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 the Office of Management and Budget (OMB) approval of an existing collection of information that was previously approved by OMB – OMB Approval Number 1117-0004, Application for Permit to Export Controlled Substances/ Application for Permit to Export Controlled Substances for Subsequent Reexport, DEA Form 161/161r.

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.

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 Controlled Substances Import and Export Act.

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 referenced DEA form 161 is available on the DEA Diversion Control Program web site (http://www.deadiversion.usdoj.gov). This form is partially interactive and can be completed

electronically, printed, signed manually, and sent to the DEA. Currently, DEA Form 161 is also available for online submission. However, the online version of DEA Form 161r is currently under development. Respondents have the option to submit the return information (Certificate of Exportation/Reexportation) by mail or by email.

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:

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 79

FR 21953-21954, published on 04/18/2014 and the 30 day Federal Register Notice of Information Collection, 79 FR 35574, published on 06/23/2014. 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:

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:

Annual Hour Burden: 3,083

Reporting is required on DEA Form 161 for exports and DEA Form 161r for reexports.

Form	Number of Respondents	Average Annual	Average Time per	Total Annual Burden	Cost to Respondent ($57.37 per burden

		Responses	Response (hours)*	(hours)	hour)
161	123	5,109	0.5	2,555	$146,552
161r	24	703	0.75	528	$30,291
			Total	**3,083**	**$176,843**

* Includes time to submit Certification of Export and Certification of Reexport.

This estimate is based on the population of the regulated industry participating in this business activity. The DEA assumes that a transportation, storage, and distribution manager (SOC 11-3071) will complete the form on behalf of the registrant. The median hourly wage for that position according to the Bureau of Labor Statistics' May 2013 Occupational Employment Statistics is $40.33 (http://www.bls.gov/oes/current/oes_nat.htm). Applying 42.25% load for benefits, the loaded median hourly wage is $57.37. Therefore, the overall cost of burden hours is $176,843.

13. Estimated Cost of Burden:

Cost of Burden Hours: $176,843 (from above).

Cost of mailing application for exports to the DEA based on full-year 2013 data:

Mailing 5,109 responses @ $18.55 per response (UPS, up to 8 oz, one zone, overnight) = $94,772.

Cost of mailing application for reexports to the DEA.

Mailing 703 responses @ $18.55 per response (UPS, up to 8 oz, one zone, overnight) = $13,041.

The certifications regarding the initial export and subsequent reexport will be provided to the DEA via facsimile or email.

Total cost to respondents: $284,656

14. Estimated Annualized Cost to Federal Government:

Review and analysis of data:
2 GS-14 (20% of time): $48,172
2 GS-13 (75% of time): $152,871
1 GS-12 (25% of time): $21,426

TOTAL COST TO GOVERNMENT: $222,468

There is no actual cost to the Federal Government for this activity as all costs are recovered from the registrants through registration fees, as required by 21 U.S.C. 886a.

15. Reasons for Change in Burden:

There has been no program change. Changes in the number of respondents and responses fluctuate based on the registrant population and number of exports and reexports of controlled substances, while increases in mailing rates are established by the market.

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.