4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0903]

Providing Submissions in Electronic Format--Postmarketing Safety Reports for Vaccines; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a document entitled "Providing Submissions in Electronic Format--Postmarketing Safety Reports for Vaccines; Guidance for Industry." The guidance document provides information and recommendations pertaining to the electronic submission of postmarketing safety reports involving vaccine products marketed for human use with approved biologics license applications (BLAs), including individual case safety reports (ICSRs) and attachments to ICSRs (ICSR attachments), into the Vaccine Adverse Event Reporting System (VAERS). VAERS is a national vaccine safety surveillance program that is co-sponsored by the Centers for Disease Control and Prevention (CDC) and FDA. FDA published in the Federal Register a final rule requiring that certain postmarketing safety reports for human drug and biological products, including vaccines, be submitted to FDA in an electronic format that the Agency can process, review, and archive. The guidance is intended to help applicants required to submit postmarketing safety reports involving vaccine products to comply with the final rule. The

guidance announced in this notice finalizes the draft guidance of the same title, dated July 2014, and supersedes the document entitled "Guidance for Industry: How to Complete the Vaccine Adverse Event Report System Form (VAERS-1)" dated September 1998.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. 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: Paul E. Levine, Jr., Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled "Providing Submissions in Electronic Format--Postmarketing Safety Reports for Vaccines; Guidance for Industry." The guidance document provides information and recommendations pertaining to the electronic submission of postmarketing safety reports involving vaccine products marketed for human use

with approved BLAs, including ICSRs and ICSR attachments, into VAERS. VAERS is a national vaccine safety surveillance program established in response to the National Childhood Vaccine Injury Act of 1986, which requires health professionals and vaccine manufacturers to report specific adverse events that occur after the administration of routinely recommended vaccines. VAERS is co-sponsored by CDC and FDA. The guidance is applicable to vaccine products marketed for human use with approved BLAs for which CBER has regulatory responsibility. The guidance does not apply to any other biological product. Postmarketing ICSRs and ICSR attachments for biological products, which are not addressed by the guidance, are processed into the FDA Adverse Event Reporting System database.

In the Federal Register of June 10, 2014 (79 FR 33072), FDA published a final rule requiring that certain postmarketing safety reports for human drug and biological products, including vaccines, be submitted to FDA in an electronic format that the Agency can process, review, and archive. The guidance is intended to help those applicants required to submit postmarketing safety reports involving vaccine products to comply with the final rule.

In the Federal Register of July 18, 2014 (79 FR 42022), FDA announced the availability of the draft guidance of the same title dated July 2014. FDA received a few comments on the draft guidance and those comments were considered as the guidance was finalized. The guidance includes changes to clarify the reporting requirements and technical process for submitting reports to VAERS. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated July 2014 and supersedes the document entitled "Guidance for Industry: How to Complete the Vaccine Adverse Event Report System Form (VAERS-1)" dated September 1998.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on Providing Submissions in Electronic Format--Postmarketing Safety Reports for Vaccines. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This 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 21 CFR part 310 and part 314 have been approved under OMB control number 0910-0230. The collections of information in 21 CFR 310.305(e)(2), 314.80(g)(2), 329.100(c)(2), and 600.80(h)(2) (Form FDA 3500A), have been approved under OMB control number 0910-0770. The collection of information in 21 CFR part 600 is approved under OMB control number 0910-0308. The collection of information in Form FDA 3500A is approved under OMB control number 0910-0291.

III. 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.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.

Dated: August 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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