

(OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by February 7, 2011.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or e-mailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0553. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleston, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, e-mail: [Daniel.Gittleston@fda.hhs.gov](mailto:Daniel.Gittleston@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Medical Devices: Recommended Glossary and Educational Outreach to Support Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use—(OMB Control Number 0910-0553)—Extension**

Section 502 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 352), among other things, establishes requirements for the label or

labeling of a medical device so that it is not misbranded. Section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262) establishes requirements that manufacturers of biological products must submit a license application for FDA review and approval prior to marketing a biological product for introduction into interstate commerce.

In the **Federal Register** of November 30, 2004 (69 FR 69606), FDA published a notice of availability of the guidance entitled “Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use.” The guidance document provides guidance for the voluntary use of selected symbols in place of text in labeling. It provides the labeling guidance required for: (1) In vitro diagnostic devices (IVDs), intended for professional use under 21 CFR 809.10, FDA’s labeling requirements for IVDs; and (2) FDA’s labeling requirements for biologics, including IVDs under 21 CFR parts 610 and 660. Under section 502(c) of the FD&C Act, a drug or device is misbranded, “\* \* \* If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.”

The guidance document recommends that a glossary of terms accompany each IVD to define the symbols used on that

device’s labels and/or labeling. Furthermore, the guidance recommends an educational outreach effort to enhance the understanding of newly introduced symbols. Both the glossary and educational outreach information will help to ensure that IVD users will have enough general familiarity with the symbols used, as well as provide a quick reference for available materials, thereby further ensuring that such labeling satisfies the labeling requirements under section 502(c) of the FD&C Act and section 351 of the PHS Act.

The likely respondents for this collection of information are IVD manufacturers who plan to use the selected symbols in place of text on the labels and/or labeling of their IVDs.

The glossary activity is inclusive of both domestic and foreign IVD manufacturers. FDA receives submissions from approximately 689 IVD manufacturers annually. The number of hours per response for the glossary and educational outreach activities were derived from consultation with a trade association and FDA personnel. The 4-hour estimate for a glossary is based on the average time necessary for a manufacturer to modify the glossary for the specific symbols used in labels or labeling for the IVDs manufactured.

In the **Federal Register** of October 5, 2010 (75 FR 61494), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Section 502 of the FD&C Act/Section 351 of the PHS Act	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Glossary .....	689	1	689	4	2,756

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: January 3, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-74 Filed 1-6-11; 8:45 am]

**BILLING CODE 4160-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[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 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 draft guidance. This draft guidance is a revision of the draft guidance for industry of the same title published on December 16, 2008.

**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 March 8, 2011. Submit written comments on the proposed collection of information by March 8, 2011.

**ADDRESSES:** Submit written requests for single copies of the 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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft 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:*  
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, 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 revised draft guidance for industry entitled "Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic." In the **Federal Register** of December 16, 2008 (73 FR 76364), FDA published notice of the availability of a draft guidance of the same title. 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 revised draft 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.

**II. Revisions to the 2008 Draft Guidance**

FDA is issuing a revised draft guidance that includes recommendations for planning, notification, and documentation for firms that report postmarketing adverse events. The revised draft guidance recommends that each firm's pandemic influenza continuity of operations plan (COOP) include instructions for reporting adverse events and a plan for the submission of stored reports that were not submitted within regulatory timeframes. The revised draft 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.

These recommendations represent collections of information under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520) discussed in section IV of this document. In issuing this revised draft guidance, FDA considered all comments that were submitted in response to the December 2008 draft guidance. Most comments requested that greater clarity be

provided in certain sections; FDA has revised these sections accordingly.

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 FD&C 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.

**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. 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.

**IV. Paperwork Reduction Act of 1995**

Under the PRA, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information that they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA, 44 U.S.C. 3506(c)(2)(A), requires Federal agencies to provide a 60-day notice in the **Federal Register** for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing this notice of the proposed collection of information set forth in this document.

With respect to the collection of information associated with this draft guidance, FDA invites comments on the following topics: (1) Whether the proposed information collected is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimated burden of the proposed information collected, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of information collected on the respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

The draft guidance explains FDA's approach to enforcement of adverse event reporting requirements for drugs, biologics, medical devices, and dietary supplements during 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 Agency recommends that each firm's pandemic influenza COOP include instructions for reporting adverse events, including a plan for the submission of stored reports that were not submitted within regulatory timeframes. The draft guidance explains that firms that are unable to fulfill normal adverse event reporting requirements during an influenza pandemic should: (1) Maintain documentation of the conditions that

prevent them from meeting normal reporting requirements, (2) notify the appropriate FDA organizational unit responsible for adverse event reporting compliance when the conditions exist and when the reporting process is restored, and (3) maintain records to identify what reports have been stored.

Based on the number of manufacturers that would be covered by the draft guidance, we estimate that approximately 5,000 firms will add to their COOP: (1) Instructions for reporting adverse events and (2) a plan for submitting stored reports that were not submitted within regulatory timeframes. We estimate that each firm will take approximately 50 hours to prepare the adverse event reporting plan for its COOP.

