4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Draft Guidance for Industry: Providing Submissions in Electronic Format--Postmarketing Safety Reports for Vaccines; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry: Providing Submissions in Electronic Format--Postmarketing Safety Reports for Vaccines" dated July 2014. The draft guidance document provides information and recommendations pertaining to the electronic submission of postmarketing safety reports involving vaccine products marketed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). FDA recently 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 The draft guidance, when finalized, is intended to help applicants required to submit postmarketing safety reports comply with the final rule. The draft guidance, when finalized, also will supersede the document entitled "Guidance for Industry: How to Complete the Vaccine Adverse Event Report System Form (VAERS-1)" dated September 1998.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New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 The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-7800. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.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: John Reilly, 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 draft document entitled "Guidance for Industry: Providing Submissions in Electronic Format--Postmarketing Safety Reports for Vaccines" dated July 2014. The draft guidance provides information and recommendations pertaining to the

electronic submission of postmarketing safety reports involving vaccine products, including ICSRs and ICSR attachments, into VAERS. The guidance is applicable to vaccine products marketed for human use with approved BLAs for which CBER has regulatory responsibility. This guidance does not apply to any other biologic product.

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 draft guidance, when finalized, is intended to help applicants subject to postmarketing safety reporting requirements comply with the final rule. Along with other information, the draft guidance provides updated information about the following: (1) Options for submitting ICSRs and ICSR attachments, as well as other postmarketing safety reports to FDA in electronic format, (2) the notification sent to submitters when FDA has received the electronic postmarketing safety report, and (3) procedures for requesting temporary waivers from the electronic submission requirement. The draft guidance, when finalized, also will supersede the document entitled "Guidance for Industry: How to Complete the Vaccine Adverse Event Reporting System Form (VAERS-1)" dated September 1998.

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 FDA's current thinking on this topic. 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 requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

The information collection resulting from this draft guidance is covered by the information collection provisions of the June 10, 2014, final rule entitled "Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements." The information collection provisions of the final rule have been submitted to the Office of Management and Budget (OMB) for review, as required under section 3507(d) of the Paperwork Reduction Act. Prior to the effective date of the final rule, FDA will publish a notice in the Federal Register announcing OMB's decision to approve, modify, or disapprove the information collection provisions in the final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. 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 draft guidance at either http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.

Dated: July 14, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

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