

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.

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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