4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0755]

Guidance for Industry on Providing Submissions in Electronic Format--Postmarket Non-Expedited Individual Case Safety Reports; Technical Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance to industry entitled "Providing Submissions in Electronic Format--Postmarket Non-Expedited ICSRs; Technical Questions and Answers." The guidance provides firms with information on the appropriate electronic file format to use when electronically submitting to FDA postmarket non-expedited individual case safety reports (ICSRs) on adverse drug experiences.[1] The guidance explains that firms that had previously submitted non-expedited ICSRs in an electronic format that is not supported by FDA should contact the Center for Drug Evaluation and Research (CDER) or Center for Biologics and Evaluation and Research (CBER) and resubmit their non-expedited ICSRs in a compatible electronic format.

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 Office of

[1] For purposes of this guidance, adverse drug experience includes an adverse experience associated with use of a drug or biological product, including a therapeutic vaccine.

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 guidance document.

Submit electronic comments on the guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFD-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jeffrey Trunzo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4447, Silver Spring, MD 20993-0002, 301-796-2029, email: jeffrey.trunzo@fda.hhs.gov; 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 guidance entitled "Providing Submissions in Electronic Format--Postmarket Non-Expedited ICSRs; Technical Questions and Answers." The guidance provides firms with information on the appropriate electronic file format to use when electronically submitting to FDA postmarket non-expedited ICSRs for adverse drug experiences. The guidance explains that firms that had previously submitted non-expedited ICSRs in an electronic format that is not supported by FDA should contact CDER or CBER and resubmit their non-expedited ICSRs in a compatible electronic format.

FDA regulations at §§ 314.80(c)(2) and 600.80(c)(2) (21 CFR 314.80(c)(2) and 600.80(c)(2)) require applicants to submit postmarket periodic safety reports at prescribed intervals. Each periodic safety report must contain a descriptive portion and the non-expedited ICSRs[2] for the reporting interval. The descriptive portion can be submitted as a periodic adverse drug experience report[3]; a periodic adverse experience report[4]; a periodic safety update report[5]; or a periodic benefit–risk evaluation report.[6]

Non-expedited ICSRs can be submitted on paper or electronically. When submitted electronically, the non-expedited ICSRs should be submitted in XML format. This is because FDA is currently able to process electronic submissions of non-expedited ICSRs only in XML, prepared according to International Conference on Harmonisation (ICH) standards for database-to-database transmission of information.[7] When submitted in this compatible electronic format, non-expedited ICSRs can be downloaded into the FDA Adverse Event Reporting System (FAERS) database through the Electronic Submission Gateway.

We have become aware that some firms have submitted non-expedited ICSRs to the electronic Common Technical Document (eCTD) in a portable document file (pdf) format together with the descriptive portion of the periodic safety report.

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[2] As described in §§ 314.80(c)(2)(ii)(b) and 600.80(c)(2)(ii)(B). Non-expedited ICSRs were previously referred to as periodic ICSRs.

[3] As described in § 314.80.

[4] As described in § 600.80.

[5] FDA allows firms with approved waivers (under 21 CFR 314.90 and 600.90) to use the ICH E2C Periodic Safety Update Report format when submitting the descriptive portion of periodic safety reports.

[6] FDA allows firms with approved waivers (under 21 CFR 314.90 and 600.90) to use the ICH E2C(R2) Periodic Benefit-Risk Evaluation Report format when submitting the descriptive portion of periodic safety reports.

FDA does not have a systematic method to identify non-expedited ICSRs that are submitted to the eCTD in pdf format together with the descriptive portion of the periodic safety report. In addition, non-expedited ICSRs submitted to the eCTD in pdf format cannot be downloaded into the FAERS database. Lack of access to non-expedited ICSRs in FAERS hinders FDA's ability to monitor product safety and public health. Furthermore, submission in pdf format prevents public access to the non-expedited ICSRs through FAERS.[8]

FDA is issuing this guidance as level 2 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on the submission of non-expedited ICSRs in an electronic format supported by FDA. 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

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[7] See FAERS Electronic Submissions at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm115894.htm.

[8] FAERS data are available to the public as quarterly data files or by written Freedom of Information request to FDA. See http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm082193.htm.

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 previously approved collections of information found in FDA regulations 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 § 314.80 have been approved under OMB control number 0910-0230. The collections of information in § 600.80 have been approved under OMB control number 0910-0308.

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: July 18, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-17747 Filed 07/23/2013 at 8:45 am; Publication Date: 07/24/2013]