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. DEA is working to make these forms fully interactive so they may be submitted electronically.

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.

9. Payment or Gift to Claimants: There are no such payments or gifts to respondents.

10. Assurance of Confidentiality: Confidential business information is protected under Department of Justice regulations. Information submitted is considered confidential because it contains proprietary information. DEA Forms 161 and 161r are not part of a Privacy Act System of Records since the information does not concern individuals, only business entities.

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

DEA Form 161 [exportation of controlled substances]:

Number of respondents:	90
Frequency of response:	As needed
Average annual responses:	2,200

Average time per response: 30 minutes (0.5 hour)
Total Annual burden: 1,100 hours

Cost to Respondent:

2,200 responses @ 30 minutes per response = 1,100 hours
@ $10 per burden hour = $11,000

DEA Form 161r [reexportation of controlled substances]:
Number of respondents: 30
Frequency of response: As needed
Average annual responses: 400
Average time per response: 45 minutes (0.75 hrs)
Annual burden [DEA Form 161r]: 300 hours

Average annual response for certifying initial export 400
Average time per response certifying initial export has occurred 15 min (0.25 hrs)
Annual burden for certifying initial export has occurred 100 hours

Average annual response for certifying reexport [assumes three separate reexports to second countries] 1,200
Average time per response certifying reexport has occurred 15 min (0.25 hrs)
Annual burden for certifying reexport has occurred 300 hours

Total annual hour burden for DEA Form 161r, certifying initial export and reexport: 700 hours

Cost to Respondent:

400 responses for reexport @ 0.75 hour per response = 300 hours
@ $10 per burden hour = $3,000

400 responses certifying initial exportation @ 0.25 hour per response = 100 hours
@ $10 per burden hour = $1,000

1,200 responses certifying reexportation @ 0.25 hour per response = 300 hours
@ $10 per burden hour = $3,000

Total annual cost burden for DEA Form 161r, certifying initial export and reexport: $7,000

Total hour burden for Forms 161, 161r (includes certification of initial export and subsequent reexport): 1,800 hours

Total cost burden for Forms 161, 161r (includes certification of initial export and subsequent

reexport): $18,000

This estimate is based on the population of the regulated industry participating in this business activity. 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 2,200 responses @ $13.35 per response (Federal Express, up to 8 oz, one zone, overnight) = $29,370.

Cost of mailing application for reexports to DEA

Mailing 400 responses @ $13.35 per response (Federal Express, up to 8 oz, one zone, overnight) = $5,340.

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

Total cost to respondents: $34,710

14. Estimated Annualized Cost to Federal Government:

Estimated annualized cost to Government:

Printing (Annually): $100
Mailing Cost (Annually): $39
The Forms 161 and 161r are available on the Diversion Control Program web site.

Review and analysis of data:
2 GS-11 (70% of time): $110,226
1 GS-12 (30% of time): $ 28,309

Subsequent analysis of data:
2 GS-11 (10% of time): $15,747
1 GS-12 (5% of time): $ 4,719

TOTAL COST TO GOVERNMENT: $159,140.00

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 a program change. The Controlled Substances Export Reform Act of 2005 (Pub. L. 109-57) permits the exportation of Schedule I and II and narcotic Schedule III and IV controlled substances to a country for subsequent exportation to a second country and requires documentation that the controlled substances have been reexported to a second country. Previous law did not allow this. Because of this change, DEA has created a new Form 161r, Application for Permit to Export Controlled Substances for Subsequent Reexport. Further, DEA is requiring that persons reexporting controlled substances notify DEA of the initial export of those controlled substances to the first country, necessitating an increase in hour burden of 100 hours. Finally, changes made by Pub. L. 109-57 require that certification of reexportation be provided to DEA; this certification is a new aspect of this collection, necessitating an increase in hour burden of 300 hours. Although DEA estimates that it takes 15 more minutes (0.25 more hours) to complete DEA Form 161r, Application for Permit to Export Controlled Substances for Subsequent Reexport, as compared with DEA Form 161, Application for Permit to Export Controlled Substances, this increase in time for the new Form 161r is offset by the need to submit fewer DEA Forms 161. Previously, reexportation of Schedule I and II controlled substances and narcotic controlled substances in Schedule III and IV, was not permitted; persons exporting controlled substances sent them to the actual country of destination, rather than sending them to one country and then reexporting them to the (second) country of destination. Thus, individual DEA Forms 161 were required to handle each individual country of destination. DEA anticipates fewer DEA Forms 161 being submitted now that reexportation of these specific controlled substances is permitted.

16. Plans for Publication: There are no plans to publish the information.

17. Expiration Date Approval: It would be an administrative burden to replace existing forms when nothing of substance changed except Date of Expiration, therefore, approval is requested not to list Date of Expiration.

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.