DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0322]

Draft Guidance for Industry on Dosage Delivery Devices for Over-The-Counter Liquid Drug Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry titled ''Dosage Delivery Devices for OTC Liquid Drug Products.'' FDA is issuing this guidance because of ongoing concerns about potentially serious accidental drug overdoses that can result from the use of dosage delivery devices with markings inconsistent or incompatible with the labeled dosage directions for over-the-counter (OTC) liquid drug products.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by February 3, 2010.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Spencer Salis, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, rm. 5216 Silver Spring, MD 20993–0002, 301–796–3327.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry titled ''Dosage Delivery Devices for OTC Liquid Drug Products.'' This document is intended to provide guidance to firms that are manufacturing, marketing, or distributing OTC liquid drug products packaged with dosage delivery devices (e.g., calibrated cups, droppers, syringes, or spoons). The Agency has determined that many OTC liquid drug products in the marketplace are packaged with dosage delivery devices that bear markings that are inconsistent with the labeled dosage directions, contain superfluous markings, or are missing necessary markings. FDA is issuing this guidance because of ongoing concerns about potentially serious accidental drug overdoses that can result from the use of dosage delivery devices with markings that are inconsistent or incompatible with the labeled dosage directions for OTC drug products. FDA recommends that dosage delivery devices be included for all OTC drug products that are liquid formulations; they should bear markings that are consistent with the labeled dosage directions; and they should be labeled in a manner that attempts to ensure that they are used only with the products with which they are included.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). When finalized the guidance will represent the agency's current thinking on ''Dosage Delivery Devices for OTC Liquid Drug Products.'' 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**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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 with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.regulations.gov*.

Dated: October 30, 2009.

David Horowitz,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0526]

Food and Drug Administration's Safe Use Initiative; Availability of Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the launch of its Safe Use Initiative with the release of a report titled ''FDA's Safe Use Initiative—Collaborating to Reduce Preventable Harm from Medicines.'' FDA is opening a docket to enable the public to comment on the report and the initiative. In addition, a safe use Web site has been created to facilitate transparency as the initiative moves forward. The initiative proposes a series of next steps, including working with interested partners—patients, consumers, caretakers, healthcare practitioners, pharmacists, healthcare systems, health insurers, drug manufacturers, and other Federal agencies—to select specific candidate cases of preventable, drug-related harm for analysis, intervention proposals, and evaluation metrics. The report identifies some specific areas of concern that could benefit from Safe Use Initiative partnerships.

DATES: Submit electronic or written comments at any time.

ADDRESSES: Submit written comments on the information in this docket to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the information.

FOR FURTHER INFORMATION CONTACT: Karen Weiss, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg 51, rm. 6122, Silver Spring, MD 20993, 301–796–5400.

SUPPLEMENTARY INFORMATION:

I. Background

Tens of millions of people in the United States depend on prescription