

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Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of July 27, 2020. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table.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.*

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**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](mailto: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.*

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## 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