



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1393]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0233. Also include the FDA docket number found in brackets in the heading of this document.

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

21 CFR Part 60--OMB Control Number 0910-0233--Extension

SUPPLEMENTARY INFORMATION: 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 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 (USPTO) 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 USPTO based on a statutory formula.

When a patent holder submits an application for patent term extension to USPTO, USPTO requests information from FDA, including the length of the regulatory review period for the patented product. If USPTO 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 or 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 petition 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.

Since 1992, 20 requests for revision of the regulatory review period have been submitted under §60.24(a). In years 2013, 2014, and 2015, a total of five requests were 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.

In the Federal Register of November 1, 2016 (81 FR 75824), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received in response to the notice.

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

Table 1.--Estimated Annual Reporting Burden¹

21 CFR Section	No. of Respondents	No. of responses per respondent	Total Annual Responses	Average Burden per Response	Total Hours
60.24(a).....	3	1.66	5	100	500
60.30.....	1	1	1	50	50
60.40.....	1	1	1	10	10
Total					560

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

Dated: April 19, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.
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