

**SUPPORTING STATEMENT FOR
Application for Permit to Import Controlled Substances for Domestic and/or Scientific
Purposes pursuant to 21 U.S.C. 952 – DEA Form 357**

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).

A. JUSTIFICATION

1. 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. 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. 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. 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. 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. 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. There are no special circumstances applicable to this information collection.

8. The 60-Day Notice was published in the Federal Register on September 11, 2023 (88 FR 62397). The comment period ended on November 13, 2023. No comments were received.

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

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

12.

Estimated Annualized Respondent Cost and Hour Burden

Activity	Number of Respondents	Frequency	Total Annual Responses	Time Per Response	Total Annual Burden (Hours)	Hourly Rate ¹	Monetized Value of Respondent Time ²
DEA-357 (paper)	124	8.3	71	21min	24.85	67.6744408	\$1,682
DEA-357 (online)			958	15min	239.50	67.6744408	\$16,208
Unduplicate d Totals	124		1,029	0.26	264.35		\$17,890

Total number of respondents: 124
 Number of responses per respondent per year: 8.2983
 87097 (average)

¹ Median hourly wage, Bureau of Labor Statistics, Occupational and Employment and Wages, May 2022, 11-3071 Transportation, Storage, and Distribution Managers (https://www.bls.gov/oes/current/oes_nat.htm).

² Monetized value is based on the loaded wage multiplied by the total annual burden, in hours. Bureau of Labor Statistics, “Employer Costs for Employee Compensation – March 2023” (ECEC) reports that average benefits for private industry is 29.97% of total compensation. The 29.97% of total compensation equates to 42.8% (29.97% / 70.07%) load on wages and salaries. The median wage of \$47.39 times (1 + 0.428) = \$67.67 per hour for the loaded wage.

Total annual responses	1,029
Total annual hour burden	264.35
Average burden, per collection:	0.255
Average burden, per respondent:	2.1575 8
Total responses received on paper:	71
Total responses received online:	958
Percent of responses received online:	93.1%

Burden dollars:

Estimate hourly wage (\$/hour):	\$47.39
Load for benefits (percent of labor rate):	<u>42.8%</u>
Loaded labor rate (\$/hour):	\$67.67
Number of responses:	1,029
Burden per response (hours):	0.2569
Burden dollars per response (\$):	\$ 17.3856
Total burden dollars	\$ 17,889.74

13. There are no start up costs associated with this 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 \$19.50³ per response applied to 71 paper responses results in a total cost burden of \$1,385. Therefore, the average cost burden is \$1.28076 per response.

14. The estimated annual cost to the Federal Government is \$454,351. This includes annual salaries for a GS-14 Staff Coordinator, GS-13 Import/Export Specialist, GS-13 Program Analyst, GS-12 Program Analyst, and GS-8 equivalent secretary. The two program analysts will be full time, while the other three staff members will provide part-time labor support equivalent to between 3% and 15% of their total annual labor.

Labor Category	Number	Annual Rate (\$)*	Load**	% of Time	Cost (\$)
Staff Coordinator - GS-14	1	150,016.00	1.74146493	3%	7,837
Import/Export Specialist - GS-13	1	126,949.00	1.74146493	10%	22,108
Program Analyst - GS-12	1	106,759.00	1.74146493	100%	185,917

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

Program Analyst - GS-13	1	126,949.00	1.74146493	100%	221,077
Secretary, Contract or (GS-8 equiv)	1	66,654.00	1.74146493	15%	17,411
Total	5				454,351

*Government salary figures are based on Washington, DC locality pay at step 5 for each grade level.

**Load of 74.15% for benefits based on the ECEC for “State and local government.” The ECEC does not include figures for the Federal Government.

15. The decrease 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.

	2020 Approved Burden	2023 Requested Burden	Difference
Annual responses	1,949	1,029	-920
Annual burden hours	497	264	-233
Annual cost (\$)	32,236	17,890	-14,346

(*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. DEA will not publish the results of the information collected.

17. DEA does not object to displaying the expiration date for this collection.

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

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS.

This collection does/does not contain statistical data.