

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 the 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 the DEA to monitor and control the importation and exportation of controlled substances. Analysis of these documents provides the 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 (INCB) 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 referenced DEA Form 236 is available to be submitted through the DEA Office of Diversion Control secure network application on the DEA Diversion Control Program web site (<http://www.deadiversion.usdoj.gov>). Currently, 37% of DEA Forms 236 are 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 236 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 236. The 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:

The 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 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:

Public comment was solicited in the 60-day Federal Register Notice of Information Collection, 81 FR 38219, published on June 13, 2016 and the 30-day Federal Register Notice of Information Collection, 81 FR 53165, published on August 11, 2016. The DEA did not receive any 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 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	Total Annual Hours
DEA 236 (paper)	90	3,969	0.3 hours (18 minutes)	1,191
DEA 236 (electronic)	67	2,352	0.25 hours (15 minutes)	588
Total	157	6,321		1,779

Total number of respondents: 157

Number of responses per respondent per year: 40.3 (average)

Total annual responses: 6,321

Total annual hour burden: 1,779

Average Burden: Per Collection: 0.28 hour

Per Respondent: 11.3 hour

Total responses received on paper: 3,969

Total responses received electronically: 2,352

Percentage of responses received electronically: 37%

Burden dollars:

Estimate hourly wage (\$/hour): ¹	\$41.65
Load for benefits (percent of labor rate): ²	43.3%
Loaded labor rate (\$/hour): ³	\$59.67
Total annual burden dollar:	\$106,136
Average burden dollars per collection:	\$16.79

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. The estimated cost burden is \$9.75 per response.⁴ The delivery cost of \$9.75 per response applied to 3,969 paper responses results in a total cost burden of \$38,698.

Estimated annual cost burden: \$38,698

14. Estimated Annualized Costs to Federal Government:

Estimated Annual Labor Cost to Government:

Labor Category	Number	% of time	Cost⁵
Program Analyst – GS-13	1	100%	\$ 147,501
Import Export Specialist – GS-13	1	100%	\$ 147,501
Total:			\$ 295,003

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 – December 2015” (ECEC) reports that average benefits for private industry is 30.2% of total compensation. The 30.2% of total compensation equates to 43.3% (30.2% / 69.8%) load on wages and salaries.

3 $\$41.65 \times (1 + 0.433) = \59.67 .

4 Based on a major express carrier’s national 3-day flat rate for envelopes.

5 Government salary figures are based on Washington, DC locality pay at step 5 for each grade level and include 41% load for benefits based on the ECEC for “State and local government” (adjusted for paid leave). The ECEC does not include figures for the Federal Government.

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:

There was a decimal placement error in the 2014 approved burden for annual burden hours. The correct burden hours is 1,502 ($1,415.1 + 86.75 = 1,502$, not $1,415.1 + 867.5 = 2,283$). The change in burden hour reflects the correction of this error and an increase in the number of responses. The increase in the burden dollars is due to higher estimate for shipping cost per paper response and a change in calculation method.* Because the vast majority of paper responses are delivered via express carrier, the delivery cost per paper response was adjusted from \$0.49 (postage) to \$9.75. 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.

	2014 Approved Burden	2016 Requested Burden	Difference
Annual responses	5,064	6,321	1,257
Annual burden hours	2,283	1,779	(504)
Annual burden dollars (\$)	60,570	144,834	84,264

(*In prior information collection requests, the estimated cost burden was described as “a usual and customary business expense not directly associated with this information collection.” The DEA believes the estimated cost 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 an 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.