

Notices

Federal Register

Vol. 84, No. 193

Friday, October 4, 2019

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Doc. No. AMS-SC-19-0080; SC19-930-2 N]

Tart Cherries; Notice of Request for Extension and Revision of a Currently Approved Information Collection

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Agricultural Marketing Service's (AMS) intent to request an extension for and revision to a currently approved information collection for Tart Cherries Grown in Michigan, New York, Pennsylvania, Oregon, Utah, Washington, and Wisconsin, pursuant to Marketing Order No. 930.

DATES: Comments on this notice must be received by December 3, 2019 to be assured of consideration.

ADDRESSES: Interested persons are invited to submit written comments concerning this notice. Comments must be sent to the Docket Clerk, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250-0237; Fax: (202) 720-8938; or internet: www.regulations.gov. Comments should reference the docket number and the date and page number of this issue of the **Federal Register** and will be available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: www.regulations.gov. All comments submitted in response to this notice will be included in the record and will be made available to the public. Please be advised that the identity of individuals or entities submitting the comments will

be made public on the internet at the address provided above.

FOR FURTHER INFORMATION CONTACT:

Andrew Hatch, Chief, Rulemaking Services Branch, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Room 1406-S, Washington, DC 20250-0237; Telephone: (202) 720-6862, Fax: (202) 720-8938, or Email: andrew.hatch@usda.gov.

Small businesses may request information on complying with this regulation by contacting Antoinette Carter, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250-0237; Telephone: (202) 720-2491, Fax: (202) 720-8938, or Email: richard.lower@usda.gov.

SUPPLEMENTARY INFORMATION:

Title: Tart Cherries Grown in Michigan, New York, Pennsylvania, Oregon, Utah, Washington, and Wisconsin. Marketing Order No. 930 (7 CFR part 930).

OMB Number: 0581-0177.

Expiration Date of Approval: January 31, 2020.

Type of Request: Extension and revision of a currently approved information collection.

Abstract: Marketing order programs provide an opportunity for producers of fresh fruits, vegetables, and specialty crops, in a specified production area, to work together to solve marketing problems that cannot be solved individually. Marketing order regulations help ensure adequate supplies of high quality product and adequate returns to producers. Marketing orders are authorized under the Agricultural Marketing Agreement Act of 1937 (Act), as amended (7 U.S.C. 601-674). The Secretary of Agriculture oversees these operations and issues regulations recommended by a committee of representatives from the respective commodity industry.

The information collection requirements in this request are essential to carry out the intent of the AMAA and to administer the program, which has operated since 1996.

The Federal marketing order for tart cherries (7 CFR part 930) regulates the handling of tart cherries grown in Michigan, New York, Pennsylvania, Oregon, Utah, Washington, and

Wisconsin. The marketing order authorizes volume regulations that provide for a reserve pool in times of heavy cherry supplies. The marketing order also provides for minimum grade and size regulations, and market research and development projects, including paid advertising. These provisions are not currently in use.

The marketing order, and rules and regulations issued thereunder, authorizes the Cherry Industry Administrative Board (Board), the agency responsible for local administration of the marketing order, to require handlers and growers to submit certain information. Much of this information is compiled in aggregate and provided to the Board to assist in carrying out marketing decisions.

The Board has developed 11 forms as a means for persons to file the required and minimum necessary reports with the Board, such as tart cherry inventories, shipments, diversions, and background data. All the information provided is needed to effectively carry out the requirements of the marketing order and fulfill the intent of the AMAA as expressed in the marketing order. Since this marketing order regulates canned and frozen forms of tart cherries, reporting requirements will be in effect all year.

Eleven U.S. Department of Agriculture (USDA) forms are also included in this request. Tart cherry growers and handlers nominated by their peers to serve as representatives on the Board must submit nomination forms to the USDA. Formal rulemaking amendments to the marketing order must be approved in grower referenda authorized and conducted by the USDA. In addition, USDA may conduct a referendum to determine industry support for continuation of the marketing order. Finally, handlers are asked to sign an agreement to indicate their willingness to comply with the provisions of the marketing order if the order is amended. A standardized background form and combined Acceptance Statement for nominees to multiple committees is included in OMB No. 0581-0177.

The information collected is used only by authorized representatives of the USDA, including AMS, Specialty Crops Programs' regional and headquarters staff, and authorized Board

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