



**BILLING CODE: 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 (USPTO) will submit to the Office of Management and Budget (OMB) for clearance the following proposal for an information collection under the provisions of the Paperwork Reduction Act of 1995.

*Agency:* United States Patent and Trademark Office, Department of Commerce

*Title:* Patent Term Extension

*OMB Control Number:* 0651-0020

*Form Number(s):* There are no forms in this information collection

*Type of Request:* Revision of a currently approved information collection

*Number of Respondents:* 620 respondents

*Average Hours Per Response:* The USPTO estimates that it will take the public from 1 hour to 25 hours to gather the necessary information, prepare the appropriate form or document, and submit the information to the USPTO.

*Burden Hours:* 4,102 hours

*Hourly Cost Burden:* \$1,796,676

*Non hourly Cost Burden:* \$209,889

*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 United States Department of Agriculture (USDA). 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 5 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 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 information 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:* Nicholas A. Fraser, e-mail: Nicholas\_A.\_Fraser@omb.eop.gov

Once submitted, the request will be publicly available in electronic format through [reginfo.gov](http://reginfo.gov). Follow the instructions to view Department of Commerce information collections currently under review by OMB.

Further information can be obtained by:

- E-mail: [InformationCollection@uspto.gov](mailto:InformationCollection@uspto.gov). Include "0651-0020 information request" in the subject line of the message.
- Mail: Kimberly Hardy, Office of the Chief Administrative Officer, 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 Nicholas A. Fraser, OMB Desk Officer, via e-mail to [Nicholas\\_A.\\_Fraser@omb.eop.gov](mailto:Nicholas_A._Fraser@omb.eop.gov), or by fax to 202-395-5167, marked to the attention of Nicholas A. Fraser .

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[FR Doc. 2020-01849 Filed: 1/30/2020 8:45 am; Publication Date: 1/31/2020]