

## Food and Drug Administration, HHS

## § 60.28

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 Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. 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 REG-

ISTER, including a statement giving the reasons for the revision.

(Information collection requirements approved by the Office of Management and Budget under control number 0910-0233)

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

### § 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 Dockets Management Branch (HFA-305), rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

[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

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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.

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(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 or registered mail (return receipt requested) or by personal delivery.

(Information collection requirements approved by the Office of Management and Budget under control number 0910–0233)

#### § 60.32 Applicant response to petition.

(a) The applicant shall file with FDA a written response to the petition no later than 30 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 extension application.

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

#### § 60.34 FDA action on petitions.

(a) Within 90 days after FDA receives a petition filed under § 60.30(a), the agency will either deny the petition under paragraph (b) or (c) of this section or investigate and determine under § 60.36 whether the applicant acted with due diligence during the regulatory review period. FDA will publish its due diligence determination in the FEDERAL REGISTER, notify PTO of the due diligence determination in writing, and send copies of the notice to PTO, the applicant, and the petitioner.

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

(1) The petition is not filed in accordance with § 60.30;

(2) The petition is not filed in accordance with § 10.20;

(3) The petition does not contain the information required by § 10.30;

(4) The petition fails to contain information or allegations upon which it may reasonably be determined that the