Supporting Statement for Paperwork Reduction Act Submission
Application for Import Quota for Ephedrine, Pseudoephedrine, and Phenylpropanolamine
OMB Approval Number 1117-0047

Part A. Justification

1. Necessity of Information:

Title 21, United States Code (U.S.C.), Section 952, and Title 21, Code of Federal Regulations (CFR), § 1315.34 require that persons who desire to import the List I chemicals Ephedrine, Pseudoephedrine, or Phenylpropanolamine during the next calendar year shall apply to DEA on DEA Form 488 for an import quota for those List I chemicals. The Controlled Substances Act states: "It shall be unlawful for any person to import … ephedrine, pseudoephedrine, and phenylpropanolamine, … except … such amounts of … ephedrine, pseudoephedrine, and phenylpropanolamine as the Attorney General finds to be necessary to provide for medical, scientific, or other legitimate purposes" (21 U.S.C. 952).

2. Needs and Uses:

DEA uses DEA Form 488, Application for Import Quota for ephedrine, pseudoephedrine, and phenylpropanolamine, to determine the estimated need for ephedrine, pseudoephedrine, and phenylpropanolamine and to establish import quotas for United States companies importing these List I chemicals. United States companies importing Ephedrine, Pseudoephedrine, and Phenylpropanolamine must apply on DEA Form 488 each year for assignment of their individual import quota.

3. Use of Technology:

Currently DEA Form 488 is available on the DEA Diversion Control Program web site (http://www.deadiversion.usdoj.gov). This form is partially interactive--it may be completed electronically, but must be printed, signed manually, and sent to DEA. DEA is working to develop a fully interactive version of this form which could be completed and submitted electronically and expects this version to be completed by October, 2011.

4. Efforts to Identify Duplication:

Quotas are unique to DEA, therefore there is no duplication of information requested as part of DEA Form 488, Application for Import Quota for Ephedrine, Pseudoephedrine, and Phenylpropanolamine.

5. Methods to Minimize Burden on Small Businesses:

This collection does not have a significant economic impact upon small entities within the meaning and intent of the Regulatory Flexibility Act, 5 U.S.C. 601, et seq.

6. Consequences of Less Frequent Collection:

If the collection is not conducted or conducted less frequently, DEA would not have sufficient data to set production quotas and would be unable to determine the amounts necessary to meet medical, scientific, or other legitimate purposes.

7. Special Circumstances Influencing Collection:

None of the circumstances in Item 7 apply to this collection.

8. Reasons for Inconsistencies with 5 CFR 1320.6:

DEA establishes and participates in training seminars, industry meetings, and conferences, with the regulated industry (importers of List I chemicals). These meetings are held regularly and provide an open forum to discuss matters of mutual concern, including quota application procedures, with industry representatives. DEA also provides consultation with industry respondents on an individual basis if needed.

DEA did not receive any comments concerning this collection.

9. Payment or Gift to Claimants:

There are no such gifts or payments 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:

This collection does not include questions of a sensitive nature.

12. Estimate of Hour Burden:

Respondents complete DEA Form 488, Application for Import Quota for Ephedrine, Pseudoephedrine, and Phenylpropanolamine, annually. A respondent may submit multiple responses.

DEA Form 488:

Number of Respondents: 57
Frequency of Response: 1.4 Per Respondent
Average time per response: 1 hour
Total annual responses: 80

Total annual burden: 80 hours

Cost to respondents:

DEA Form 488 Number of Responses x Time per Response x $103.15 per hour for a purchasing manager = Total Industry Labor Costs

80	x	1 hour	x $103.15	=	$8,252

All wage rates are based on the BLS OES Industry-Specific Occupational Employment and Wage Estimates for the Pharmaceutical and Medicine Manufacturing, June 2010. The wages are adjusted for fringe at 44 percent of wages based on Employer Costs for Employer Compensation, BLS March 2010 and overhead rate of 56 percent.

13. Estimate of Cost Burden:

Respondents are assumed to submit their Form 488 to DEA by a package service (United States Postal Service Express Mail Flat Rate Envelope).
DEA Form 488 mailing cost:
80 responses x $18.30 per response = $1,464

14. Estimated Annualized Costs to Federal Government:

Estimated annual cost to Federal government:

Personnel Salaries:

Analysis of quota information:

1 Drug Science Officer - GS-601-13 step 5 (49% of time) $49,443
1 supervisory Drug Science Officer - GS-601-14 step 5 (12% of time) $14,309
1 Secretary - GS-318-7 step 5 (49% of time) $23,441

Total Cost: $87,193

There is no actual cost to the Government for this activity as all costs are recovered from registrants through registration fees, as required by the Department of Justice and Related Agencies Appropriations Act of 1991.

15. Reasons for Change in Burden:

There have not been any program changes. The adjustment occurred based on responses received.

16. Plans for Publication:

There are no plans to publish the information collected.

17. Expiration Date Approval:

As an administrative burden would be created if DEA was required to replace expired forms when no substantive information regarding the form had changed, DEA is seeking approval to not display the expiration date for OMB approval of the information collected.

18. Exceptions to the Certification Statement:

There are no exceptions to the certification statement.

Part B. Statistical Methods

The Drug Enforcement Administration does not employ statistical methods in this information collection.