

employees. Authorized Board employees and the industry are the primary users of the information, and AMS is the secondary user.

*Estimate of Burden:* Public reporting burden for this collection of information is estimated to average .227 hours per response.

*Respondents:* Tart cherry growers and for-profit businesses handling fresh and processed tart cherries produced in Michigan, New York, Pennsylvania, Oregon, Utah, Washington, and Wisconsin.

*Estimated Number of Respondents:* 642.

*Estimated Number of Responses:* 3,258.

*Estimated Number of Responses per Respondent:* 5.07.

*Estimated Total Annual Burden on Respondents:* 740 hours.

Comments are invited on: (1) Whether this collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (2) the accuracy of the agency's estimate of the burden of the collection of information including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of the collection of information on those who respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments should reference this docket number and be sent to the USDA in care of the Docket Clerk at the address above. All comments received within the provided comment period will be available for public inspection during regular business hours at the same address.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

AMS is committed to compliance with the E-Government Act to promote the use of the internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes.

A 60-day comment period is provided to allow interested persons to respond to the notice.

Dated: September 30, 2019.

**Bruce Summers,**  
Administrator, Agricultural Marketing Service.

[FR Doc. 2019-21568 Filed 10-3-19; 8:45 am]

BILLING CODE 3410-02-P

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

[Docket No. APHIS-2019-0039]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; Porcine Circovirus Vaccine, Type 1-Type 2 Chimera, Killed Virus, Mycoplasma Hyopneumoniae Bacterin

**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 Porcine Circovirus Vaccine, Type 1-Type 2 Chimera, Killed Virus, Mycoplasma Hyopneumoniae Bacterin 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 for Patents, 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 November 4, 2019. We will consider all due diligence petitions that we receive on or before April 1, 2020.

**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-2019-0039>.

- *Postal Mail/Commercial Delivery:* Please send your request or petition to Docket No. APHIS-2019-0039, 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-2019-0039> 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. Barbara J. Sheppard, Senior Staff Veterinary Medical Officer, Center for

Veterinary Biologics, Policy, Evaluation, and Licensing, VS, APHIS, USDA, 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 the U.S. 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 U.S. 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 for Patents 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 Porcine Circovirus Vaccine, Type 1-Type 2 Chimera, Killed Virus, Mycoplasma Hyopneumoniae Bacterin. Subsequent to this approval, the U.S. Patent and Trademark Office received a patent term restoration application for Porcine Circovirus Vaccine, Type 1-Type 2 Chimera, Killed Virus, Mycoplasma Hyopneumoniae Bacterin (U.S. Patent No. 9,585,951) from Zoetis, Inc., and the U.S. Patent and Trademark Office requested APHIS' assistance in determining this patent's eligibility for patent term restoration. In a letter dated November 1, 2018, APHIS advised the U.S. Patent and Trademark Office that this veterinary biologic had undergone a regulatory review period and that the approval of Porcine Circovirus Vaccine, Type 1-Type 2 Chimera, Killed Virus, Mycoplasma Hyopneumoniae Bacterin represented the first permitted commercial licensing or use of the product. Subsequently, the U.S. Patent and Trademark Office requested that APHIS determine the product's regulatory review period.

APHIS has determined that the applicable regulatory review period for Porcine Circovirus Vaccine, Type 1-Type 2 Chimera, Killed Virus, Mycoplasma Hyopneumoniae Bacterin is 1,376 days. Of this time, 0 days occurred during the testing phase of the regulatory review period, and 1,376 days occurred during the approval phase. These periods were derived from the following dates:

1. *The date the application for a license was initially submitted for approval under the Virus-Serum-Toxin Act:* April 28, 2014. APHIS has verified the applicant's claim that the application was initially submitted on April 28, 2014.

2. *The date the license was issued:* February 1, 2018. APHIS has verified the applicant's claim that the license for the commercial marketing of the vaccine was issued on February 1, 2018.

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 1,376 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 September 2019.

**Kevin Shea,**

*Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 2019-21677 Filed 10-3-19; 8:45 am]

**BILLING CODE 3410-34-P**

## DEPARTMENT OF AGRICULTURE

### Farm Service Agency

#### Information Collection Request; Organic Certification Cost Share Program

**AGENCY:** Farm Service Agency, USDA.

**ACTION:** Notice; request for comment.

**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 a revision and an extension of a current information collection request associated with the Organic Certification Cost Share Program (OCCSP). OCCSP provides cost share assistance to producers and handlers of agricultural products who are obtaining or renewing their certification under the National Organic Program (NOP). Certified operations may receive up to 75 percent of their certification costs paid. Certain State agencies also submit

applications to FSA to administer OCCSP in their States.

**DATES:** We will consider comments that we receive by December 3, 2019.

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

- *Federal eRulemaking Portal:* Go to <http://regulations.gov>. Follow the online instructions for submitting comments.
- *Mail:* Farm Service Agency, USDA, Tona Huggins, 1400 Independence Avenue SW, Mail Stop 0517, Washington, DC 20250-0517.

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 may be obtained from Tona Huggins at the above address.

#### FOR FURTHER INFORMATION CONTACT:

Tona Huggins, (202) 205-9847; email: [tona.huggins@usda.gov](mailto:tona.huggins@usda.gov). Persons with disabilities who require alternative means for communication should contact the USDA Target Center at (202) 720-2600 (voice).

#### SUPPLEMENTARY INFORMATION:

##### Description of Information Collection

*Title:* Organic Certification Cost Share Program.

*OMB Number:* 0560-0289.

*Expiration Date of Approval:* 03/31/2020.

*Type of Request:* Extension.

*Abstract:* FSA is requesting comments from all interested individuals and organizations on a revision and an extension of a currently approved information collection request associated with OCCSP. Producers and handlers will apply for cost share payments, and State Agencies will establish agreements to get funds and to disburse payments to qualified producers or handlers.

The burden hours increased by 21,290 hours since the last OMB approval. The reason for the increase is due to increased participation in the NOP. The travel times have been removed from the request. The respondents may submit applications by mail and many respondents go to the county offices to do regular and customary business with FSA for other FSA programs; this means no travel time is required specifically for the information collection and therefore, it is no longer included in the burden hour reporting.

For the following estimated total annual burden on respondents, the