and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Sunita Shukla, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6334, Silver Spring, MD 20993–0002, 301–796–6406.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled ''Community-Acquired Bacterial Pneumonia: Developing Drugs for Treatment.'' The purpose of this guidance is to assist sponsors in the clinical development of antibacterial drugs for the treatment of CABP. This guidance finalizes the draft guidance entitled ''Community-Acquired Bacterial Pneumonia: Developing Drugs for Treatment'' issued on January 10, 2014 (79 FR 1874). FDA considered comments received on the draft guidance as the guidance was finalized. Revisions from the draft to the final guidance include clarification around the time to assess the primary efficacy endpoint (Day 4), updates to the CABP trial population based on the Pneumonia Patient Outcomes Research Team scores, evaluation of intravenous drug formulation, and analysis populations. In addition, editorial changes were made to improve clarity. Issuance of this guidance fulfills a portion of the requirements of Title VIII, section 804, of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), which requires FDA to review and, as appropriate, revise not fewer than 3 guidance documents per year for the conduct of clinical trials with respect to antibacterial and antifungal drugs. Issuance of this final guidance, which revises and finalizes the draft recommendations in the previously published draft guidance, fulfills a portion of the requirements of Public Law 112–144.

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 ''Community-Acquired Bacterial Pneumonia: Developing Drugs for Treatment.'' 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

This guidance refers to previously approved FDA collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR parts 312 and 314 and in 21 CFR 201.56 and 201.57 have been approved under OMB control numbers 0910–0014, 0910–0001, and 0910–0572, respectively.

III. Electronic Access

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

Dated: June 22, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–13746 Filed 6–24–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1528]

Pfizer Inc., 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 July 27, 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 060567	Lidocaine Hydrochloride (HCl); Oxytetracycline Injection, 2%; 50 milligrams (mg)/milliters (mL), and 2%; 125 mg/mL.	Pfizer Inc., 235 East 42nd St., New York, NY 10017.
ANDA 062612	Gentamicin Sulfate Injection, Equivalent to (EQ) 10 mg base/mL.	Hospira, Inc., 275 North Field Dr., Bldg. H1, Lake Forest, IL 60045.
ANDA 062811	Clindamycin Phosphate Solution, EQ 1% base	G&W Laboratories Inc., 301 Helen St., South Plainfield, NJ 07080.
ANDA 063333	Cefoperazone Sodium for Injection, EQ 1 gram (gm) base/vial.	Pfizer Inc.

Application No.	Drug	Applicant
ANDA 078288	Ondansetron HCl Injection, EQ 2 mg base/mL	Baxter Healthcare Corp., 1 Baxter Parkway, Deerfield, IL 60015.
ANDA 080426	Hydrocortisone Lotion, 0.5%	Bausch Health Americas Inc., 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
ANDA 090813	Levetiracetam Injection, 500 mg/5 mL (100 mg/mL)	Fresenius Kabi USA, LLC., Three Corporate Dr., Lake Zurich, IL 60047.
ANDA 201751	Articaine HCl; Epinephrine Bitartrate Injection, 4%; EQ 0.0085 mg base/1.7 mL; 4%; EQ 0.005 mg base/mL.	Hansamed Ltd., 4761 Tara Ct., West Bloomfield, MI 48323.
ANDA 202684	Levonorgestrel Tablets, 0.75 mg	Alvogen PB Research and Development LLC, U.S. Agent for Lotus Pharmaceutical Co., Ltd. Nantou Plant, 44 Whippany Rd., Suite 300, Morristown, NJ 07960.
ANDA 204796	Capreomycin Sulfate for Injection, EQ 1 gm base/vial	Hisun Pharmaceuticals USA, Inc., U.S. Agent for Hisun Pharmaceutical (Hangzhou) Co., Ltd., 200 Crossing Blvd., 2nd Floor, Bridgewater, NJ 08807.
ANDA 205943	Ethinyl Estradiol; Levonorgestrel Tablets, 0.02 mg, 0.15 mg; 0.025 mg, 0.15 mg; 0.03 mg, 0.15 mg; 0.01 mg, N/A.	Lupin Pharmaceuticals, Inc., 111 South Calvert St., Baltimore, MD 21202.
ANDA 212191	Fluoxetine HCl Tablets, EQ 60 mg base	G&W Laboratories, Inc.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of July 27, 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 July 27, 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: June 19, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–13661 Filed 6–24–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Committee on Rural Health and Human Services

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 National Advisory Committee on Rural Health and Human Services (NACRHHS) has scheduled a public meeting. Information about NACRHHS and the agenda for this meeting can be found on the NACRHHS website at *https://www.hrsa.gov/advisory-committees/rural-health/index.html.*

DATES: July 30, 2020, 12:00 p.m.–5:00 p.m. Eastern Time.

ADDRESSES: The meeting scheduled on July 30, 2020, will be held by teleconference/webinar. Instructions for joining the meeting remotely will be posted on the NACRHHS website 30 calendar days before the date of the meeting. For meeting information updates, go to the NACRHHS website meeting page at *https://www.hrsa.gov/advisory-committees/rural-health/meetings/index.html.*

FOR FURTHER INFORMATION CONTACT: Steven Hirsch, Administrative Coordinator at the Federal Office of Rural Health Policy, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857; 301–443–7322; or *shirsch@hrsa.gov.*

SUPPLEMENTARY INFORMATION: NACRHHS provides advice and recommendations to the Secretary of HHS (Secretary) on policy, program development, and other matters of significance concerning both rural health and rural human services.

At this meeting, NACRHHS will discuss the development of a vision statement that emphasizes rural community transformation, sustainable services, and resiliency. By focusing on this vision, NACRHHS will define what it wants to accomplish and how to articulate a policy framework that informs the HHS leadership and empowers rural communities. The intent is to use this process to create a path forward that would help NACRHHS identify policies that empower rural communities to ensure access to core health and human service needs that are focused on local residents and are seen as an essential part of the economic fabric.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting. Requests to submit a written statement or make oral comments to NACRHHS should be sent to Steven Hirsch, using the contact information above, at least 3 business days prior to the meeting.

Individuals who plan to attend the teleconference/webinar meeting and need special assistance or another reasonable accommodation should notify Steven Hirsch at the address and phone number listed above at least 10 business days prior to the meeting.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020–13670 Filed 6–24–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which