4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0074]

Guidance for Industry on Medication Guide Distribution Requirements and Inclusion of Medication Guides in Risk Evaluation and Mitigation Strategies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Medication Guides--Distribution Requirements and Inclusion in Risk Evaluation and Mitigation Strategies (REMS)." This guidance addresses two topics pertaining to Medication Guides for drug and biological products. First, the guidance addresses when FDA intends to exercise enforcement discretion regarding when a Medication Guide must be provided with a drug or biological product that is dispensed to a health care professional for administration to a patient instead of being dispensed directly to the patient for self-administration or to the patient's caregiver for administration to the patient. Second, the guidance addresses when a Medication Guide will be required as part of a REMS. The guidance is intended to answer questions that have arisen concerning these topics.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and

Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the 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.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Medication Guides--Distribution Requirements and Inclusion in Risk Evaluation and Mitigation Strategies (REMS)." This guidance provides information for industry, health care providers, and authorized dispensers of prescription drug products. The guidance addresses two topics pertaining to Medication Guides for drug and biological products.

Medication Guides are primarily for prescription drug and biological products used on an outpatient basis without direct supervision by a health care professional. Questions have arisen concerning when a Medication Guide must be provided with a drug or biological product that is dispensed to a health care professional for administration to a patient in certain situations, for example, in an inpatient setting or an outpatient setting such as a clinic or infusion center. This guidance is intended to articulate the circumstances under which FDA intends to exercise enforcement discretion regarding Medication Guide distribution.

The second topic addressed by the guidance is when a Medication Guide will be required as part of a REMS. Under section 505-1(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355-1(e)), FDA may require that a REMS for a drug include one or more of the elements described in section 505-1(e), including the requirement for an applicant to develop a Medication Guide for distribution to each patient when the drug is dispensed (when the criteria in part 208 (21 CFR part 208) are met). Since the enactment of the Food and Drug Administration Amendments Act of 2007, FDA has, as a matter of policy, considered any new Medication Guide (or safety-related changes to an existing Medication Guide) to be part of a REMS. However, the Agency has the authority to determine, based on the risks of a drug and

public health concern, how a Medication Guide should be required when the standard in part 208 is met. Based on the risks and public health concern, the Agency may require: (1) A Medication Guide in accordance with part 208 that is not an element of a REMS or (2) A Medication Guide in accordance with part 208 and section 505-1 of the FD&C Act that is an element of a REMS, which may include other elements of a REMS (such as elements to assure safe use).

In the Federal Register of February 28, 2011 (76 FR 10908), FDA announced the availability of a draft guidance for industry entitled "Medication Guides--Distribution Requirements and Inclusion in Risk Evaluation and Mitigation Strategies (REMS)." The notice gave interested parties the opportunity to comment by May 31, 2011. The Agency considered all of the comments received and made minor editorial and clarifying changes to the guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on when FDA intends to exercise enforcement discretion regarding Medication Guide distribution and inclusion of Medication Guides in REMS. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. 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. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 314.70 and 601.12 have been approved under OMB control numbers 0910-0001 and 0910-0338, respectively; the collections of information in part 208 have been approved under OMB control number 0910-0393.

IV. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, or http://www.regulations.gov.

Dated: November 14, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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