

SUPPORTING STATEMENT

Requirements on Content and Format of Labeling for Human
Prescription Drug and Biological Products

(Docket Number 2000N-1269)(formerly Docket No. 00N-1269)

OMB Control Number 0910-0572

Expiration Date 01/31/2009

A. Justification

1. Circumstances of Information Collection

This information collection approval request is for a Food and Drug Administration (FDA) final rule amending FDA regulations governing the content and format of labeling for human prescription drug and biological products. The final rule revises current regulations to require that the prescription drug labeling of such new and recently approved products include Highlights of prescribing information and a table of contents. The final rule reorders certain sections, requires minor content changes, and sets minimum graphical requirements. The final rule also revises current regulations for prescription drug labeling of older products by clarifying certain requirements and requiring that all FDA-approved patient labeling for the product be reprinted with or accompany the labeling.

2. Purpose and Use of Information

The final rule is part of FDA's strategic initiative to manage the risks of medical product use and reduce adverse events involving the products that it regulates. The revisions to the content and format of labeling will make it easier for health care practitioners to access, read, and use information in prescription drug labeling, thereby increasing the extent to which they rely on labeling to obtain information. The revisions reflect those that the agency believes will enhance the safe and effective use of prescription drug products, and in turn, reduce the number of adverse reactions resulting from medication errors due to misunderstood or incorrectly applied drug information.

The new requirements are important to the success of other initiatives aimed at improving patient care and decreasing the likelihood of medication errors. For example, the DailyMed, a collaboration between FDA and the National Library of Medicine will be an innovative means of disseminating up-to-date and comprehensive medication information electronically for use in information systems that support patient care. The DailyMed will make current information about FDA-regulated products readily available

to physicians, other health care practitioners, and patients. In addition, prescription drug labeling in the new format may also be utilized with electronic prescribing systems under development.

3. Use of Improved Information Technology

As discussed in this document, the drug product labeling affected by this rule is submitted to FDA for approval as part of the NDA, ANDA, BLA or a supplement to an application. FDA has undertaken many initiatives to improve information technology used to submit these applications to the agency.

In the Federal Register of December 11, 2003, FDA issued a final rule amending FDA regulations governing the format in which certain labeling is required to be submitted for review with NDAs, certain BLAs, ANDAs, supplements, and annual reports. The final rule requires the electronic submission of the content of labeling (i.e., the content of the package insert or professional labeling, including all text, tables, and figures) in NDAs, certain BLAs, ANDAs, supplements, and annual reports electronically in a form that FDA can process, review, and archive. The agency views this final rule on content and format of labeling as an essential step toward the success of its

electronic labeling initiative. The labeling format required by this rule for new and more recently approved products should facilitate transition to an electronic format.

The following guidances for industry have been developed to improve the use of information technology in the submission of marketing applications for human drugs and related reports:

- "Providing Regulatory Submissions in Electronic Format--NDAs" (January 28, 1999). This guidance provides information on how to submit a complete archival copy of an NDA in electronic format and applies to the submission of original NDAs as well as to the submission of supplements and amendments to NDAs.
- "Providing Regulatory Submissions in Electronic Format--General Considerations" (January 28, 1999). This guidance includes a description of the types of electronic file formats that the agency is able to accept to process, review, and archive electronic documents. The guidance also states that documents submitted in electronic format should enable the user to: (1) Easily view a clear and legible copy of the information; (2) print each document page by page while maintaining fonts, special orientations, table formats, and page numbers; and (3) copy text and

images electronically into common word processing documents.

- "Providing Regulatory Submissions to the Center for Biologics Evaluation and Research (CBER) in Electronic Format" (November 12, 1999). This guidance provides information to assist applicants in submitting documents in electronic format for review and archive purposes as part of a BLA, product license application (PLA), or establishment license application (ELA).
- "Providing Regulatory Submissions in Electronic Format-- Prescription Drug Advertising and Promotional Labeling" (January 31, 2001). This draft guidance discusses issues related to the electronic submission of advertising and promotional labeling materials for prescription drug and biological products.
- "Providing Regulatory Submissions in Electronic Format-- ANDAs" (June 27, 2002). This guidance discusses issues related to the electronic submission of ANDAs and supplements and amendments to those applications.
- "Providing Regulatory Submissions in Electronic Format-- Annual reports for NDAs and ANDAs" (August 2003). This guidance discusses issues related to the electronic submission of annual reports for NDAs and ANDAs.

