

**SUPPORTING STATEMENT**  
**United States Patent and Trademark Office**  
**Patent Term Extension**  
**OMB CONTROL NUMBER 0651-0020**  
**January 2020**

**A. JUSTIFICATION**

**1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the information collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.**

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.

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 application 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(e). Under this provision 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. 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. In addition, this information collection covers requests for review of final eligibility decisions, and 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 extend the term of an original patent under the provisions at 35 U.S.C. 154 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 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 instances when the USPTO may reduce the amount of patent term adjustment granted if delays were caused by an applicant’s failure to make a reasonable effort to respond within three months of the mailing date of a communication from the USPTO. 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 3 month period.

**2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new information collection, indicate the actual use the agency has made of the information received from the current information collection.**

The public uses this information collection to file: patent term extension applications, including interim applications under 35 U.S.C. § 156(d)(5); follow-on documentation related to the extension applications, including requests for interim extensions under 35 U.S.C. § 156(e)(2); 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.

The information collected, maintained, and used in this information collection is based on OMB and USPTO guidelines. This includes the basic information quality standards established in the Paperwork Reduction Act (44 U.S.C. Chapter 35), in OMB Circular A-130, and in the USPTO information quality guidelines.

Table 1 lists the specific statutes and regulations authorizing the USPTO to collect this information and outlines how this information is used by the public and the USPTO:

**Table 1: Information Requirements and Needs and Uses of Information Collected**

Item #	Requirement	Statute	Regulation	Form #	Needs and Uses
1	Application to Extend Patent Term Under 35 U.S.C. § 156	35 U.S.C. § 156(d)(1)-(4)	37 CFR 1.740-1.741	No Form Associated	<ul style="list-style-type: none"> <li>Used by the public to apply for a patent term extension.</li> <li>Used by the USPTO and the United States Department of Health and Human Services or the United States Department of Agriculture to determine eligibility of a patent for extension and to determine the period of extension.</li> </ul>

Item #	Requirement	Statute	Regulation	Form #	Needs and Uses
2	Request for Interim Extension Under 35 U.S.C. § 156(e)(2)	35 U.S.C. § 156(e)(2)	37 CFR 1.760	No Form Associated	<ul style="list-style-type: none"> <li>Used by the public to request an interim extension.</li> <li>Used by the USPTO to trigger an interim extension before processing of the application has been completed.</li> </ul>
3	Petition to Review Final Eligibility Decision Under 37 CFR 1.750	35 U.S.C. § 156(d)	37 CFR 1.750	No Form Associated	<ul style="list-style-type: none"> <li>Used by the public to petition the USPTO to review final eligibility decisions.</li> <li>Used by the USPTO to review final eligibility decisions, as long as the petition is filed within a set time.</li> </ul>
4	Initial Application for Interim Extension Under 35 U.S.C. § 156(d)(5)	35 U.S.C. § 156(d)(5)	37 CFR 1.790	No Form Associated	<ul style="list-style-type: none"> <li>Used by the public to apply for an interim extension.</li> <li>Used by the USPTO to determine eligibility of a patent for interim extension.</li> </ul>
5	Subsequent Application for Interim Extension Under 35 CFR 1.790	35 U.S.C. § 156(d)(5)	37 CFR 1.790	No Form Associated	<ul style="list-style-type: none"> <li>Used by the public to apply for a subsequent interim extension.</li> <li>Used by the USPTO to determine eligibility of a patent for subsequent interim extension.</li> </ul>
6	Response to Requirement to Elect	35 U.S.C. § 156(c)(4)	37 CFR 1.785(b)	No Form Associated	<ul style="list-style-type: none"> <li>Used by the public to elect which patent of more than one patent to extend.</li> <li>Used by the USPTO to determine which patent of more than one patent to extend, or which regulatory review period of more than one regulatory review period to use in the determination of the length of patent term extension.</li> </ul>
7	Response to Request to Identify Holder of Regulatory Approval	35 U.S.C. § 156(d)(1)(E)	37 CFR 1.785(d)	No Form Associated	<ul style="list-style-type: none"> <li>Used by the public to declare eligibility to apply for a patent term extension.</li> <li>Used by the USPTO to determine eligibility of patent owner to obtain an extension of a patent.</li> </ul>
8	Declaration to Withdraw an Application to Extend Patent Term	35 U.S.C. § 156	37 CFR 1.770	No Form Associated	<ul style="list-style-type: none"> <li>Used by the public to withdraw an application to extend a patent term.</li> <li>Used by the USPTO to avoid extending patents that the patent owner no longer seeks to extend.</li> </ul>
9	Petition for Reconsideration of Patent Term Adjustment Determination	35 U.S.C. § 154(b)(3)(B)(ii)	37 CFR 1.705	No Form Associated	<ul style="list-style-type: none"> <li>Used by the patentee to correct errors in the USPTO's patent term adjustment determination.</li> <li>Used by the USPTO to determine whether its patent term adjustment determination is in error.</li> <li>Used by the USPTO to determine the correct patent term adjustment.</li> </ul>
10	Petition for Reinstatement of Reduced Patent Term Adjustment	35 U.S.C. § 154(b)(3)(C)	37 CFR 1.705	No Form Associated	<ul style="list-style-type: none"> <li>Used by the patentee to request reinstatement of reduced patent term adjustment.</li> <li>Used by the USPTO to determine whether the patentee is entitled to reinstatement of reduced patent term adjustment.</li> </ul>

