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

Conjugate Vaccine). MENHIBRIX is a vaccine indicated for active immunization to prevent invasive disease caused by *Neisseria meningitides* serogroups C and Y and *Haemophilus influenzae* type b. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for MENHIBRIX (U.S. Patent Nos. 5,693,326 and 5,955,079) from the Henry M. Jackson Foundation for the Advancement of Military Medicine, and the Patent and Trademark Office requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated March 4, 2013, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of MENHIBRIX represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for MENHIBRIX is 2,924 days. Of this time, 1,886 days occurred during the testing phase of the regulatory review period, while 1,038 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* June 14, 2004. The applicant claims June 12, 2004, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 14, 2004, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262)*: August 12, 2009. FDA has verified the applicant's claim that the biologics license application (BLA) for MENHIBRIX (BLA 125363) was initially submitted on August 12, 2009.

3. *The date the application was approved:* June 14, 2012. FDA has verified the applicant's claim that BLA 125363 was approved on June 14, 2012.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,825 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by July 28, 2014. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 24, 2014. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic petitions. 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. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to *http://www.regulations.gov*, Docket No. FDA–2013–S–0610. Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 21, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–12294 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–2013–E–0410; FDA–2013–E–0411; FDA–2013–E–0412]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for MYRBETRIQ 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 drug 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 drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug 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 drug 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 drug product MYRBETRIQ (mirabegron). MYRBETRIQ is indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary