Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions

0910-0233

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

FDA's patent extension activities are conducted under the authority of the Drug Price Competition and Patent Term Restoration Act of 1984 (21 U.S.C. 355(j)) and the Generic Animal Drug and Patent Term Restoration Act of 1988 (35 U.S.C. 156). New human drug, animal drug, human biological, medical device, food additive, or color additive products regulated by the FDA must undergo FDA safety, or safety and effectiveness, review before marketing is permitted. Where the product is covered by a patent, part of the patent's term may be consumed during this review, which diminishes the value of the patent. In enacting the Drug Price Competition and Patent Term Restoration Act of 1984 and the Generic Animal Drug and Patent Term Restoration Act of 1988, Congress sought to encourage development of new, safer, and more effective medical and food additive products. It did so by authorizing the U.S. Patent and Trademark Office (PTO) to extend the patent term by a portion of the time during which FDA's safety and effectiveness review prevented marketing of the product. The length of the patent term extension is generally limited to a maximum of 5 years, and is calculated by PTO based on a statutory formula. When a patent holder submits an application for patent term extension to PTO, PTO requests information from FDA, including the length of the regulatory

review period for the patented product. If PTO concludes that the product is eligible for patent term extension, FDA publishes a notice that describes the length of the regulatory review period and the dates used to calculate that period. Interested parties may request, under § 60.24 (21 CFR 60.24), revision of the length of the regulatory review period, or may petition under § 60.30 (21 CFR 60.30) to reduce the regulatory review period by any time where marketing approval was not pursued with "due diligence."

The statute defines due diligence as "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." As provided in § 60.30(c), a due diligence petition "shall set forth sufficient facts, including dates if possible, to merit an investigation by FDA of whether the applicant acted with due diligence." Upon receipt of a due diligence petition, FDA reviews the petition and evaluates whether any change in the regulatory review period is necessary. If so, the corrected regulatory review period is published in the Federal Register. A due diligence petitioner not satisfied with FDA's decision regarding the petition may, under § 60.40 (21 CFR 60.40), request an informal hearing for reconsideration of the due diligence determination. Petitioners are likely to include persons or organizations having knowledge that FDA's marketing permission for that product was not actively pursued throughout the regulatory review period. The information collection for which an extension of approval is being sought is the use of the statutorily created due diligence petition.

2. Purpose and Use of Information Collection

Applicants must submit: (1) requests for revision of the regulatory review period under 21 CFR 60.24; (2) due diligence petitions under 21 CFR 60.30; and requests for hearings under

21 CFR 60.40 regarding decisions on the petitions.

3. Use of Improved Information Technology and Burden Reduction

Submissions to the Agency may be made electronically.

4. Efforts to Identify Duplication and Use of Similar Information

Since these data collections are voluntary, and each collection relates to a specific regulated product, it is not likely that there will be a duplication of information.

5. Impact on Small Businesses or Other Small Entities

Small businesses and individuals may occasionally be involved. This situation is likely to arise when the patent holder has filed the patent term extension application or has not assigned or licensed the patent to the product's manufacturer. Since none of the regulation's submission requirements are beyond the capability of an individual, the rule makes no special considerations.

6. Consequences of Collecting the Information Less Frequently

The Patent Term Restoration Act requires FDA to accept petitions and collect the information in question when it is offered. Failure to do so would violate the Patent Term Restoration Act.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances that require the information to be collected in a manner inconsistent with the guidelines set forth in 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In the Federal Register of November 14, 2013 (78 FR 68454), FDA published a 60-day

notice for public comment. No comments were submitted that pertained to the information collection estimates.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift is contemplated under the terms of this collection.

10. Assurance of Confidentiality Provided to Respondents

No assurance of confidentiality for the petitions is made because none of the information in the application for patent term extension is confidential. When FDA is asked by PTO to make a determination of a regulatory review period under the Patent Term Restoration Act, FDA must publish in the *Federal Register* "a notice of such determination together with the factual and legal basis for such determination." Any person is permitted to comment on the FDA determination and to file comments to the docket. For this reason, when FDA receives a copy of a patent term extension application from PTO, a public docket is opened for each application and the public is permitted to examine the application and make comments. Therefore, confidentiality for the petitions is not guaranteed.

11. Justification for Sensitive Questions

No information of a sensitive nature is collected.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

Since 1992, 15 requests for revision of the regulatory review period have been submitted under § 60.24(a). For 2010, 2011, and 2012, a total of three requests have been submitted under § 60.24(a). During that same time period, there have been no requests under §§ 60.30 and 60.40; however, for purposes of this information collection approval, we are estimating that we

may receive one submission annually.

FDA estimates the burden of this information collection as follows:

Table 1 – Estimated Annual Reporting Burden

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
60.24(a)	1	1	1	100	100
60.30	1	1	1	50	50
60.40	1	1	1	10	10
Total					160

12b. Annualized Cost Burden Estimate

There are labor costs resulting from this information. Based on an average industry wage rate of $75 per hour (averaged from wages for upper management, middle management, and clerical support, plus overhead and personnel benefits), and multiplied times the total hour burden estimated above (160), the total cost burden to respondents is approximately $12,000.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital costs, start-up, operating or maintenance costs associated with this collection of information.

14. Annualized Cost to the Federal Government

The cost is expected to be approximately $75.00 per hour to review each submission under this information collection. Each submission would take on average 16 hours to review. Therefore, the total Federal cost would be $1,200.

15. Explanation for Program Changes or Adjustments

The number of submissions and respondents under this information collection remains the same.

16. Plans for Tabulation and Publication and Project Time Schedule

The information collected under these regulations and the FDA determination on the petitions will be published individually in the *Federal Register* as provided for in the regulations.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

This request does not seek approval to exempt display of the OMB approval date on any documents that are associated with this reporting requirement.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.