4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0604]

Electronic Submission of Postmarketing Safety Reports Involving Vaccine Products; Notice of Pilot Project

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Center for Biologics Evaluation and Research (CBER) in the Food and Drug Administration (FDA) is announcing a pilot project to evaluate its current systems for receiving postmarketing safety reports involving vaccine products electronically for processing into the Vaccine Adverse Event Reporting System (VAERS). As part of this pilot project, CBER also plans to assess the updated International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) E2B(R3) specification for electronic transmission of vaccine Individual Case Safety Reports (ICSRs). Participation in the pilot project is open to firms that submit postmarketing reports into VAERS. CBER plans to accept participation from up to six applicants. The pilot project is intended to provide industry and CBER regulatory review staff with an opportunity to evaluate current system capabilities for sending and receiving postmarketing safety reports for vaccine products using FDA's Electronic Submissions Gateway (ESG), including the use of the updated ICH E2B(R3) specification.

DATES: Submit an electronic request to participate in this pilot project by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: If you are interested in participating in this pilot project, you should submit an electronic request to CBER_eSubmitter_program@fda.hhs.gov.

FOR FURTHER INFORMATION CONTACT: Lise Stevens, Food and Drug Administration, Center for Biologics Evaluation and Research, 10903 New Hampshire Ave., Bldg. 71, rm. 7323, Silver Spring, MD 20993-0002, 240 402-8169, email: lise.stevens@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

CBER regulates certain biological products, including vaccines, and is committed to advancing the public health through innovative activities that help ensure the safety, effectiveness, and timely delivery of these products to patients. This includes improving the processes for providing certain regulatory submissions to FDA.

CBER is announcing a pilot project to evaluate its current systems for receiving postmarketing safety reports involving vaccine products electronically for processing into VAERS. VAERS is a cooperative program for vaccine safety of the FDA and the Centers for Disease Control and Prevention. VAERS collects postmarketing surveillance information about adverse events (unlabeled, serious events) that occur after the administration of U.S. licensed vaccines. This includes the collection of ICSRs that report on adverse experiences related to an individual patient or subject.

As part of this pilot project, CBER also wishes to assess the updated ICH E2B(R3) specification for electronic transmission of vaccine ICSRs. The ICH E2B(R3) specification addresses the electronic submission of ICSRs and is intended to improve the inherent quality of the data, enabling improved handling and analysis of ICSR reports.

In the Federal Register of February 21, 2014 (79 FR 9908), FDA announced the availability of a guidance for industry entitled "E2B(R3) Electronic Transmission of Individual Case Safety Reports (ICSRs): Implementation Guide--Data Elements and Message Specification" (the E2B(R3) implementation guidance), as well as an appendix to the guidance entitled "ICSRs Appendix to the Implementation Guide--Backwards and Forwards Compatibility." The E2B(R3) implementation guidance provides recommendations on the data elements, terminology, and exchange standards for the electronic submission of ICSRs. The E2B(R3) implementation guidance also provides information for the development of software tools for creating, editing, sending, and receiving electronic ICSR messages. The E2B(R3) implementation guidance is available on FDA's Web site at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

II. Pilot Project Participation

The pilot project to evaluate FDA's current systems for receiving postmarketing safety reports involving vaccine products electronically into VAERS, as well as to assess the updated ICH E2B(R3) specification, is to last for approximately 3 months, but it may be extended as needed. During the pilot, CBER staff will be available to answer any questions or concerns that may arise. Pilot project participants will be asked to comment on their experience in the pilot. These comments and discussions will assist CBER in its development of this electronic program.

III. Requests for Participation

Requests to participate in the pilot project should be sent electronically to CBER_eSubmitter_program@fda.hhs.gov. You should include the following information in your request: Contact name, contact phone number, and contact email address. Once requests for participation are received, FDA will contact interested applicants to discuss the pilot project.

FDA is seeking a limited number of participants (no more than six) to participate in this pilot project. The pilot project is expect to last approximately 3 months but may be extended as needed.

Dated: May 21, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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