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Draft Guidance for Industry on Dosage Delivery Devices for Over-The-Counter Liquid Drug Products; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry titled ''Dosage Delivery Devices for OTC Liquid Drug Products.''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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by February 3, 2010.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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.

[FR Doc. E9–26531 Filed 11–04–09; 8:45 am]

BILLING CODE 4160–01–S

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

and over-the-counter (OTC) medications to stay healthy. Yet it is widely known that too many people incur preventable injury and even die from medication errors or misuse. Preventable injuries can result from a variety of sources, including informational errors (mistakes made in prescribing or using a medicine because of inadequate information); unintended, or accidental exposure; intentional drug misuse and abuse; and rarely because of manufacturing and/or distribution defects. The Institute of Medicine (IOM) estimates that 1.5 million preventable injuries, or adverse drug events, occur in the United States healthcare system each year,[1,2] at a cost exceeding $4 billion annually. Additionally, incorrect use of OTC medications results in thousands of preventable injuries. Furthermore, unintended exposure to medications causes a significant number of injuries and deaths, mainly in children. Between 2003 and 2006 alone, more than 9,000 children were accidentally exposed to prescription opioid drugs.[3]

These potentially avoidable injuries and deaths represent our society's collective failure to adequately manage medication risks. Because the shortcomings in the healthcare system have been broadly acknowledged, FDA and many other healthcare stakeholders have been working hard to improve the way in which the nation's healthcare system manages medication risks. However, much more needs to be done, and coordinated cross-sector efforts, involving all stakeholders, would have the greatest impact.

To this end, FDA is launching the Safe Use Initiative, through which it will collaborate with stakeholders—including patients, consumers, caretakers, healthcare practitioners, pharmacists, healthcare systems, health insurers, drug manufacturers, and Federal agencies—to identify specific candidate cases associated with important, measurable amounts of preventable harm. In the coming months, FDA plans to develop, through extensive consultation with all interested public and private stakeholders, a general list of candidate cases for collaborative analysis and intervention. FDA also intends to work with federal partners to develop population-based national estimates of preventable harm from medications, categorized by drug, drug classes, and therapeutic situations. In addition to opening a docket to receive public input, FDA plans to hold a series of public meetings to gather broad public feedback as the candidate list is being developed. It is FDA's goal to implement a small number of interventions during the next 12 months.

For more information, see FDA's Safe Use Web page at *http://www.fda.gov/Drugs/DrugSafety/ucm187806.htm*.

II. Submission of Feedback on the Contents of This Docket

Interested parties may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments on this information. Submit a single copy of electronic comments or two paper copies of any mailed comments. Individuals may submit one paper copy. Comments should be identified with the docket number found in brackets in this document's heading. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. FDA will accept electronic comments or submissions only at *http://www.regulations.gov*.

Dated: October 30, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–26530 Filed 11–4–09; 8:45 am]

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[1] Institute of Medicine of the National Academies, *Preventing Medication Errors*, National Academies Press, p. 124, 2007.

[2] Ibid, p. 4. The IOM defines an adverse drug event (ADE) as any injury due to medication. Examples include a wrong dosage leading to injury (e.g., rash, confusion, or loss of function) or an allergic reaction occurring in a patient not known to be allergic to a given medication.

[3] Bailey, J.E., E. Campagna, R.C. Dart, ''The Underrecognized Toll of Prescription Opioid Abuse on Young Children,'' *Annals of Emergency Medicine*, 53:4129–24, 2009.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflicts in Motor Function.

Date: November 13, 2009.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone Conference Call)

Contact Person: Dana Jeffrey Plude, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3176, MSC 7848, Bethesda, MD 20892, 301–435–2309, *pluded@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Review of BSCH Member Conflict Applications

Date: November 17, 2009.

Time: 2:30 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz Carlton Hotel, 1150 22nd Street, NW., Washington, DC 20037.

Contact Person: Jose H. Guerrier, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, 301–435–1137, *guerriej@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Genes, Genomes, and Genetics.

Date: November 19, 2009.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Melrose Hotel, 2430 Pennsylvania Avenue, NW., Washington, DC 20037.

Contact Person: Michael A. Marino, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2216, MSC 7890, Bethesda, MD 20892, (301) 435–0601, *marinomi@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 30, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–26689 Filed 11–4–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as