- "Providing Regulatory Submissions in Electronic Format-- Postmarketing Periodic Adverse Drug Experience Reports" (June 2003). This guidance discusses general issues related to the electronic submission of postmarketing periodic adverse drug experience reports for NDAs, ANDAs, and BLAs.
- "Providing Regulatory Submissions in Electronic Format-- Annual reports for NDAs and ANDAs" (August, 2003). This draft guidance discusses issues related to the electronic submission of annual reports, for NDAs and ANDAs.
- "Providing Regulatory Submissions in Electronic Format-- Human Pharmaceutical Product Applications and Related Submissions" (August 2003). This draft guidance discusses issues related to the electronic submission of ANDAs, BLAs, INDs, NDAs, master files, advertising material, and promotional material.
- "Providing Regulatory Submissions in Electronic Format-- General Considerations" (October 2003). This draft guidance discusses general issues common to all types of electronic regulatory submissions.
- "Providing Regulatory Submissions in Electronic Format-- Content of Labeling" (February 2004). This draft guidance discusses issues related to the submission of the content of labeling in electronic format for marketing applications for human drug and biological products.

These guidance documents are available at FDA's web site <http://www.fda.gov/cder/guidance/index.htm>.

4. Efforts to Identify Duplication

The information collection required as a result of this proposed rulemaking does not duplicate any other information collection.

5. Involvement of Small Entities

Under the Regulatory Flexibility Act, FDA analyzes regulatory options that would minimize any significant impact on small entities. FDA also assists small businesses in complying with regulatory requirements.

The agency believes that this rule would not have a significant impact on most small entities, as defined by the Regulatory Flexibility Act. However, it is possible that a few small firms may be significantly affected by the final rule.

1999 Census data suggests that approximately 91 percent of biological product manufacturers and no more than 87 percent of the pharmaceutical preparation manufacturing establishments could be considered small. Despite the large number of small manufacturers, large companies manufacture most prescription drug products.

Although the agency cannot predict the number of new approvals granted to small entities, the following estimates are based on 5 years of recent submissions (65 FR 81082 at 81110, updated for 1997-2001). On average, 17 small entities will receive product approvals each year. In addition, about 64 small entities will be affected during years 3 to 7 of the rule, when applicants with products approved 5 years prior to the effective date of the final rule must submit reformatted prescription drug labeling for approval. Only six firms will have more than two existing products affected by the rule. Of these six, four firms will have two products affected in the same year and one firm will have three products affected in a single year.

The compliance requirements for small entities under this final rule are the same as those for other affected entities. Compliance primarily involves: (1) designing prescription drug labeling that conforms to the content and format requirements, and (2) once the labeling is approved by FDA, ensuring that all future printed prescription drug labeling is in the new format with the required minimum font size. Because manufacturers already submit labeling with NDAs, BLAs, and efficacy supplements to FDA, no

additional skills will be required to comply with the final rule.

The group of small entities likely to bear the highest total costs under the final rule are those firms that have: (1) Existing products with prescription drug labeling that must be revised in the first year or (2) more than one affected high-volume product per year, such as a small firm with two or three recently approved, high-volume products that must undergo prescription drug labeling reformatting simultaneously in the same year. However, the high-cost small entities are also the small firms with the highest sales of affected product; thus, their incremental cost per unit sold is likely to be relatively low. In contrast, small firms with a single, low-volume product would have lower costs of compliance, but the incremental cost per unit sold would be higher.

The agency illustrated possible impacts on small entities with different production volumes. Prescription drug labeling costs are estimated for a small firm with a single carton-enclosed product (marketed under an NDA) that must: (1) Have its labeling reformatted in year 3 of the rule and (2) add patient information in year 1. Table 1 outlines the projected per-unit and total costs to the firm with 3 different levels of production: 1,000, 10,000, and

100,000 units produced per year. In addition to the costs identified in table 1, a very small number of small firms might incur equipment costs to include longer prescription drug labeling in carton-enclosed products. It is likely, however, that this one-time capital cost (estimated at \$200,000) will affect a total of no more than two or three small firms in the 10 years following implementation of the rule.

