

Supporting Statement for Paperwork Reduction Act Submissions
Controlled Substances Import/Export Declaration
(DEA Form 236)
OMB Approval # 1117-0009

The Drug Enforcement Administration (DEA) seeks approval by the Office of Management and Budget (OMB) for an existing collection of information that was previously approved by OMB – OMB Approval # 1117-0009, Controlled Substances Import/Export Declaration (DEA Form 236).

Part A. Justification

1. Necessity of Information:

DEA Form 236 provides DEA with oversight and control over the importation and exportation of controlled substances. 21 CFR part 1312, promulgated pursuant to 21 U.S.C. 952 and 21 U.S.C. 953, requires registrants who desire to import non-narcotic substances in schedules III, IV, and V or to export non-narcotic substances in schedules III and IV and any other substance in schedule V, to furnish a controlled substances import declaration/controlled substances export invoice on a DEA Form 236 (if those activities are not otherwise subject to import/export permit requirements). In addition, Article 12 of the Convention on Psychotropic Substances of 1971 (Convention) requires a system of export declarations for certain substances controlled under the Convention.

2. Needs and Uses:

DEA Form 236 enables DEA to monitor and control the importation and exportation of controlled substances. Analysis of these documents provides DEA with important intelligence regarding the international commerce in controlled substances and assists in the identification of suspected points of diversion. In addition, the compiled data is reported to the International Narcotics Control Board annually, as required by Article 16 of the Convention. Failure to require import/export declarations, and the information provided thereon, would violate the requirements imposed by the Controlled Substances Act (CSA) and the United States' international obligations.

3. Use of Information Technology:

The DEA Form 236 is available to be submitted through the Diversion Control Division secure network application on DEA's Diversion Control Program web site (<http://www.deadiversion.usdoj.gov>). Currently, 100% of DEA Forms 236 are submitted electronically.

4. Efforts to Identify Duplication:

DEA has made efforts to identify and prevent duplication of the collection of information. The existing DEA Form 236 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 236. DEA does not anticipate any additional impact on small businesses or other small entities since the initial 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:

DEA uses the information collected to monitor the import and export of controlled substances. Information is provided each time the registrant proposes to import or export 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:

Public comment was solicited in the 60-day Notice of Information Collection in the *Federal Register* at 85 FR 34241, which published on June 3, 2020. DEA did not receive any comments concerning this collection. The 30-day Notice of Information Collection was published in the *Federal Register* at 85 FR 48267, 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 236 is submitted on an as-needed basis by registrants who desire to import non-narcotic substances in schedules III, IV, and V or to export non-narcotic substances in schedules III and IV and any other substance in schedule V.

	Number of Annual Respondents	Number of Annual Responses	Average Time per Response (hour)	Total Annual Hours
DEA-236	323	8,154	0.25	2,039
Total	323	8,154		2,039

Total number of respondents: 323

Number of responses per respondent per year: 25.2446 (average)

Total annual responses: 8,154

Total annual hour burden: 2,039

Average Burden: Per Collection: 0.25 hour

Per Respondent: 6.3111 hour

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
Total annual burden dollar:	\$132,258
Average burden dollars per collection:	\$16.22

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.

14. Estimated Annualized Costs to Federal Government:

Estimated Annual Labor Cost to Government:

Labor Category	Number	% of time	Cost⁴
Program Analyst – GS-13	1	100%	\$ 186,762
Import Export Specialist – GS-13	1	100%	\$ 186,762
Total:			\$ 373,525

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

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 \times (1 + 42.7\%) = \64.85 .

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

15. Reasons for Change in Burden:

The increase in annual responses and annual burden hours reflects adjustments related to normal business activity. The decrease in the burden dollars is due to the elimination of estimate for shipping cost per paper response 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.

	2017 Approved Burden	2020 Requested Burden	Difference
Annual responses	6,32 1	8,15 4	1,83 3
Annual burden hours	1,77 9	2,03 9	26 0
Annual cost (\$)	144,83 4	132,25 8	(12,576)

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 an exception for this collection of information.

Part B. Statistical Methods

DEA does not employ statistical methods in this information collection.