

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:

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

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

Additionally, DEA mandates 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:

DEA amended 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 DEA (by filing a DEA Form 486/486A through 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. DEA specifies 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 DEA incorporates 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 DEA (by filing a DEA Form 486 through 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. DEA amends § 1313.32 to require that notifications of international transactions are not deemed filed until a transaction identification number has been issued by DEA. This change is designed to ensure that electronically submitted notifications are received by 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:

DEA requires mandatory electronic submissions of DEA Forms 486 and 486a. Respondents create accounts on DEA Office of Diversion Control Web site (<http://www.deadiversion.usdoj.gov>). The accounts are used to submit forms and update contact information. One hundred percent (100%) of forms 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 486/486A 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 486/486A. DEA does not anticipate any additional impact on small businesses or other small entities since the initial 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. Consequences of Less Frequent Collection:

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 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:

DEA solicited public comment in the 60 Day Notice of Information Collection that was published in the *Federal Register* at 85 FR 34239, on June 3, 2020. DEA received no comments concerning this collection.

The 30 Day Notice of Information Collection was published in the *Federal Register* at 85 FR 48269, 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. This 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 in accordance with 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. Estimated Hour Burden:

Respondents report imports, exports and international transactions of listed chemicals using DEA Forms 486 and 486A:

The below table presents information regarding the number of respondents, responses, and associated burden hours.

	Number of Annual Respondents	Number of Annual responses	Average Time per Response (hours)	Total Annual Hours
DEA-486 - Import	132	2,153	0.33 (20 minutes)	718
DEA-486 - Export	227	13,142	0.28 (17 minutes)	3,724
DEA-486 - International	20	424	0.28 (17 minutes)	120
DEA-486A - Import	38	697	0.40 (24 minutes)	279
Total	417	16,416		4,840

Total number of respondents: 417

Number of responses per respondent per year: 39.367 (average)

Total annual responses: 16,416

Total annual hour burden: 4,840

Average Burden: Per Collection: 0.29484 hour
Per Respondent: 11.6 hour

Total responses received on paper: 0

Total responses received electronically: 16,416

Percentage of responses received electronically: 100%

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

	<u>DEA 486</u>	<u>DEA 486A</u>	<u>Total</u>
Number of responses	15,719	697	16,416
Total annual hours	4,561	279	4,840
Average burden per response (hour)	0.2901		
	82	0.4000	
Burden dollars per response (\$)	\$ 18.82	\$ 25.95	
Total burden dollars	\$ 295,832	\$ 18,087	\$ 313,919

Average cost burden per response: \$19.12273 (calculated)

13. Estimated Cost of Burden:

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 + 0.427) = \64.87 .

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
Staff Coordinator - GS-14	1	\$ 137,491	1.605	20%	\$ 44,138
Technical Information Specialist - GS-14	1	\$ 137,491	1.605	20%	\$ 44,138
Import/Export Specialist - GS-13	3	\$ 116,353	1.605	100%	\$ 560,287
Secretary - GS-7	1	\$ 55,158	1.605	5%	\$ 4,427
Total					\$ 652,991

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

**Load of 60.5% for benefits based on the ECEC for “State and local government.” The ECEC does not include figures for the Federal Government.

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:

The increase in annual responses, annual burden hours, and annual cost reflect adjustments related to normal business activity. 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	13,661	16,416	2,755
Annual burden hours	4,422	4,840	418
Annual cost (\$)	242,781	313,919	71,138

16. Plans for Publication:

DEA will not publish the results of the information collected.

17. Expiration Date of Approval:

DEA does not object to the OMB displaying the expiration date.

18. Exceptions to the Certification Statement:

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.