Table 1.--Estimated Costs for Hypothetical Small Firm with a Single Product, Under Three Alternative Levels of Production ¹

Cost Category	Number of Units Produced and Sold Each Year		
	100,000	10,000	1,000
Example 1--Revise labeling of product approved less than 1 year prior to effective date:			
Prescription drug labeling redesign/application	\$8,700	\$8,700	\$8,700
Printing trade labeling ²	\$200	\$20	\$2
Printing prescription drug labeling not accompanying drug products ³	\$1,050	\$105	\$10
Total	\$9,950	\$8,825	\$8,712
Additional cost per unit sold	\$0.10	\$0.88	\$8.71
Example 2--Add printed patient information to existing labeling for a product:			
Prescription drug labeling redesign	\$2,850	\$2,850	\$2,850

Printing trade labeling ⁴	\$750	\$75	\$8
Printing longer PDR ⁵	\$19,500	\$19,500	N/A
Total	\$23,100	\$22,425	\$2,858
Additional cost per unit sold	\$0.23	\$2.24	\$2.86

¹ Numbers may not sum due to rounding.

² Number of pieces of trade labeling printed is calculated as units produced/year plus 10 percent wastage factor, at an incremental printing cost of \$0.001791 per labeling.

³ To calculate the cost for printing labeling not accompanying drug products, the number of units is adjusted by the ratio of the average number of pieces printed for mailings to the average number printed as trade labeling (i.e., 1.126), and multiplied by the incremental printing cost of \$0.0085 per piece.

⁴ Number of pieces of trade labeling printed is calculated as units produced/year plus 10 percent wastage factor, at an incremental printing cost of \$0.006837 per labeling.

⁵ Assume that prescription drug labeling is already being printed in the PDR. Most low-volume products (i.e., less than 10,000 units per year) will not have labeling in the PDR.

6. Consequences If Information Collected Less Frequently

The part of a prescription drug product's approved labeling directed to health care practitioners is the primary mechanism through which FDA and drug manufacturers communicate essential, science-based prescribing information to health care professionals. The primary purpose of prescription drug labeling is to provide practitioners with the essential information they need to prescribe the drug safely and effectively for the care of patients. This purpose would be hindered without the information collection requirements set forth in the proposal.

7. Consistency with the Guidelines in 5 CFR 1320.5(d)(2)

There is no inconsistency resulting from this final rule.

8. Consultation Outside the Agency

As required under section 3506(c)(2)(B) of the Paperwork Reduction Act, FDA provided an opportunity for public comment on the information collection provisions of the December 22, 2000, proposed rule. FDA received no comments on the information collection estimates.

FDA received many written comments other aspects of the proposed rule from manufacturers, trade associations, health care practitioners, consulting firms, and individuals. Comments expressed broad agreement that prescription drug labeling could be more effective in communicating drug information to health care practitioners and overwhelming support for the agency's goal of improving the content and format of prescription drug labeling to make information more useful and accessible to practitioners. Comments from manufacturers, while strongly supportive of the agency's efforts to improve the content and format of labeling, generally expressed concerns about some of the major elements of the proposal, especially the inclusion of Highlights. The final rule contains a

summary of the comments received and the agency's responses.

9. Remuneration of Respondents

FDA has not provided and has no intention to provide any payment or gift to respondents under this rule.

10. Assurance of Confidentiality

Confidentiality of the information submitted under these regulations is protected under 21 CFR 314.430, 21 CFR 601, and 21 CFR part 20. The unauthorized use or disclosure of trade secrets required in applications is specifically prohibited under Section 310(j) of the Act.

11. Questions of a Sensitive Nature

There are no questions of a sensitive nature.

12. Estimated Reporting Burden

a. The Reporting Burdens for the General Requirements
(§ 201.56)

The reporting burdens for the general requirements in § 201.56(a) are the same as those for former § 201.56(a) through (c) and are estimated in table 2a and 2b as part of the burdens associated with § 201.57. Section 201.56(b)

and (c) sets forth the categories of affected drugs and their implementation schedule, generating no reporting burdens. Section 201.56(d) sets forth the required sections and subsections associated with the revised format in § 201.57; therefore, its associated reporting burdens are estimated in table 2a and 2b under the requirements at § 201.57. Sections 201.56(e) and 201.80 codify former labeling requirements at §§ 201.56(d) and (e) and 201.57, with minor clarifications, for older prescription drugs. The requirements in these sections impose no new reporting burdens, as they were previously incurred to produce existing labeling.

b. Annual Burden for Labeling Design, Testing, and Submitting to FDA for NDAs Submitted on or After the Effective Date of the Final Rule (§§ 201.56 and 201.57)

New drug product applicants must: (1) Design and create prescription drug labeling containing Highlights, Contents, and FPI, (2) test the designed labeling (e.g., to ensure that the designed labeling fits into carton-enclosed products), and (3) submit it to FDA for approval.

