# SUPPORTING STATEMENT United States Patent and Trademark Office Terminal Disclaimers OMB CONTROL NUMBER 0651-New 2024

#### 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.

Terminal disclaimers have been reviewed and approved by the Office of Management and Budget (OMB) under OMB control number 0651-0031 (Patent Processing). On May 10, 2024, the USPTO published a Notice of Proposed Rulemaking ("proposed rule") in the Federal Register that would add a new requirement for an acceptable terminal disclaimer that is filed to obviate (that is, overcome) nonstatutory double patenting. See Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting, 89 FR 40439 (RIN 0651-AD76).1 As specified in proposed §1.321, the rule change would require terminal disclaimers filed to obviate nonstatutory double patenting to include an agreement by the disclaimant that the patent in which the terminal disclaimer is filed, or any patent granted on an application in which a terminal disclaimer is filed, will be enforceable only if the patent is not tied and has never been tied directly or indirectly to a patent by one or more terminal disclaimers filed to obviate nonstatutory double patenting in which: any claim has been finally held unpatentable or invalid as anticipated or obvious by a federal court in a civil action or by the USPTO, and all appeal rights have been exhausted; or a statutory disclaimer of a claim is filed after any challenge based on anticipation or obviousness to that claim has been made.

The item in this proposed new information collection relates solely to the impacts of proposed § 1.321 on the filing of terminal disclaimers. In particular, this proposed new information collection accounts for the estimated decrease in burden hours and filing fees that will result from the estimated 20% of applicants and patent owners that will opt not to file a terminal disclaimer containing the proposed agreement, at least during an initial period after the effective date of the corresponding final rule.

The estimates for the item in this proposed new information collection are based on the estimated volume provided in a 60-day notice published on January 29, 2024 (89 FR 5500)<sup>2</sup>, for the corresponding item (Statutory Disclaimer, including terminal disclaimer) that is covered under OMB control number 0651-0031.

<sup>&</sup>lt;sup>1</sup> https://www.govinfo.gov/content/pkg/FR-2024-05-10/pdf/2024-10166.pdf.

<sup>&</sup>lt;sup>2</sup> https://www.govinfo.gov/content/pkg/FR-2024-01-29/pdf/2024-01722.pdf.

Table 1 provides the specific statute and regulation authorizing the USPTO to collect terminal disclaimers:

**Table 1: Information Requirements** 

Item No.	Requirement	Statute	Regulation	
1	Statutory Disclaimer, including terminal disclaimer	35 U.S.C. 253	37 CFR 1.321	

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.

Terminal disclaimers are covered under an existing information collection (control number 0651-0031; Patent Processing). This proposed new information collection would account only for the impacts of proposed § 1.321 on the filing of terminal disclaimers.

The information that would be collected, maintained, and used in this proposed new 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), OMB Circular A-130, and the USPTO and OMB's information quality guidelines.

Table 2 outlines how the changes under proposed § 1.321 on the filing of terminal disclaimers would be used by the public and the USPTO:

Table 2: Needs and Uses

Item No.	Form and Function	Form No.	Needs and Uses
	Statutory Disclaimer, including terminal disclaimer	PTO/AIA/25	Used by an owner (in whole or in part) of a patent or a patent to be granted to agree that the patent in which the terminal disclaimer is filed, or any patent granted on an application in which a terminal disclaimer is
		PTO/SB/25	filed, will be enforceable only if the patent is not tied and has never been tied directly or indirectly to a patent by one or more terminal disclaimers filed to obviate nonstatutory double patenting in which: any claim has
		PTO/SB/25a	been finally held unpatentable or invalid as anticipated or obvious by a federal court in a civil action or by the USPTO, and all appeal rights have
1		PTO/AIA/26	been exhausted; or a statutory disclaimer of a claim is filed after any challenge based on anticipation or obviousness to that claim has been
_		PTO/SB/26	made.
		PTO/SB/26a	Used by the USPTO to ensure it does not issue a patent to a common owner or inventor with a claim that conflicts with a claim of a second
		PTO/AIA/63	patent, unless the terminal disclaimer includes the additional agreement that the patent with the terminal disclaimer will not be enforced if any
		PTO/SB/63	claim of the second patent is invalidated by prior art.  • Used by the public to focus on addressing the validity of the claims of a
			single patent to resolve a dispute where there are multiple patents tied by terminal disclaimers.

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.

The USPTO prefers that terminal disclaimers be filed electronically through the USPTO patent electronic filing system (Patent Center), the USPTO's online filing and viewing system for patent applications and related documents. For those respondents who choose to not file electronically, terminal disclaimers may be submitted by mail or hand delivery.

