Notices

Federal Register
Vol. 68, No. 68
Wednesday, April 9, 2003

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

Animal and Plant Health Inspection Service

[Docket No. 03–033–1]

National Wildlife Services Advisory Committee; Meeting

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act, we are giving notice of a meeting of the National Wildlife Services Advisory Committee.

DATES: The meeting will be held on June 24, 2003, from 8 a.m. to 5 p.m. and June 25, 2003, from 8 a.m. to noon.

ADDRESSES: The meeting will be held at the USDA Center at Riverside, 4700 River Road, Riverdale, MD.

FOR FURTHER INFORMATION CONTACT: Mrs. Joanne Garrett, Director, Operational Support Staff, WS, APHIS, 4700 River Road, Unit 87, Riverdale, MD 20737–1234, (301) 734–7921.

SUPPLEMENTARY INFORMATION: The National Wildlife Services Advisory Committee (Committee) advises the Secretary of Agriculture concerning policies, program issues, and research needed to conduct the Wildlife Services (WS) program. The Committee also serves as a public forum enabling those affected by the WS program to have a voice in the program's policies.

The meeting will focus on operational and research activities and will be open to the public. Due to time constraints, the public will not be able to participate in the Committee's discussions. However, written statements concerning meeting topics may be filed with the Committee before or after the meeting by sending them to Mrs. Joanne Garrett at the address listed under **FOR FURTHER INFORMATION CONTACT,** or may be filed at the meeting. Please refer to Docket No. 03–033–1 when submitting your statements.

This notice of meeting is given pursuant to section 10 of the Federal Advisory Committee Act (5 U.S.C. App. II).

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

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 03–8600 Filed 4–8–03; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 03–035–1]

Determination of Regulatory Review Period for Purposes of Patent Extension; Poulvac® ST 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 Poulvac® ST 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 9, 2003. We will consider all due diligence petitions that we receive on or before October 6, 2003.

ADDRESSES: You may submit revision requests and due diligence petitions by postal mail/commercial delivery or by e-mail. If you use postal mail/commercial delivery, please send four copies of your request or petition (an original and three copies) to: Docket No. 03–035–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your request or petition refers to Docket No. 03–035–1. If you use e-mail, address your request or petition to *regulations@aphis.usda.gov.* Your request or petition must be contained in the body of your message; do not send attached files. Please include your name and address in your message and ''Docket No. 03–035–1'' on the subject line.

You may request a copy of the regulatory review period determination by writing to Dr. Patricia L. Foley, USDA, APHIS, VS, CVB–LPD, 510 South 17th Street, Suite 104, Ames, IA 50010–8197, or by calling (515) 232–5785. Please refer to the docket number, date, and complete title of this notice when requesting copies.

A copy of the regulatory review period determination and any revision requests or due diligence petitions that we receive on this determination are available for public inspection in our reading room. The reading room 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) 690–2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html.*

FOR FURTHER INFORMATION CONTACT: Dr. Albert P. Morgan, Chief Staff Officer, Operational Support Section, Center for Veterinary Biologics, Licensing and Policy Development, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737–1231; phone (301) 734–8245; fax (301) 734–4314. For information regarding the regulatory review period determination, contact Dr. Patricia L. Foley, APHIS, VS, CVB–LPD, 510 South 17th Street, Suite 104, Ames, IA 50010–8197; phone (515) 232–5785.

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'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