Based on information received from the pharmaceutical industry, FDA estimated that it took applicants approximately 3,200 hours to design, test, and submit prescription drug labeling to FDA as part of an NDA or BLA

under former labeling requirements (see row 1 of table 2a). FDA estimates that it will take an additional 149 hours to generate Highlights and Contents and otherwise comply with the additional requirements of the final rule (see row 2 of table 2a). Therefore, it will take a total of approximately 3,349 hours to design, test, and submit new labeling. Approximately 85 applicants would submit approximately 107 new applications (NDAs and BLAs) to FDA per year, totaling 358,343 hours (see Total of table 2a).

c. Burden Associated with Revised Labeling Supplements for Applications Approved Within 5 Years Prior to the Effective Date of the Rule (§ 201.57)

The final rule requires that prescription drug applications approved during the 5 years before, or pending on, the effective date conform to format and content requirements at § 201.57. For these products, applicants must redesign and negotiate the labeling, including Highlights and Contents, test the redesigned labeling, and prepare and submit that labeling to FDA for approval. Based on information provided in the "Analysis of Economic Impacts" in the final rule, labeling supplements for a total of approximately 344 innovator products would be submitted to the FDA over a 5-year period (beginning in year 3 and ending in year 7 after the effective date of the

rule). Approximately 172 applicants would submit these labeling supplements. The time required for redesigning, testing, and submitting the labeling to FDA is estimated to be approximately 196 hours per application, totaling 67,424 hours (see row 1 of table 2b).

d. Burden Associated with Revised Labeling for Efficacy Supplements Submitted on or after the Effective Date of the Rule (§§ 201.56(d) and 201.57)

Efficacy supplemental applications for older drugs submitted on or after the effective date of the final rule are subject to the content and format requirements at §§ 201.56(d) and 201.57. To meet these requirements, applicants must revise the existing labeling for these products. Each year an increasing number of innovator drug labeling will have been revised, and over time, very few efficacy supplements independently will generate labeling revisions as a result of this final rule. According to information in the economic analysis, the total number of affected efficacy supplements over 10 years is estimated at 324, with a decreasing number each year over the 10-year period. For purposes of this analysis, the total burden for efficacy supplements is summarized in row 2 of table 2b. Over 10 years, approximately 172 applicants will trigger approximately 324 efficacy supplements, each one

requiring approximately 196 hours to revise the labeling in the application, totaling 63,504 hours. In addition, a minimal annual reporting burden, probably even lower than the 7 per year, will continue indefinitely (see row 2 of table 2b).

e. Burden Associated with Revised Labeling for Efficacy Supplements for Approved Generic Drug Products (§ 201.57)

The reporting burden for generic products subject to the requirements of the final rule has only been estimated for those products requiring revisions to their existing labeling. Reporting burdens for generating newly approved labeling for generic products (§ 314.94(8)) is already approved under OMB control number 0910-0001. According to the data in the economic analysis, beginning in year 3 and continuing throughout the 10-year period analyzed, approximately 42 generic applications per year must submit labeling supplements to comply with the final rule. For purposes of this analysis, approximately 336 already approved generic drug applications must submit labeling supplements over the 10-year period after the effective date of the rule. The time required to revise and submit this labeling to FDA would be approximately 27 hours per application, totaling 9,072 hours (see row 3 of table 2b). In addition to this burden, a minimal reporting burden

associated with a very small number of generic applications referencing older drugs may continue indefinitely.

f. Requirement That FDA-Approved Patient Labeling Accompany Prescription Drug Labeling Within 1 Year (§§ 201.57 and 201.80)

Within 1 year, all FDA-approved patient labeling must either accompany or be reprinted immediately following the prescription drug labeling (§§ 201.57(c)(18) and 201.80(f)(2)). An estimated 80 products will need to revise labeling as a result of this requirement. Approximately 18 applicants would be subject to this requirement. The agency estimates approximately 38 hours per product as a one-time labeling revision, totaling 3,040 hours (see row 4 of table 2b).

g. Annualized Adjustments to Estimated Burden Hours (§§ 201.56 and 201.57)

FDA must request an extension of approval of this information collection every three years. For purposes of OMB approval for the first three-year period, FDA divided the Total Hours in Table 2b (143,040 hours) by three to provide OMB an annualized estimate of burdens associated with labeling revisions to already-approved prescription drug products as a result of this final rule (47,680 hours). This annualized estimate was added to the total

estimated hours for new drug applications in Table 2a (47,680 hours + 358,343 hours = 406,023 hours). Therefore, FDA requested approval for a total of 406,023 hours.

