

industry entitled “Patient Counseling Information Section of Labeling for Human Prescription Drug and Biological Products—Content and Format.” The recommendations in the draft guidance are intended to help ensure that the labeling is clear, useful, informative, and to the extent possible, consistent in content and format.

**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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by November 18, 2013.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201,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, or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448. 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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to 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:** Jonas Santiago, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6358, Silver Spring, MD 20993-0002, 301-796-5346; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448, 301-827-6210.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a draft guidance for industry entitled “Patient Counseling Information Section of Labeling for Human Prescription Drug and Biological Products—Content and Format.” This draft guidance provides recommendations for the “Patient Counseling Information” section on the following: How to decide what topics to include in the section,

how to present information within the section, and how to format and organize section contents.

This guidance is one of a series of guidances FDA is developing, or has developed, to assist applicants with the content and format of the labeling for human prescription drug and biological products. In the **Federal Register** of January 24, 2006 (71 FR 3922), FDA published a final rule on labeling for human prescription drug and biological products. The final rule and additional guidances can be accessed at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/LawsActsandRules/ucm084159.htm>. The labeling requirements and these guidances are intended to make information in prescription drug labeling easier for health care practitioners to access, read, and use.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance represents the Agency’s current thinking on the content and format of the “Patient Counseling Information” section of labeling for human prescription drug and biological 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 either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). 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, and will be posted to the docket at <http://www.regulations.gov>.

##### **III. The Paperwork Reduction Act of 1995**

This draft guidance also 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 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910-0572.

##### **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/default.htm> or <http://www.regulations.gov>.

Dated: September 12, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **Food and Drug Administration**

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

##### **Guidance for Industry on Electronic Source Data 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 guidance for industry entitled “Electronic Source Data in Clinical Investigations.” This document provides guidance to sponsors, contract research organizations (CROs), clinical investigators, and others involved in the capture, review, and retention of electronic source data in FDA-regulated clinical investigations. This guidance promotes capturing source data in electronic form, and it is intended to assist in ensuring the reliability, quality, integrity, and traceability of data from electronic source to electronic regulatory submission.

**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, or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448 (the guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800); or the Division of Small Manufacturers, International and

Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, 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:** Ron Fitzmartin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1160, Silver Spring, MD 20993-0002, 301-796-5333; or Jonathan Helfgott, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5369, Silver Spring, MD 20993-0002, 301-796-5636.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a guidance for industry entitled "Electronic Source Data in Clinical Investigations." This document provides guidance to sponsors, CROs, clinical investigators, and others involved in the capture, review, and retention of electronic source data in FDA-regulated clinical investigations. This guidance promotes capturing source data in electronic form, and it is intended to assist in ensuring the reliability, quality, integrity, and traceability of data from electronic source to electronic regulatory submission.

With the use of computerized systems for capturing clinical study data, it is common to find at least some source data recorded electronically. Common examples include, but are not limited to, clinical data initially recorded in electronic health records maintained by healthcare providers and institutions, electronic laboratory reports, electronic medical images from devices, and electronic diaries completed by study subjects.

Capturing source data electronically and transmitting it to the electronic case report form (eCRF) should help to: (1) Eliminate unnecessary duplication of data; (2) reduce the possibility for transcription errors; (3) encourage entering source data during a subject's visit, where appropriate; (4) eliminate

transcription of source data prior to entry into an eCRF; (5) facilitate remote monitoring of data; (6) promote real-time access for data review; and (7) facilitate the collection of accurate and complete data.

In the **Federal Register** of November 20, 2012 (77 FR 69632), FDA issued a draft version of this guidance entitled "Electronic Source Data in Clinical Investigations." The comment period on the draft guidance ended on March 26, 2013 (see the correction notice of December 26, 2012 (77 FR 76049)). Most of the comments sought clarification on the topics discussed in the guidance. We have reviewed all comments received on the draft guidance. As a result of the public comments, we have clarified the following sections of the guidance: I. Introduction, II. Background, III. Electronic Source Data (and its subsections), and IV. Use and Description of Computerized Systems in Clinical Investigations. We have also updated the Glossary definitions, added a References section, and added reference citations throughout the guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the Agency's current thinking on the capture, review, and retention of electronic source 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 either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). 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, and will be posted to the docket at <http://www.regulations.gov>.

##### **III. Paperwork Reduction Act of 1995**

This guidance refers to 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). This guidance pertains to sponsors, clinical investigators, CROs, and others involved in the capture, review, and retention of

electronic source data in FDA-regulated clinical investigations and who send certain information to FDA or others, or who keep certain records and make them available to FDA inspectors. The information collection discussed in the guidance is contained in our investigational new drug regulations in part 312 (21 CFR part 312) and approved under OMB control number 0910-0014, including §§ 312.62(b) and 312.58(a). In addition, the collection of information in 21 CFR part 11, as discussed in the guidance, is approved under OMB control number 0910-0303. OMB approval of the information collection in the guidance entitled "Computerized Systems Used in Clinical Investigations," as mentioned in the guidance, is discussed in the May 10, 2007 (72 FR 26638), **Federal Register** Notice of Availability of that guidance. The capture, review, and retention of electronic source data, as described in this guidance, would not result in any new costs, including capital costs or operating and maintenance costs, because sponsors and others already have and are experienced with using the computer-based equipment and software necessary to be consistent with the guidance.

##### **IV. Electronic Access**

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

Dated: September 12, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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