4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0610]

# Guidance for Industry on Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic; 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 "Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic." The guidance discusses FDA's intended approach to enforcement of adverse event reporting requirements for drugs, biologics, medical devices, and dietary supplements during an influenza pandemic. The Agency makes recommendations to industry for focusing limited resources on reports related to products indicated for the prevention and treatment of influenza and other specific types of reports indicated in the guidance.

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:

Regarding pandemic influenza:

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Office of Counterterrorism and Emerging Threats,

Food and Drug Administration,

10903 New Hampshire Ave.,

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Regarding human drug products:

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10903 New Hampshire Ave.,

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Regarding human biological products:

Stephen Ripley,

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Rockville, MD 20852-1448,

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Regarding medical device products:

Deborah Moore,

Center for Devices and Radiological Health,

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Regarding dietary supplements:

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SUPPLEMENTARY INFORMATION:

## I. Background

FDA is announcing the availability of a guidance for industry entitled "Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza

Pandemic." FDA anticipates that during an influenza pandemic, industry and FDA workforces may be reduced while reporting of adverse events related to widespread use of medical products indicated for the treatment and prevention of influenza may increase, although the extent of these possible changes is unknown. The guidance discusses FDA's intended approach to enforcement of adverse event reporting requirements for drugs, biologics, medical devices, and dietary supplements during an influenza pandemic.

The guidance provides recommendations for planning, notification, and documentation for firms that report postmarketing adverse events. The guidance recommends that each firm's pandemic influenza continuity of operations plan include instructions for reporting adverse events and a plan for the submission of stored reports that were not submitted within regulatory timeframes. The guidance recommends that firms that are unable to fulfill normal adverse event reporting requirements during an influenza pandemic do the following:

- Document the conditions that prevent them from meeting normal reporting requirements,
- Notify the appropriate FDA organizational unit responsible for adverse event reporting compliance when these conditions exist and when the reporting process is restored, and
- Maintain records to identify what reports have been stored.

This guidance does not address monitoring and reporting of adverse events that might be imposed as a condition of authorization for products authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360bbb-3). This guidance also does not address monitoring and reporting of adverse events as required by

regulations establishing the conditions for investigational use of drugs, biologics, and devices. (See 21 CFR parts 312 and 812.)

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 postmarketing adverse event reporting for medical products and dietary supplements during pandemic influenza. 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. 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. The Paperwork Reduction Act of 1995

This guidance contains information collection provisions that 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 collection of information in this guidance was approved under OMB control number 0910-0701.

The guidance also refers to previously approved collections of information found in FDA's adverse event reporting requirements in 21 CFR 310.305, 314.80, 314.98, 600.80, 606.170, 640.73, 1271.350, and 21 CFR part 803. These regulations contain collections of information that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44

U.S.C. 3501-3520) and are approved under OMB control numbers 0910-0116, 0910-0291, 0910-0230, 0910-0308, 0910-0437, and 0910-0543. In addition, the guidance also refers to adverse event reports for nonprescription human drug products marketed without an approved application and dietary supplements required under sections 760 and 761 of the FD&C Act (21 U.S.C. 379aa and 379aa-1), which include collections of information approved under OMB control numbers 0910-0636 and 0910-0635.

## IV. Electronic Access

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

Dated: February 17, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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