Table 2a.--Estimated Reporting Burden for New Drug Applications¹

Category (21 CFR section)	Number of Respondents	Number of Responses per Respondent	Total Responses	Hours per Response	Total Hours
Annual burden associated with former labeling requirements (former 201.56(d) and 201.57)	85	1.26	107	3,200	342,400
Additional annual burden associated with requirements of this final rule (201.56(d) and 201.57)	85	1.26	107	149	15,943
Total				3,349	358,343

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2b.--Estimated Reporting Burdens for Labeling Revisions to Already-Approved Drug Products¹

Category (21 CFR section)	Year(s) In Which Burdens Occur Following Rule's Effective Date	Number of Respondents	Number of Responses per Respondent	Total Responses	Hours per Response	Total Hours	Total Capital Costs
Burden associated with revised labeling for applications approved within 5 years prior to the rule's effective date (201.57)	Beginning year 3, ending year 7	172	2.0	344	196	67,424	\$3.3 million
Burden associated	Beginning	172	1.88	324	196	63,504	\$2.5

with revised labeling for efficacy supplements submitted on or after the rule's effective date (201.56(d) and 201.57)	year 1, diminishing over time						million
Burden associated with revised labeling for efficacy supplements for generic drug products (201.57)	Beginning year 3, continuing annually thereafter	42	8	336 (for years 1-10)	27	9,072	\$2.5 million
Burden as a result of having FDA-approved patient labeling accompany drug labeling within 1 year (201.57(c)(18) and 201.80(f)(2))	Year 1 only	18	4.44	80	38	3,040	\$400,000
Total						143,040	Up to \$8.7 million (see table 17)

¹There are no operating and maintenance costs associated with this collection of information.

13. Estimates of Total Cost Burden to Respondents

FDA has estimated an average industry wage rate of \$50.00 per hour for preparing and submitting the information collection requirements under OMB Control Number 0910-0001. Using the averaged wage rate of \$50.00 per hour, and multiplied times the annual burden hours estimated in 12.g above, the total cost burden to respondents is \$20,301,150 (406,023 hours x \$50).

14. Estimates of Annualized Cost Burden to the Government

Using the estimate of \$50.00 per hour as the hourly wage for FDA reviewers to review labeling submissions under the proposal, and estimating that it takes an average of approximately 40 hours to review each of the estimated 1,191 submissions, the annualized cost to FDA as a result of this proposed rulemaking would be \$3,822,000 (40 hours x 1,911 submissions x \$50).

15. Changes In Burden

The changes in burden from the proposed rule are the result of accounting for:

- generic drug labeling changes inadvertently omitted from the proposed rule
- current estimates for current submissions
- removal of the proposed requirement for labeling not subject to the final rule to review and revise labeling if there are unsubstantiated claims within one year

16. Time Schedule, Publication, and Analysis Plans

There are no publications.

17. Displaying of OMB Expiration Date

The agency is not seeking to display the expiration date for OMB approval of the information collection.

18. Exception to the Certification Statement - Item 19

There are no exceptions to the certification statement identified in Item 19, "Certification for Paperwork Reduction Act Submission," of OMB Form 83-I.

PAPERWORK REDUCTION ACT SUBMISSION

Please read the instructions before completing this form. For additional forms or assistance in completing this form, contact your agency's Paperwork Clearance Officer. Send two copies of this form, the collection instrument to be reviewed, the supporting statement, and any additional documentation to: Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503.