We estimate that approximately 500 firms will be unable to fulfill normal adverse event reporting requirements because of conditions caused by an influenza pandemic and that these firms will notify the appropriate FDA organizational unit responsible for adverse event reporting compliance when the conditions exist. Although we do not anticipate such pandemic influenza conditions to occur every year, for purposes of the PRA, we estimate that each of these firms will notify FDA approximately once each year, and that each notification will take approximately 8 hours to prepare and submit.

Concerning the recommendation in the draft guidance that firms unable to fulfill normal adverse event reporting requirements maintain documentation

of the conditions that prevent them from meeting these requirements and also maintain records to identify what adverse event reports have been stored and when the reporting process is restored, we estimate that approximately 500 firms will each need approximately 8 hours to maintain the documentation and that approximately 500 firms will each need approximately 8 hours to maintain the records. Therefore, the total recordkeeping burden that would result from the draft guidance would be 258,000 hours.

The draft 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 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, 0910–0437, and 0910–0543. In addition, the draft 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.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

	Number of respondents	Number of responses per respondent	Total responses	Hours per response	Total hours
Notify FDA when normal reporting is not feasible .....	500	1	500	8	4,000
Total .....	.....	.....	.....	.....	4,000

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this information collection.

TABLE 2—ESTIMATED RECORDKEEPING BURDEN <sup>1</sup>

	Number of recordkeepers	Number of records per recordkeeping	Total records	Hours per record	Total hours
Add adverse event reporting plan to COOP .....	5,000	1	5,000	50	250,000
Maintain documentation of influenza pandemic conditions and resultant high absenteeism .....	500	1	500	8	4,000
Maintain records to identify what reports have been stored and when the reporting process was restored .....	500	1	500	8	4,000
Total .....	.....	.....	.....	.....	258,000

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this information collection.

## V. 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: January 3, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-D-0643]

#### Draft Guidance for Industry on Electronic Source Documentation in Clinical Investigations; 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 "Electronic Source Documentation in Clinical Investigations." This document provides guidance to sponsors, contract research organizations (CROs), data management centers, and clinical investigators on capturing, using, and archiving electronic data in FDA-regulated clinical investigations. It also describes FDA's recommended procedures for ensuring the reliability, quality, integrity, and traceability of electronic source data and source records maintained at the site for FDA inspection.

**DATES:** Although you can comment on any guidance at any time (*see* 21 CFR 10.115(g)(5)), to ensure that FDA considers your comments on the draft guidance before it begins work on the final version of the guidance, submit electronic or written comments on the draft guidance by April 7, 2011.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Office of Critical Path Programs, Office

of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4173, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. 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.

#### FOR FURTHER INFORMATION CONTACT:

Leonard Sacks, Office of Critical Path Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg., 32, rm. 4174, Silver Spring, MD 20993-0002, 301-796-8502.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Electronic Source Documentation in Clinical Investigations." This guidance is intended to be used together with the guidances for industry<sup>1</sup> entitled:

- *Computerized Systems Used in Clinical Investigations*,
- *Part 11, Electronic Records; Electronic Signatures—Scope and Application*, and
- *General Principles of Software Validation; Final Guidance for Industry and FDA Staff*.

With the increasing use of computerized systems in clinical investigations, it is common to find source data documented in an electronic format, *e.g.*, clinical data initially documented in electronic health records maintained by hospitals and institutions, electronic case report forms, laboratory reports that are electronically generated, electronic medical images from devices, and electronic diaries provided by study subjects. When paper source documents are available for review, tracing of data in paper-based studies can be performed easily. However, when source data is electronic, the data is traced through complex data capture, transmission, and archival processes. This guidance recommends practices that will help ensure that electronic source data and source records are accurate, legible,

original, attributable (*e.g.*, user name and password), and contemporaneously entered; and meet the regulatory requirements for recordkeeping and retention.

The following specific topics related to electronic source data are discussed:

- The identification of the *data element* as the basic unit of information in the electronic case report form;
- The description of a source of each data element;
- Information about the electronic creation, modification, transmission, and storage of source data and documents;
- Investigator responsibilities with respect to reviewing and archiving electronic data;
- Transmission of the data to the sponsor and/or other designated parties; and
- Preservation of data integrity.

The 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 capturing, using, and archiving electronic data in FDA-regulated clinical investigations. 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*) 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. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 §§ 312.62(b) and 312.64(b) have been approved under OMB control number 0910-0014; and the collection of information in §§ 812.140 and 812.150 has been approved under OMB control number 0910-0078.

<sup>1</sup> FDA guidances are available on FDA's Web page at <http://www.fda.gov/RegulatoryInformation/Guidances/default.htm>. FDA guidances are issued and updated regularly. We recommend you check the Web site to ensure that you have the most up-to-date version of a guidance.