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*Due diligence petition*. A petition submitted under § 124.30 of this part.

*Informal hearing*. A hearing that is not subject to the provisions of 5 U.S.C. 554, 556, and 557 and that is conducted as provided in 21 U.S.C. 321(x).

*License applicant*. Any person who, in accordance with part 102 of this chapter, submits an application to the Animal and Plant Health Inspection Service of the U.S. Department of Agriculture for a U.S. Veterinary Biological Product License.

*Patent*. A patent issued by the Patent and Trademark Office of the United States Department of Commerce.

*Person*. Any individual, firm, partnership, corporation, company, association, educational institution, State or local government agency, or other organized group of any of the foregoing, or any agent, officer, or employee of any thereof.

*PTO*. The Patent and Trademark Office of the United States Department of Commerce.

[58 FR 11369, Feb. 25, 1993, as amended at 68 FR 6346, Feb. 7, 2003]

## Subpart B—Eligibility Assistance

### § 124.10 APHIS liaison with PTO.

Upon receipt of a copy of an application for extension of the term of a veterinary biologic patent from PTO, APHIS will assist PTO in determining whether a patent related to a biological product is eligible for patent term extension by:

(a)(1) Verifying whether the product was subject to a regulatory review period before its commercial marketing or use;

(2) Determining whether the permission for commercial marketing or use of the product after the regulatory review period was the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred, and, if so, whether it was the first permitted commercial marketing or use of the veterinary biological product for administration to a food-producing animal;

(3) Ascertaining whether the patent term restoration application was submitted within 60 days after the product was approved for marketing or use; and

(4) Providing such other information as may be necessary and relevant to PTO's determination of whether a patent related to a product is eligible for patent term restoration.

(b) APHIS will notify PTO of its findings in writing, send a copy of this notification to the applicant, and make a copy available for public inspection in room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

## Subpart C—Regulatory Review Period

### § 124.20 Patent term extension calculation.

(a) As provided in 37 CFR 1.779 of PTO's regulations, in order to determine a product's regulatory review period, APHIS will review the information in each application to determine the lengths of the following phases of the review period, and will then find their sum:

(1) The number of days in the period beginning on the date authorization to prepare an experimental biological product under the Virus-Serum-Toxin Act became effective and ending on the date an application for a license was initially submitted under the Virus-Serum-Toxin Act; and

(2) The number of days in the period beginning on the date an application for a license was initially submitted for approval under the Virus-Serum-Toxin Act and ending on the date such license was issued.

(b) A license application is ''initially submitted'' on the date it contains sufficient information to allow APHIS to commence review of the application. A product license is issued on the date of the APHIS letter informing the applicant of the issuance. The issuance of a license releases the product for commercial marketing or use.

### § 124.21 Regulatory review period determination.

(a) Not later than 30 days after the receipt of an application from PTO, APHIS shall determine the regulatory

review period. Once the regulatory review period for a product has been determined, APHIS will notify PTO in writing of the determination, send a copy of the determination to the applicant, and make a copy available for public inspection in room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

(b) APHIS will also publish a notice of the regulatory review period determination in the FEDERAL REGISTER. The notice will include the following:

(1) The name of the applicant;

(2) The trade name and true name of the product;

(3) The number of the patent for which an extension of the term is sought;

(4) The approved indications or uses for the product;

(5) The regulatory review period determination, including a statement of the length of each phase of the review period and the dates used in calculating each phase.

### § 124.22 Revision of regulatory review period determination.

(a) Any interested person may request a revision of the regulatory review period determination within the 30 day period beginning on its publication in the FEDERAL REGISTER. The request must be sent to the Director, Center for Veterinary Biologics, Policy, Evaluation, and Licensing, 1920 Dayton Avenue, P.O. Box 844, Ames, IA 50010. The request must specify the following:

(1) The identity of the product;

(2) The identity of the applicant for patent term restoration;

(3) The docket number of the FEDERAL REGISTER notice announcing the regulatory review period determination; and

(4) The basis for the request for revision, including any documentary evidence.

(b) If APHIS decides to revise its prior determination, APHIS will notify PTO of the decision, and will send a copy of notification to the applicant and the person requesting the revision (if different from the applicant) with a request for comments within 10 days of notification. If no comment on the proposed revision is received, APHIS will publish the revision in the FEDERAL REGISTER, and include a statement giving the reasons for the revision. If comment is received, APHIS will make a final determination regarding the revision based on such comment and will then publish the revision in the FEDERAL REGISTER, giving reasons for its determination.

[59 FR 11369, Feb. 25, 1993, as amended at 59 FR 67617, Dec. 30, 1994; 64 FR 43045, Aug. 9, 1999; 75 FR 20773, Apr. 21, 2010]

### § 124.23 Final action on regulatory review period determination.

APHIS will consider its regulatory review period determination to be final upon expiration of the 180-day period for filing a due diligence petition under §124.30 unless it receives:

(a) New information from PTO records, or APHIS records, that affects the regulatory review period determination;

(b) A request under §124.22 for revision of the regulatory review period determination;

(c) A due diligence petition filed under §124.30; or

(d) A request for a hearing filed under §124.40.

[58 FR 11369, Feb. 25, 1993; 58 FR 29028, May 18, 1993]

## Subpart D—Due Diligence Petitions

### § 124.30 Filing, format, and content of petitions.

(a) Any interested person may file a petition with APHIS, no later than 180 days after the publication of a regulatory review period determination under §124.21, alleging that a license applicant did not act with due diligence in seeking APHIS approval of the product during the regulatory review period.

(b) The petition must be filed with APHIS under the docket number of the FEDERAL REGISTER notice of the agency's regulatory review period determination. The petition must contain any additional information required by this subpart.