Supporting Statement for Paperwork Reduction Act Submission
Application for Import Quota for Ephedrine, Pseudoephedrine, and Phenylpropanolamine
DEA Form 488
OMB Approval Number 1117-0047

Part A. Justification

1. Necessity of Information:

Purpose of collection: Title 21, United States Code (U.S.C.), Section 952, and Title 21, Code of Federal Regulations (CFR), §1315.34require 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:

Intended 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:

Since September, 2011, DEA Form 488 has been available to be completed and submitted electronically. DEA Form 488 is also available on the DEA Diversion Control Program web site (http://www.deadiversion.usdoj.gov) as a blank form that may be printed, completed, signed, and sent to DEA.

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 (including Worksheet A), annually. A respondent may submit multiple responses.

DEA Form 488:

Number of Respondents: 22
Frequency of Response: 2.4 Per Respondent
Average time per response: 1 hour
Total annual responses: 52

Total annual burden: 52hours

Estimates are based on the population of the regulated industry participating in this business activity. DEA assumes that a purchasing manager (SOC 11-3061 2010 Standard Occupational Classification) will complete the form on behalf of the registrant. The median hourly wage for that position according to the Bureau of Labor Statistics' 2010 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 325400 – Pharmaceutical and Medicine Manufacturing is $47.75 (http://www.bls.gov/oes/current/oes/naics4_325400.htm#11-0000). Therefore, the cost of burden hours is $2,483.

13. Estimate of Cost Burden:

Respondents are assumed to submit their Form 488to DEA by a package service (United States Postal Service Express Mail Flat Rate Envelope). Envelopes are $17.40 if paid for online (https://www.usps.com/ship/express-mail-flat.htm?).
DEA Form 488 mailing cost:
52 responses x $17.40per response = $904.80

14. Estimated Annualized Costs to Federal Government:

Personnel Salaries:

Analysis of quota information:
1 Drug Science Officer - GS-601-14 (29% of time) $34,580
1 supervisory Drug Science Officer - GS-601-14 (6% of time) $7,155
1 Secretary - GS-318-7 (19% of time) $9,090

Total Cost: $50,825

All Government labor costs are rounded up to the nearest dollar. Costs are calculated by using the DC-Baltimore pay tables for the current year for the grade listed, step 5.

All costs to the Federal Government for these activities are recovered from registrants through registration fees, as required by the Departments of Commerce, Justice State, the Judiciary, and Related Agencies Appropriations Act of 1993.

15. Reasons for Change in Burden:

There have not been any program changes. Adjustments have occurred based on responses received. The table below summarizes the changes since the last renewal of this information collection.

	2011 Approved Burden	**2012 Requested Burden**	**Difference**
Annual responses	80	52	(28)
Annual burden hours	80	52	(28)
Annual cost	$1,464	$904.80	($559)

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.