1. Agency/Subagency originating request FDA	2. OMB control number b. <input type="checkbox"/> None a. <u>0910 - 0561</u>
3. Type of information collection (<i>check one</i>) a. <input checked="" type="checkbox"/> New Collection b. <input type="checkbox"/> Revision of a currently approved collection c. <input type="checkbox"/> Extension of a currently approved collection d. <input type="checkbox"/> Reinstatement, without change, of a previously approved collection for which approval has expired e. <input type="checkbox"/> Reinstatement, with change, of a previously approved collection for which approval has expired f. <input type="checkbox"/> Existing collection in use without an OMB control number For b-f, note Item A2 of Supporting Statement instructions	4. Type of review requested (<i>check one</i>) a. <input checked="" type="checkbox"/> Regular submission b. <input type="checkbox"/> Emergency - Approval requested by <u>at close of comment period</u> c. <input type="checkbox"/> Delegated 5. Small entities Will this information collection have a significant economic impact on a substantial number of small entities? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No 6. Requested expiration date a. <input checked="" type="checkbox"/> Three years from approval date b. <input type="checkbox"/> Other Specify: <u> </u> /
7. Title Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products	
8. Agency form number(s) (<i>if applicable</i>)	
9. Keywords: prescription drug labeling, FDA-approved patient labeling	
10. Abstract.	
11. Affected public (<i>Mark primary with "P" and all others that apply with "x"</i>) a. <input type="checkbox"/> Individuals or households b. <input checked="" type="checkbox"/> Business or other for-profit c. <input type="checkbox"/> Not-for-profit institutions d. <input type="checkbox"/> Farms e. <input type="checkbox"/> Federal Government f. <input type="checkbox"/> State, Local or Tribal Government	12. Obligation to respond (<i>check one</i>) a. <input type="checkbox"/> Voluntary- (guidance document) b. <input checked="" type="checkbox"/> Required to obtain or retain benefits c. <input type="checkbox"/> Mandatory
13. Total Reporting burden a. Number of respondents 172 b. Total responses <u>1,911</u> 1. Percentage of these responses collected electronically <u>approximately 75 %</u> c. Total hours requested <u>406,023</u> d. Current OMB inventory <u>no currently approved inventory</u> e. Difference f. Explanation of difference 1. Program change 2. Adjustment	14. Annual reporting and recordkeeping cost burden (<i>in thousands of dollars</i>) a. Total annualized capital/startup costs <u>0</u> b. Total annual costs (O&M) <u>0</u> c. Total annualized cost requested <u>0</u> d. Current OMB inventory <u>0</u> e. Difference <u>0</u> f. Explanation of difference 1. Program change 2. Adjustment
15. Purpose of information collection (<i>Mark primary with "P" and all others that apply with "X"</i>) a. <input type="checkbox"/> Application for benefits b. <input type="checkbox"/> Program evaluation c. <input type="checkbox"/> General purpose statistics d. <input type="checkbox"/> Audit e. <input type="checkbox"/> Program planning or management f. <input type="checkbox"/> Research g. <input checked="" type="checkbox"/> Regulatory or compliance	16. Frequency of recordkeeping or reporting (<i>check all that apply</i>) a. <input type="checkbox"/> Recordkeeping b. <input type="checkbox"/> Third party disclosure c. <input checked="" type="checkbox"/> Reporting 1. <input checked="" type="checkbox"/> On occasion 2. <input type="checkbox"/> Weekly 3. <input type="checkbox"/> Monthly 4. <input type="checkbox"/> Quarterly 5. <input type="checkbox"/> Semi-annually 6. <input type="checkbox"/> Annually 7. <input type="checkbox"/> Biennially 8. <input type="checkbox"/> Other (describe)
17. Statistical methods	18. Agency Contact (person who can best answer questions regarding

Does this information collection employ statistical methods <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	the content of this submission) Name: <u>Karen Nelson</u> Phone: <u>827-1482</u>
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1. Certification for Paperwork Reduction Act Submissions

On behalf of this Federal Agency, I certify that the collection of information encompassed by this request complies with 5 CFR 1320.9

NOTE: The text of 5 CFR 1320.9, and the related provisions of 5 CFR 1320.8(b)(3), appear at the end of the instructions. *The certification is to be made with reference to those regulatory provisions as set forth in the instructions.*

The following is a summary of the topics, regarding the proposed collection of information, that the certification covers:

- (a) It is necessary for the proper performance of agency functions;
- (b) It avoids unnecessary duplication;
- (c) It reduces burden on small entities;
- (d) It used plain, coherent, and unambiguous terminology that is understandable to respondents;
- (e) Its implementation will be consistent and compatible with current reporting and recordkeeping practices;
- (f) It indicates the retention period for recordkeeping requirements;
- (g) It informs respondents of the information called for under 5 CFR 1320.8(b)(3):
 - (i) Why the information is being collected;
 - (ii) Use of information;
 - (iii) Burden estimate;
 - (iv) Nature of response (voluntary, required for a benefit, mandatory);
 - (v) Nature and extent of confidentiality; and
 - (vi) Need to display currently valid OMB control number;
- (h) It was developed by an office that has planned and allocated resources for the efficient and effective management and use of the information to be collected (see note in Item 19 of instructions);
- (i) It uses effective and efficient statistical survey methodology; and
- (j) It makes appropriate use of information technology.

If you are unable to certify compliance with any of the provisions, identify the item below and explain the reason in Item 18 of the Supporting Statement.

Signature of Senior Official or designee

Date

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