DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2016–0115]

Determination of Regulatory Review Period for Purposes of Patent Extension; Lawsonia Intracellularis Bacterin Vaccine

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service has determined the regulatory review period for Lawsonia Intracellularis Bacterin Vaccine and is publishing this notice of that determination as required by law. We have made this determination in response to the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that veterinary biologic.

DATES: We will consider all requests for revision of the regulatory review period determination that we receive on or before May 4, 2017. We will consider all due diligence petitions that we receive on or before October 2, 2017.

ADDRESSES: You may submit revision requests and due diligence petitions by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0115.*
- *Postal Mail/Commercial Delivery:* Please send your request or petition to Docket No. APHIS–2016–0115, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

A copy of the regulatory review period determination and any revision requests or due diligence petitions that we receive on this determination may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0115* or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Donna Malloy, Operational Support Section, Center for Veterinary Biologics, Policy, Evaluation, and Licensing, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737–1231; (301) 851–3426.

For information concerning the regulatory review period determination contact Dr. Patricia L. Foley, Center for Veterinary Biologics, Policy, Evaluation, and Licensing, VS, APHIS, 1920 Dayton Avenue, P.O. Box 844, Ames, IA 50010; (515) 337–6100.

SUPPLEMENTARY INFORMATION: The provisions of 35 U.S.C. 156, '' Extension of patent term,'' provide, generally, that a patent for a product may be extended for a period of up to 5 years as long as the patent claims a product that, among other things, was subject to a regulatory review period before its commercial marketing or use. (The term ''product'' is defined in that section as ''a drug product'' [which includes veterinary biological products] or ''any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.'') A product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

The regulations in 9 CFR part 124, ''Patent Term Restoration'' (referred to below as the regulations), set forth procedures and requirements for the Animal and Plant Health Inspection Service's (APHIS') review of applications for the extension of the term of certain patents for veterinary biological products pursuant to 35 U.S.C. 156. As identified in the regulations, the responsibilities of APHIS include:

- Assisting Patent and Trademark Office of the U.S. Department of Commerce in determining eligibility for patent term restoration;
- Determining the length of a product's regulatory review period;
- If petitioned, reviewing and ruling on due diligence challenges to APHIS' regulatory review period determinations; and
- Conducting hearings to review initial APHIS findings on due diligence challenges.

The regulations are designed to be used in conjunction with regulations issued by the Patent and Trademark Office concerning patent term extension, which may be found at 37 CFR 1.710 through 1.791.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For veterinary biologics, the testing phase begins on the date the authorization to prepare an experimental veterinary biologic became effective and runs until the approval phase begins. The approval phase begins on the date an application for a license was initially submitted for approval and ends on the date such license was issued. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award, APHIS' determination of the length of a regulatory review period for a veterinary biologic will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(5)(B).

APHIS recently licensed for production and marketing the veterinary biologic Lawsonia Intracellularis Bacterin Vaccine. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Lawsonia Intracellularis Bacterin Vaccine (U.S. Patent No. 5,610,059) from Intervet Inc., a subsidiary of Merck Animal Health, and the Patent and Trademark Office requested APHIS' assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 19, 2016, APHIS advised the Patent and Trademark Office that this veterinary biologic had undergone a regulatory review period and that the approval of Lawsonia Intracellularis Bacterin Vaccine represented the first permitted commercial licensing or use of the product. Subsequently, the Patent and Trademark Office requested that APHIS determine the product's regulatory review period.

APHIS has determined that the applicable regulatory review period for Lawsonia Intracellularis Bacterin Vaccine is 1,544 days. Of this time, 186 days occurred during the testing phase of the regulatory review period, and 1,358 days occurred during the approval phase. These periods were derived from the following dates:

1. *The date that APHIS started confirmatory testing on the master seed for use in products containing Lawsonia intracellularis:* June 20, 2011. APHIS has verified the applicant's claim that the master seed to be used in the Lawsonia Intracellularis Bacterin Vaccine was first put on test by APHIS on June 20, 2011.

2. *The date the application for a license was initially submitted for approval under the Virus-Serum-Toxin Act:* December 23, 2011. APHIS has verified the applicant's claim that the application was initially submitted on December 23, 2011.

3. *The date the license was issued:* September 11, 2015. APHIS has verified the applicant's claim that the license for the commercial marketing of the vaccine was issued on September 11, 2015.

