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 September 10, 2015, from 9:30 a.m. to 5 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 August 26, 2015. 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 August 18, 2015. 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 August 19, 2015.

Closed Presentation of Data: On September 10, 2015, 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 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 physical disabilities or special needs. If you require special 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: August 4, 2015.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2015–19547 Filed 8–7–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Joint Meeting of the 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: Joint meeting of the 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 September 11, 2015, from 8 a.m. to 5 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 discuss new drug application (NDA) 208090, oxycodone extended-release capsules for oral use, submitted by Collegium Pharmaceuticals, proposed for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative options are inadequate. This product has been formulated with the intent to provide abuse-deterrent properties. Pharmacokinetic data demonstrate that, in order to deliver the intended amount of oxycodone, the drug product must be taken with food. The committees will be asked to discuss the potential safety risks and the potential effects on efficacy associated with the extent of the food effect, and potential fluctuations in oxycodone levels that may occur if the product is not taken consistently with the same amount of food. In addition, the committees will be asked to review and discuss whether the data characterizing the abuse-deterrent properties support the likelihood that this drug product will have a meaningful effect on abuse and whether potential benefits to the public from abuse-deterrent properties outweigh potential risks to patients from the effect of food. The committees will be asked to vote on whether this product should be approved for marketing in the United States.

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 September 11, 2015, from 9:30 a.m. to 5 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 August 27, 2015. Oral presentations from the public will be scheduled approximately between 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 August 19, 2015. 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 August 20, 2015.

Closed Presentation of Data: On September 11, 2015, 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 product.

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

Dated: August 4, 2015.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2015–19548 Filed 8–7–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Health Center Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of Class Deviation from Competition Requirements for the Health Center Program.

SUMMARY: In accordance with the Awarding Agency Grants Administration Manual (AAGAM) Chapter 2.04.103, the Bureau of Primary Health Care (BPHC) has been granted a class deviation from the exceptions to maximum competition requirements contained in the AAGAM Chapter 2.04.104A–5 to provide additional funding without competition to the 144 Health Center Program award recipients whose budget period ends November 30, 2015, for up to 5 months. The extension allows BPHC to eliminate the December 1 budget period start date by redistributing these grants to established start dates later in the fiscal year, thereby allowing award recipients comparable opportunity to prepare and submit applications while allowing BPHC to remain compliant with internal process timelines.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: Health Center Program award recipients with a project period end date of November 30, 2015.

Amount of Non-Competitive Awards: $85,451,535.

Period of Supplemental Funding: December 1, 2015, to maximum April 30, 2016.

CFDA Number: 93.224.

Authority: Section 330 of the Public Health Service Act, as amended (42 U.S.C. 254b, as amended).

Justification: Targeting the nation's neediest populations and geographic areas, the Health Center Program currently funds nearly 1,300 health centers that operate approximately 9,000 service delivery sites in every state, the District of Columbia, Puerto Rico, the Virgin Islands, and the Pacific Basin. In 2013, more than 21 million patients, including medically underserved and uninsured patients, received comprehensive, culturally competent, quality primary health care services through the Health Center Program award recipients. Due to the vast size of the Health Center Program, the active grants are distributed across seven budget periods that begin on the first of the month, December through June.

BPHC uses the information award recipients report annually via the Uniform Data System (UDS) to objectively determine the patient and service area requirements that new and continuing applications must address. The requirements are available for applicant use in June. The deviation allows BPHC to redistribute the award recipients with December 1 starting dates to budget period start dates later in the fiscal year, thus allowing these award recipients comparable opportunity to prepare and submit applications while allowing BPHC to remain compliant with internal process timelines. By September 15, 2015, $85,451,535 will be awarded to these 144 award recipients to continue approved activities for up to 5 months. Award recipients will report progress and financial obligations made during their budget period extension through routine reports.

TABLE 1—AWARD RECIPIENTS

Grant No.	Award recipient name	State	New budget period start	Prorated award amount ($)
H80CS00057	The Providence Community Health Centers, Inc	RI	January	460,800
H80CS00058	East Boston Neighborhood Health Center Corporation	MA	February	561,147
H80CS00059	Wood River Health Services, Inc	RI	May	425,646
H80CS00060	East Harlem Council for Human Services, Inc	NY	April	652,402
H80CS00061	William F. Ryan Community Health Center, Inc	NY	January	691,645
H80CS00062	Newark Community Health Centers, Inc	NJ	February	633,059
H80CS00063	Consejo De Salud De Puerto Rico, Inc	PR	January	733,064