FOOD AND DRUG ADMINISTRATION
Patent Term Restoration, Due Diligence Petitions,
Filing, Format, and Content of Petitions

OMB Control No. 0910-0233

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The information collection supports Food and Drug Administration (FDA) regulations regarding patent extension under 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). The regulations have been promulgated under 21 CFR Part 60: *Patent Term Restoration*

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 period, 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 diligenc*e." 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 may, under § 60.40 (21 CFR 60.40), request an informal hearing for reconsideration of the due diligence determination.

Accordingly, we are requesting information collection approval for the provisions found in 21 CFR Part 60, and as discussed in more detail below.

2. Purpose and Use of Information Collection

Under agency regulations, respondents requesting patent extension 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. FDA uses the information to determine whether such petitions may be granted.

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

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

The information collection requirements apply to all respondents alike. FDA provides small business assistance information on its Website at: http://www.fda.gov/ForIndustry/SmallBusinessAssistance/SmallBusinessRepresentatives/guidance, and within various agency components including the Center for Drug Evaluation and Research's (CDER) Small Business and Industry Assistance Office (SBIA), available at:

CDER SBIA
Office of Communications
10001 New Hampshire Avenue
Hillandale Building, 4th Floor
Silver Spring, MD 20993
(866) 405-5367
(301) 796-6707
CDERSBIA@fda.hhs.gov

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with existing laws and regulations. Collection

occurs occasionally.

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 1, 2016 (81 FR 75824), FDA published a 60-day notice for public comment. We received no comments.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift is provided to respondents to the information 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, 17 requests for revision of the regulatory review period have been submitted under § 60.24(a). In years 2013, 2014, and 2015, a total of two requests were received 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.

We therefore estimate the burden of the information collection as follows:

Table 1 – Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
60.24(a); revision of regulatory review determination	3	1.66	5	100	500
60.30; due diligence petitions	1	1	1	50	50
60.40; due diligence hearings	1	1	1	10	10
TOTAL			7		560

[1] There are no capital or operating and maintenance costs associated with the information collection.

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 using data provided by the Bureau of Labor Statistics: https://www.bls.gov/), and multiplied by the average burden per response 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

We estimate the cost to the Federal government to be $1,000. We believe it takes an average of 16 hours to review a submission under the information collection. Using the hourly wage rate for a GS-13/5 employee in the Washington/Metropolitan area of $51.48, and multiplying that by 16 hours equals $ 823.68. Adding additional costs for management review we have rounded the estimated costs to $1,000 annually.

15. Explanation for Program Changes or Adjustments

A review of our records shows the number of respondents and the number of submissions *per respondent* has increased since our last request for OMB approval. This results in corresponding increases to both the number of annual responses and burden hours. Accordingly, we have made appropriate adjustments in our estimate to reflect this fluctuation.

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

Display of OMB Expiration Date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.