section 512(i) of the Act. For purposes of this section, the regulatory review period for an animal drug shall mean either the regulatory review period relating the drug's approval for use in nonfood-producing animals or the regulatory review period relating to the drug's approval for use in food-producing animals, whichever is applicable.

[53 FR 7305, Mar. 7, 1988, as amended at 57 FR 56262, Nov. 27, 1992; 64 FR 400, Jan. 5, 1999]

§ 60.24 Revision of regulatory review period determinations.

(a) Any person may request a revision of the regulatory review period determination within 60 days after its initial publication in the FEDERAL REGISTER. The request shall be sent to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The request shall specify the following:

(1) The type of action requested;

(2) The identity of the product;

(3) The identity of the applicant;

(4) The FDA docket number; and

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

(b) Unless the applicant is the person requesting the revision, the applicant shall respond to the request within 15 days. In responding to the request, the applicant may submit information which is relevant to the events during the regulatory review period but which was not included in the original patent term restoration application. A request for a revision is not equivalent to a due diligence petition under § 60.30 or a request for a hearing under § 60.40. If no response is submitted, FDA will decide the matter on the basis of the information in the patent term restoration application, request for revision, and FDA records.

(c) FDA shall apply the provisions of § 60.22 in considering the request for a revision of the regulatory review period determination. lf FDA revises its prior determination, FDA will notify PTO of the revision, send a copy of this notification to the applicant, and publish the revision in the FEDERAL REGISTER, including a statement giving the reasons for the revision.

[53 FR 7305, Mar. 7, 1988, as amended at 59 FR 14364, Mar. 28, 1994; 67 FR 9585, Mar. 4, 2002]

§ 60.26 Final action on regulatory review period determinations.

(a) FDA will consider a regulatory review period determination to be final upon expiration of the 180-day period for filing a due diligence petition under § 60.30 unless FDA receives:

(1) New information from PTO records, FDA records, or FDA centers that affects the regulatory review period determination;

(2) A request under § 60.24 for revision of the regulatory review period determination;

(3) A due diligence petition filed under § 60.30; or

(4) A request for a hearing filed under § 60.40.

(b) FDA will notify PTO that the regulatory review period determination is final upon:

(1) The expiration of the 180-day period for filing a due diligence petition; or

(2) If FDA has received a request for a revision, a due diligence petition, or a request for a hearing, upon resolution of the request for a revision, the petition, or the hearing, whichever is later. FDA will send a copy of the notification to the applicant and file a copy of the notification in the docket established for the application in FDA's Division of Dockets Management (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

[53 FR 7305, Mar. 7, 1988, as amended at 59 FR 14364, Mar. 28, 1994]

§ 60.28 Time frame for determining regulatory review periods.

(a) FDA will determine the regulatory review period for a product within 30 days of the receipt of a written request from PTO for such a determination and a copy of the patent term restoration application.

(b) FDA may extend the 30-day period if:

(1) A related FDA action that may affect the regulatory review period determination is pending; or