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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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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:

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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.[1] 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

[1] 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.

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 groups.[2] 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

[2] 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.

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.[3]

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/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.

[3] 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.

Dated: _November 1, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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