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Dated: October 25, 2011.

**George H. Sheldon,**

*Acting Assistant Secretary for Children and Families.*

[FR Doc. 2011-28675 Filed 11-4-11; 8:45 am]

BILLING CODE 4184-40-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-D-0771]

#### **Draft Blueprint for Prescriber Education for Long-Acting/Extended-Release Opioid Class-Wide Risk Evaluation and Mitigation Strategy; Availability; Request for Comments**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Blueprint for Prescriber Education for

the Long-Acting/Extended-Release Opioid Class-Wide REMS" (Blueprint). The draft Blueprint contains core messages intended for use by continuing education (CE) providers to develop educational materials to train prescribers of long-acting and extended-release opioids under the required risk evaluation and mitigation strategy (REMS) for these products (Opioid REMS). FDA seeks stakeholder input on the document. After comments are received, FDA will revise the Blueprint as appropriate, incorporate it into the Opioid REMS when it is approved, and post it on FDA's Web site for use by CE providers.

**DATES:** Submit either electronic or written comments on the draft Blueprint by December 7, 2011.

**ADDRESSES:** See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft Blueprint. Submit electronic comments on the draft Blueprint 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.

**FOR FURTHER INFORMATION CONTACT:** Michie I. Hunt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6153, Silver Spring, MD 20993-0002, (301) 796-3504.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

The Food and Drug Administration Amendments Act of 2007 (FDAAA) gave FDA the authority to require manufacturers to develop and implement a REMS when necessary to ensure the benefits of a drug or biological product outweigh its risks.

##### *A. REMS for Long-Acting and Extended-Release Opioids*

On February 6, 2009, FDA sent letters to manufacturers of certain opioid drug products indicating that these drugs will be required to have a REMS to ensure that the benefits of the drugs continue to outweigh the risks.<sup>1</sup> The affected opioid drugs include long-acting and extended-release brand name and generic products and are formulated with the active ingredients buprenorphine, fentanyl, hydromorphone, methadone, morphine,

oxycodone, oxymorphone, and tapentadol. After sending the letters, FDA held a series of meetings with stakeholders and convened an advisory committee to obtain input on the appropriate elements of the Opioid REMS.

On April 19, 2011, in conjunction with the Office of National Drug Control Policy (ONDCP) release of the Obama Administration's *Epidemic: Responding to America's Prescription Drug Abuse Crisis*—a comprehensive action plan to address the national prescription drug abuse epidemic, FDA issued letters to application holders directing them to submit a REMS within 120 days and describing the elements that needed to be included in the REMS (REMS notification letters). The central component of the Opioid REMS program is an education program for prescribers (e.g., physicians, nurse practitioners, physician assistants) and patients.

##### *B. REMS Prescriber Education*

In the REMS notification letters, FDA provided an outline of the required prescriber education. The outline specified that the education must include information on weighing the risks and benefits of opioid therapy, choosing patients appropriately, managing and monitoring patients, and counseling patients on the safe use of these drugs. In addition, the education must include information on how to recognize evidence of, and the potential for, opioid misuse, abuse, and addiction. The REMS notification letters stated that although there is no mandatory requirement that prescribers take the course as a precondition to dispensing the medication to patients, application holders will be required to establish goals for the number of prescribers trained, collect the information about the number of prescribers who took the courses, and report the information to FDA as part of periodic required assessments.

##### *C. CE Providers Will Conduct Prescriber Education*

The REMS notification letter expressed FDA's expectation that the training would be conducted by accredited, independent continuing education providers. FDA later elaborated on its vision for prescriber education stating that we expect the CE training to be provided without cost to the healthcare professionals and that sponsors would offer unrestricted grants to accredited CE providers to develop CE for the appropriate prescriber

<sup>1</sup> See the Opioid REMS Meeting Invitation Template at <http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM163652.pdf> and the Opioids Products Chart at <http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163654.htm>.

groups.<sup>2</sup> We believe having the training provided by CE organizations will be an incentive and will not create new burdens on prescribers because most healthcare professionals are routinely engaged in CE activity.

