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

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 DEA on DEA Form 357. Also, by Executive Order of the President, DEA is required to streamline the export/import process and to utilize the International Trade Data System.

2. Needs and Uses:

DEA mandates 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.

In § 1312.12(d), DEA provides clear instructions on the process of return information for controlled substances imported under permit procedures, which is submitted electronically as part of DEA Form 357. Specifically in § 1312.12(d), DEA requires 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 DEA's Diversion Control Division secure network application (available on DEA Diversion Control Division Web site-(http://www.deadiversion.usdoj.gov) 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, enables DEA to monitor and control the importation of controlled substances exclusively for domestic and/or scientific purposes. Analysis of this document provides 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 DEA to enforce CSIEA.

3. Use of Information Technology:

Applications, declarations, and notices filed through DEA's Diversion Control Division secure network application is not be deemed filed until DEA assigns a single-use, randomly-generated, unique identifier. This identifier is referenced as the "transaction identification number" except for permits, where the transaction identification number continues to be called the "permit number" to correspond with current business practice. A permit number is assigned once DEA approves an application for a permit. A transaction identification number is assigned once DEA reviews a declaration, notice, or other filing for completeness and it is accepted for filing. Although issuance of a transaction identification number signifies 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 DEA. 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.

DEA Form 357 is designed to require only the minimum essential data from the respondents for DEA to exercise control over the suitability for issuance of an Import Permit. The reference DEA Form 357 is available on DEA's 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 DEA. Currently, 95% of DEA form 357 is submitted electronically.

4. Efforts to Identify Duplication:

DEA makes 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 DEA.

5. Impact on Small Businesses or Entities:

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

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 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:

DEA solicited public comment in the 60 Day Notice of Information Collection that was published in the *Federal Register* at 85 FR 34237, on June 3, 2020. DEA received no comments concerning this collection.

The 30 Day Notice of Information Collection was published in the *Federal Register* at 85 FR 48270, on August 10, 2020.

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 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, DEA will give written notice to the submitter to allow an opportunity to object within a reasonable time prior to any disclosure by 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)	171	104	0.35	36
DEA-357 (online)		1,845	0.25	461
Total	**171**	**1,949**	**0.26**	**497**

Total number of respondents:	171	
Number of responses per respondent per year:	11.3 977	(average)
Total annual responses	1,949	
Total annual hour burden	497	
Average burden, per collection:	0.255	
Average burden, per respondent:	2.9	
Total responses received on paper:	104	
Total responses received online:	1,849	
Percent of responses received online:	95%	

Burden dollars:

Estimate hourly wage ($/hour):[1]	$45.46
Load for benefits (percent of labor rate):[2]	42.7%
Loaded labor rate ($/hour):[3]	$64.87
Number of responses:	1,949

1 Median hourly wage, Bureau of Labor Statistics, Occupational and Employment and Wages, May 2019, 11-3071 Transportation, Storage, and Distribution Managers (https://www.bls.gov/oes/current/oes_nat.htm).

2 Bureau of Labor Statistics, "Employer Costs for Employee Compensation – December 2019" (ECEC) reports that average benefits for private industry is 29.9% of total compensation. The 29.9% of total compensation equates to 42.7% (29.9% / 70.1%) load on wages and salaries.

3 $45.46 x (1 + 0.427) = $64.87.

Burden per response (hours):	0.255
Burden dollars per response ($):	$ 16.54
Total burden dollars	**$ 32,236**

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 104 paper responses results in a total cost burden of $2,028.

Estimated annual cost burden: $2,028

14. Estimated Annualized Cost to Federal Government:

Estimated annual labor cost:

Labor Category	Number	Annual rate ($)*	Load**	% of time	Cost ($)
Staff Coordinator - GS-14	1	137,491	1.605	3%	6,621
Import/Export Specialist - GS-13	1	116,353	1.605	80%	149,410
Program Analyst - GS-11	1	81,634	1.605	80%	104,827
Secretary, Contractor (GS-8 equivalent)	1	61,088	1.605	15%	14,708
Total					**275,566**

*Government salary figures are based on Washington, DC locality pay at step 5 for each grade level.
**Load of 60.5% for benefits based on the ECEC for "State and local government." The ECEC does not include figures for the Federal Government.

Total cost to government: $275,566

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 annual responses and annual burden hours reflect adjustments related to normal business activity. The decrease in the burden dollars is due to the elimination of most of shipping cost per paper response as most responses have moved to electronic responses, 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.

4 2 x $9.75 = $19.50. $9.75 is based on a major express carrier's national 3-day flat rate for envelopes.

	2017 Approved Burden	2020 Requested Burden	Difference
Annual responses	1,332	1,949	617
Annual burden hours	333	497	164
Annual cost ($)	43,552	32,236	(11,316)

(*The annual cost ($) in the 2017 approved burden includes the estimated cost burden. The cost burden is excluded in the annual cost for the 2020 requested burden. This change in calculation method is employed in this and future information collection requests.)

16. Plans for Publication:

DEA will not publish the results of the information collected.

17. Expiration Date Approval:

DEA does not object to OMB displaying the expiration date.

18. Exceptions to the Certification Statement:

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

DEA does not employ statistical methods in this information collection.