Supporting Statement for Paperwork Reduction Act Submissions

DEA Form 161

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, Section 1312.21 require that any person who desires to export controlled substances listed in Schedule I or II, and any narcotic substance listed in Schedule 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.

2. Needs and Uses: The form is entitled Application for Permit to Export Controlled Substances and is intended to provide the information necessary for DEA to prepare 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 of specific controlled substances would impair DEA's enforcement of the Controlled Substances Import and Export Act.

3. Use of Technology: This form and the information collection is mandated by law to maintain a closed distribution system of controlled substances. The form is designed to require only the minimum essential data from the respondents in order for DEA to exercise sufficient control over the export of controlled substances. Currently, the DEA Form 161 is available for download on the DEA Diversion Control Program web site at http://www.deadiversion.usdoj.gov. This is a partially interactive form—it may be completed online, printed, signed and mailed to DEA. DEA is working to make this form fully interactive so it 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 controlled substances and therefore cannot be collected less frequently. 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 in item 7 of the supporting statement that are 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, 28 CFR 16.8 and 16.9. Information submitted is considered confidential because it contains proprietary information. DEA-161 forms 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

Number of respondents:	222
Frequency of response: As needed	
Average annual responses:	2,444
Average time per response:	30 minutes (0.5 hour)
Total Annual burden:	1,222 hours

Cost to Respondent:

2,444 responses @ 30 minutes per response
@ $10 per burden hour = $12,220
Mailing 2,444 responses @ $0.37 per response = $904.28

TOTAL COST TO RESPONDENT: $13,124.28

This estimate is based on the population of the regulated industry participating in this business activity. There are no costs associated with this information collection aside from the $10 hourly charge businesses would experience to fulfill this information collection. This is a usual and customary business expense not directly associated with this information collection.

13. Estimate of Cost Burden: There is no cost burden beyond those which exist in the normal course of business and those burden hours listed above.

14. Estimated Annualized Cost to Federal Government:

Estimated annual cost to Government:

Printing (Annually): $4,032
Mailing Cost (Annually): $1,008

Reviewing and analysis of data:
1 GS-11 (25% of time): $18,348.16
1 GS-12 (5% of time): $4,398.21
1 GS-13 (5% of time): $5,230.27

Subsequent analysis of data:
1 GS-12 (25% of time): $21,991.04
1 GS-13 (5% of time): $5,230.27

TOTAL COST TO GOVERNMENT: $55,197.95

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 are due to fluctuation in registrant population.

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 in all field locations 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.