

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-