

OMB Control No. 0910-0233

Docket No. 01N-0114

September 21, 2001

Supporting Statement for
FOR PATENT TERM RESTORATION

A. JUSTIFICATION

1. Circumstances Necessitating Recordkeeping

The Patent Term Restoration Program was established because of the statutory requirements of the Drug Price Competition and Patent Term Restoration Act of 1984 as amended by the Generic Animal Drug and Patent Term Restoration Act of 1988. (The Patent Term Restoration Act). (See attachment "A").

The Patent Term Restoration Act created a program under which patent holders whose patents claimed certain products regulated by FDA (or USDA) could have the patent term extended by a period of time proportional to that which elapsed while the products awaited FDA (or USDA) marketing approval. This program is intended to create new incentives for research and development of certain products, such as human drug products, that require government approval before marketing.

FDA's regulations for this program contain three separate provisions for information collection: 21 CFR, sections 60.24(a), 60.30, and 60.40. (See attachment "B".) All three provisions provide for voluntary submissions.

21 CFR 60.24(a) Revision of Regulatory Review Period Determinations: Reporting. Section 60.24(a), allows any person to request a revision or correction of FDA's regulatory review period determination. This section is intended to provide a simple procedure for revision of the regulatory review period calculation. While such errors are extremely rare, a regulatory mechanism is necessary to allow for correction of errors.

21 CFR 60.30 Due Diligence Petitions - Filing Format and Content: Reporting. Section 60.30 sets out procedures by which any person may petition FDA to determine whether an applicant for patent term extension had exercised due diligence in seeking FDA approval of the product during the product's regulatory review period. Accordingly, the due diligence petition must allege that the applicant did not act with due diligence while seeking FDA approval during the premarketing approval process.

The Patent Term Restoration Act required the Department of Health and Human Services to promulgate regulations that govern due diligence determinations. To meet this statutory requirement, section 60.30 provides that persons challenging one of FDA's due diligence findings, must supply FDA with the kind of information required of all citizen's petitions. (21

CFR 10.30). The burden for this information collection is approved under OMB Number 0910-0183. This information includes the type of action requested, a statement of the grounds for the request, and basic identification information (such as the petitioner's name, address, and telephone number). Without this type of data, FDA could not effectively respond to the petition.

21 CFR 60.40 Due Diligence Hearing - Request for Hearing: Reporting.

Section 60.40 implements the statutory provisions requiring the Secretary to hold informal hearings on due diligence decisions. This section also requires that the information specified in 21 CFR 10.30 (citizen's petitions) be included in the request for a hearing. As with section 60.30, FDA could not respond to the request unless this information was available.

This collection of information is required by 35 USC 156(d)(2)(b)(I) and (ii). (See attachment "A".) The collection will fulfill statutory requirements and facilitate implementation of the patent term restoration program. FDA and the U.S. Patent and Trademark Office (PTO) jointly implement the Patent Term Restoration Act.

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

The small number of actual and potential petitions means that creation of special procedures for measures such as electronic submission via modem or floppy disk would not be cost justified. Alignment with procedures established for higher volume programs may be a practical measure in the future if compatibility can be established.

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. There probably will be only one respondent for each product whose status is challenged, thus further reducing the possibility of duplication.

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 Friday, March 23, 2001, (66 FR 16249) a 60-day notice for public comment was published in the Federal Register. There have been no comments received regarding this collection of information. Other consultation with non-agency personnel has to date only included PTO. Specifically, FDA consults with Karin Tyson, Senior Legal Advisor (703-306-3159), and Stephen G. Kunin, Deputy Assistant Commissioner for Patent Policy and Projects (703-305-9054).

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 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. Sensitive Information

No information of a sensitive nature is collected.

12. Estimated Hour Burden

Estimated Annual Collection Burden					
CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
21 CFR 60.24	1	1	1	100	100
21 CFR 60.30	0	0	0	0	0
21 CFR 60.40	0	0	0	0	0
Total					100

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

13. Cost to Respondents

FDA has received few requests for action related to this law and/or regulations. The estimated burden for a request for revision of the patent term, a due diligence petition or a request for a hearing would require between 20 - 100 hours each for any respondent. The salary for a private attorney would average at \$200 per hour, so the cost would be \$4,000 - \$20,000.

14. Costs to Federal Government

The cost during FY '98 is expected to be \$1,148 - \$5,740 based on a time requirement of 20 - 100 hours per petition and an average grade level of 12 step 5, a salary of \$25.56, and an estimated \$3.14 per person hour for related overhead expenses [$\$25.56 + \$3.14 = \$28.70$; $\$28.70 \times 40 = \$1,148$; $\$28.70 \times 200 = \$5,740$].

15. Reasons for Cost Adjustments

The costs to the Federal Government have increased to reflect the higher salary and overhead expenses for GS 12-5 employees. The current OMB inventory of burden hours for this collection of information is 200. Information collected under these regulations has decreased over the past three years resulting in a 100 hour decrease.

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 recordkeeping 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.