



DEPARTMENT OF COMMERCE

Patent and Trademark Office

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Patent Term Extension and Adjustment

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of information collection; request for comments.

SUMMARY: The United States Patent and Trademark Office (hereafter “USPTO” or “Agency”) will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. The USPTO invites comments on the information collection renewal of 0651-0020, which helps the USPTO assess the impact of its information collection requirements and minimize the reporting burden to the public. Public comments were previously requested via the *Federal Register* on November 19, 2025, during a 60-day comment period (90 FR 52043). This notice allows for an additional 30 days for public comments.

DATES: To ensure consideration, you must submit comments regarding this information collection on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Written comments and recommendations for this information collection should be submitted within 30 days of the publication of this notice on the following website, <http://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under 30-day Review–Open for Public Comments” or by using the search function and entering either the title of the information collection or the OMB Control Number,

0651-0020. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT:

- This information collection request may be viewed at <http://www.reginfo.gov>. Follow the instructions to view the Department of Commerce, USPTO information collections currently under review by OMB.
- E-mail: InformationCollection@uspto.gov. Include “0651-0020 information request” in the subject line of the message.
- Mail: Justin Isaac, Office of the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450.
- Telephone: Jeffrey West, Senior Legal Advisor, 571-272-2226.

SUPPLEMENTARY INFORMATION:

Title: Patent Term Extension and Adjustment.

OMB Control Number: 0651-0020.

Abstract: 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 five years. The USPTO administers 35 U.S.C. 156 through 37 CFR §§ 1.710–1.791.

This information collection covers information gathered in patent term extension applications submitted under 35 U.S.C. 156(d). Under this provision, an application for patent term extension must identify the approved product; the patent to be extended; and the claims included in the patent that cover the approved product, a method of using the approved product,

or a method of manufacturing the approved product. 35 U.S.C. 156(d) also requires the submission of information that enables the USPTO to determine the eligibility of the patent for extension, and the rights that will be derived from the extension, and information to enable the USPTO and the Secretary of Health and Human Services or the Secretary of Agriculture to determine the period of the extension. Additionally, 35 U.S.C. 156(d) requires the applicant for patent term extension to provide a brief description of the activities undertaken by the applicant during the regulatory review period with respect to the approved product and the significant dates of these activities.

This information collection also covers information gathered in requests for interim extensions pursuant to 35 U.S.C. 156(d)(5) and 156(e)(2). Under 35 U.S.C. 156(d)(5), an interim extension may be granted if the applicable regulatory review period that began for a product is reasonably expected to extend beyond the expiration of the patent term in effect. Under 35 U.S.C. 156(e)(2), an interim extension may be granted if the term of an eligible patent for which an application for patent term extension has been submitted would expire before a certificate of extension is issued. In addition, this information collection covers requests for review of final eligibility decisions, and requests to withdraw an application requesting a patent term extension after it is submitted.

Separate from the extension provisions of 35 U.S.C. 156, the USPTO may in some cases adjust the term of an original patent under the provisions of 35 U.S.C. 154 due to certain delays in the prosecution of the patent application, including delays caused by interference and derivation 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 USPTO determination of patentability. The USPTO administers 35 U.S.C. 154 through 37 CFR §§ 1.701–1.705. 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, allow

the applicant an opportunity to request reconsideration of the USPTO's patent term adjustment determination. This information collection covers information gathered in such a request.

In addition, this information collection covers information collected when the USPTO reduces the amount of a granted patent term adjustment if delays were caused by an applicant's failure to make a reasonable effort to respond to a communication from the USPTO within three months of the communication's mailing date. Applicants may petition for reinstatement of a reduction in patent term adjustment with a showing that, in spite of all due care, the applicant was unable to respond to a communication from the USPTO within the three-month period.

Forms: None.

Type of Review: Extension and revision of a currently approved information collection.

Affected Public: Private sector.

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

Frequency: On occasion.

Estimated Number of Annual Respondents: 903 respondents.

Estimated Number of Annual Responses: 903 responses.

Estimated Time per Response: The USPTO estimates that the responses in this information collection will take the public approximately 1 hour to 25 hours to complete. This includes the time to gather the necessary information, create the document, and submit the completed item to the USPTO.

Estimated Total Annual Respondent Burden Hours: 6,807 hours.

Estimated Total Annual Respondent Non-hourly Cost Burden: \$489,440. The postage costs have increased since the publication of the 60-day ***Federal Register*** notice, from \$11.20 to \$12.25 for the Priority Mail legal flat rate envelope used for mailed submissions. As a result, the estimated postage costs have increased from \$101 to \$110. This accounts for the added \$9 to the estimated total annual non-hourly cost burden.

Justin Isaac,

Information Collections Officer, Office of the Chief Administrative Officer, United States Patent

and Trademark Office.

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