Item #	Requirement	Statute	Regulation	Form #	Needs and Uses
11	Petition to Accord a Filing Date to an Application Under 37 CFR 1.740 for Extension of a Patent Term	35 U.S.C. § 156(d)(1)-(4)	37 CFR 1.741(b)	No Form Associated	<ul style="list-style-type: none"> <li>Used by the patentee to request review of a notice of an incomplete application for extension of a patent term and to request a filing date.</li> <li>Used by the USPTO to determine the filing date for an application for extension of a patent term.</li> </ul>

**3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological information collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of information collection. Also describe any consideration of using information technology to reduce burden.**

Except for the Application to Extend Patent Term Under 35 U.S.C. § 156 and the Initial Application for Interim Extension Under 35 U.S.C. § 156(d)(5), customers may submit the items in this information collection electronically through Electronic Filing System (EFS-Web), the USPTO's online filing system for patent applications and related documents. EFS-Web allows customers to file requests related to patent term extensions and adjustments through their standard Web browser without downloading special software, changing their documentation preparation tools, or altering their workflow processes. Customers may create their requests using the tools and processes that they already use and then convert those documents into standard PDF files that are submitted through EFS-Web to the USPTO.

Registered and unregistered users can file documents through EFS-Web. The documents of registered users are protected using a Public Key Infrastructure (PKI) system and digital certificates which provide authentication and encryption security. For filers who are not registered, the documents are submitted to EFS-Web using Transport Layer Security (TLS) or Secure Socket Layer (SSL) protocol.

EFS-Web offers many benefits to filers, including immediate notification that a submission has been received by the USPTO, automated processing of requests, and avoidance of postage and other paper delivery costs. Users can access EFS-Web from any computer with an Internet connection. Since EFS-Web is hosted on the USPTO's secure servers and not on the individual's personal computer, USPTO staff can update EFS-Web without requiring any action from the user. Customers can submit fee payments and other requests in real time. The PDF forms can be passed around to multiple users for collaboration.

EFS-Web integrates with the Patent Application Information Retrieval (PAIR) system, the USPTO's online database that is available through the USPTO Web site. PAIR uses digital certificates to permit only authorized individuals to access information about

pending patent applications and to maintain the confidentiality and integrity of the information as it is transmitted over the Internet. Information for issued patents, including patent term adjustments, is available to the general public. The USPTO also publishes determinations on applications for patent term extensions directly on the USPTO Web site.

**4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.**

This information is collected only when an applicant submits a request related to a patent term extension or patent term adjustment. Requests for patent term extensions can only be filed with the USPTO. The information needed by the USPTO, the FDA, the USDA, or other Federal government agencies to consider such requests is not already available from any other source. This information is not collected elsewhere and does not result in a duplication of effort.

**5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.**

The USPTO does not expect that this information collection will have a significant economic impact on a substantial number of small businesses or other small entities. Patent term extensions under 35 U.S.C. § 156 are only for patents for drug products, medical devices, food or color additives, or methods of using or manufacturing such products, devices, or additives. Patent term extensions are typically requested by large pharmaceutical companies because of the expense required to develop and obtain marketing approval for such inventions. USPTO estimates that 25% of these responses are submitted by small entities. The same information is required from every respondent, and this information is not available from any other source.

