

**SUPPLEMENTARY INFORMATION:** In FR Doc. 2011-33555, appearing on page 82300 in the **Federal Register** of Friday, December 30, 2011 (76 FR 82300), the following corrections are made:

1. On page 82300, in the third column, in the **DATES** section, the submission date for comments should be corrected to "April 9, 2012". We are extending the comment period from February 28, 2012, to 60 days after this correction notice publishes to allow the public sufficient time to comment.

2. On page 82301, in the first column, in the second full paragraph in the **SUPPLEMENTARY INFORMATION** section, the last sentence is corrected to read: "This document solicits comments on certain labeling requirements for blood and blood components, including Source Plasma, finalized as part of a rule FDA published on January 3, 2012, entitled 'Revisions to Labeling Requirements for Blood and Blood Components, Including Source Plasma.'" We are making this change because the final rule inadvertently did not publish on December 30, 2011.

Dated: February 2, 2012.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2012-2827 Filed 2-7-12; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0001]

#### Endocrinologic and Metabolic Drugs 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). The meeting will be open to the public.

*Name of Committee:* Endocrinologic and Metabolic Drugs 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 March 28 and 29, 2012 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. Information regarding special

accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

*Contact Person:* Paul Tran, 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: [EMDAC@fda.hhs.gov](mailto:EMDAC@fda.hhs.gov), or FDA Advisory Committee Information Line, 1 (800) 741-8138 (301) 443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. 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 and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

*Agenda:* On both days, the committee will discuss the role of cardiovascular assessment in the preapproval and postapproval settings for drugs and biologics developed for the treatment of obesity.

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 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 March 14, 2012. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 10 a.m. on March 29, 2012. 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 6, 2012. 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 7, 2012.

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 Paul Tran 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: February 2, 2012.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2012-2760 Filed 2-7-12; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0067]

#### Assessment of Analgesic Treatment of Chronic Pain—A Public Workshop; Request for Comments

**AGENCY:** Food and Drug Administration.

**ACTION:** Notice of public workshop; request for comments.

The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), is announcing a public workshop to hear a discussion of the available data on the efficacy of analgesics in the treatment of chronic non-cancer pain (CNCP). The focus of the presentations and discussions by scientific experts and other stakeholder

groups will be on the available clinical data from both randomized clinical trials and other studies of the efficacy of opioid analgesics, and comparison of that data to the data from studies of non-opioid analgesics used in the treatment of CNCP.

**Date and Time:** The public workshop will be held on May 30, 2012, from 1 p.m. to 5:15 p.m. and on May 31, 2012, from 8:30 a.m. to 5 p.m.

**Location:** The workshop will be held at the Natcher Auditorium, Natcher Conference Center, National Institutes of Health Campus, 45 Center Dr., Bethesda, MD 20892.

**Contacts:** Mary C. Gross, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6178, Silver Spring, MD 20993-0002, (301) 796-3519; or Matthew Sullivan, Center for Drug Evaluation, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 3160, Silver Spring, MD 20993-0002, (301) 796-1245.

**Registration:** If you wish to attend the workshop or provide oral comments during the open session of the meeting, please email your registration to [CDER\\_ChronicPain\\_Workshop@FDA.HHS.GOV](mailto:CDER_ChronicPain_Workshop@FDA.HHS.GOV) by May 15, 2012. Those without email access may register by contacting one of the persons listed in the *Contacts* section of the document. Please provide complete contact information for each attendee, including name, title, affiliation, address, email address, and telephone number. Registration is free and will be on a first-come, first-served basis. Registrants will receive confirmation once they have been accepted for the workshop. Onsite registration on the day of the meeting will be based on space availability. If registration reaches maximum capacity, FDA will post a notice closing the meeting registration for the workshop at: <http://www.fda.gov/Drugs/NewsEvents/ucm283979.htm>.

An open session of the meeting will be held between 3:45 p.m. and 5 p.m. on May 30, 2012, during which time public comments will be accepted. We will try to accommodate all persons who wish to speak at this open session; however, the duration of each speaker's testimony may be limited by time constraints.

**Comments:** Submit either electronic or written comments by August 1, 2012. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with the docket

number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

If you need special accommodations due to a disability, contact Mary Gross or Matthew Sullivan (see *Contacts*) at least 7 days in advance.

#### **SUPPLEMENTARY INFORMATION:**

#### **I. Introduction**

CNCP is a major cause of pain and disability for millions of Americans. The prescribing of opioids for pain has risen steadily in the United States over the past two decades, including the prescribing of opioids to treat CNCP. Questions have been raised about the efficacy of opioids in the treatment of CNCP, including which patients benefit from the chronic use of opioids, the durability of analgesia provided by opioid analgesics, and how best to manage the use of these drugs. Addressing this uncertainty begins with a discussion of the available scientific data on the use of opioids in chronic painful conditions. The discussion will include health care professionals, clinical investigators, regulators, manufacturers, patients, caregivers, and advocacy groups. Where gaps in our knowledge are identified, it will be important to discuss the research that needs to be undertaken to better understand the effectiveness of all analgesics for the treatment of chronic non-cancer pain, and opioid analgesics in particular.

The purpose of the meeting is to provide a forum to discuss the available data on the use of analgesics in the treatment of CNCP, beginning with a discussion of the underlying mechanisms of chronic pain and the epidemiology of chronic pain in the United States. Next, data on the efficacy of opioids and other analgesics in the treatment of chronic pain from a variety of sources will be reviewed. Those sources will include randomized controlled trials, epidemiological studies, case series and other types of studies. Patient and clinician perspectives on the pharmaceutical treatment of CNCP will be presented by people living with chronic pain and those who treat or care for patients with chronic pain. Finally, a general assessment of the available data and discussion of future research needs and next steps will be used to inform future actions that can help guide appropriate therapy for patients with CNCP.

FDA will be considering the following questions during the workshop:

1. What is currently known about the mechanisms of chronic pain?

2. How might this knowledge affect the use of pharmaceuticals chronically for the treatment of pain?

3. What is known regarding use of pain biomarkers (e.g., phenotyping, imaging, genotyping)?

4. What is known about the sources of chronic pain, the populations affected by it, and trends in current use of pharmaceuticals in its treatment?

5. What data are available from controlled trials that have examined the use of pharmaceuticals in the treatment of chronic pain?

6. What data are available from other sources on the use of pharmaceuticals in the treatment of chronic pain?

7. Can populations and individuals who would benefit from chronic use of pharmaceuticals be identified?

8. Can individuals at high risk for adverse effects be identified?

9. What more should be known about the use of pharmaceuticals to treat chronic pain?

FDA will post the agenda and additional workshop background material approximately 5 days before the workshop at <http://www.fda.gov/Drugs/NewsEvents/ucm283979.htm>.

#### **II. Transcripts**

Please be advised that approximately 30 days after the public workshop, a transcript will be available. It will be accessible at <http://www.regulations.gov> and may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: February 2, 2012.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2012-2757 Filed 2-7-12; 8:45 am]

**BILLING CODE 4160-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **Notice of Intent To Prepare an Environmental Impact Statement and Notice of Scoping Meeting**

**AGENCY:** National Institutes of Health, Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** In accordance with the National Environmental Policy Act, 42