#### *D. The Blueprint Will Provide the Basic Outline and Core Messages for CE*

In response to the April REMS notification letter, application holders, through an industry working group, submitted an expanded outline of the potential topics to be covered in the CE, noting that education incorporating all of the topics in the outline could require 30 or more hours of education. FDA's expectation is that the initial or basic REMS related CE that should be offered to all prescribers of long-acting and extended-release opioids should consist of a "core" content of about 2 to 3 hours. FDA has reviewed the industry submission and developed a basic outline and the core messages that FDA believes should be conveyed to prescribers in this basic educational module. After it is completed and approved as part of the REMS, the Blueprint will be posted on FDA's Web site for use by CE providers in developing CE courses. Although FDA recognizes that additional training modules could be helpful, FDA's goal is to require basic education for all prescribers of long-acting and extended-release opioids, and at this time, FDA does not intend to develop or approve messages as part of the REMS beyond those approved in the basic core module. Using the Blueprint on FDA's Web site, CE providers can develop accredited CE in the manner they choose.<sup>3</sup>

With this document, FDA is announcing the availability of the Agency's draft Blueprint for prescriber education and soliciting public comment. The draft Blueprint is available on the Internet at [www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/](http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/)

<sup>2</sup> See FDA Opioid REMS Meeting with Industry (May 16, 2011), at <http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm258184.htm> and Preliminary Responses to Industry Questions About Opioid REMS at <http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm258113.htm>.

<sup>3</sup> Since early May 2011, FDA has held teleconferences and met with representatives from the CE accreditor and provider communities. We have expressed our interest in understanding the challenges of the CE providers, including the need to be in compliance with the Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support and the need to ensure that the content of CE remains beyond the control of industry. We are confident that the ACCME standards will be met and ACCME will be satisfied that FDA will control the content of REMS CE.

*UCM277916.pdf*. FDA will consider any comments submitted and make appropriate revisions before approving the Blueprint as a part of the Opioid REMS.

## II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments on the draft Blueprint. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: November 1, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-28669 Filed 11-4-11; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-D-0689]

#### **Draft Guidance for Industry and Food and Drug Administration Staff; De Novo Classification Process (Evaluation of Automatic Class III Designation); Availability; Extension of Comment Period**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is extending to January 3, 2012, the comment period for the notice entitled "Draft Guidance for Industry and Food and Drug Administration Staff; De Novo Classification Process (Evaluation of Automatic Class III Designation); Availability," that appeared in the **Federal Register** of October 3, 2011 (76 FR 61103). In that document, FDA announced the availability of a draft guidance for industry and FDA staff and requested comments. The Agency is taking this action due to a discrepancy in the comment period in the notice as compared to the comment period listed in the guidance document.

**DATES:** Submit either electronic or written comments by January 3, 2012.

**ADDRESSES:** Submit electronic comments on the draft guidance 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. Identify comments with the docket number found in brackets in the heading of this document.

#### **FOR FURTHER INFORMATION CONTACT:**

Melissa Burns, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, Rm. 1646, Silver Spring, MD 20993-0002, (301) 796-5616; or

Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville, Pike, Suite 200N, Rockville, MD 20852, (301) 827-6210.

## I. Background

In the **Federal Register** of October 3, 2011 (76 FR 61103), FDA published a notice with a 60-day comment period to request comments on the draft guidance for industry and FDA staff entitled "De Novo Classification Process (Evaluation of Automatic Class III Designation)." Comments on the draft guidance will assist FDA in the development of a final guidance for industry and FDA staff on the de novo classification process.

The Agency received a comment that the 60-day comment period in the notice was inconsistent with the 90-day comment period in the draft guidance document. FDA is extending the comment period for the notice until January 3, 2012. The Agency believes that this extension allows adequate time for interested persons to submit comments without significantly delaying action by the Agency.

## II. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

## III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all Center for Devices and Radiological Health (CDRH) guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available