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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Draft Guidance for Industry on Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic.” The draft guidance discusses FDA’s intended approach to enforcement of adverse event reporting requirements for drugs, biologics, medical devices, and dietary supplements during the Federal Government Response Stages of an influenza pandemic. The agency makes recommendations to industry for focusing limited resources on reports related to influenza-related products and other specific types of reports indicated in the draft guidance.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm.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, Training and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800.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. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding pandemic influenza: Carmen Maher, Office of Counterterrorism and Emerging Threats (HF-29), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4067.

Regarding human drug products: Solomon Iyasu, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4447, Silver Spring, MD 20993-0002, 301-796-2370.

Regarding human biological products: Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

Regarding medical device products: Deborah Moore, Center for Devices

and Radiological Health (HFZ-533), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 240-276-3442.

Regarding dietary supplements: John Sheehan, Center for Food Safety and Applied Nutrition (HFS-315), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1488.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft 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 influenza-related products may increase, although the extent of these possible changes is unknown. This draft guidance discusses FDA’s intended approach to enforcement of adverse event reporting requirements for drugs, biologics, medical devices, and dietary supplements in the event of an influenza pandemic. The draft guidance provides recommendations to permit industry to focus their limited resources on reports related to influenza-related products and other specific types of reports. The draft guidance indicates FDA’s intention not to object if, during Federal Government Response Stage 5, certain required adverse event reports are not provided within the timeframes required by statute and regulation, as long as any delayed reports are then provided during Federal Government Response Stage 6.

This draft 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 act) (21 U.S.C. 360bbb-3). This draft 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 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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**) 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

III. Paperwork Reduction Act of 1995

The draft guidance explains FDA's approach to enforcement of adverse event reporting requirements for drugs, biologics, medical devices, and dietary supplements during the Federal Government Response Stages of an influenza pandemic, including an intent not to object to changes in the timing of submission of certain reports during some stages of the pandemic response. The draft guidance refers to reporting requirements found in 21 CFR 310.305, 314.80, 314.98, 600.80, 606.170, 640.73, 1271.350, and part 803. These regulations contain collections of information 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) and are approved under OMB control numbers 0910–0116, 0910–0291, 0910–0230, 0910–0308, and 0910–0543.

The draft guidance also refers to adverse event reports required under sections 760 and 761 of the act (21 U.S.C. 379aa and 379aa-1), which are addressed in two draft guidances for industry. FDA's October 15, 2007, notices of availability for those draft guidances, entitled "Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application" (72 FR 58316) and "Questions and Answers Regarding Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act" (72 FR 58313), describe related proposed collections of information. As required by the PRA, FDA published analyses of the information collection provisions of the October 2007 draft guidances and will submit the collection of information analyses to OMB for approval prior to issuing final guidances.

IV. 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.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/cdrh/guidance.html> or <http://www.cfsan.fda.gov/~dms/guidance.html> or <http://www.regulations.gov>.

Dated: 12/3/08
December 3, 2008.



Jeffrey Shuren,
Associate Commissioner for Policy and Planning.
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