

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

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, and any narcotic substance listed in Schedules III or IV must have an export permit. To obtain the permit, an application for permit must be made to DEA on DEA Form 161 for exports, and new DEA Form 161r for reexports.

2. **Needs and Uses:** 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 provide the information necessary for DEA to prepare a Permit to Export, DEA Form 36, which is required to accompany and document the exportation of specific controlled substances. Failure to require a permit for exportation and reexportation of specific controlled substances would impair DEA's enforcement of the Controlled Substances Import and Export Act.

3. **Use of Technology:** These forms and the information collection is mandated by law to maintain a closed distribution system of controlled substances. The forms are designed to require only the minimum essential data from the respondents for DEA to exercise sufficient control over the export and reexport of controlled substances. Currently, the DEA Forms 161 and 161r are available for download on the DEA Diversion Control Program web site at <http://www.deadiversion.usdoj.gov>. These are partially interactive forms—they may be completed online, printed, signed and mailed to DEA.

4. **Efforts to Identify Duplication:** There is no duplication of this collection of information since the function is unique to DEA.

5. **Methods to Minimize Burden on Small Businesses:** This collection of information does not impact small businesses or other small entities.

6. **Consequences of Less Frequent Collection:** Information is provided by registrants each time registrants propose to export or reexport controlled substances and therefore cannot be collected less frequently. Persons who reexport to a second country Schedule I and II and narcotic

Schedule III and IV controlled substances must submit, 30 days following the initial exportation and 30 days following the reexportation, documentation that the controlled substances have been exported and reexported, respectively. This is because, without the reporting of both the exportation to the first country, and the reporting of the reexportation to the second country as mandated by statute, a scenario could arise in which DEA has issued a permit authorizing a reexport, yet be without sufficient documentation to determine whether the shipment (i) has remained for many months in the first country without being reexported, (ii) has been improperly reexported to a different second country than that indicated on the reexport application, or (iii) was properly reexported to the second country but the reexporter failed to notify DEA within 30 days as required by the statute. Failure to collect the information would impair 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 practice.

7. Special Circumstances Influencing Collection: There are no special circumstances applicable to this information collection.

8. Reasons for Inconsistencies with 5 CFR 1320.6: There are no circumstances that require the collection of data that would be inconsistent with the guidelines set forth in 5 CFR 1320.8(d). DEA meets regularly with the affected industry to discuss policies, programs and regulations.

DEA did not receive any comments concerning this collection.

9. Payment or Gift to Claimants: There are no such payments or gifts 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. The 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 business information per 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: Questions of a sensitive nature are not included in reporting requirements.

12. Estimate of Hour Burden:

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

Form	Number of Respondents	Average Annual Responses	Average Time per Response (hours)	Total Annual Burden (hours)	Cost to Respondent (\$38.22 per burden hour)
161	69	5,577	0.5	2,788.5	\$106,576.47
161r	12	196	0.75	147	\$5,618.34
Certification of Export	-	196	0.25	49	\$1,872.78
Certification of Reexport*	-	236	0.25	58.8	\$2,247.34
Total Cost Burden				3,043.3	\$116,314.93

* Assumes three separate reexports to second countries

This estimate is based on the population of the regulated industry participating in this business activity. 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' 2009 Occupational Employment Statistics is \$38.22 (http://www.bls.gov/oes/current/oes_nat.htm). This is a usual and customary business expense not directly associated with this information collection.

13. Estimate of Cost Burden:

Cost of mailing application for exports to DEA

Mailing 5,577 responses @ \$18.55 per response (UPS, up to 8 oz, one zone, overnight) = \$103,453.35.

Cost of mailing application for reexports to DEA

Mailing 196 responses @ \$18.55 per response (UPS, up to 8 oz, one zone, overnight) = \$3,635.80.

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

Total cost to respondents: \$107,089.15

14. Estimated Annualized Cost to Federal Government:

Review and analysis of data:

2 GS-12 (80% of time): \$139,898.88

1 GS-12 (30% of time): \$26,231.04

1 GS-09 (50% of time): \$30,145.92

1 GS-05 (20% of time): \$7,958.27

Subsequent analysis of data:

2 GS-12 (10% of time): \$17,487.36

1 GS-12 (5% of time): \$4,371.84

TOTAL COST TO GOVERNMENT: \$226,093.31

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 the Department of Justice and Related Agencies Appropriations Act of 1993.

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 the information.

17. Expiration Date Approval: DEA is not seeking approval to not display the expiration date on forms. DEA will update the expiration date on Forms 161 and 161r upon approval for renewal.

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.