Supporting Statement

PATENT TERM RESTORATION

OMB Control No. 0910-0233

Docket Number 2007N-0240

Expires January 31, 2011

A. JUSTIFICATION

1. Circumstances Necessitating Recordkeeping

FDA's patent extension activities are conducted under the authority of the Drug Price Competition and Patent Term Restoration Act of 1984 and the Animal Drug and Patent Term Restoration Act of 1988 (35 U.S.C. Section 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 35 U.S.C. Section 156, 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 five 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

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product is eligible for patent term extension, FDA publishes a notice, which describes the length of the regulatory review period, and the dates used to calculate that period. Interested parties may request, under 21 CFR 60.24, revision of the length of the regulatory review period, or may petition under 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 21 CFR 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 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. How, By Whom, Purpose of Collection

Applications for patent term extension are filed with PTO, since PTO has jurisdiction over the patents. Under the Patent Term Restoration Act, PTO determines whether the applicants have satisfied eligibility criteria, and PTO issues certificates of extension. FDA's responsibility

under the Patent Term Restoration Act is to assist PTO in determining a product's eligibility and in calculating a product's regulatory review period. In calculating the regulatory review period, FDA is required to reduce the regulatory review period by the length of time an applicant was not diligent in obtaining premarket government approval. The Patent Term Restoration Act provides that any interested person may ask FDA to make and publish a due diligence determination which may later be challenged at a hearing requested by any interested person.

Information gathered from the petition will be used to determine whether FDA's original regulatory review period determination should be revised, whether the applicant was duly diligent in pursuing marketing approval, and whether a hearing on due diligence would be held. Failure to collect this information would make it difficult for FDA to fulfill its duties under the Patent Term Restoration Act.

3. Consideration Given to Information Technology

Submissions to the agency may be made electronically.

4. Identification of Duplicate 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. Small Businesses

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. Less Frequent Collection

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. Collection Circumstances

There are no special circumstances that require the information to be collected in a manner inconsistent with the guidelines set forth in 5 CFR 1320.6.

8. Consultations with Persons Outside FDA

In accordance with 5 CFR 1320.8(d), on July 9, 2007 (72 FR 37242) a 60-day notice for public comment was published in the Federal Register. No comments were submitted that pertained to the information collection estimates.

9. Payment of Gift

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

10. Confidentiality Provisions

No assurance of confidentiality for the petitions is made because none of the information in theapplication 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. Sensitive Information

No information of a sensitive nature is collected.

12. Estimates of Annualized Hour and Burdens

Since 1992, 9 requests for revision of the regulatory review period have been submitted under 21 CFR 60.24. Four regulatory review periods have been altered. Two due diligence petitions have been submitted to FDA under 21 CFR 60.30. There have been no requests for hearings under 21 CFR 60.40 regarding the decisions on such petitions.

FDA estimates the burden of this collection of information as follows:

	Estimated Annual Reporting Burden				
21 CFR Part 60	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
60.24(a) 60.30 60.40	9 2 0	1 0 0	9 2 0	100 50 0	900 100 0
Total					1000

There are no capital costs or operating and maintenance costs associated with this collection of information.

12b. Estimates of Annualized Cost Burden

The cost would be approximately $100,000. This is based on a total of 1000 burden hours at a total cost of approximately $100 per hour to prepare each submission.

13. Capital Cost Burdens

There are no start up or capital cost burdens.

14. Costs to Federal Government

The cost is expected to be approximately $50.00 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 $8,800.

15. Reasons for Cost Adjustments

The number of submissions under this information collection have increased, and the calculations for the respondent and federal burdens have been revised.

16. Publications

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. Display of OMB Approval Date

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 "Certification for Paperwork Reduction Act Submissions" for this collection requirement.