public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Notification of the Intent To Use an Accredited Person Under the Accredited Persons Inspection Program (Formerly Requests for Inspection Under the Inspection by Accredited Persons Program)—(OMB Control Number 0910–0569)—Extension

Section 201 of the Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250) amended section 704 of the Federal Food, Drug, and Cosmetic Act by adding subsection (g) (21 U.S.C. 374(g)). This amendment authorized FDA to establish a voluntary third-party inspection program applicable to manufacturers of class II or class III medical devices who meet certain eligibility criteria. In 2007, the program was modified by the Food and Drug Administration Amendments Act of 2007 by revising eligibility criteria and by no longer requiring prior approval by FDA. To reflect the revisions, FDA modified the title of the collection of information and on March 2, 2009, issued a guidance entitled ''Manufacturer's Notification of the Intent to Use an Accredited Person Under the Accredited Persons Inspection Program Authorized by Section 228 of the Food and Drug Administration Amendments Act of 2007.'' This guidance supersedes the Agency's previous guidance regarding requests for third-party inspection and may be found on the Internet at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085187.htm*. This guidance is intended to assist device establishments in determining whether they are eligible to participate in the AP Program and, if so, how to submit notification of their intent to use the program. The AP Program applies to manufacturers who currently market their medical devices in the United States and who also market or plan to market their devices in foreign countries. Such manufacturers may need current inspections of their establishments to operate in global commerce.

There are approximately 8,000 foreign and 10,000 domestic manufacturers of medical devices. Approximately 5,000 of these firms only manufacture class I devices and are, therefore, not eligible for the AP Program. In addition, 40 percent of the domestic firms do not export devices and therefore are not eligible to participate in the AP Program. Further, 10 to 15 percent of the firms are not eligible due to the results of their previous inspection. FDA estimates there are 4,000 domestic manufacturers and 4,000 foreign manufacturers that are eligible for inclusion under the AP Program. Based on communications with industry, FDA estimates that on an annual basis approximately 20 of these manufacturers may use an AP in any given year.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/21 U.S.C. section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Notification regarding use of an accredited person—374(g)	20	1	20	15	300

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: May 22, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–12282 Filed 5–27–14; 8:45 am]

BILLING CODE 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 June 27, 2014.

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.

[FR Doc. 2014–12291 Filed 5–27–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2012–E–1244 and FDA–2012–E–1245]

Determination of Regulatory Review Period for Purposes of Patent Extension; MENHIBRIX

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for MENHIBRIX and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human biological product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov*.
Submit written petitions (two copies are required) and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit petitions electronically to *http://www.regulations.gov* at Docket No. FDA–2013–S–0610.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Management, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6257, Silver Spring, MD 20993–0002, 301–796–7900.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product MENHIBRIX (Meningococcal Groups C and Y and Haemophilus b Tetanus Toxoid