Pursuant to section 10(b) of the Leahy-Smith America Invents Act (AIA), the USPTO provides a 50% reduction in the fees for certain patent filings by small entity applicants, such as independent inventors, small businesses, and nonprofit organizations who meet the definition of a small entity provided at 37 CFR 1.27. Also pursuant to section 10(b) of the AIA, the USPTO provides a 75% reduction in the fees set or adjusted under section 10(a) of the Act for certain patent filings by applicants who meet the definition of a micro entity provided at 35 U.S.C. § 123 and 37 CFR 1.29.

The reduced patent fees for small and micro entity filers of the Petition to Accord a Filing Date to an Application Under 37 CFR 1.740 for Extension of a Patent Term are listed at 37 CFR 1.17(f). No significant burden is placed on small or micro entities, in that small entities must only identify themselves as such in order to obtain these benefits, and micro entities must only provide a certification of micro entity status. An assertion or certification of small or micro entity status, respectively, only needs to be filed once in an application or patent (although a fee may be paid in the micro entity

amount only if the applicant or patentee is still entitled to micro entity status on the date the fee is paid).

**6. Describe the consequence to Federal program or policy activities if the information collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.**

The information for a patent term or interim extension is collected only when the applicant files an application with the USPTO and could not be collected less frequently. If the information were not collected as provided in 35 U.S.C. § 156(d)(1) or (d)(5), the Director of the USPTO, the Secretary of FDA, and the Secretary of USDA would not have access to the information required to determine whether the applicant is eligible for a patent term extension and, if so, the period of the extension.

There is no requirement that any patent owner apply for an extension. However, if a request for an extension is made, sufficient information is required by the agencies to determine whether the statutory requirements for the special benefit have been met. There is no set frequency of periodic intervals in which the information requested must be supplied. The submission of a request for a patent term extension is at the discretion of the patent owner and is normally limited to one submission within 60 days of approval of a product for commercial use or sale by the FDA or the USDA.

The information for the petitions for reconsideration of patent term adjustment determination and for reinstatement of reduced patent term adjustment is collected only as requested and is not found elsewhere. If the information were not collected, the USPTO would not be able to comply with the statute and regulations that permit applicants to request reconsideration of a patent term adjustment determination.

**7. Explain any special circumstances that would cause an information collection to be conducted in a manner:**

- requiring respondents to report information to the agency more often than quarterly;
- requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- requiring respondents to submit more than an original and two copies of any document;
- requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records, for more than 3 years;
- in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;
- requiring the use of a statistical data classification that has not been reviewed and approved by OMB;
- that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data

security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or

- requiring respondents to submit proprietary trade secrets, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

There are no special circumstances associated with this collection of information.

**8. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the agency in response to these comments. Specifically address comments received on cost and hour burden.**

Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of information collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every 3 years - even if the collection of information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.

A 60-Day Notice was published in the *Federal Register* on November 19, 2019 ([84 Fed. Reg. 63857](#)). The comment period ended on January 21, 2020. No public comments were received.

The USPTO has long-standing relationships with groups from whom patent application information is collected, such as the American Intellectual Property Law Association, as well as patent bar associations, independent inventor groups, and users of our public search facilities. Their views are expressed in regularly scheduled meetings and considered in developing proposals for information collection requirements. There have been no comments or concerns expressed by these or similar organizations concerning the time to provide the information required under this program.

**9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.**

This information collection does not involve a payment or gift to any respondent.

**10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy. If the information collection requires a systems of records notice (SORN) or privacy impact assessment (PIA), those should be cited and described here.**

Confidentiality of patent applications is governed by statute (35 U.S.C. § 122) and regulation (37 CFR 1.11 and 1.14). The USPTO has a legal obligation to maintain the confidentiality of the contents of unpublished patent applications and related documents. Upon publication of an application or issuance of a patent, the patent application file is made available to the public, subject to the provisions for providing only a redacted copy of the file contents.

