

**Supporting Statement for Paperwork Reduction Act Submissions**  
**Application for Permit to Export Controlled Substances (DEA Form 161)**  
**Application for Permit to Export Controlled Substances for Subsequent Reexport (DEA**  
**Form 161R)**  
**OMB Approval # 1117-0004**

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 # 1117-0004, Application for Permit to Export Controlled Substances (DEA Form 161) Application for Permit to Export Controlled Substances for Subsequent Reexport (DEA Form 161R).

**Part A. Justification**

1. Necessity of Information:

Section 1003 of the Controlled Substances Import and Export Act (CSIEA) (21 U.S.C. 953) and Title 21, Code of Federal Regulations (21 CFR), Sections 1312.21 and 1312.22 require that any person who desires to export or reexport controlled substances listed in schedules I or II, any narcotic substance listed in schedules III or IV, or any non-narcotic substance in schedule III which the Administrator has specifically designated by regulation in §1312.30, or any non-narcotic substance in schedule IV or V which is also listed in schedule I or II of the Convention on Psychotropic Substances, must have an export permit. To obtain the export permit, an application for the permit must be made to the DEA on DEA Form 161 for exports, and DEA Form 161R for reexports.

2. Needs and Uses:

These forms and the information collection help maintain a closed system of distribution. DEA Form 161, Application for Permit to Export Controlled Substances, and DEA Form 161R, Application for Permit to Export Controlled Substances for Subsequent Reexport, are intended to enable the DEA to monitor and control the export of certain controlled substances to other countries. This information is also necessary for the DEA to prepare a Permit to Export, DEA Form 36, which is required in order to lawfully export specific controlled substances. The permit for exportation and reexportation of specific controlled substances enables the DEA to enforce the CSIEA.

3. Use of Information Technology:

These forms are designed to require only the minimum essential data from the respondents for the DEA to exercise control over the export and reexport of certain controlled substances. The DEA Form 161 is available on the DEA Diversion Control Program web site (<http://www.deadiversion.usdoj.gov>). The electronic version of the DEA Form 161R is currently being developed. Additionally, interactive versions of the forms can be completed electronically, printed, signed manually, and sent to the DEA. Currently, 34% of DEA Form 161 and 0% of DEA Form 161R are submitted electronically for a combined rate of 29%. Respondents have the

option to submit the return information (Certificate of Exportation/Reexportation) online, by mail or by email.

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4. Efforts to Identify Duplication:

The DEA has made efforts to identify and prevent duplication of the collection of information. The existing DEA Forms 161 and 161R are 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 Forms 161 and 161R. The DEA does not anticipate any additional impact on small businesses or other small entities since the initial approval of this form, accordingly, 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:

Information is provided by registrants each time registrants propose to export or reexport certain controlled substances and therefore cannot be collected less frequently. The Attorney General may authorize any controlled substance that is in schedule I or II, or is a narcotic drug in schedule III or IV, to be exported from the United States to a country for subsequent export from that country to another country. Within 30 days after the controlled substance is exported from the first country to the second country, the person who exported the controlled substance from the United States delivers to the Attorney General documentation certifying that such export from the first country has occurred. 21 USC 953(f)(6). This is required by statute. Failure to collect the information would impair the DEA's enforcement of the statute and compliance with requirements under international treaties. Businesses and other for-profit entities participating in this information collection maintain the requested data as part of usual and customary business practices.

7. Special Circumstances Influencing Collection:

2. 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 38220, published June 13, 2016 and the 30-day Federal Register Notice of Information Collection, 81 FR 53163, published 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:

3. 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.

12. Estimated Hour Burden:

DEA Forms 161 and 161R are submitted on an as-needed basis by registrants who desire to obtain a permit to export or reexport controlled substances listed in schedules I or II, any narcotic substance listed in schedules III or IV, or any non-narcotic substance in schedule III which the Administrator has specifically designated by regulation in §1312.30, or any non-narcotic substance in schedule IV or V which is also listed in schedule I or II of the Convention on Psychotropic Substance.

	<b>Number of Annual Respondents*</b>	<b>Number of Annual responses</b>	<b>Average Time per Response</b>	<b>Total Annual Hours</b>
DEA 161 (paper)	134	3,377	0.5	1,689
DEA 161 (electronic)		1,769	0.5	885
DEA 161R (paper)		970	0.75	728
<b>Total</b>	<b>134</b>	<b>6,116</b>		<b>3,301</b>

\* Based on the number of registration numbers. A respondent may use any of the three form/versions above. Separately counting the number of respondents for each form/version would result in multiple counts of the same respondent. Therefore, the number of combined respondents is used.

Total number of respondents: 134

Number of responses per respondent per year: 45.6 (average)

Total annual responses: 6,116  
Total annual hour burden: 3,301

Average Burden: Per Collection: 0.54 hour  
Per Respondent: 24.6 hour

Total responses received on paper: 4,347  
Total responses received electronically: 1,769  
Percentage of responses received electronically: 29%

Burden dollars:

Estimate hourly wage (\$/hour): <sup>1</sup>	\$41.65		
Load for benefits (percent of labor rate): <sup>2</sup>	43.3%		
Loaded labor rate (\$/hour): <sup>3</sup>	\$59.67		
	<u>DEA 161</u>	<u>DEA 161R</u>	<u>Total</u>
Number of responses:	5,146	970	6,116
Burden per response (hours):	0.5	0.75	
Burden dollars per response (\$):	\$ 29.8352	\$ 44.7529	
Total burden dollars	\$ 153,532	\$ 43,410	196,942

### 13. Estimated Cost of 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 is delivered to DEA by an express carrier with respondent-paid means for return delivery. The estimated cost burden is \$19.50 per response.<sup>4</sup> The delivery cost of \$19.50 per response applied to 4,347 paper responses results in a total cost burden of \$84,766.50.

Estimated annual cost burden: \$84,766.50

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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](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  $42 \times \$9.75 = \$409.50$ . \$9.75 is based on a major express carrier's national 3-day flat rate for envelopes.

**Total burden dollars plus cost of burden:**

	DEA 161	DEA 161R	Total
Number of responses	5,146	970	6,116
Responses with shipping cost	3,377	970	4,347
Total shipping cost	\$ 65,852	\$ 18,915	\$ 84,767
Total burden dollars	\$ 153,532	\$ 43,410	\$ 196,942
Total burden dollars plus shipping cost	\$ 219,384	\$ 62,325	\$ 281,709
<b>Average total burden dollars plus shipping cost per response</b>	<b>\$ 42.6319</b>	<b>\$ 64.2529</b>	

14. Estimated Annualized Cost to Federal Government:

Estimated Annual Labor Cost to Government:

Labor Category	Number	% of time	Cost <sup>5</sup>
Unit Chief – GS-14	1	25%	\$ 43,575
Program Analyst – GS-13	1	60%	\$ 88,501
Import Export Specialist – GS-13	1	25%	\$ 36,875
<b>Total:</b>			<b>\$ 168,951</b>

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:

The increase in burden hours is due to an increase in the number of responses. The increase in the burden dollars is due to increase in burden hours 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.

	2014 Approved Burden	2016 Requested Burden	Difference
Annual responses	5,812	6,116	304
Annual burden hours	3,083	3,301	218
Annual burden dollars (\$)	107,813	281,709	173,896

(\*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

<sup>5</sup> 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.

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:

There are no plans to publish this information.

17. Expiration Date of Approval:

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

18. Exceptions to the Certification Statement:

There are no exceptions to the certification statement.

**Part B. Statistical Methods**

The Drug Enforcement Administration will not be employing statistical methods in this information collection.