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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-1160]

Center for Biologics Evaluation and Research eSubmitter Program for Electronic Submission of Postmarketing Adverse Event Reports for Human Vaccine Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency), Center for Biologics Evaluation and Research (CBER) is announcing the availability of a Vaccine Adverse Event Reporting System (VAERS) eSubmitter program for the electronic submission of postmarketing individual case safety reports (ICSRs) and ICSR attachments of adverse events for human vaccine products (VAERS eSubmitter program). The VAERS eSubmitter program is a free software program for voluntary use that is intended to help persons subject to mandatory postmarketing requirements for vaccines including applicants, manufacturers, packagers, and distributors to electronically submit ICSRs and ICSR attachments as required by the final rule titled "Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements." The VAERS eSubmitter program creates a simple and efficient mechanism for the secure electronic submission of postmarketing ICSRs and ICSR attachments into the VAERS database without the need for an internal database that is compatible with the International Conference on Harmonisation (ICH)-based direct database to database submission system.

FOR FURTHER INFORMATION CONTACT: Bioinformatics Support Staff, Office of Review Management, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, CBERICSRSUBMISSIONS@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of the VAERS eSubmitter program for the electronic submissions of postmarketing ICSRs and ICSR attachments of adverse events for human vaccine products. The VAERS eSubmitter program is available for voluntary use by applicants and others required to report postmarketing adverse events, as described above, to submit an initial or follow-up ICSR document for human vaccine products. The eSubmitter application software, which can be downloaded free of charge, assists users in the preparation of submissions that contain the minimum elements necessary for FDA to perform a comprehensive review.

The eSubmitter ICSR template for vaccines is designed to ensure that those submitting postmarketing ICSRs and ICSR attachments include necessary information in these regulatory submissions. It is also designed to guide users of the system as they complete the ICSR file creation and submission process. The VAERS eSubmitter program will help to improve the consistency, quality, and completeness of ICSR submissions and make the submission and review process more user-friendly for those required to report postmarketing adverse events for human vaccine products.

FDA published in the Federal Register of June 10, 2014 (79 FR 33072), a final rule titled "Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements," which requires, in part, that applicants and other adverse event reporters submit

postmarketing ICSRs and ICSR attachments to CBER in an electronic format that the Agency can process, review, and archive. The final rule became effective June 10, 2015. Postmarketing ICSRs and ICSR attachments sent to CBER for human vaccines are processed into the VAERS database. As discussed in the preamble to the final rule and in CBER's final guidance for industry "Providing Submissions in Electronic Format – Postmarketing Safety Reports for Vaccines," dated August 2015 (August 2015 Guidance), FDA is providing two voluntary options for electronic submission of ICSRs and ICSR attachments into VAERS: (1) Direct database to database submission through the Electronic Submissions Gateway (ESG), and (2) submission of safety reports through the VAERS eSubmitter program as described on the CBER eSubmitter Web Page (available at: http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm191387.htm). Applicants and others required to report postmarketing adverse events can choose either option to electronically submit ICSRs and ICSR attachments to VAERS.

The ICSR eSubmitter software is a government-issued software provided in support of the Government Paperwork Elimination Act of 1998 (44 U.S.C. 3504). As users of the eSubmitter software, applicants and others required to report postmarketing adverse events are not required to perform their own file validation process. The purpose of the ICSR eSubmitter template is to facilitate the electronic submission of postmarketing vaccine safety reports using internationally adopted data standards to enhance regulatory review, exchange and dissemination of vaccine safety information. Applicants and others who choose to use the eSubmitter program for required postmarketing reporting of adverse events for human vaccine products must first download the eSubmitter software and then manually enter information into the ICSR template form to create each electronic ICSR or ICSR attachment for submission to FDA through the ESG for uploading to the VAERS database. Further information on submitting ICSRs and ICSR

attachments using eSubmitter is included in the August 2015 Guidance (available at: http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Vaccines/default.htm), and on the CBER eSubmitter web page referenced above.

Dated: April 25, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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