Patent Center allows customers to electronically file patent applications and associated documents through their standard Web browser without downloading special software, changing their documentation preparation tools, or altering their workflow processes.

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.

Terminal disclaimers may be collected during the pendency of a patent application or term of a patent. The information provided in a terminal disclaimer is not collected elsewhere during the prosecution of a patent application or term of a patent.

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

Pursuant to section 10(b) of the Leahy-Smith America Invents Act (AIA), Pub. L. 112-29, as amended by the Unleashing American Innovators Act of 2022 (UAIA), Pub. L. 117-103, the USPTO provides a 60% reduction in the fees for certain patent filings by small entity applicants, such as persons, small businesses, and nonprofit organizations who meet the definition of a small entity provided at 37 CFR 1.27(a). Also pursuant to section 10(b) of the AIA, the USPTO provides an 80% 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.

However, the fee under 37 CFR 1.20(d) for filing a terminal disclaimer is not one of the fees for which the USPTO provides a discount.

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.

This proposed new information collection relates solely to the impacts of proposed § 1.321 on the filing of terminal disclaimers. The USPTO is proposing to revise § 1.321 because, even with the protections currently provided by a terminal disclaimer, multiple patents tied by terminal disclaimers that are directed to obvious variants of an invention could deter competition due to the prohibitive cost of challenging each patent separately

in litigation or administrative proceedings. The proposed rule is intended to promote competition by lowering the cost of challenging groups of patents tied by terminal disclaimers, resulting in reduced barriers to market entry and lower costs for consumers. The proposed rule furthers the objectives of Executive Order 14036 on "Promoting Competition in the American Economy," 86 FR 36987 (July 14, 2021).<sup>3</sup>

- 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 three 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 proposed new 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,

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<sup>&</sup>lt;sup>3</sup> https://www.govinfo.gov/content/pkg/FR-2021-07-14/pdf/2021-15069.pdf.

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 proposed rule that contained the proposed new information collection was published in the *Federal Register* on May 10, 2024 (89 FR 40439). The comment period for this proposed rule will end on July 9, 2024.

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

This proposed new 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 system of records notice (SORN) or privacy impact assessment (PIA), those should be cited and described here.

The 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 (37 CFR 1.11(a) and 1.217). Terminal disclaimers may be filed in either a patent application or patent. Accordingly, the USPTO will maintain the confidentiality of a terminal disclaimer filed in a patent application until the application publishes or issues as a patent. A terminal disclaimer filed in a patent will be immediately available to the public.

Applications filed through Patent Center are maintained in confidence as required by 35 U.S.C. 122(a) until the application is published or issued as a patent. The confidentiality, security, integrity, authenticity, and non-repudiation of patent applications submitted electronically through Patent Center are maintained using TLS or SSL protocols. The USPTO posts the file contents of issued patents and application publications on its website. 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, or unless one or more specific conditions for power to inspect or access are met pursuant to 37 CFR 1.14(c)-(j). Patent applicants and/or their designated representatives can view the current status of their patent application through Patent Center.

In order to protect the confidentiality of credit card account information when making fee payments to the USPTO or through the USPTO as an office of indirect filing, customers should submit credit card payments on a separate credit card payment form provided by the USPTO for this purpose. The USPTO will not include the credit card information submitted using the provided credit card payment forms among the patent records open to public inspection. If a customer supplies their credit card information on a form or a document (e.g., in correspondence related to a patent) other than a credit card payment form provided by the USPTO, the USPTO will not be liable if the credit card information becomes public knowledge.

The applicable PIA for this information collection is the Privacy Impact Assessment for the Patent End to End (PE2E) System (March 14, 2022), which is available at <a href="https://osec.doc.gov/opog/privacy/pto%20pias/PE2E">https://osec.doc.gov/opog/privacy/pto%20pias/PE2E</a>-

<u>PIA\_SAOP\_Approval\_Delegation.pdf</u></u>. PE2E is a Master system portfolio consisting of next generation Patents Automated Information Systems (AIS). The goal of PE2E is to make the interaction of USPTO's users as simple and efficient as possible in order to accomplish user goals. PE2E will be a single web-based examination tool providing users with a unified and robust set of tools. PE2E will overhaul the current patents examination baseline through the development of a new system that replaces the existing tools used in the examination process. The project stakeholders desire a simple, unified interface that does not require launching of separate applications in separate windows, and that supports new and improved IT advances. There are 14 subsystems under PE2E, including Patent Center.

