

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’s 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 Poulvac® ST Vaccine. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Poulvac® ST Vaccine (U.S. Patent No. 4,735,801) from the Board of Trustees of Leland Stanford Junior University, and the Patent and Trademark Office

requested APHIS’ assistance in determining this patent’s eligibility for patent term restoration. In a letter dated January 22, 2003, APHIS advised the Patent and Trademark Office that this veterinary biologic had undergone a regulatory review period and that the approval of Poulvac® ST Vaccine (Salmonella Typhimurium Vaccine, Live Virus) 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 Poulvac® ST Vaccine is 1,695 days. Of this time, 128 days occurred during the testing phase of the regulatory review period, and 1,567 days occurred during the approval phase. These periods were derived from the following dates:

1. *The date the authority to prepare an experimental biological product under the Virus-Serum-Toxin Act (21 U.S.C. 151 et seq.) became effective:* September 26, 1996. APHIS has verified the applicant’s claim that the test was begun on September 26, 1996.

2. *The date the application for a license was initially submitted for approval under the Virus-Serum-Toxin Act:* January 31, 1997. APHIS has verified the applicant’s claim that the application was initially submitted on January 31, 1997.

3. *The date the license was issued:* May 16, 2001. APHIS has verified the applicant’s claim that the license for the commercial marketing of the vaccine was issued on May 16, 2001.

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 for patent extension, this applicant seeks 1,695 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.

Done in Washington, DC, this 2nd day of April, 2003.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 03-8601 Filed 4-8-03; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation

Notice of Request for Extension of a Currently Approved Information Collection

AGENCY: Commodity Credit Corporation, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Commodity Credit Corporation’s (CCC) intention to request an extension for a currently approved information collection in support of the Regulations—Financing Commercial Sales of Agricultural Commodities under Title I, Public Law 480; Request for Vessel Approval, Form CCC-105 and Request for Vessel Approval Form CCC-105 (cotton); and Declaration of Sale, Form FAS-359.

DATES: Comments on this notice must be received by June 9, 2003, to be assured of consideration.

FOR FURTHER INFORMATION OR COMMENTS

CONTACT: William Hawkins, Director, Program Administration Division, Foreign Agricultural Service, U.S. Department of Agriculture, Stop 1031, Washington, DC 20250-1031, telephone (202) 720-3241.

SUPPLEMENTARY INFORMATION:

Title: Regulations—Financing Commercial Sales of Agricultural Commodities under Title I, Pub. L. 480 (0551-0005); Request for Vessel Approval, Form CCC-105 (0551-0008); and Request for Vessel Approval Form CCC-105 (cotton) and Declaration of Sale, Form FAS-359 (0551-0009).

OMB Numbers: 0551-0005 (Records and Rule Keeping) and 0551-0008 (Request for Vessel Approval Form) and

0551-0009 (Declaration of Sale Form). These will be combined into OMB Number 0551-0005 if this request is approved.

Expiration Date of Approval: August 31, 2003.

Type of Request: Extension and revision of currently approved information collections, with change to combine 0551-0005 (Records and Rule Keeping); 0551-0008 (Request for Vessel Approval) and 0551-0009 (Declaration of Sale Form).

Abstract: Title I of The Agricultural Trade Development and Assistance Act of 1954, as amended, (Pub. L. 83-480) authorizes the CCC to finance the sale and exportation of agricultural commodities on concessional credit terms. Suppliers of commodities and ocean transportation must retain records for 3 years. Prospective commodity suppliers must provide information for the Department to determine eligibility. Commodity suppliers must report details of sales for price approval and submit to USDA, for approval, information on any amendments to the sales. Shipping agents nominated by importing countries must submit information to allow identification of possible conflicts of interest. Shipping agents or embassies submit pertinent shipping information on Form CCC-105 to facilitate approval by CCC of shipping arrangements. This approval is necessary to assure compliance with cargo preference requirements at the lowest cost to CCC. Agents submit this document in order that USDA can generate the CCC-106, a necessary payment document. Ocean carriers then receive payment for ocean freight. Commodity suppliers must report details of sales for price approval. Form FAS-359, "Declaration of Sale," is the written record, signed by the commodity supplier, of the terms of sale as reported by telephone. When signed by the General Sales Manager, it provides evidence of the USDA price approval required for CCC financing.

