

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Display Date	01/28/07
Publication Date	01/29/07
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Food and Drug Administration

[Docket No. 01N-0114]

**Agency Information Collection Activities; Submission for OMB Review; Comment Request; Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

**ADDRESSES:** Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

**FOR FURTHER INFORMATION CONTACT:** Karen L. Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**SUPPLEMENTARY INFORMATION:** In compliance with section 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions—  
Part 60 (21 CFR Part 60) (OMB Control Number 0910–0233)—Extension**

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. 156). New human drug, animal drug, human biological, medical device, food additive, or color additive products regulated by 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. 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 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, revision of the length of the regulatory review period, or may petition, under § 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, 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.

Since 1992, five requests for revision of the regulatory review period have been submitted under § 60.24. One regulatory review period has been altered. No due diligence petitions have been submitted to FDA, under § 60.30, and consequently there have been no requests for hearings, under § 60.40, regarding the decisions on such petitions.

In the **Federal Register** of March 23, 2001 (66 FR 16249), the agency requested comments on the proposed collection of information. There were no comments received.

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

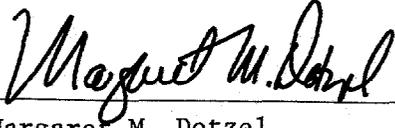
TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
60.24(a) .....	1	1	1	100	100
60.30 .....	0	0	0	0	0
60.40 .....	0	0	0	0	0
<b>Total</b> .....					<b>100</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: 6/25/01  
June 25, 2001.

oc01165



Margaret M. Dotzel,  
Associate Commissioner for Policy.

CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL



[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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