

§ 60.24

subjects as part of a clinical investigation to be filed with FDA to secure premarket approval of the device.

(2) The approval phase either:

(i) Begins on the date an application for premarket approval of the device is initially submitted under section 515 of the Act and ends on the date the application is approved; or

(ii) Begins on the date a notice of completion of a product development protocol is initially submitted under section 515 of the Act and ends on the date the protocol is declared to be completed.

(d) For animal drugs:

(1) The testing phase begins on the date a major health or environmental effects test is begun or the date on which the agency acknowledges the filing of a notice of claimed investigational exemption for a new animal drug, whichever is earlier, and ends on the date a marketing application under section 512 of the Act is initially submitted to FDA.

(2) The approval phase begins on the date a marketing application under section 512 of the Act is initially submitted to FDA and ends on the date the application is approved.

(e) For purposes of this section, a "major health or environmental effects test" may be any test which:

(1) Is reasonably related to the evaluation of the product's health or environmental effects, or both;

(2) Produces data necessary for marketing approval; and

(3) Is conducted over a period of no less than 6 months duration, excluding time required to analyze or evaluate test results.

(f) For purposes of determining the regulatory review period for any product, a marketing application, a notice of completion of a product development protocol, or a petition is *initially submitted* on the date it contains sufficient information to allow FDA to commence review of the application. A marketing application, a notice of completion of a product development protocol, or a petition is *approved* on the date FDA sends the applicant a letter informing it of the approval or, by order declares a product development protocol to be completed, or, in the case of food and color additives, on the

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effective date of the final rule listing the additive for use as published in the FEDERAL REGISTER or, in the case of a new animal drug in a Category II Type A medicated article, on the date of publication in the FEDERAL REGISTER of the notice of approval pursuant to 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 to 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. If 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

(2) PTO requests that FDA temporarily suspend the determination process; or

(3) PTO or FDA receives new information about the product that warrants an extension of the time required for the determination of the regulatory review period.

(c) This section does not apply to applications withdrawn by the applicant or applications that PTO determines are ineligible for patent term restoration.

Subpart D—Due Diligence Petitions

§ 60.30 Filing, format, and content of petitions.

(a) Any person may file a petition with FDA, no later than 180 days after the publication of a regulatory review period determination under § 60.20, that challenges FDA's determination by alleging that the applicant for patent term restoration did not act with due diligence in seeking FDA approval of the product during the regulatory review period.

(b) The petition shall be filed in accordance with § 10.20, under the docket number of the FEDERAL REGISTER notice of the agency's regulatory review period determination, and shall be in the format specified in § 10.30. The petition shall contain the information specified in § 10.30 and any additional information required by this subpart. If any provision of § 10.20 or § 10.30 is inconsistent with any provision of this part, FDA will consider the petition in accordance with this part.

(c) The petition shall claim that the applicant did not act with due diligence during some part of the regulatory review period and shall set forth sufficient facts, including dates if possible, to merit an investigation by FDA of whether the applicant acted with due diligence.

(d) The petition shall contain a certification that the petitioner has served a true and complete copy of the petition upon the applicant by certified