3510-16-P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Submission for OMB Review; comment request; Patent Term Extension

The United States Patent and Trademark Office (USTPO) will submit to the Office of

Management and Budget (OMB) for clearance the following proposal for collection of

information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter

35).

Agency: United States Patent and Trademark Office, Commerce

Title: Patent Term Extension

OMB Control Number: 0651-0020

Form Number(s): N/A

Type of Request: Renewal

Number of Respondents: 1,340

Average Hours Per Response: 1 hour to 25 hours, depending upon the instrument

used*.*

Burden Hours: 6,187 hours

Cost Burden: $351,505.08

Needs and Uses: The patent term restoration portion of the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417), which is codified at 35 U.S.C. 156, permits the United States Patent and Trademark Office (USPTO) to extend the term of protection under a patent to compensate for delay during regulatory review and approval by the Food and Drug Administration (FDA) or Department of Agriculture. Only patents for drug products, medical devices, food additives, or color additives are potentially eligible for extension. The maximum length that a patent may be extended under 35 U.S.C. 156 is five years. The USPTO administers 35 U.S.C. 156 through 37 CFR 1.710–1.791. Separate from the extension provisions of 35 U.S.C. 156, the USPTO may in some cases extend the term of an original patent due to certain delays in the prosecution of the patent application, including delays caused by interference proceedings, secrecy orders, or appellate review by the Patent Trial and Appeal Board or a Federal court in which the patent is issued pursuant to a decision reversing an adverse determination of patentability. The patent term provisions of 35 U.S.C.154(b), as amended by Title IV, Subtitle D of the Intellectual Property and Communications Omnibus Reform Act of 1999, require the USPTO to notify the applicant of the patent term adjustment in the notice of allowance and give the applicant an opportunity to request reconsideration of the USPTO's patent term adjustment determination. The USPTO administers 35 U.S.C. 154 through 37 CFR 1.701–1.705.

The public uses this information collection to file requests related to patent term extensions and reconsideration or reinstatement of patent term adjustments. The

information in this collection is used by the USPTO to consider whether an applicant is eligible for a patent term extension or reconsideration of a patent term adjustment and, if so, to determine the length of the patent term extension or adjustment.

Affected Public: Businesses or other for-profits; not-for-profit institutions.

Frequency: On occasion

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer：Kimberly R. Keravuori, e-mail: Kimberly_R_Keravuori@omb.eop.gov.

Once submitted, the request will be publicly available in electronic format through reginfo.gov. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Further information can be obtained by:

- E-mail: InformationCollection@uspto.gov. Include "0651-0020 copy request" in the subject line of the message.
- Mail: Marcie Lovett, Records Management Division Director, OCIO, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450.

Written comments and recommendations for the proposed information collection should be sent on or before [INSERT DATE 30 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER] to Kimberly R. Keravuori, OMB Desk Officer, via e-mail

to Kimberly_R_Keravuori@omb.eop.gov, or by fax to 202-395-5167, marked to the

attention of Kimberly R. Keravuori.

Dated: October 20, 2016

Marcie Lovett

Records Management Division Director, OCIO

United States Patent and Trademark Office.

BILLING CODE 3510–16–P