The Privacy Act of 1974 (Pub. L. 93-579) requires that an applicant be given certain information in connection with the items covered under this information collection. The applicable Privacy Act System of Records Notice for this information collection is COMMERCE/PAT-TM-7 Patent Application Files (SORN 7), available at 78 FR 19243 (March 29, 2013). The purpose of SORN 7 is to disclose how the USPTO intends to use, maintain, and protect the information that it has collected to carry out the duties of the USPTO to examine patent applications and issue patents. SORN 7 manages all applicant records including name, citizenship, residence, post office address, and other information pertaining to the applicant's activities in connection with the invention for which a patent is sought or has been granted.

This SORN identifies the categories of individuals covered by 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. Categories of records in the system comprises the following: oath or declaration of applicant including name, citizenship, residence, post office address, and other information pertaining to the applicant's activities in connection with the invention for which a patent is sought.

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<sup>&</sup>lt;sup>4</sup> https://www.govinfo.gov/content/pkg/FR-2013-03-29/pdf/2013-07341.pdf.

The information in SORN 7 is protected from disclosure to third parties in accordance with the Privacy Act until the application is published under 35 U.S.C. 122(b) or issued as a patent under 35 U.S.C. 153. Prior to application publication or patent issuance, the information in SORN 7 is protected from disclosure to third parties in accordance with the Privacy Act, except that disclosure is permitted for the following routine uses including, but not limited: to law enforcement and investigation in the event that the system of records indicates a violation or potential violation of law; to a Federal, state, local, or international agency, in response to its request regarding personnel matters; to an agency, organization, or individual for the purpose of performing audit or oversight operations as authorized by law; to non-federal personnel under contract to the agency; to a court for adjudication and litigation; to the Department of Justice for Freedom of Information Act (FOIA) assistance; to members of Congress working on behalf of an individual; to National Archives and Records Administration for inspection of records: to the Office of Management and Budget (OMB) for legislative coordination and clearance; to the Office of Personal Management (OPM) for personnel research purposes; to the General Services Administration for the inspection of records.

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 proposed new 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 3 calculates the burden hours and costs of this proposed new information collection to the public, based on the following factors:

#### Respondent Calculation Factors

The respondents to this information collection are primarily from the private sector. The USPTO estimates that it will receive approximately 39,960 responses per year under this information collection. The USPTO estimates that approximately 27% of these responses will be submitted by small entities. The USPTO estimates that approximately 99% of the annual responses for this collection will be filed 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 15 minutes to submit the information to the USPTO. Using these burden factors, USPTO estimates that the total respondent hourly burden for this information collection is 9,990 hours per year.

#### Cost Burden Calculation Factors

The USPTO uses a professional rate of \$447 per hour for respondent cost burden calculations, which is the mean rate for attorneys in private firms as shown in the 2023 *Report of the Economic Survey* 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 by attorneys. Using this hourly rate, the USPTO estimates that the total respondent cost burden for this information collection is \$4,465,530 per year.

Table 3: Burden Hour/Burden Cost to Private Sector Respondents

Ite m No	Item	Estimated Annual Responde	Response s per Responde	Estimate d Annual Respons	Estimate d Time for	Estimated Burden (hour/year)	Rate⁵ (\$/ hour)	Estimated Annual Respondent	
		nts	nt	es	Respons e (hours)	(c) x (d) = (e)		Cost Burden (e) x (f) = (g)	
		(a)	(b)	(a) x (b) = (c)	(d)		(f)		
1	Statutory Disclaimer, including terminal disclaimer	39,960	1	39,960	0.25	9,990	\$447	\$4,465,530	
	Totals	39,960		39,960		9,990		\$4,465,530	

<sup>&</sup>lt;sup>5</sup> 2023 Report of the Economic Survey published by the Committee on Economics of Legal Practice of the American Intellectual Property Law Association (AIPLA); the USPTO uses the mean IP billing rate for attorneys in private firms which is \$447 per hour. (https://www.aipla.org/home/news-publications/economic-survey; pg F-27).

- 13. Provide an estimate for the total annual cost burden to respondents or recordkeepers 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 therefor, 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.

There are no additional maintenance costs, capital start-up costs, recordkeeping costs, or postage associated with this proposed new information collection that are not already accounted for in OMB control number 0651-0031 (Patent Processing). However, the USPTO estimates that the total annual (non-hour) cost burden for this information collection, in the form of filing fees is \$6,793,200.