The information collected is used by CCC to manage, plan, evaluate and account for government resources. The reports and records are required to ensure the proper and judicious use of public funds.

Estimate of Burden: The public reporting burden for these collections is estimated to average 8 hours per Record Keeping, 5 hours per Vessel Approval and 2 hours per Declaration of Sale response.

Respondents: Suppliers of commodities and ocean transportation; prospective commodity suppliers; shipping agents; and business or other-for-profit.

Estimated Number of Respondents: 45 per annum.

Estimated Total Annual Burden of Respondents: 565.00 hours.

Copies of this information collection can be obtained from Kimberly Chisley, the Agency Information Collection Coordinator, at (202) 720-2568.

Requests for Comments: Send comments regarding (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (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 those who are to respond, including through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments may be sent to William Hawkins, Director, Program Administration Division, Foreign Agricultural Service, U.S. Department of Agriculture, Stop 1031, Washington, DC 20250-1031, or to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503. Persons with disabilities who require an alternative means for communication of information (Braille, large print, audiotape, etc.) should contact USDA's Target Center at (202) 720-2600 (voice and TDD). 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.

Signed at Washington, DC, on March 27, 2003.

A. Ellen Terpstra,

Administrator, Foreign Agricultural Service.

[FR Doc. 03-8598 Filed 4-8-03; 8:45 am]

BILLING CODE 3410-10-P

DEPARTMENT OF AGRICULTURE

Farm Service Agency

Commodity Credit Corporation Information Collection; Payment Eligibility and Payment Limitation Determinations Under the Noninsured Crop Disaster Assistance Program

AGENCIES: Farm Service Agency and the Commodity Credit Corporation, USDA.

ACTION: Notice; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the

Farm Service Agency (FSA) and the Commodity Credit Corporation (CCC), is seeking comments from all interested individuals and organizations on a currently approved information collection with revision. This information collection is used to support payment eligibility and payment limitation determinations for a multiple programs including the Conservation Reserve Program, the Price Support Programs, and the Direct and Counter-Cyclical Program authorized by the Farm Security and Rural Investment Act of 2002, and the Noninsured Crop Disaster Assistance Program.

DATES: Comments on this notice must be received on or before June 9, 2003, to be assured consideration. Comments received after that date will be considered to the extent practicable.

ADDRESSES: Comments concerning this notice should be addressed to Farm Service Agency, Attn: James Baxa, Agricultural Program Specialist, Production, Emergencies, and Compliance Division, Farms Service Agency, United States Department of Agriculture, STOP 0517, Room 4752, South Building, 1400 Independence Avenue, SW., Washington, DC 20250-0517. Comments also may be submitted via facsimile to (202) 720-4941 or by e-mail to james.baxa@wdc.usda.gov.

FOR FURTHER INFORMATION CONTACT: James Baxa, Agricultural Program Specialist at (202) 720-4189, or Diane Sharp, Director of Production, Emergencies, and Compliance Division at (202) 720-7641.

SUPPLEMENTARY INFORMATION:

Description of Information Collection

Title: Payment Eligibility and Payment Limitation Determinations under the Noninsured Crop Disaster Assistance Program.

OMB Control Number: 0560-0096.

Expiration Date of Approval: March 31, 2003.

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

Abstract: The collection of the information is necessary to determine the eligibility of individuals and entities as defined at 7 CFR part 1400 for payment eligibility and payment limitation in a multiple programs including, but not limited to, the Conservation Reserve Program, the Price Support Programs, the Direct and Counter-Cyclical Program and the Noninsured Corp Disaster Assistance Program. The regulations at 7 CFR part 1400, as amended, provide for an "actively engaged in farming" and "person" determinations to be made for