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 application for patent extension, this applicant seeks 1,544 days of patent term extension.

Section 124.22 of the regulations provides that any interested person may request a revision of the regulatory review period determination within 30 days of the date of this notice (see **DATES** above). The request must specify the following:

- The identity of the product;
- The identity of the applicant for patent term restoration;
- The docket number of this notice; and
- The basis for the request for revision, including any documentary evidence.

Further, under § 124.30 of the regulations, any interested person may file a petition with APHIS, no later than 180 days after the date of this notice (see **DATES** above), alleging that a license applicant did not act with due diligence in seeking APHIS approval of the product during the regulatory review period. The filing, format, and content of a petition must be as described in the regulations in ''Subpart D–Due Diligence Petitions'' (§§ 124.30 through 124.33).

Authority: 35 U.S.C. 156; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 30th day of March 2017.

Jere L. Dick,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2017–06640 Filed 4–3–17; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Farm Service Agency

Information Collection Request; Generic Clearance for the Collection of Qualitative Customer Feedback on the Farm Service Agency Service Delivery

AGENCY: Farm Service Agency, USDA.

ACTION: Notice; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Farm Service Agency (FSA) is requesting comments from all interested individuals and organizations on an extension with a revision of a currently approved information collection associated with the Generic Clearance for the Collection of Qualitative Customer Feedback on FSA Service Delivery. This option is a fast track for approval to streamline the timing to implement certain types of surveys and related collection of information. FSA uses the approval to cover the instruments of collection (such as a survey, a window pop-up survey, a focus group, or a comment card), which are designed to get customer feedback on FSA service delivery for various programs. This request for approval broadly addresses FSA's need for information about what our customers think of our services so that we can improve service delivery; specific information collection activities will be incorporated into the approval as the need for the information is identified. For example, when we implement a new program and provide information about the services for the program on our Web site, we may provide a voluntary customer service questionnaire about how well the program is working for our customers, specifically within the area of customer service. FSA is requesting to increase the number of respondents in the fast track approval due to an anticipated increase in the number of customer respondents responding to customer service surveys that will be sent to a broader scope and greater number of FSA customers.

DATES: We will consider comments that we receive by June 5, 2017.

ADDRESSES: We invite you to submit comments on this notice. In your comments, include the date, volume, and page number of this issue of the **Federal Register**, the OMB control number and the title of the information collection. You may submit comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Mary Ann Ball, USDA, Farm Service Agency, Room 3754–S, 1400 Independence Ave SW., Washington, DC 20250–0572.

You may also send comments to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

Copies of the information collection instruments may be requested by contacting Mary Ann Ball at the above address.

FOR FURTHER INFORMATION CONTACT: Mary Ann Ball, (202) 720–4283.

SUPPLEMENTARY INFORMATION:

Title: Generic Clearance for the Collection of Qualitative Customer Feedback on Farm Service Agency Service Delivery.

OMB Control Number: 0560–0286.

Type of Request: Extension with a revision.

Abstract: FSA program staff have created several feedback instruments (customer surveys) and submitted them to the FSA information collection coordinator for approval under the current approved information collection of 0560–0286, Generic Clearance for the Collection of Qualitative Customer Feedback on Farm Service Agency Service Delivery. FSA program staff continue to use the fast track approval to submit a new customer instruments to the FSA information collection coordinator for approval, which takes less time rather than going through a regular Paperwork Reduction Act process. As a result, program staff are able to quickly implement certain types of surveys and related collection of information using OMB control number of 0560–0286. For example, when we implement a new program and provide information about the programs on our Web site, FSA may provide a voluntary customer service questionnaire about how well the program is working for our customers, specifically within the area of customer service. The information collection provides a means to gather qualitative customer and stakeholder feedback in an efficient, timely manner that is consistent with FSA's commitment to improving service delivery. By qualitative feedback, we mean information, generally from customers, that provides useful insights on perceptions and opinions based on experiences with FSA service delivery. Such information does not include statistical surveys that yield quantitative results that can be generalized to the population. The qualitative feedback will:

- Provide insights into customer or stakeholder perceptions, experiences, and expectations,
- Provide an early warning of issues with service, and
- Focus attention on areas where communication, training, or changes in operations might improve delivery of products or services.

The collection will allow for ongoing, collaborative, and actionable communication between FSA and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

The solicitation of feedback will target areas such as: Timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. Responses will be assessed to plan and inform efforts to improve or maintain the