

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.

[FR Doc. 2011-94 Filed 1-6-11; 8:45 am]

BILLING CODE 4110-01-P

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Draft Guidance for Industry on Electronic Source Documentation in Clinical Investigations; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Electronic Source Documentation in Clinical Investigations."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can comment on any guidance at any time (*see* 21 CFR 10.115(g)(5)), to ensure that FDA considers your comments on the draft guidance before it begins work on the final version of the guidance, submit electronic or written comments on the draft guidance by April 7, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Critical Path Programs, Office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 *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to 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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 industry¹ 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,

¹ 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.

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.

IV. Electronic Access

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

Dated: January 1, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-1981-N-0361 (formerly 81N-0391), FDA-1981-N-0077 (formerly 81N-0393), FDA-1981-N-0248 (formerly 81N-0396), FDA-1982-N-0225 (formerly 82N-0078), FDA-1982-N-0046 (formerly 82N-0095), FDA-1982-N-0264 (formerly 82N-0096), FDA-1982-N-0310 (formerly 82N-0311), and FDA-1983-N-0137 (formerly 83N-0095); DESI 5213, 6290, 6303, 6514, 8658, 11935, and 12152]

Drugs for Human Use; Drug Efficacy Study Implementation; Oral Prescription Drugs Offered for Relief of Symptoms of Cough, Cold, or Allergy; Withdrawal of Hearing Requests; Opportunity To Affirm Outstanding Hearing Requests; Final Resolution of Dockets

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that all outstanding hearing requests pertaining to Docket Nos. 81N-0391, 82N-0078, and 82N-0311 have been withdrawn and therefore, shipment in interstate commerce of the products identified in those dockets, or any identical, related, or similar product that is not the subject of an approved new drug application (other than an over-the-counter (OTC) product that complies with an applicable OTC monograph), is unlawful as of the effective date of this notice. FDA is also offering an opportunity to affirm outstanding hearing requests in Docket Nos. 81N-0393, 81N-0396, 82N-0095, 82N-0096, and 83N-0095. FDA will assume that companies with outstanding hearing requests that do not respond to this notice are no longer

interested in pursuing their requests, and will deem the requests withdrawn.

DATES: Effective Date: This notice is effective February 7, 2011. Hearing requests must be affirmed by notifying FDA by February 7, 2011. Hearing requests not affirmed within that time frame will be deemed withdrawn.

ADDRESSES: All communications in response to this notice should be identified with the appropriate docket number, and directed to the appropriate office listed as follows:

To affirm or withdraw hearing requests: Sakineh Walther, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5242, Silver Spring, MD 20993-0002.

All other communications: Sakineh Walther, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5242, Silver Spring, MD 20993-0002.

FOR FURTHER INFORMATION CONTACT:

Sakineh Walther, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5242, Silver Spring, MD 20993-0002, 301-796-3349, e-mail:

sakineh.walther@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

When initially enacted in 1938, the Federal Food, Drug, and Cosmetic Act (FD&C act) required that “new drugs” be approved for safety by FDA before they could legally be sold in interstate commerce.¹ To this end, the FD&C Act made it the sponsor’s responsibility, prior to marketing a new drug, to submit a new drug application (NDA) to FDA to prove that its drug was safe. Between 1938 and 1962, if a drug obtained approval, FDA considered drugs that were identical, related, or similar (IRS)² to the approved drug to be “covered” by that approval, and allowed those IRS

¹ A “new drug” is defined by the FD&C Act as a drug that “is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a ‘new drug’ if at any time prior to the enactment of this FD&C Act it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use * * *.” (21 U.S.C. 321(p)).

² Section 310.6(b)(1) (21 CFR 310.6(b)(1)) provides: “An identical, related, or similar drug includes other brands, potencies, dosage forms, salts, and esters of the same drug moiety as well as of any drug moiety related in chemical structure or known pharmacological properties.”

drugs to be marketed without independent approval.

In 1962, Congress amended the act to require that new drugs be proven effective for their labeled indications, as well as safe, in order to obtain FDA approval. This amendment also necessitated that FDA conduct a retrospective evaluation of the effectiveness of the drug products that FDA had approved as safe between 1938 and 1962. FDA contracted with the National Academy of Science/National Research Council (NAS/NRC) to make an initial evaluation of the effectiveness of over 3,400 products that had been approved only for safety between 1938 and 1962. The NAS/NRC reports for these drug products were submitted to FDA in the late 1960s and early 1970s. The agency reviewed and re-evaluated the reports and published its findings in **Federal Register** notices. FDA’s administrative implementation of the NAS/NRC reports was called the Drug Efficacy Study Implementation (DESI). DESI covered the approximately 3,400 products specifically reviewed by the NAS/NRC, as well as the even larger number of IRS products that entered the market without FDA approval.

In the early 1970s, FDA granted temporary exemptions³ from the time limits established⁴ for completing certain phases of the DESI program for certain oral prescription drugs offered for relief of cough, cold, allergy, and related symptoms. The exemptions were granted because of the close relationship between these prescription drugs and drugs sold over the counter (OTC) that were subject to the ongoing OTC drug review (*see* 21 CFR part 330). Postponement of final evaluations of these DESI prescription products enabled the agency to consider the recommendations of the OTC review panel in addition to any evidence submitted by NDA holders and other parties in response to various DESI notices covering relevant products.

All drugs covered by the DESI review are “new drugs” under the FD&C Act. If FDA’s final DESI determination classifies a drug product as lacking substantial evidence of effectiveness for one or more indications, that drug product and those IRS to it may no longer be marketed for such indications and are subject to enforcement action as unapproved new drugs. If FDA’s final DESI determination classifies the drug product as effective for one or more of its labeled indications, the drug can be marketed for such indications, provided

³ 38 FR 34481 (December 14, 1973).

⁴ 38 FR 4006 (February 9, 1973) and 37 FR 15022 (July 27, 1972).