Supporting Statement for Paperwork Reduction Act Submissions
Application for Permit to Import Controlled Substances for Domestic and/or Scientific Purposes pursuant to 21 U.S.C. 952
(DEA Form 357)
OMB Approval # 1117-0013

The Drug Enforcement Administration (DEA) seeks approval by the Office of Management and Budget (OMB) for a revision of an existing collection of information that was previously approved by OMB – OMB Approval # 1117-0013, Application for Permit to Import Controlled Substances for Domestic and/or Scientific Purposes pursuant to 21 (DEA Form 357).

Part A. Justification

1. Necessity of Information:

Section 1002 of the Controlled Substances Import and Export Act (CSIEA) (21 U.S.C. 952) and Title 21, Code of Federal Regulations (21 CFR), Sections 1312.11, 1312.12 and 1312.13 requires any person who desires to import controlled substances listed in schedules I or II, any narcotic substance listed in schedules III or IV, or any non-narcotic substance in schedule III which the Administrator has specifically designated by regulation in §1312.30, or any nonnarcotic substance in schedule IV or V which is also listed in schedule I or II of the Convention on Psychotropic Substances, must have an import permit. To obtain the permit to import controlled substances for domestic and or scientific purposes, an application for the permit must be made to the DEA on DEA Form 357.

2. Needs and Uses:

As part of the implementation of the ITDS, the DEA is mandating electronic filing of return information for any person who desires to import any controlled substance listed in schedule I or II or any narcotic controlled substance listed in schedule III, IV, or V or any non-narcotic controlled substance in schedule III which the Administrator has specifically designed by regulation in 21 CFR 1312.30 or any non-narcotic controlled substance in schedule IV or V which is also listed in schedule I or II of the Convention on Psychotropic Substances.

The DEA is adding § 1312.12(d) to provide clear instructions on the process of return information for controlled substances imported under permit procedures, which will be submitted electronically as part of the DEA Form 357. Specifically in § 1312.12(d), the DEA is requiring that within 30 calendar days of actual receipt of a controlled substance at the importers registered location, or within 10 calendar days after receipt of a written request by the Administration, whichever is sooner, the importer must report to the Administration through the DEA Diversion Control Division secure network application (available on the DEA Diversion Control Division Web site) that such import occurred and the details of the transaction.

This form and the information collection help maintain a closed system of distribution. DEA Form 357, Application for Permit to Import Controlled Substances for Domestic and/or Scientific Purposes, is intended to enable the DEA to monitor and control the importation of controlled substances exclusively for domestic and/or scientific purposes. Analysis of this document provides the DEA with important intelligence regarding the international commerce in controlled substances and assists in the identification of suspected points of diversion. The permit to import controlled substances for domestic and/or scientific purposes enables the DEA to enforce CSIEA.

3. Use of Information Technology:

With the implementation of ITDS, applications, declarations, and notices filed through the DEA Office of Diversion Control secure network application would generally not be deemed filed until the DEA assigns a single-use, randomly-generated, unique identifier. This identifier would be referenced as the "transaction identification number" except for permits, where the transaction identification number would continue to be called the "permit number" to correspond with current business practice. A permit number would be assigned once the DEA has approved an application for a permit. A transaction identification number would be assigned once the DEA reviews a declaration, notice, or other filing for completeness and it is accepted for filing. Although issuance of a transaction identification number would signify that the declaration, notice, or other filing has been reviewed for completeness, the issuance of the transaction identification number does not mean that such filing has been "approved" by the DEA. The DEA reserves the right to cancel an import or export permit or declaration for cause and suspend shipments of listed chemicals in accordance with applicable regulations.

This form is designed to require only the minimum essential data from the respondents for the DEA to exercise control over the suitability for issuance of an Import Permit. The reference DEA Form 357 is available on the DEA Diversion Control Program website (http://www.deadiversion.usdoj.gov). This form is partially interactive and can be completed electronically, printed, signed manually, and sent to the DEA. Currently, 9% of DEA form 357 is submitted electronically.

4. Efforts to Identify Duplication:

The DEA has made efforts to identify and prevent duplication of the collection of information. The existing DEA form 357 is not duplicative. The collection of this information is unique to the DEA.

5. Impact on Small Businesses or Entities:

This is a routine three-year renewal of DEA Form 357. The DEA does not anticipate any additional impact on small business or other small entities since the last approval of this form. The collection will not have a significant economic impact on small businesses or

other small entities within the meaning and intent of the Regulatory Flexibility Act, 5 U.S.C. 601-612.

6. Consequences of Less Frequent Collection:

The DEA uses the information collected to monitor the import of controlled substances. Information is provided each time the registrant proposes to import controlled substances and therefore cannot be collected less frequently. Failure to collect the information would impair the DEA's enforcement activities and violate the requirements imposed by the CSA and the United States' international obligations.

7. Special Circumstances Influencing Collection:

There are no special circumstances applicable to this information collection.

8. Consultation with persons outside the Agency:

The notice of proposed rulemaking on the Revision of Import and Export Requirements for Controlled Substances, Listed Chemicals, and Tableting and Encapsulating Machines, Including Changes To Implement the International Trade Data System; Revision of Reporting Requirements for Domestic Transactions in Listed Chemicals and Tableting and Encapsulating machines; and Technical Amendments (RIN 1117-AB41) was published in the Federal Register at 81 FR 63576, on September 15, 2016. The DEA received no comments concerning this collection.

The final rulemaking on the Revision of Import and Export Requirements for Controlled Substances, Listed Chemicals, and Tableting and Encapsulating Machines, Including Changes To Implement the International Trade Data System; Revision of Reporting Requirements for Domestic Transactions in Listed Chemicals and Tableting and Encapsulating machines; and Technical Amendments (RIN 1117-AB41) was published in the Federal Register at 81 FR 96992, on December 30, 2016. The DEA received no comments concerning this collection.

