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 petitions. It is only necessary to send one set of comments. It is no longer necessary to send three copies of mailed comments. However, if you submit a written petition, you must submit three copies of the petition. Identify comments with the docket number found in brackets in the heading of this document.

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: February 14, 2011.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 2011–5312 Filed 3–8–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–E–0332]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for CERVARIX and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application 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 along with three copies and 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: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

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 recently approved for marketing the human biological product CERVARIX (human papillomavirus bivalent (types 16 and 18) vaccine). CERVARIX is indicated for prevention of the following diseases caused by oncogenic human papillomavirus types 16 and 18: cervical cancer; cervical intraepithelial neoplasia grade 2 or sores and adenocarcinoma in situ; and cervical intraepithelial neoplasia grade 1. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for CERVARIX (U.S. Patent No. 7,351,533) from MedImmune, LLC., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 26, 2010, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of CERVARIX 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 CERVARIX is 4,027 days. Of this time, 3,094 days occurred during the testing phase of the regulatory review period, while 933 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:* October 9, 1998. The applicant claims September 8, 1998, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was October 9, 1998, 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):* March 29, 2007. FDA has verified the applicant's claim that the biologics license application (BLA) for CERVARIX (BLA 125259/0) was submitted on March 29, 2007.

3. *The date the application was approved:* October 16, 2009. FDA has verified the applicant's claim that BLA 125259/0 was approved on October 16, 2009.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 562 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 May 9, 2011. 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 September 5, 2011. 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 petitions. It is only necessary to send one set of comments. It is no longer necessary to send three copies of mailed comments. However, if you submit a written petition, you must submit three copies of the petition. Identify comments with the docket number found in brackets in the heading of this document.

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: February 14, 2011.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 2011–5310 Filed 3–8–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, e-mail *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer at (301) 443–1129.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the agency; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Supplemental Information Request for the Submission of the Updated State Plan for the Home Visiting Program (OMB No. 0915–0336)—[Extension]

On March 23, 2010, the President signed into law the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148), historic and transformative legislation designed to make quality, affordable health care available to all Americans, reduce costs, improve health care quality, enhance disease prevention, and strengthen the health care workforce. Through a provision authorizing the creation of the Maternal, Infant, and Early Childhood Home Visiting Program, (*http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h3590enr.txt.pdf*, pages 216–225), the Act responds to the diverse needs of children and families in communities at risk and provides an unprecedented opportunity for collaboration and partnership at the Federal, State, and community levels to improve health and development outcomes for at-risk children through evidence-based home visiting programs.

The Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program is designed: (1) To strengthen and improve the programs and activities carried out under Title V; (2) to improve coordination of services for at-risk communities; and (3) to identify and provide comprehensive services to improve outcomes for families who reside in at-risk communities.

To achieve the legislative requirements of the MIECHV program, the following application steps were required:

The first step was submission of an application for funding: the Funding Opportunity Announcement (FOA) HRSA–10–275 was issued on June 10, 2010, and State applications were due July 9, 2010. These applications were to include plans for completing the statewide needs assessment and initial State plans for developing the program in order to meet the criteria identified in the legislation. Submission of the needs assessments in the form and manner required by the Secretary is also a required condition for States to receive FY 2011 Title V Block Grant allotments. On September 20, 2010, all 50 States, the District of Columbia, and five U.S. territories submitted needs assessments that identified communities at risk. The needs assessments submitted were approved, and all 56 applicants have received FY 2011 Title V Block Grant funds.

As a condition of receiving the remaining grant award made to States in July 2010, each of the 56 applicants is also required to develop an Updated State Plan for a State Home Visiting Program. The Secretary of Health and Human Services must approve the Updated State Plan before the release of the remaining grant funds.

The information requested for the Updated State Plan is intended to help States view their proposed State Home Visiting Program as a service strategy aimed at developing a comprehensive, high-quality early childhood system that promotes maternal, infant, and early childhood health, safety and development, and strong parent-child relationships in the targeted community(ies) at risk. Ultimately, the information provided will help States develop a comprehensive plan that addresses community risk factors, builds on strengths identified in the targeted community(ies), and responds to the specific characteristics and needs of families in each of these communities.

The annual estimate of burden is as follows:

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Section 1: Identification of the State's Targeted At-Risk Community(ies)	56	1	56	30	1,680
Section 2: State Home Visiting Program Goals and Objectives	56	1	56	30	1,680
Section 3: Selection of Proposed Home Visiting Model(s) and Explanation of How the Model(s) Meet the Needs of Targeted Community(ies)	56	1	56	30	1,680
Section 4: Implementation Plan for Proposed State Home Visiting Program	56	1	56	60	3,360