Version 1.0.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Fatima Frye, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1192, Silver Spring, MD 20993–0002, 301–796–5333, *fatima.frye@fda.hhs.gov;* or Jack Zhang, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7318, Silver Spring, MD 20993–0002, 240–402–8187, *jack.zhang@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On December 17, 2014, FDA published final guidance for industry ''Providing Regulatory Submissions in Electronic Format—Standardized Study Data'' (eStudy Data) posted on FDA's Study Data Standards Resources Web page at *http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm.* The eStudy Data guidance implements the electronic submission requirements of section 745A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379k–1(a)) for study data contained in new drug applications, abbreviated new drug applications, biologics license applications, and investigational new drug applications submitted to CDER or CBER by specifying the format for electronic submissions. The eStudy Data guidance states that a **Federal Register** notice will specify the transition date for updates to standards (with the month and day for the transition date corresponding to March 15).

The transition date for the end of FDA support for Define.xml Version 1.0 is March 15, 2017. Therefore, FDA support for Define.xml Version 1.0 will end for studies that start after March 15, 2018. The FDA Data Standards Catalog (see *http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm*) will be updated to list March 15, 2018, as the ''date support ends.''

II. Electronic Access

Persons with access to the Internet may obtain the referenced material at *http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm.*

Dated: March 10, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–05958 Filed 3–16–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committees: Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee.

General Function of the Committees: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 8, 2016, from 8 a.m. to 4 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

Contact Person: Stephanie L. Begansky, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *AADPAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committees will be asked to discuss new drug application (NDA) 207621, oxycodone hydrochloride and naltrexone hydrochloride extended-release capsules, submitted by Pfizer, Inc., with the proposed indication of management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. The product is an extended-release formulation intended to have abuse-deterrent properties based on the

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.

[FR Doc. 2016–05999 Filed 3–16–16; 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; 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.* 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.

[FR Doc. 2016–05998 Filed 3–16–16; 8:45 am]

BILLING CODE 4165–15–P

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.