

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 a revision of 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.

As part of the implementation of the International Trade Data System (ITDS), the DEA is mandating electronic filing of return information for any person who desires 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 substance export invoice on a DEA Form 236.

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 provide 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.

The DEA is amending to § 1312.18(e) to provide clear instructions on the process of return information for controlled substances imported under declaration procedures, which will be submitted electronically as part of the DEA Form 236 (Import declaration). The amended regulation states that within 30 calendar days of the actual import, or within 10 calendar days after the receipt of a written request by the

Administration to the importer, whichever is sooner, the importer must report to the Administration utilizing the secure network application available on the DEA Office of Diversion Control Web site certifying that such import occurred and the details of the transaction. The report must include information relating to key dates of the transaction and actual quantities involved in the import process.

The DEA is amending to § 1312.27(d) in the final rule to provide clear instructions on the process of return information for controlled substances exported and reexported under declaration procedures, which will be submitted electronically as part of the DEA Form 236 (Export declaration). The amended regulation states that within 30 calendar days after the controlled substance is exported or within 10 calendar days after receipt of a written request by the Administration to the exporter, whichever is sooner, the exporter must report to the Administration through the DEA Office of Diversion Control Web secure network application (available on the DEA Office of Diversion Control Web site) certifying that such export has occurred and the details of the transaction. The report must include information relating to key dates of the transaction and actual quantities involved in the import process. For reexports under declaration procedures, the amended regulation states that within 30 calendar days after the controlled substance is exported from the first country to the second country, or within 10 calendar days after the receipt of a written request by the Administration to the exporter, whichever is sooner, the exporter must report to the Administration through the DEA Office of Diversion Control Web secure network application (available on the DEA Office of Diversion Control Web site) certifying that such export from the first country has occurred and the details of the transaction. The report must include the name of the second country and the quantity shipped.

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.

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 revision 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:

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 236 is submitted on an as-needed basis by any person who desires 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 substance export invoice.

	Number of Annual Respondents	Number of Annual responses	Average Time per Response (Hrs)	Total Annual Hours
DEA 161	341	6,026	0.25	1,507
Total	341	6,026		1,507

Total number of respondents: 341
Total annual responses 6,026
Number of responses per respondent per year: 17.7 (average)
Total annual hour burden 1,507

Average burden, per collection (hrs): 0.25
Average burden, per respondent (hrs): 4.42

Burden dollars:

Estimate hourly wage (\$/hour): ¹	\$36.13
Load for benefits (percent of labor rate): ²	44.1%
Loaded labor rate (\$/hour): ³	\$52.06
Number of responses:	6,026
Burden per response (hours):	0.25
Burden dollars per response:	<u>\$ 13.0151</u>
Total burden dollars	\$ 78,429

13. Estimate of Cost Burden:

The estimated annual cost burden is zero. Respondents are not estimated to incur any a) additional start-up cost or capital expenditure, or b) additional operation and maintenance costs or purchase services as a result of this information collection.

14. Estimated Annualized Cost to Federal Government:

Estimated Annual Cost to Federal Government:

Labor Category	Number	Annual rate (\$) ⁴	Load ⁵	% of time	Cost (\$)
Program Analyst – GS-13	1	104,431	1.41	100%	147,501
Import/Export Specialist – GS-13	1	104,431	1.41	100%	147,501
Total					295,003

Total cost to government: 295,003

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

15. Reasons for Change in Burden:

Although there is an increase in the number of responses, the decrease in burden hours is due to all responses being submitted on line and the reduced time to complete online

1 Median hourly wage, Bureau of Labor Statistics, Occupational and Employment and Wages, May 2014, 41-4011 Sales Representatives, Wholesale and Manufacturing, Technical and Scientific Products (http://www.bls.gov/oes/current/oes_nat.htm).

2 Bureau of Labor Statistics, “Employer Costs for Employee Compensation – December 2014” (ECEC) reports that average benefits for private industry is 30.2% of total compensation. The 30.6% of total compensation equates to 44.1% (30.6% / 69.4%) load on wages and salaries.

3 $\$36.13 \times (1 + 0.441) = \52.06 .

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

5 The ECEC does not include figures for the Federal Government, 41% load for benefits based on the ECEC for “State and local government” (adjusted for paid leave).

forms. The increase in the burden dollars is due to a change in calculation method.* There have been no statutory changes affecting this information collection. The main regulatory change affecting this information collection is the mandatory use of online DEA Form 236 as part of the implementation of ITDS. . 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	6,026	962
Annual burden hours	2,283	1,507	(777)
Annual cost (\$)	60,570	78,429	17,859

(*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.