II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction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). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively. The collections of information referred to in the guidance for clinical trial sponsors ''Establishment and Operation of Clinical Trial Data Monitoring Committees'' have been approved under OMB control number 0910–0581.

III. 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.

IV. 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: February 17, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–4290 Filed 2–23–12; 8:45 am]

BILLING CODE 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: Carmen Maher, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4146, Silver Spring, MD 20993–0002, 301–796–8510.

Regarding human drug products: Toni Piazza-Hepp, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4480, Silver Spring, MD 20993–0002, 301–796–0520.

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, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3230, Silver Spring, MD 20993–0002, 301–796–6106.

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 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.

[FR Doc. 2012–4288 Filed 2–23–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request: STAR METRICS (Science and Technology for America's Reinvestment: Measuring the EffecTs of Research on Innovation, Competitiveness and Science)

Summary: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Director, National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on Oct 5, 2011 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: STAR METRICS (Science and Technology for America's Reinvestment: Measuring the EffecTs of Research on Innovation, Competitiveness and Science). *Type of Information Collection Request:* Extension of OMB number 0925–0616, expiration date 03/31/2012. *Need and Use of Information Collection:* The aim of STAR METRICS is twofold. The goal of STAR METRICS is to continue to provide mechanisms that will allow participating universities and Federal agencies with a reliable and consistent means to account for the number of scientists and staff that are on research institution payrolls, supported by federal funds. In subsequent generations of the program, it is hoped that STAR METRICS will allow for measurement of science impact on economic outcomes (such as job creatfon), on knowledge generation (such as citations, and patents) as well as on social and health outcomes.

Frequency of Response: Quarterly.~

Affected Public: Universities and other research institutions.

Type of Respondents: University administrators.

The annual reporting burden is as follows:

Estimated Number of Respondent: 100.

Estimated Number of Responses per Respondent: 4.

Average Burden Hours per Response: 2.5.

Estimated Total Annual Burden Hours Requested: 1,315.

The annualized cost to respondents is estimated to be $65,750. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

A.12–1—ESTIMATES OF ANNUAL BURDEN HOURS

	Number of respondents	Frequency of response	Average time per response (in hours)	Annual hour burden
Stage I: One time data input	7	1	45	315
Stage 2: Ongoing quarterly data input	100	4	2.5	1,000
Total				1,315

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the functioning of the National Cancer Institute, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information,