make selection determinations for the competitive awards and monitor compliance with program requirements.