

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2013-N-0001]

**Device Good Manufacturing Practice 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 (Agency or FDA). The meeting will be open to the public.

*Name of Committee:* Device Good Manufacturing Practice Advisory Committee.

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

*Date and Time:* The meeting will be held on April 11, 2013, from 8 a.m. to 6 p.m.

*Location:* Hilton Washington DC North/Gaithersburg, Salons A, B, C and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301-977-8900.

*Contact Person:* Natasha Facey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg 66, rm. 1544, Silver Spring, MD 20993-0002, 301-796-5290, [Natasha.Facey@fda.hhs.gov](mailto:Natasha.Facey@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:* On April 11, 2013, the committee will discuss the potential effects of extreme weather and natural disasters on medical device manufacturing chain processes and marketed medical device safety and quality. The committee will further discuss how to optimize the use of FDA's current regulatory framework to address risks and vulnerabilities to the manufacturing chain resulting from extreme weather conditions. Future

steps may be identified to help industry mitigate or better tolerate challenges to the manufacturing chain as a result of extreme weather conditions. In a separate **Federal Register** notice, FDA is seeking additional broad public input about the effects of extreme weather on medical device safety and quality.

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:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before April 4, 2013. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 p.m. Oral presentations from industry, professional organizations, and societies that have an interest in this topic 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 March 27, 2013. 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 March 29, 2013.

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 AnnMarie Williams, Committee Management Staff,

at [AnnMarie.Williams@fda.hhs.gov](mailto:AnnMarie.Williams@fda.hhs.gov) or 301-796-5966, 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/ucm11462.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: February 14, 2013.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2013-03963 Filed 2-20-13; 8:45 am]

**BILLING CODE 4160-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request**

**ACTION:** Notice.

**SUMMARY:** In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Health Resources and Services Administration (HRSA) will submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB). Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. To request a copy of the clearance requests submitted to OMB for review, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Reports Clearance Office at (301) 443-1984.

*Information Collection Request Title:* Drug Pricing Program Reporting Requirements (OMB No. 0915-0176)—[Extension].

*Abstract:* Section 602 of Public Law 102-585, the Veterans Health Care Act of 1992, enacted section 340B of the Public Health Service Act (PHS Act), "Limitation on Prices of Drugs Purchased by Covered Entities." Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a pharmaceutical pricing agreement with the Secretary of Health and Human Services in which

the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula. Covered entities which choose to participate in the section 340B drug discount program must comply with the requirements of 340B(a)(5) of the PHS Act. Section 340B(a)(5)(A) prohibits a covered entity from accepting a discount for a drug that would also generate a Medicaid rebate. Further, section 340B(a)(5)(B) prohibits a covered entity from reselling or otherwise transferring a discounted drug to a person who is not a patient of the entity.

In response to the statutory mandate of section 340B(a)(5)(C) to develop audit guidelines and because of the potential for disputes involving covered entities and participating drug manufacturers, the HRSA Office of Pharmacy Affairs (OPA) developed a dispute resolution process for manufacturers and covered entities as well as manufacturer guidelines for audit of covered entities.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to

develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

The annual estimate of burden is as follows:

Reporting/Notification requirement	Number of respondents	Responses per respondent	Total responses	Hours/response	Total burden hours
<b>AUDITS</b>					
Good Faith Resolution <sup>1</sup> .....	10	1	10	40	400
Audit Notification of Entity <sup>1</sup> .....	10	1	10	4	40
Audit Workplan <sup>1</sup> .....	8	1	8	10	80
Audit Report <sup>1</sup> .....	6	1	6	10	60
Entity Response .....	6	1	6	8	48
<b>DISPUTE RESOLUTION</b>					
Mediation Request .....	10	4	40	10	400
Rebuttal .....	10	1	10	16	160
<b>TOTAL</b> .....	<b>50</b>	<b>.....</b>	<b>80</b>	<b>.....</b>	<b>1188</b>

<sup>1</sup> Prepared by the manufacturer.

**Recordkeeping Burden:**

Recordkeeping requirement	Number of recordkeepers	Hours of recordkeeping	Total burden
Dispute Records .....	50	0.5	25

**ADDRESSES:** Submit your comments to the desk officer for HRSA, either by email to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-5806. Please direct all correspondence to the "attention of the desk officer for HRSA."

*Deadline:* Comments on this ICR should be received within 30 days of this notice.

Dated: February 13, 2013.

**Bahar Niakan,**

*Director, Division of Policy and Information Coordination.*

[FR Doc. 2013-03912 Filed 2-20-13; 8:45 am]

**BILLING CODE 4165-15-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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

would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Child Health and Human Development Special Emphasis Panel; Demographic/ Behavioral Population Science.

*Date:* March 12, 2013.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hotel Lombardy, 2019 Pennsylvania Avenue NW., Washington, DC 20006.

*Contact Person:* Marita R. Hopmann, Ph.D., Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892, 301-435-6911, [hopmannm@mail.nih.gov](mailto:hopmannm@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)