

| Application No. | Drug | Applicant |
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| NDA 020716 | Vicoprofen (hydrocodone bitartrate and ibuprofen) Tablets, 7.5 milligrams (mg)/200 mg. | AbbVie Inc., 1 North Waukegan Rd., North Chicago, IL 60064. |
| NDA 021692 | Ultram ER (tramadol HCl) Extended-Release Tablets, 100 mg, 200 mg, and 300 mg. | Valeant Pharmaceuticals North America LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807. |
| NDA 207621 | Troxyca ER (oxycodone HCl and naltrexone HCl) Extended-Release Capsules, 10 mg/1.2 mg, 20 mg/2.4 mg, 30 mg/3.6 mg, 40 mg/4.8 mg, 60 mg/7.2 mg, and 80 mg/9.6 mg. | Pfizer Inc., 235 East 42nd St., New York, NY 10017. |
| NDA 207975 | Vantrela ER (hydrocodone bitartrate) Extended-Release Tablets, 15 mg, 30 mg, 45 mg, 60 mg, and 90 mg. | Teva Branded Pharmaceutical Products R&D, Inc., 41 Moores Rd., P.O. Box 4011, Frazer, PA 19355. |

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of May 2, 2018. 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 May 2, 2018 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 21, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-06579 Filed 3-30-18; 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 Service Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, notice is hereby given that a meeting is scheduled for the National Advisory Committee on Rural Health and Human Services (NACRHHS). This meeting will be open to the public. Information about the NACRHHS and the agenda for this meeting can be obtained by accessing the NACRHHS website at <http://www.hrsa.gov/advisorycommittees/rural/>.

DATES: The meeting will be held on April 16, 2018, from 8:45 a.m.–5:00 p.m. EDT, April 17, 2018, from 8:30 a.m.–5:15 p.m. EDT, and April 18, 2018, from 8:30 a.m.–11:00 a.m. EDT.

ADDRESSES: This meeting will be held at The Saratoga Hilton. The address for the meeting is 534 Broadway Saratoga Springs, NY 12866-2209, (855) 605-0316.

FOR FURTHER INFORMATION CONTACT: Steve Hirsch, MSLS, Administrative Coordinator, NACRHHS, HRSA, 17W29-C, 5600 Fishers Lane, Rockville, MD 20857, Telephone (301) 443-0835, Fax (301) 443-2803.

SUPPLEMENTARY INFORMATION: NACRHHS provides counsel and recommendations to the Secretary with respect to the delivery, research, development, and administration of health and human services in rural areas. During the meeting the Committee will examine the issues of Assessing and Mitigating the Effect of Adverse Childhood Experiences and Health Insurance Markets in Rural Areas; conduct site visits to the Adirondack Health Institute in Glens Falls, New York and St. Vincent de Paul Catholic Church in Cobleskill, New York, to visit the Head Start Program; and summarize key findings and develop a work plan for the next quarter. Members of the public will also have the opportunity to provide comments.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018-06651 Filed 3-30-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Vaccine Advisory Committee

AGENCY: National Vaccine Program Office, 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 is hereby giving notice that a meeting is scheduled to be held of the National Vaccine Advisory Committee (NVAC). The meeting will be open to the public via teleconference; a public comment session will be held during the meeting.

DATES: The meeting will be held on May 3, 2018, from 10:30 a.m. to 12:30 p.m. ET. The confirmed meeting times and agenda will be posted on the NVAC website at <http://www.hhs.gov/nvpo/nvac/meetings/index.html> as soon as they become available.

ADDRESSES: Instructions regarding attending this meeting will be posted one week prior to the meeting at: <http://www.hhs.gov/nvpo/nvac/meetings/index.html>. Pre-registration is required for members of the public who wish to attend the meeting and who wish to participate in the public comment session. Individuals who wish to attend the meeting and/or participate in the public comment session should register at <http://www.hhs.gov/nvpo/nvac/meetings/index.html>.

FOR FURTHER INFORMATION CONTACT: National Vaccine Program Office, U.S. Department of Health and Human Services, Room 715H, Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201. Phone: (202) 690-5566; email: nvac@hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to Section 2101 of the Public Health Service Act (42 U.S.C. 300aa-1), the Secretary of Health and Human Services was mandated to establish the National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The NVAC was established to provide advice and make recommendations to the Director of the National Vaccine Program on matters related to the Program's responsibilities. The Assistant Secretary for Health serves as Director of the National Vaccine Program. The public meeting will be dedicated to the deliberation of the draft recommendations written by