The DEA meets regularly with the affected industry to discuss policies, programs, and regulations. These meetings provide an open forum to discuss matters of mutual concern with representatives of those entities from whom the information is obtained.

9. Payment or Gift to Claimants:

This collection of information does not propose to provide any payment or gift to respondents.

10. Assurance of Confidentiality:

Information requested in this collection may be considered confidential business information if marked as such in accordance with 28 CFR 16.8(c) and Exemption 4 of the Freedom of Information Act (FOIA). Submitters who are required to furnish commercial or financial information to the government are protected from the competitive disadvantages that could result from disclosure of such information. The information is protected by the DEA through secure storage, limited access, and federal regulatory and DEA procedures. In the event a FOIA request is made to obtain information that has been designated as confidential business information per 28 CFR 16.8(c) and Exemption 4 of FOIA, the DEA will give written notice to the submitter to allow an opportunity to object within a reasonable time prior to any disclosure by the DEA.

11. Justification for Sensitive Questions:

This collection of information does not ask any questions of a sensitive nature.

12. Estimate of Hour Burden:

DEA Form 357 is submitted on an as-needed basis by registrants who desire to import schedules I or II, any narcotic substance listed in schedules III or IV, or any non-narcotic substance in schedule III or any nonnarcotic substance in schedule IV or V.

	Number of Annual Respondents*	Number of Annual responses	Average Time per Response (Hours)	Total Annual Hours
DEA-357 (paper)	151	1,213	0.25	303
DEA-357 (online)		119	0.25	30
Total	**151**	**1,332**	**0.25**	**333**

* Based on the number of unique registration numbers. A respondent may use paper or online forms. Separately counting the number of respondents for each version would result in multiple counts of the same respondent. Therefore, the number of combined respondents is used.

Total number of respondents:	151	
Number of responses per respondent per year:	8.8	(average)
Total annual responses	1,332	
Total annual hour burden	333	
Average burden, per collection:	0.25	
Average burden, per respondent:	2.2	
Total responses received on paper:	1,213	
Total responses received online:	119	
Percent of responses received online:	9%	

Burden dollars:

Estimate hourly wage ($/hour):[1]		$41.65
Load for benefits (percent of labor rate):[2]		43.5%
Loaded labor rate ($/hour):[3]		$59.76
Number of responses:		1,332
Burden per response (hours):		0.25
Burden dollars per response ($):	$	14.9390
Total burden dollars	**$**	**19,899**

13. Estimate of Cost Burden:

Respondents are not estimated to incur any additional start-up cost or capital expenditure as a result of this information collection. However, respondents are expected to incur shipping costs.

The vast majority of the paper responses are delivered to DEA by an express carrier with respondent-paid means for return delivery. The estimated cost burden is $19.50 per response.[4] The delivery cost of $19.50 per response applied to 1,213 paper responses results in a total cost burden of $23,653.50.

Estimated annual cost burden: $23,653.50

14. Estimated Annualized Cost to Federal Government:

Estimated annual production cost:

Item	Cost	
Printing	$	158
Mailing	$	1,332
Total	**$**	**1,490**

Estimated annual labor cost:

Labor Category	Number	Annual rate ($)	Load	% of time	Cost ($)
Unit Chief - GS-14	1	123,405	1.41	3%	5,229
Import/Export Specialist - GS-13	1	104,431	1.41	80%	118,001

1 Median hourly wage, Bureau of Labor Statistics, Occupational and Employment and Wages, May 2015, 11-3071 Transportation, Storage, and Distribution Managers (http://www.bls.gov/oes/current/oes_nat.htm).
2 Bureau of Labor Statistics, "Employer Costs for Employee Compensation – March 2016" (ECEC) reports that average benefits for private industry is 30.3% of total compensation. The 30.3% of total compensation equates to 43.5% (30.3% / 69.7%) load on wages and salaries.
3 $41.65 x (1 + 0.435) = $59.76.
4 2 x $9.75 = $19.50. $9.75 is based on a major express carrier's national 3-day flat rate for envelopes.

Labor Category	Number	Annual rate ($)	Load	% of time	Cost ($)
Program Analyst - GS-11	1	73,270	1.41	80%	82,791
Secretary, Contractor (GS-8 equivalent)	1	54,831	1.41	15%	11,617
Total					**217,638**

Total cost to government: $219,128

All costs are recovered from registrants through registration fees, as required by the CSA. 21 U.S.C. 886a.

15. Reasons for Change in Burden:

The increase in burden hours is due to an increase in the number of responses. The increase in the burden dollars is due to increase in burden hours, updated estimated shipping cost, and a change in calculation method.* There have been no statutory or regulatory changes affecting this information collection. The table below summarizes the changes since the last renewal of this information collection.

	2013 Approved Burden	2016 Requested Burden	Difference
Annual responses	1,265	1,332	67
Annual burden hours	316	333	17
Annual cost ($)	557	43,552	42,995

(*In prior information collection requests, the estimated labor burden was implied as a usual and customary business expense not directly associated with this information collection. The DEA believes the estimated labor burden associated with this information collection should be included. This change in calculation method is employed in this and future information collection requests.)

16. Plans for Publication:

The DEA will not publish the results of the information collected.

17. Expiration Date Approval:

The DEA does not object to OMB displaying the expiration date.

18. Exceptions to the Certification Statement:

The DEA is not seeking and exception to the certification statement “Certification for Paperwork Reduction Act Submissions” for this collection of information.

Part B. Statistical Methods

The DEA does not employ statistical methods in this information collection.