Applications filed through EFS-Web are maintained in confidence as required by 35 U.S.C. § 122(a) until the application is published or a patent is issued. The confidentiality, security, integrity, authenticity, and non-repudiation of patent applications submitted electronically through EFS-Web are maintained using PKI technology and digital certificates for registered users. Applications electronically-filed by non-registered users are protected using TLS or SSL protocols. The USPTO posts issued patents and application publications on its Web site. The information covered under this information collection will not be released to the public unless it is part of an issued patent or application publication. Patent applicants and/or their designated representatives can view the current status of their patent application through the PAIR system. Patent term extensions involve issued patents and therefore typically do not have confidentiality issues, but there may be confidentiality considerations for patent term adjustments.

This information collection contains information which is subject to the Privacy Act. This information is collected on petitions and applications filed to obtain various patent extensions. Patent Application information collection activities are covered under the Systems of Records Notice ([SORN COMMERCE/PAT-TM-7; Patent Application Files](#)) at 78 FR 19243, published on March 29, 2013. This SORN identifies the categories of records in the system containing applicants for patent, including inventors, legal representatives for deceased or incapacitated inventors, and other persons authorized by law to make applications for patent.

**11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.**

None of the required information in this information collection is considered to be sensitive.



**12. Provide estimates of the hour burden of the collection of information. The statement should:**

- **Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desirable. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the variance. Generally, estimates should not include burden hours for customary and usual business practices.**
- **If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens.**
- **Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included under 'Annual Cost to Federal Government'.**

Table 2 calculates the burden hours and costs of this information collection to the public, based on the following factors:

- **Respondent Calculation Factors**

The USPTO estimates that approximately 620 responses per year will be submitted for this activity. Approximately 25% of these respondents are small entities. It is estimated that all respondents will be private sector companies. Approximately 91% of the total responses for this information collection will be submitted electronically.

These estimates are based on the Agency's long-standing institutional knowledge of and experience with the type of information collected by these items.

- **Burden Hour Calculation Factors**

The USPTO estimates that it will take the public from 1 to 25 hours, depending on the complexity and type of filing, to gather the necessary information, prepare the appropriate documents, and submit the information to the USPTO.

These estimates are based on the Agency's long-standing institutional knowledge of and experience with the type of information collected and the length of time necessary to complete responses containing similar or like information.

- Cost Burden Calculation Factors**

The USPTO uses a professional rate of \$438 per hour for respondent cost burden calculations, which is the mean rate for attorneys in private firms as shown in the [2017 Report of the Economic Survey](#)<sup>1</sup>, published by the Committee on Economics of Legal Practice of the American Intellectual Property Law Association (AIPLA). The USPTO expects that the information in this information collection will be prepared for by attorneys.

**Table 2: Burden Hour/Burden Cost to Respondents**

#	Item Name	Time per Response (a)	Annual Responses (b)	Total Annual Hour Burden (c)=(a) x (b)	Hourly Cost Burden Rate (d)	Total Annual Cost for Time Spent (e)=(c) x (d)
1	Application to Extend Patent Term Under 35 U.S.C. § 156	25	100	2,500	\$438	\$1,095,000
2	Request for Interim Extension Under 35 U.S.C. § 156(e)(2)	1	10	10	\$438	\$4,380
3	Petition to review final Eligibility Decision Under 37 CFR 1.750	25	4	100	\$438	\$43,800
4	Initial Application for Interim Extension Under 37 CFR 1.790	20	2	40	\$438	\$17,520
5	Subsequent Application for Interim Extension Under 37 CFR 1.790	1	1	1	\$438	\$438
6	Response to Requirement to Elect	1	35	35	\$438	\$15,330
7	Response to Request to Identify Holder of Regulatory Approval	2	1	2	\$438	\$876
8	Declaration to Withdraw an Application to Extend Patent Term	2	1	2	\$438	\$876
9	Petition for Reconsideration of Patent Term Adjustment Determination	3	450	1,350	\$438	\$591,300
10	Petition for Reinstatement of Reduced Patent Term Adjustment	4	15	60	\$438	\$26,280
11	Petition to Accord a Filing Date to an Application Under 37 CFR 1.740 for Extension of a Patent Term	2	1	2	\$438	\$876
	<b>Total</b>	----	<b>620</b>	<b>4,102</b>	---	<b>\$1,796,676</b>

<sup>1</sup> <https://www.aipla.org/detail/journal-issue/economic-survey-2017>

13. Provide an estimate for the total annual cost burden to respondents or record keepers resulting from the collection of information. (Do not include the cost of any hour burden already reflected on the burden worksheet).

