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, Application for Permit to Export Controlled Substances for Subsequent Reexport Among Members of the European Economic Area – DEA Form 161R–EEA
OMB Approval # 1117-0004

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# 1117-0004, Application for Permit to Export Controlled Substances – DEA Form 161, Application for Permit to Export Controlled Substances for Subsequent Reexport – DEA Form 161R, Application for Permit to Export Controlled Substances for Subsequent Reexport Among Members of the European Economic Area – DEA Form 161R–EEA.

Part A. Justification

1. Necessity of Information:

Section 1003 of the Controlled Substances Import and Export Act (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.

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 export or reexport controlled substances listed in schedule I or II, any narcotic substance listed in schedules III or IV, or any non-narcotic substance in schedule II 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, 1971. As part of the implementation of ITDS, the DEA is establishing a new DEA Form 161R–EEA to be used by registrants who export controlled substances for reexport among members of the European Economic Area. The existing DEA Form 161R would remain in use for exports of controlled substances that will be reexported to countries that are not members of the European Economic Area.

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, DEA Form 161r, Application for Permit to Export Controlled Substances for Subsequent Reexport, and the new form, DEA Form 161–EEA, Application for Permit to Export Controlled Substances for Subsequent Reexport Among Members of the European Economic Area, 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 236, 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 Controlled Substances Import and Export Act.

The DEA is amending § 1312.22 to provide clear instructions on the process of return information for controlled substances subject to export permit requirements, which will be submitted electronically as part of the DEA Form 161. Specifically, in § 1312.22 the DEA is requiring that within 30 calendar days after a controlled substance is released by a customs officer at the port of export from the United States in accordance with the permitting process , or within 10 calendar days after receipt of a written request by the Administration to the exporter, whichever is sooner, the exporter must file a report with the Administration utilizing the secure network application available on the DEA Office of Diversion Control Web site that such export has occurred and the specifics of the transaction. The report must include information relating to key dates of the transaction(s) and actual quantities involved in the export process.

As part of implementation of ITDS, the DEA is establishing a new DEA Form 161R–EEA, "Application for Permit to Export Controlled Substances for Subsequent Reexport Among Members of the European Economic Area," to be used by registrants who export controlled substances for reexport among members of the European Economic Area. Specifically, in § 1312.22, the DEA is requiring that within 30 calendar days after the controlled substance is released by a customs officer at the port of export the exporter must file a report with the Administration through the DEA Office of Diversion Control secure network application of the particulars of the transaction. . The exporter must additionally file similar return information within 30 days of the controlled substances being exported from the first country to the second country and for each subsequent reexport among members of the European Economic Area.

3 Use of Information Technology:

With the implementation of ITDS, the DEA will require the mandatory electronic application requirements for controlled substance exports into § 1312.22. Applicants for a permit to export controlled substances would be required to access, complete, and submit the DEA Form 161 and 161r, as appropriate, through the DEA Office of Diversion Control secure network application. This requirement would also be incorporated into a new § 1312.03, which references applicable forms for part 1312, and would state that such forms are electronic.

Also, the new DEA Form 161R–EEA, and associated return information, would be required to be accessed, completed, and submitted to the DEA through the DEA Office of Diversion Control secure network application

Other than for transshipments, current DEA regulations requiring export permits to be issued in multiples via paper form would be eliminated in favor of regulations making such information available via digital means. The DEA would continue to issue original permits under existing practices, and would still transmit the original permit to the pertinent foreign competent national authorities (CNAs); however, the DEA would eliminate issuing the other copies. Moreover, the "copies" currently issued by the DEA to registrants would only be accessible through the DEA Office of Diversion Control secure network application. The DEA would assign each approved permit a permit number (a unique identifier). Once the permit has been issued, registrants would be able to use the assigned permit number to access the digital copy of the permit, or the "official record of the permit." Corresponding changes would be made throughout DEA export regulations. These changes will reference the data downloads from the secure network application by the registrant as an "official record of the permit" instead of a "copy."

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 new DEA Form 161R–EEA is not duplicative. These are brand new forms. The collection of this information is unique to the DEA.

5. Impact on Small Businesses or Entities:

The DEA does not anticipate any additional impact on small business or other small entities since the last approval of this form. The revised collection will not have a significant economic impact on small business 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:

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. 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. Estimate of 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.

	Number of Annual Respondents*	Number of Annual responses	Average Time per Response	Total Annual Hours
DEA 161	125	5,386	0.5	2,693
DEA 161R/161R-EEA		789	0.75	592
Total	**125**	**6,175**		**3,285**

* 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:	125	
Number of responses per respondent per year:	49.4	(average)
Total annual responses	6,175	
Total annual hour burden	3,285	
Average burden, per collection:	0.53	
Average burden, per respondent:	26.3	
Total responses received on paper:	0	
Total responses received online:	6,175	
Percent of responses received online:	100%	

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

	DEA 161	DEA 161R/ 161R-EEA	Total
Number of responses:	5,386	789	6,175
Burden per response (hours):	0.5	0.75	
Burden dollars per response ($):	$ 26.0303	$ 39.0454	

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 x (1 + 0.441) = $52.06.

Total burden dollars	$ 140,199	$ 30,807	171,006

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 Labor Cost to Government:

Labor Category	**Number**	**% of time**	**Cost** [4]
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
Total cost to government:			**$ 168,951**

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 statutory and regulatory changes affecting this information collection. The changes result in the mandatory use of online DEA Forms 161 and 161R and the creation of the new DEA Form 161R-EEA 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	5,812	6,175	363
Annual burden hours	3,083	3,285	202
Annual burden dollars ($)	107,813	171,006	63,193

(*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.)

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.

16. Plans for Publication:

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

17. Expiration Date of 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