



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Agency Information Collection Activities; Proposed Collection; 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) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to

<http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2013-N-1393 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions." Received

comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 11601 Landsdown Street, 10A63, North Bethesda, MD 20852, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions--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 (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 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 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 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 (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). For 2013, 2014 and 2015, a total of 5 requests have been 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.

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

Table 1.--Estimated Annual Recordkeeping Burden¹

21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	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: October 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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