

§ 60.30

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(c) This section does not apply to applications withdrawn by the applicant or applications that PTO determines are ineligible for patent term restoration.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

applicant did not act with due diligence during the applicable regulatory review period; or

(5) The petition fails to allege a sufficient total amount of time during which the applicant did not exercise due diligence such that, even if the petition were granted, the petition would not affect the maximum patent extension the applicant sought in the application.

§ 60.36 Standard of due diligence.

(a) In determining the due diligence of an applicant, FDA will examine the facts and circumstances of the applicant's actions during the regulatory review period to determine whether the applicant exhibited that 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. FDA will take into consideration all relevant factors, such as the amount of time between the approval of an investigational exemption or research permit and the commencement of a clinical investigation and the amount of time required to conduct a clinical investigation.

(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 or applicant for patent term restoration shall be imputed to the applicant for patent term restoration.

Subpart E—Due Diligence Hearings

§ 60.40 Request for hearing.

(a) Any person may request, not later than 60 days after the publication under § 60.34(a) of FDA's due diligence determination, that FDA conduct an informal hearing on the due diligence determination.

(b) The request for a hearing under this section shall:

(1) Be sent by mail, personal delivery, or any other mode of written communication to the Dockets Management Branch and filed under the relevant product file;

(2) Specify the facts and the action that are the subject of the hearing;

(3) Provide the name and address of the person requesting the hearing; and

(4) Certify that the requesting party has served a true and complete copy of the request upon the petitioner and the applicant by certified or registered mail (return receipt requested) or by personal delivery.

(c) The request shall state whether the requesting party seeks a hearing within 30 days or 60 days of FDA's receipt of the request.

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§ 60.42 Notice of hearing.

Ten days before the hearing, FDA will notify the requesting party, the applicant, and the petitioner, orally or in writing, of the date, time, and location of the hearing. The agency will provide the requesting party, the applicant, and the petitioner with an opportunity to participate as a party in the hearing.

§ 60.44 Hearing procedures.

The due diligence hearing shall be conducted in accordance with this part, supplemented by the nonconflicting procedures in part 16. During the due diligence hearing, the applicant and the petitioner shall enjoy all the rights and privileges accorded a person requesting a hearing under part 16. The standard of due diligence set forth in § 60.36 will apply in the due diligence hearing. The party requesting the due diligence hearing shall have the burden of proof at the hearing.

§ 60.46 Administrative decision.

Within 30 days after the completion of the due diligence hearing, the Commissioner will affirm or revise the determination made under § 60.34(a) and will publish the due diligence redetermination in the FEDERAL REGISTER, notify PTO of the redetermination, and send copies of the notice to PTO and to the requesting party, the applicant, and the petitioner.