

## § 124.23

### § 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.

(c) The petition must allege that the applicant failed to act with due diligence sometime during the regulatory review period and must set forth sufficient facts to merit an investigation by APHIS of whether the applicant acted with due diligence.

(d) The petition must contain a certification that the petitioner has served a true and complete copy of the petition on interested parties by certified or registered mail (return receipt requested) or by personal delivery.

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### § 124.31 Applicant response to petition.

(a) The applicant may file with APHIS a written response to the petition no later than 20 days after the applicant's receipt of a copy of the petition.

(b) The applicant's response may present additional facts and circumstances to address the assertions in the petition, but shall be limited to the issue of whether the applicant acted with due diligence during the regulatory review period. The applicant's response may include documents that were not in the original patent term extension application.

(c) If the applicant does not respond to the petition, APHIS will decide the matter on the basis of the information submitted in the patent term restoration application, the due diligence petition, and APHIS records.

### § 124.32 APHIS action on petition.

(a) Within 90 days after APHIS receives a petition filed under § 124.30, the Under Secretary for Marketing and Regulatory Programs shall make a determination under paragraphs (b) or (c) of this section or under § 124.33 whether the applicant acted with due diligence during the regulatory review period. APHIS will publish its determination in the FEDERAL REGISTER together with factual and legal basis for the determination, notify PTO of the determination in writing, and send copies of the determination to PTO, the applicant, and the petitioner.

(b) APHIS may deny a due diligence petition without considering the merits of the petition if:

(1) The petition is not filed in accordance with § 124.30;

(2) The petition does not contain information or allegations upon which APHIS may reasonably determine that the applicant did not act with due diligence during the applicable regulatory review period; or

(3) The petition fails to allege a sufficient total amount of time during which the applicant did not exercise due diligence so that, even if the petition were granted, the petition would not affect the maximum patent term

extension which the applicant is entitled to under 35 U.S.C. 156.

[59 FR 11369, Feb. 25, 1993, as amended at 64 FR 43045, Aug. 9, 1999]

#### § 124.33 Standard of due diligence.

(a) In determining the due diligence of an applicant, APHIS will examine the facts and circumstances of the applicant's actions during the regulatory review period to determine whether the applicant exhibited the degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period. APHIS will take into consideration all relevant factors, such as the amount of time between the approval of an experimental use permit and licensure of the veterinary biological product.

(b) For purposes of this Part, the actions of the marketing applicant shall be imputed to the applicant for patent term restoration. The actions of an agent, attorney, contractor, employee, licensee, or predecessor in interest of the marketing applicant shall be imputed to the applicant for patent term restoration.

### Subpart E—Due Diligence Hearing

#### § 124.40 Request for hearing.

(a) Any interested person may request, within 60 days beginning on the date of publication of a due diligence determination by APHIS in accordance with §124.32, that APHIS conduct an informal hearing on the due diligence determination.

(b) The request for a hearing must:

- (1) Be in writing;
- (2) Contain the docket number of the FEDERAL REGISTER notice of APHIS's regulatory review period determination;
- (3) Be delivered to the Director, Center for Veterinary Biologics, Policy, Evaluation, and Licensing, 1920 Dayton Avenue, P.O. Box 844, Ames, IA 50010.
- (4) Contain a full statement of facts upon which the request for hearing is based;
- (5) Contain the name, the address, and the principal place of business of the person requesting the hearing; and

(6) Contain a certification that the person requesting the hearing has served a true and complete copy of the request upon the petitioner of the due diligence determination and the applicant for patent term extension by certified or registered mail (return receipt requested) or by personal service.

(c) The request must state whether the requesting party seeks a hearing not later than 30 days after the date APHIS receives the request, or, at the request of the person making the request, not later than 60 days after such date.

[58 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]

#### § 124.41 Notice of hearing.

No later than ten days before the hearing, APHIS will notify the requesting party, the applicant, the petitioner, and any other interested person of the date, time, and location of the hearing.

#### § 124.42 Hearing procedure.

(a) The presiding officer shall be appointed by the Administrator of APHIS from officers and employees of the Department who have not participated in any action of the Secretary which is the subject of the hearing and who are not directly responsible to an officer or employee of the Department who has participated in any such action.

(b) Each party to the hearing shall have the right at all times to be advised and accompanied by an attorney.

(c) Before the hearing, each party to the hearing shall be given reasonable notice of the matters to be considered at the hearing, including a comprehensive statement of the basis for the action taken or proposed by the Secretary which is the subject of the hearing and any general summary of the information which will be presented at the hearing in support of such action.

(d) At the hearing the parties to the hearing shall have the right to hear a full and complete statement of the action which is the subject of the hearing together with the information and reasons supporting such action, to conduct reasonable questioning, and to present any oral and written information relevant to such action.