



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0057]

Guidance for Industry and Food and Drug Administration Staff on Best Practices for Conducting and Reporting Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data;

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 and FDA staff entitled "Best Practices for Conducting and Reporting Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data." The guidance is intended to describe best practices pertaining to conducting and documenting pharmacoepidemiologic safety studies that use electronic healthcare data. The guidance includes recommendations for documenting the design, analysis, and results of such studies to optimize FDA's review of protocols and final reports that are submitted to the Agency.

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. 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 human drug products: Judy Staffa, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 274, Silver Spring, MD 20993-0002.

Regarding human biological products: Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration (HFM-17), 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and FDA staff entitled "Best Practices for Conducting and Reporting Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data." The primary goals of this guidance are to provide the following:

- Consistent guidance for industry and FDA to use when designing, conducting, and analyzing pharmacoepidemiologic safety studies;
- a framework for industry to use when submitting pharmacoepidemiologic safety study protocols and final reports to FDA; and
- a framework for FDA reviewers to use when reviewing and interpreting pharmacoepidemiologic safety study protocols and final reports.

This guidance does not address real-time active safety surveillance studies, as this field is still rapidly evolving, and it is not possible at this time to recommend sound best practices. The guidance is not intended to be prescriptive with regard to choice of study design or type of analysis and does not endorse any particular type of data resource or methodology. Finally, the guidance does not provide a framework for determining the appropriate weight of evidence to be given to studies from this data stream in the overall assessment of drug safety, as this appraisal represents a separate aspect of the regulatory decision-making process and is best accomplished in the context of the specific safety issue under investigation.

In the Federal Register of February 16, 2011 (76 FR 9027), FDA issued a draft version of this guidance entitled "Best Practices for Conducting and Reporting Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data Sets." The comment period on the draft guidance ended on April 18, 2011. Most of the comments sought clarification and further illustrations of issues discussed in the guidance. FDA has carefully reviewed all comments received on the draft guidance (more than 400 comments were submitted to the public docket). As a result of the public comments, FDA has clarified the following sections of the guidance: Interpretation of findings; study time frame; identification and handling of confounding and the use of statistical techniques to address confounding; exposure ascertainment; study design; outcome definition and validation; prespecified analysis plan; and the linkage and pooling of data from different data sources. Glossary definitions and references were added to different sections of the guidance to clarify terms and cite additional resources.

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 best practices for conducting and reporting pharmacoepidemiologic safety studies using electronic healthcare data.

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 provides best practices for reporting pharmacoepidemiologic safety studies using electronic healthcare data. The reports referenced in the guidance would be submitted under 21 CFR 314.81, 314.98, and 601.70. 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) and are approved under OMB control numbers 0910-0001 and 0910-0338.

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/Guidances/default.htm>, or <http://www.regulations.gov>.

Dated: May 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-11361 Filed 05/13/2013 at 8:45 am; Publication Date: 05/14/2013]