

Guide for Syndromic Surveillance available for public comment at <http://www.regulations.gov> and http://www.cdc.gov/phln/library/2011/guides/Syndromic_Surveillance_Implementation_Guide_Release_1_4.pdf

Dated: April 27, 2011.

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*Deputy Associate Director for Science,
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0322]

Guidance for Industry on Dosage Delivery Devices for Orally Ingested OTC 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 guidance for industry entitled "Dosage Delivery Devices for Orally Ingested OTC Liquid Drug Products." This document is intended to provide guidance to firms that are manufacturing, marketing, or distributing orally ingested over-the-counter (OTC) liquid drug products packaged with dosage delivery devices (e.g., calibrated cups, droppers, syringes, or spoons). 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 orally ingested OTC liquid drug products.

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. 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: Spencer Salis, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Building 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 entitled "Dosage Delivery Devices for Orally Ingested OTC Liquid Drug Products." The Agency has determined that many orally ingested 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 orally ingested OTC drug products. FDA recommends that dosage delivery devices be included for all orally ingested OTC drug products that are liquid formulations, that they should bear markings that are consistent with the labeled dosage directions, and that they should be labeled in a manner that attempts to ensure that they are used only with the products with which they are included.

In the **Federal Register** of November 5, 2009 (74 FR 57319), FDA announced the availability of a draft guidance for industry entitled "Dosage Delivery Devices for Over-the-Counter Liquid Drug Products." The notice gave interested persons an opportunity to comment by February 2, 2010. We received a number of comments from individuals, firms, and consumer groups. We have carefully considered the comments and, where appropriate, have made corrections, added information, or clarified the information in the guidance in response to the comments or on our own initiative.

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 dosage delivery devices for orally ingested 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**) 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 with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: April 28, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Committee on Rural Health and Human Services; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given that the following committee will convene its sixty-seventh meeting.

Name: National Advisory Committee on Rural Health and Human Services.

Dates and Times: June 15, 2011, 9 a.m.-4:45 p.m., June 16, 2011, 9 a.m.-4:45 p.m., June 17, 2011, 8:45 a.m.-10:30 a.m.

Place: Park Place Hotel, 300 East State Street, Traverse City, MI 49684. (231) 946-5000.

Status: The meeting will be open to the public.

Purpose: The National Advisory Committee on Rural Health and Human Services provides advice and recommendations of health and human services in rural areas.

Agenda: Wednesday morning, at 9 a.m., the meeting will be called to order by the Chairperson of the Committee, the Honorable Ronnie Musgrove. The first three presentations will be overviews of rural Michigan and the relevant health indicators. The remainder of the day the Committee will hear presentations on two of the chosen