Notices

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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. 03–045–1]

Determination of Regulatory Review Period for Purposes of Patent Extension; Fel-O-Vax® FIV 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 Fel-O-Vax® FIV 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 June 9, 2003. We will consider all due diligence petitions that we receive on or before November 4, 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. 03–045–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your revision request or due diligence petition refers to Docket No. 03–045–1. 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. 03–045–1'' on the subject line.

You may request a copy of the regulatory review period determination by writing to Dr. Larry Ludemann, 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. Larry Ludemann, 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 Fel-O-Vax® FIV Vaccine. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Fel-O-

Vax® FIV Vaccine (U.S. Patent No. 5,275,813) from the Regents of the University of California, and the Patent and Trademark Office requested APHIS' assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 11, 2003, APHIS advised the Patent and Trademark Office that this veterinary biologic had undergone a regulatory review period and that the approval of Fel-O-Vax® FIV Vaccine (Feline Immunodeficiency Virus Vaccine, Killed 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 Fel-O-Vax® FIV Vaccine is 3,853 days. Of this time, 2,442 days occurred during the testing phase of the regulatory review period, and 1,411 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:* August 28, 1991. APHIS has verified the applicant's claim that the test was begun on August 28, 1991.

2. *The date the application for a license was initially submitted for approval under the Virus-Serum-Toxin Act:* May 4, 1998. APHIS has verified the applicant's claim that the application was initially submitted on May 4, 1998.

3. *The date the license was issued:* March 14, 2002. APHIS has verified the applicant's claim that the license for the commercial marketing of the vaccine was issued on March 14, 2002.

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 3,853 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 1st day of May 2003.

Peter Fernandez,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 03–11436 Filed 5–7–03; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Forest Service

Information Collection; Economic, Social, and Cultural Aspects of Livestock Ranching

AGENCY: Forest Service, USDA.

ACTION: Notice; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Forest Service is seeking comments from all interested individuals and organizations on a new one-time information collection, Economic, Social, and Cultural Aspects of Livestock Ranching on the Santa Fe and Carson National Forests. The collection is necessary to provide baseline data on the economic, social, and cultural contributions of livestock ownership in northern New Mexico. The information provided by this study, will help the Forest Service administer grazing permits more effectively to better meet the needs of grazing permittees in northern New Mexico. The information will also be used for purposes of public education.

DATES: Comments must be received in writing on or before July 7, 2003 to be assured of consideration. Comments received after that date will be considered to the extent practicable.

ADDRESSES: Comments concerning this notice should be addressed to Carol Raish, Research Social Scientist, or to Alice M. McSweeney, Social Science Analyst, USDA Forest Service, Rocky Mountain Research Station, 333 Broadway SE., Suite 115, Albuquerque, NM 87102–3497.

Comments also may be submitted via facsimile to (505) 724–3688 or by e-mail to: *craish@fs.fed.us* or *amcsweeney@fs.fed.us.* The public may inspect comments received at 333 Broadway SE., Ste. 115, Albuquerque, NM 87106–3497 during normal business hours. Visitors are encouraged to call ahead to (505) 724–3666 to facilitate entry to the building.

FOR FURTHER INFORMATION CONTACT: Carol Raish, Rocky Mountain Research Station, telephone: (505) 724–3666, or Alice M. McSweeney, Rocky Mountain Research Station, telephone: (505) 724–3677. Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 twenty-four hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION:

Description of Information Collections

Title: Economic, Social, and Cultural Aspects of Livestock Ranching on the Santa Fe and Carson National Forests.

OMB Number: 0596–New.

Expiration Date of Approval: New.

Type of Request: New.

Abstract: Management of Federal lands is often hampered because land managing agencies lack sufficient information to understand and monitor socio-cultural values and changing attitudes toward land and resource use. This lack of up-to-date information impedes efforts of the Forest Service (FS) to work with livestock ranchers who graze their cattle under permit on Forest Service managed lands (permittees).

In northern New Mexico, many grazing permittees are descendants of Hispanic settlers who farmed and ranched in the area for 400 years. Prior to U.S. takeover of the region in 1848, much of the land now grazed under Federal permits was owned or used by local communities under Spanish and Mexican land grants. Cultural differences and historic problems over land use contribute to disagreements and misunderstandings between the permittees and Federal land managers.

The study for which this information collection is needed will encompass all grazing permittees on the Espanola District of the Santa Fe National Forest and the Canjilon District of the Carson National Forest. It will provide data on economic, social, and cultural contributions of livestock ownership to the grazing permittees of northern New Mexico. A prior pilot study conducted in 1998 on the two forests; along with