

presence of naltrexone, an opioid antagonist, in the formulation. The committees will be asked to discuss whether the data submitted by the Applicant are sufficient to support labeling of the product with the properties expected to deter abuse.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

**Procedure:** On June 8, 2016, from 9:30 a.m. to 4 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committees. Written submissions may be made to the contact person on or before May 24, 2016. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 16, 2016. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 17, 2016.

**Closed Committee Deliberations:** On June 8, 2016, from 8 a.m. to 9:30 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)). During this session, the committees will discuss the drug development program of an investigational abuse-deterrent opioid product.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Stephanie L. Begansky at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 11, 2016.

**Jill Hartzler Warner,**

*Associate Commissioner for Special Medical Programs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### National Advisory Committee on Rural Health and Human Services; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

**Name:** National Advisory Committee on Rural Health and Human Services.

**Date And Time:** April 18, 2016, 8:30 a.m.–5:00 p.m., April 19, 2016, 8:30 a.m.–5:15 p.m., April 20, 2016, 8:30 a.m.–11:00 a.m.

**Place:** Keyserling Cancer Center, 1680b Ribaut Road, Port Royal, SC 29935, (843) 522-7800.

**Status:** The meeting will be open to the public.

**Purpose:** The National Advisory Committee on Rural Health and Human Services provides counsel and recommendations to the Secretary with respect to the delivery, research, development, and administration of health and human services in rural areas.

**Agenda:** The meeting on Monday, April 18, will be called to order at 8:30 a.m. by the Chairperson of the Committee, the Honorable Ronnie Musgrove. The Committee will examine the issue of Opioid Abuse Disorder in rural areas and alternatives for emergency care in rural communities at

risk of losing their hospital. The day will conclude with a period of public comment at approximately 5:00 p.m.

The Committee will break into Subcommittees and depart for site visits Tuesday morning, April 19, at approximately 8:30 a.m. Subcommittees will visit the Beaufort County Department of Social Services and the Keyserling Cancer Center. The day will conclude at the Keyserling Cancer Center with a period of public comment at approximately 5:00 p.m.

The Committee will meet to summarize key findings and develop a work plan for the next quarter and the following meeting on Wednesday morning, April 20, at 8:30 a.m. at the Keyserling Cancer Center.

#### FOR FURTHER INFORMATION CONTACT:

Steve Hirsch, MSLS, Administrative Coordinator, National Advisory Committee on Rural Health and Human Services, Health Resources and Services Administration, Parklawn Building, 17W61, 5600 Fishers Lane, Rockville, MD 20857, Telephone (301) 443-0835, Fax (301) 443-2803.

Persons interested in attending any portion of the meeting should contact Pierre Joseph at the Federal Office of Rural Health Policy (FORHP) via telephone at (301) 945-0897 or by email at [PJoseph@hrsa.gov](mailto:PJoseph@hrsa.gov). Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the contact person listed above at least 10 days prior to the meeting. The Committee meeting agenda will be posted on the Committee's Web site at <http://www.hrsa.gov/advisorycommittees/rural/>.

**Jackie Painter,**

*Director, Division of the Executive Secretariat.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Request for Comments on National Bioethics Advisory Bodies

**AGENCY:** Presidential Commission for the Study of Bioethical Issues, Office of the Secretary, Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** The Presidential Commission for the Study of Bioethical Issues is requesting public comment on the role of past, present, and future national bioethics bodies, such as this one, in the United States and elsewhere.