#### Filing Fees

The filing fees for the item in this proposed new information collection are listed in the table below.

**Table 4: Filing Fee Costs to Respondents** 

Table 4. I	illing ree costs to Respondents			
Item No.	Item	Estimated	Amount	Totals
		Annual		
		Responses		
		(a)	(b)	(a) x (b) = (c)

1	Statutory Disclaimer, including terminal disclaimer (undiscounted entity)	28,771	\$170	\$4,891,070
1	Statutory Disclaimer, including terminal disclaimer (small entity)	10,389	\$170	\$1,766,130
1	Statutory Disclaimer, including terminal disclaimer (micro entity)	800	\$170	\$136,000
	Totals	39,960		\$6,793,200

#### <u>Postage</u>

There are no additional postage costs associated with the item in this proposed new information collection that are not already accounted for in OMB control number 0651-0031.

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 cost estimates from Items 12, 13, and 14 in a single table.

The USPTO employs a GS-7, step 1 employee to process the items in this information collection.

The USPTO estimates that the hourly rate for a GS-7, step 1 employee to process the items in this information collection is \$34.84 per hour (GS hourly rate of \$26.80 with 30% (\$8.04) added for benefits and overhead).

The USPTO estimates that it takes an employee 12 minutes to process the items in this collection.

Table 5 Burden Hour/Cost to the Federal Government

Item No.	Item	Estimated Annual Responses	Estimated Time for Response (hours)	Estimated Burden (hour/year)	Rate <sup>6</sup> (\$/hour)	Estimated Annual Government Cost
		(a) x (b) = (c)	(d)	(c) x (d) = (e)	(f)	(e) x (f) = (g)
1	Statutory Disclaimers (including terminal disclaimers)	39,960	0.20 (12 minutes)	7,992	\$34.84	\$278,441
	Totals	39,960		7,992		\$278,441

The estimated annual cost burden to the government for this information collection is \$278,441. This is a decrease of \$69,611 in cost burden due to the proposed rule. This reduction estimate is in keeping with the overall estimates in this information collection which the USPTO estimates will decrease by 20%.

15. Explain the reasons for any program changes or adjustments reported on the burden worksheet.

<sup>&</sup>lt;sup>6</sup> https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/24Tables/html/DCB\_h.aspx.

**Table 6: ICR Summary of Burden** 

	Requested	Program Change Due to New Statute	Program Change Due to Agency Discretion	Change Due to Adjustment in Agency Estimate	Change Due to Potential Violation of the PRA	Previously Approved
Annual Number of Responses	39,960	0	-9,990	0	0	49,950
Annual Time Burden (Hr)	9,990	0	-2,498	0	0	12,488
Annual Cost Burden (\$)	\$6,793,200	0	-\$1,698,300	0	0	\$8,491,500

#### Changes due to Agency Discretion

The total number of responses is projected to decrease by an estimated 9,990 due to the proposed rule. This decrease in the number of responses results in a decrease of 2,498 hours in the annual time burden estimate as well as a decrease in the (non-hour) cost of \$1,698,300.

This is a proposed new information collection to account for the impact of proposed § 1.321 on the filing of terminal disclaimers. The USPTO is proposing to revise § 1.321 because, even with the protections currently provided by a terminal disclaimer, multiple patents tied by terminal disclaimers that are directed to obvious variants of an invention could deter competition due to the prohibitive cost of challenging each patent separately in litigation or administrative proceedings.

The information displayed in this ICR summary chart (Table 6) may be different than that shown in Reginfo.gov. Reginfo.gov does not allow the USPTO to display a negative burden which would accurately reflect the decrease in estimated volumes described in this supporting statement. The burden changes shown in this section are the most accurate representation of the USPTO's burden estimates associated with the proposed rule (0651-AD76).

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 publishes applications under 35 U.S.C. 122(b) and issues patents under 35 U.S.C. 153. Also, information regarding patent applications filed and patents granted is published weekly in the Official Gazette of the United States Patent and Trademark Office on the USPTO website.<sup>7</sup>

<sup>&</sup>lt;sup>7</sup> https://www.uspto.gov/learning-and-resources/official-gazette.

## 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.

If the proposed rule is implemented in a final rule, the item in this proposed new information collection will display the expiration date for OMB approval. If OMB approves these changes under a new information collection number, the items related to terminal disclaimers may display two different control numbers representing the combined approvals of this proposed information collection and the existing OMB approval under 0651-0031.

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

This proposed new collection of information does not include any exceptions to the certification statement.

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

This proposed new collection of information does not employ statistical methods.