

Supporting Statement for Paperwork Reduction Act Submissions
Import/Export Declaration for List I and List II Chemicals
(DEA Form 486 and DEA Form 486A)
OMB Approval # 1117-0023

The Drug Enforcement Administration (DEA) seeks approval by the Office of Management and Budget (OMB) for a revision an existing collection of information that was previously approved by OMB – OMB Approval # 1117-0023, Import/Export Declaration for List I and List II Chemicals (DEA Forms 486 and 486A).

Part A. Justification

1. Necessity of Information:

The DEA import/export declarations (DEA Forms 486 and 486A), will be replaced with an electronic process. Upon receipt of a complete declaration through the Diversion Control Division secure network application, DEA will provide the importer or exporter with the notice of receipt that must then be filed with Custom Border Patrol as part of the CBP import or export filing through Automated Commercial Environment (ACE), or any successor system. DEA will also transmit the declaration information electronically to CBP so that customs officers can validate importations and exportations subject to DEA regulations.

Because of the requirement that regulated persons submit reports of regulated transactions in Listed chemicals to the DEA, the DEA is requiring such domestic regulated transaction reports to be submitted through the DEA Diversion Control Division secure network application, in addition to import and export regulated transactions. Mandatory reporting requirements for domestic regulated transactions are included as part of this rule because it allows for the DEA to create, at one time, an efficient, streamlined reporting structure of regulated activities applicable to tableting and encapsulating machines.

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 DEA Forms 486 and 486A.

2. Needs and Uses:

The DEA is amending part 1313 to provide that each regulated person who seeks to import or export a listed chemical that meets or exceeds a threshold quantity, must notify/provide a declaration to the DEA (by filing a DEA Form 486/486A through the DEA Diversion Control Division secure network application) of the intended import or export not later than 15 calendar days before the date of release by a customs officer at the port of entry. Regarding imports and exports for those entities with regular customer and regular importer status, the notification must be filed at least three business days before the date of release by a customs officer at the port of

entry. All declarations must be signed and dated by the importer or exporter and must contain the address of the final destination for the shipment. The DEA is specifying that all listed chemical declarations expire in 180 calendar days, consistent with the controlled substance import/export permits. If release by a customs officer will occur more than 180 calendar days after the declaration is deemed filed, the declarant must submit a new declaration for the transaction.

In § 1313.32 the DEA is incorporating the mandatory electronic filing of notifications of international transactions involving listed chemicals which meet or exceed the threshold amount identified in § 1310.04. The broker or trader must notify the DEA (by filing a DEA Form 486 through the DEA Diversion Control Division secure network application) of the intended international transaction not later than 15 calendar days before the transaction is to take place. The DEA is amending § 1313.32 to require that notifications of international transactions would not be deemed filed until a transaction identification number has been issued by the DEA. This change is designed to ensure that electronically submitted notifications are received by the DEA, are completed, and can be appropriately tracked and monitored; to streamline the notification filing process; and eliminate duplicate filings.

3. Use of Information Technology:

As part of the implementation of the International Trade Data System (ITDS), the DEA will require mandatory electronic submissions of DEA Forms 486 and 486a. Respondents create accounts on the DEA Office of Diversion Control Web site (<http://www.deadiversion.usdoj.gov>). The accounts are used to submit forms and update contact information. Approximately 100% of forms 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 486/486A 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 486/486A. 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 listed chemicals. Information is provided each time the registrant proposes to import or export listed chemicals 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 Controlled Substance Act (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 3 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 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. This 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 in accordance with 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.

Loaded labor rate (\$/hour): ³	\$59.67		
	<u>DEA 486</u>	<u>DEA 486A</u>	<u>Total</u>
Number of responses	12,912	749	13,661
Total annual hours	3,769	300	4,069
Average burden per response (hour)	0.2919	0.4000	
Burden dollars per response (\$)	\$ 17.4182	\$ 23.8682	
Total burden dollars	\$ 224,904	\$ 17,877	\$ 242,781

13. Estimated Cost of 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:

Cost to Federal Government:

Labor Category	Number	Annual rate	Load	% of time	Cost ⁴
Unit Chief - GS-14	1	\$ 123,405	1.41	20%	\$ 34,860
Technical Information Specialist - GS-14	1	\$ 123,405	1.41	20%	\$ 34,860
Import/Export Specialist - GS-13	3	\$ 104,431	1.41	100%	\$ 442,504
Secretary - GS-7	1	\$ 49,506	1.41	5%	\$ 3,496
Total					\$ 515,721

All costs to the Federal Government for these activities are recovered from registrants through registration fees, as required by the Controlled Substance Act (CSA). 21 U.S.C. 886a.

15. Reasons for Change in Burden:

There is no change in estimated number of annual responses and associated burden hours and

³ \$41.65 x (1 + 0.433) = \$59.67 (0.433 is rounded).

⁴ 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.

burden dollars. 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.

	2016 Approved Burden	2017 Requested Burden	Difference
Annual Responses	13,661	13,661	0
Annual burden hours	4,422	4,422	0
Annual burden dollars	\$242,781	\$242,781	\$0

16. Plans for Publication:

The DEA will not publish the results of the information collected.

17. Expiration Date of Approval:

The DEA does not object to the 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 Drug Enforcement Administration does not employ statistical methods in this information collection.