

**Supporting Statement for Paperwork Reduction Act Submissions
Application for Import Quota for Ephedrine,
Pseudoephedrine, and Phenylpropanolamine (DEA Form 488)
OMB Approval #1117-0047**

The Drug Enforcement Administration (DEA) seeks approval by the Office of Management and Budget (OMB) for an existing collection of information that was previously approved by OMB – OMB Approval #1117-0047, Application for Import Quota for Ephedrine, Pseudoephedrine, and Phenylpropanolamine (DEA Form 488).

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 Information 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. Currently, 100% of DEA Form 488 are submitted electronically.

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. Impact on Small Businesses or Entities:

This is a routine renewal of DEA Form 488. The DEA does not anticipate any additional impact on small businesses or other small entities since the initial approval of this form. The collection will not have a significant economic impact on small businesses or other small entities within the meaning and intent of the Regulatory Flexibility Act, 5 U.S.C. 601–612.

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:

There are no special circumstances applicable to this information collection.

8. Consultation with persons outside the Agency:

Public comment was solicited in the 60-day Federal Register Notice of Information Collection, 80 FR [REDACTED], published [REDACTED], 2015 and the 30-day Federal Register Notice of Information Collection, 80 FR [REDACTED], published [REDACTED], 2015. The DEA did not receive any comments concerning this collection.

The DEA meets regularly with the affected industry to discuss policies, programs, and regulations. These meetings provide an open forum to discuss matters of mutual concern with representatives of those entities from whom the information is obtained.

9. Payment or Gift to Claimants:

This collection of information does not propose to provide any payment or gift 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 the 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 as confidential business information per 28 CFR 16.8(c) and Exemption 4 of FOIA, the DEA will give written notice to the submitter to allow an opportunity to object within a reasonable time prior to any disclosure by the DEA.

11. Justification for Sensitive Questions:

This collection of information does not ask any 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:	35
Frequency of Response:	2.3 Average Per Respondent
Average time per response:	1 hour
Total annual responses:	80

Total annual burden: 80 hours

Average Burden: Per Collection: 1 hour

Per Respondent: 2.3 hours

Total responses received on paper: 0

Total responses received online: 80

Percent of responses received online: 100%

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' 2014 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 325400 – Pharmaceutical and Medicine Manufacturing is \$55.52 (<http://www.bls.gov/oes/current/oes>). Based on the BLS report, “Employer Costs for Employee Compensation – March 2015,” (<http://www.bls.gov/news.release/pdf/ecec.pdf>) an additional 43.3% load (for “private industry”) is added to the wage rate to account for benefits. Therefore, the estimated cost of burden hours of this information collection is \$6,409.

13. Estimate of Cost Burden:

The estimated annual cost burden is zero. Respondents are estimated to not incur any a) additional start-up cost or capital expenditure, or b) additional operation and maintenance costs or purchase services as a result of this information collection.

14. Estimated Annualized Cost to the Federal Government:

Personnel Salaries:

Section Chief/Supervisory Physical Scientist – GS-1301-15 (10% of time) \$22,356

Analysis of quota information:

1 Drug Science Officer - GS-601-14 (29% of time)	\$55,116
1 Supervisory Physical Scientist - GS-1301-14 (10% of time)	\$19,005
1 Secretary - GS-318-7 (19% of time)	\$14,486

Total Cost: \$110,964

All Government labor costs are rounded to the nearest dollar. Costs are based on the DC-Baltimore 2015 pay tables for the grade listed, step 5. Load of 56.25% is added to the wage rate to account for benefits. Load for “State and local government” is used as an estimate for Federal government, as the report excludes Federal government.

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.

	2012 Approved Burden	2015 Requested Burden	Difference
Annual responses	52	80	28
Annual burden hours	52	80	28
Annual cost	\$905	\$6,409	\$5,504

16. Plans for Publication:

The DEA will not publish the results of the information collected.

17. Expiration Date Approval:

The DEA does not object to OMB displaying the expiration date.

18. Exceptions to the Certification Statement:

The DEA is not seeking an exception to the certification statement “Certification for Paperwork Reduction Act Submissions” for this collection of information.

Part B. Statistical Methods

The DEA does not employ statistical methods in this information collection.