- The cost estimate should be split into two components: (a) a total capital and start-up cost component (annualized over its expected useful life) and (b) a total operation and maintenance and purchase of services component. The estimates should take into account costs associated with generating, maintaining, and disclosing or providing the information. Include descriptions of methods used to estimate major cost factors including system and technology acquisition, expected useful life of capital equipment, the discount rate(s), and the time period over which costs will be incurred. Capital and start-up costs include, among other items, preparations for collecting information such as purchasing computers and software; monitoring, sampling, drilling and testing equipment; and record storage facilities.
- If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of purchasing or contracting out information collections services should be a part of this cost burden estimate. In developing cost burden estimates, agencies may consult with a sample of respondents (fewer than 10), utilize the 60-day pre-OMB submission public comment process and use existing economic or regulatory impact analysis associated with the rulemaking containing the information collection, as appropriate.
- Generally, estimates should not include purchases of equipment or services, or portions thereof, made: (1) prior to October 1, 1995, (2) to achieve regulatory compliance with requirements not associated with the information collection, (3) for reasons other than to provide information or keep records for the government, or (4) as part of customary and usual business or private practices.

This total annual (non-hour) cost burden for this information collection is \$209,889 and is calculated in Table 3 below. Postage and filing fees are included in this information collection. This information collection has no capital start-up, maintenance, or recordkeeping costs.

### Fees

The fees associated with the requirements in this information collection are listed in the table below.

**Table 3: Filing Fees**

Item #	Item	Annual Estimated Responses	Filing Fee	Total Cost
1	Application to Extend Patent Term Under 35 U.S.C. § 156	100	\$1,120	\$112,000
4	Initial Application for Interim Extension Under 37 CFR 1.790	2	\$420	\$840

<b>5</b>	Subsequent Application for Interim Extension Under 37 CFR 1.790	1	\$220	\$220
<b>9</b>	Petition for Reconsideration of Patent Term Adjustment Determination	450	\$200	\$90,000
<b>10</b>	Petition for Reinstatement of Reduced Patent Term Adjustment	15	\$400	\$6,000
<b>11</b>	Petition to Accord a Filing Date to an Application Under 37 CFR 1.740 for Extension of a Patent Term	1	\$400	\$400
	<b>Totals</b>	<b>569</b>		<b>209,460</b>

Therefore, the total non-hourly cost in the forms of filing fees amounts to this information collection is \$209,460.

### Postage

Customers may incur postage costs when submitting some of the items covered by this information collection to the USPTO by mail. The applications to extend patent term under 35 U.S.C. 156 and the initial applications for interim extension under 37 CFR 1.790 cannot be filed electronically. The USPTO expects that 50 percent of these responses will be submitted by mail, resulting in 51 mailed submissions. (The remainder of the submission, in this category will be hand carried to USPTO.) The USPTO expects that approximately 99 percent of the remaining responses in this information collection will be submitted electronically. Of the remaining 1 percent, the vast majority will be submitted by mail, resulting in 5 additional mailed submissions. Overall for this information collection, 56 mailed submissions are expected per year. The average USPS Priority Mail postage cost for a legal flat rate envelope is estimated to be \$7.65. Therefore, the USPTO estimates that the postage costs for the mailed submissions in this information collection will total \$429.

**Table 4: Postage Costs**

<b>Item #</b>	<b>Item</b>	<b>Estimated Annual Mailed Responses</b>	<b>Amount</b>	<b>Totals</b>
<b>1</b>	Application to Extend Patent Term Under 35 U.S.C. § 156	50	\$7.65	\$383
<b>4</b>	Initial Application for Interim Extension Under 37 CFR 1.790	1	\$7.65	\$8
<b>9</b>	Petition for Reconsideration of Patent Term Adjustment Determination	5	\$7.65	\$38
	<b>Total Postage</b>	<b>56</b>	<b>---</b>	<b>\$429</b>

Therefore, the USPTO estimates that the total annual (non-hour) cost burden for this information collection, in the form of postage costs and fees is \$209,889 per year.

