This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''S11 Nonclinical Safety Testing in Support of Development of Pediatric Pharmaceuticals.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312, pertaining to the submission of nonclinical and preclinical data, including a pediatric clinical development plan, have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 58 pertaining to good laboratory practice for nonclinical laboratory studies have been approved under OMB control number 0910–0119; and the collections of information in FDA's guidance for industry on ''Expedited Programs for Serious Conditions—Drugs and Biologics'' has been approved under OMB control number 0910–0765.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.regulations.gov, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs,* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.*

Dated: May 6, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–09964 Filed 5–11–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0390]

Lederle Laboratories et al.; Withdrawal of Approval of 12 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 12 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 June 11, 2021.

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 060164	Nystatin Ointment	Lederle Laboratories, Division of American Cyanamid Co., P.O. Box 8299, Pearl River, NY 10965.
ANDA 060521	Humatin (paromomycin sulfate) Capsules, Equivalent to (EQ) 250 milligrams (mg)/base.	King Pharmaceuticals, 501 5th St., Bristol, TN 37620.
ANDA 061034	Lincomycin Hydrochloride (HCl)	The Upjohn Co. (formerly Pharmacia and Upjohn Co.), 7000 Portage Rd., Kalamazoo, MI 49001.
ANDA 061652	Oxytetracycline	Parke Davis, 201 Tabor Rd., Morris Plains, NJ 07950.
ANDA 061701	Tetracycline	Wyeth Pharmaceuticals, 1211 Sherwood Ave., Richmond, VA 23220.
ANDA 062032	Erypar (erythromycin stearate) Tablets, EQ 250 mg/base and EQ 500 mg/base.	Parke Davis.
ANDA 076490	Lithium Carbonate Extended-Release Tablets, 450 mg	Hikma Pharmaceuticals USA Inc., 1809 Wilson Rd., Columbus, OH 43228.
ANDA 083001	Triamcinolone Acetonide Foam	Lederle Laboratories.
ANDA 084803	Chlorpromazine HCl Tablets, 10 mg	Do.
ANDA 087635	Butalbital; Aspirin; Phenacetin; Caffeine, Tablets	Do.
ANDA 090102	Ranitidine HCl Syrup, EQ 15 mg base/milliliters	Torrent Pharma Inc., 150 Allen Rd., Suite 102, Basking Ridge, NJ 07920.
ANDA 206736	Rifampin for Injection, 600 mg/vial	Watson Pharmaceuticals, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Pkwy., Building A, Parsippany, NJ 07054.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of June 11, 2021. 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 June 11, 2021 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: May 5, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–09980 Filed 5–11–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that a meeting is scheduled to be held for the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB). The meeting will be open to the public via WebEx and teleconference; a pre-registered public comment session will be held during the meeting. Pre-registration is required for members of the public who wish to attend the meeting via WebEx/teleconference. Individuals who wish to send in their written public comment should send an email to *CARB@hhs.gov.* Registration information is available on the website *http://www.hhs.gov/paccarb* and must be completed by June 25, 2021. Additional information about registering for the meeting and providing public comment can be obtained at *http://www.hhs.gov/paccarb* on the Meetings page.

DATES: The meeting is scheduled to be held on June 29, 2021, from 10:00 a.m. to 3:00 p.m. and June 30, 2021, from 10:00 a.m. to 3:00 p.m. ET (times are tentative and subject to change). The confirmed times and agenda items for the meeting will be posted on the website for the PACCARB at *http://www.hhs.gov/paccarb* when this information becomes available. Pre-registration for attending the meeting is strongly suggested and should be completed no later than June 25, 2021.

ADDRESSES: Instructions regarding attending this meeting virtually will be posted one week prior to the meeting at: *http://www.hhs.gov/paccarb.*

FOR FURTHER INFORMATION CONTACT: Jomana Musmar, M.S., Ph.D., Designated Federal Officer, Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services, Room L616, Switzer Building, 330 C. St. SW, Washington, DC 20024. Phone: 202–746–1512; Email: *CARB@hhs.gov.*

SUPPLEMENTARY INFORMATION: The Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB), established by Executive Order 13676, is continued by Section 505 of Public Law 116–22, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPAIA). Activities and duties of the Advisory Council are governed by the provisions of the Federal Advisory Committee Act (FACA), Public Law 92–463, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees.

The PACCARB shall advise and provide information and recommendations to the Secretary regarding programs and policies intended to reduce or combat antibiotic-resistant bacteria that may present a public health threat and improve capabilities to prevent, diagnose, mitigate, or treat such resistance. The PACCARB shall function solely for advisory purposes.

Such advice, information, and recommendations may be related to improving: The effectiveness of antibiotics; research and advanced research on, and the development of, improved and innovative methods for combating or reducing antibiotic resistance, including new treatments, rapid point-of-care diagnostics, alternatives to antibiotics, including alternatives to animal antibiotics, and antimicrobial stewardship activities; surveillance of antibiotic-resistant bacterial infections, including publicly available and up-to-date information on resistance to antibiotics; education for health care providers and the public with respect to up-to-date information on antibiotic resistance and ways to reduce or combat such resistance to antibiotics related to humans and animals; methods to prevent or reduce the transmission of antibiotic-resistant bacterial infections; including stewardship programs; and coordination with respect to international efforts in order to inform and advance the United States capabilities to combat antibiotic resistance.

The June 29–30, 2021, public meeting will be dedicated to the council's deliberation and vote on two reports to transmit to the Secretary of Health and Human Services, the first from the Disparities in Antibiotics Access and Use Working Group, and the second from the Working Group on Antimicrobial Resistance (AMR) in Inter-Professional Education. The remainder of the two-day public meeting will include an update on the status of the antibiotic development pipeline and an open council discussion on provocative questions in AMR (no recommendations will be made), in addition to presentations from subject matter experts on Operationalizing One Health and the Environmental Dimensions of AMR. The meeting agenda will be posted on the PACCARB website at *http://www.hhs.gov/paccarb* when it has been finalized. All agenda items are tentative and subject to change.

Instructions regarding attending this meeting virtually will be posted one week prior to the meeting at: *http://www.hhs.gov/paccarb.*

Members of the public will have the opportunity to provide comments live during the meeting via conference line by pre-registering online at *http://www.hhs.gov/paccarb.* There will be two separate sessions available for public comment: An Innovation Spotlight will be held on June 29th where companies and/or organizations involved in combating antibiotic resistance have an opportunity to present their work to members of the Advisory Council; and on June 30th, where all members of the general public are welcome to provide oral comment during this separate session. Pre-registration is required for participation in these sessions with limited spots available. Further information about these two sessions can be found online at *http://www.hhs.gov/paccarb.* Written public comments can also be emailed to *CARB@hhs.gov* by midnight June 25, 2021 and should be limited to no more than one page. All public comments received prior to June 25, 2021, will be provided to Advisory Council members.

Dated: April 30, 2021.

Jomana F. Musmar,

Designated Federal Officer, Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, Office of the Assistant Secretary for Health.

[FR Doc. 2021–10014 Filed 5–11–21; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as