**14. Provide estimates of annualized costs to the Federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies may also aggregate costs estimates from Items 12, 13, and 14 in a single table.**

The USPTO estimates that the cost of a [GS-5, step 1](#)<sup>2</sup> employee is \$24.48 per hour (GS hourly rate of \$18.83 with 30% (\$5.65) added for benefits and overhead). The USPTO estimates that it takes an employee between 15 minutes (0.25 hours) and 2 hours to process the information in this information collection at an estimated cost of \$24.48 per hour. The overall costs to the Federal Government for processing this information is \$16,769.

Table 4 calculates the burden hours and costs to the Federal Government for processing this information collection:

**Table 5: Burden Hour/Cost to the Federal Government**

Item #	Item	Hours (a)	Responses (yr) (b)	Burden (hrs/yr) (c) (a x b)	Rate (\$/yr) (d)	Total Cost (\$/yr) (e) (d x e)
1	Application to Extend Patent Term Under 35 U.S.C. § 156	2.00	100	200	\$24.48	\$4,896.00
2	Request for Interim Extension Under 35 U.S.C. § 156(e)(2)	0.50	10	5	\$24.48	\$122.40
3	Petition to Review Final Eligibility Decision Under 37 CFR 1.750	0.25	4	1	\$24.48	\$24.48
4	Initial Application for Interim Extension Under 35 U.S.C. § 156(d)(5)	0.50	2	1	\$24.48	\$24.48
5	Subsequent Application for Interim Extension Under 37 CFR 1.790	0.50	1	1	\$24.48	\$24.48
6	Response to Requirement to Elect	0.25	35	9	\$24.48	\$220.32
7	Response to Request to Identify Holder of Regulatory Approval	0.25	1	1	\$24.48	\$24.48
8	Declaration to Withdraw an Application to Extend Patent Term	0.25	1	1	\$24.48	\$24.48
9	Petition for Reconsideration of Patent Term Adjustment Determination	1.00	450	450	\$24.48	\$11,016.00
10	Petition for Reinstatement of Reduced Patent Term Adjustment	1.00	15	15	\$24.48	\$367.20
11	Petition to Accord a Filing Date to an Application Under 37 CFR 1.740 for Extension of a Patent Term	0.25	1	1	\$24.48	\$24.48

<sup>2</sup> [https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2020/DCB\\_h.pdf](https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2020/DCB_h.pdf)

	Totals	- - - -	620	685	- - - -	0
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**15. Explain the reasons for any program changes or adjustments reported on the burden worksheet.**

A. OMB previously approved this information collection.

The current information collection contains:

- 1,340 responses
- 6,187 burden hours
- \$369,455 in annual (non-hourly) costs

B. Changes proposed in this request to OMB.

The proposed information collection, as outlined in the tables above, seeks to adjust the existing approval. The proposed information collection contains an estimated:

- 620 responses
- 4,102 burden hours
- \$209,889 in annual (non-hourly) costs

Changes in Responses and Burden Hours

- **Decrease of 720 estimated annual responses:** The USPTO estimates that this information collection will receive 720 fewer annual responses over the 3-year period covered by this renewal request. This adjustment also causes the number of burden hours for this activity to decrease 2,085 hours. Despite minor increases due to the rise in postage rates, the overall decrease in non-hourly costs is due to the decreased number of responses.

**16. For collections of information whose results will be published, outline plans for tabulation and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.**

The USPTO does not plan to publish this information for statistical use or for any special purpose. However, plant and utility patents granted are included weekly in the *Official Gazette of the United States Patent and Trademark Office for Patents* ([Official Gazette for Patents](#)), which is published in electronic format on the USPTO Web site. The USPTO also publishes determinations on applications for patent term extension on the

[USPTO Web site](#) as required by the Freedom of Information Act and lists any certificates of extension granted in the *Official Gazette for Patents*.

**17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.**

There are no forms in this information collection on which to display the expiration date for OMB approval.

**18. Explain each exception to the topics of the certification statement identified in “Certification for Paperwork Reduction Act Submissions.”**

This collection of information does not include any exceptions to the certificate statement.

**B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS**

This collection of information does not employ statistical methods.