Supporting Statement for Paperwork Reduction Act Submissions
Application for Procurement Quota for Controlled Substance and for Ephedrine, Pseudoephedrine, and Phenylpropanolamine (DEA Form 250)
OMB Approval #1117-0008

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 #1117-0008, Application for Procurement Quota for Controlled Substance and for Ephedrine, Pseudoephedrine, and Phenylpropanolamine (DEA Form 250).

Part A. Justification

1. Necessity of Information:

The DEA implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1242 (1970), as amended (the "CSA"). 21 U.S.C. 801–971. Through the enactment of the CSA and its amendments, Congress has established a closed system of distribution making it unlawful to handle any controlled substance (manufacture, distribute, reverse distribute, dispense, conduct research, engage in narcotic treatment or maintenance, import, export, collect, conduct chemical analysis, dispose, or possess) any controlled substance except in a manner authorized by the CSA. In order to maintain this closed system of distribution, the CSA generally requires all persons who handle controlled substances to obtain a registration issued by the Attorney General. 21 U.S.C. 822, 823, 957, and 958.

Any United States companies that desire to use any basic class of controlled substances listed in schedule I or II or the List I chemicals ephedrine, pseudoephedrine, or phenylpropanolamine for purposes of manufacturing during the next calendar year shall apply on DEA Form 250 for a procurement quota for such class. 21 U.S.C. 826 and 21 CFR 1303.12(b) and 1315.32. The DEA is required to limit the production of schedule I and II controlled substances and ephedrine, pseudoephedrine, and phenylpropanolamine to the amounts necessary to meet "the estimated legitimate medical, scientific, research and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks." 21 U.S.C. 826(c).

2. Needs and Uses:

The DEA uses DEA Form 250, Application for Procurement Quota for Controlled Substances and Ephedrine, Pseudoephedrine, and Phenylpropanolamine, to determine the estimated legitimate need for schedule I and II controlled substances and ephedrine, pseudoephedrine, and phenylpropanolamine and to establish quotas for United States companies manufacturing these products. United States companies involved in manufacturing schedule I and II controlled substance products and ephedrine,

pseudoephedrine, and phenylpropanolamine must apply on DEA Form 250 each year for assignment of their individual quota. 21 U.S.C. 826.

3. Use of Information Technology:

DEA Form 250 is available to be completed and submitted electronically. DEA Form 250 is also available on the DEA Diversion Control 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 Forms 250 are submitted electronically.

4. Efforts to Identify Duplication:

Quotas are unique to the DEA, therefore there is no duplication of information requested as part of this collection.

5. Impact on Small Businesses or Entities:

This is a routine renewal of DEA Form 250. 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, 81 FR 1219, published January 11, 2016 and the 30-day Federal Register Notice of Information Collection, 81 FR 13827, published March 15, 2016. 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 250, Application for Procurement Quota for Controlled Substance and for Ephedrine, Pseudoephedrine, and Phenylpropanolamine (including Worksheet A), annually. A respondent may submit multiple applications.

DEA Form 250:

Schedule I and II controlled substances:

Number of Respondents:	283
Frequency of Response:	Annually/as needed
Total annual responses:	2,682
Average time per response:	0.5 hours

Total annual burden: 1,341 hours

List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine:

Number of respondents:	134
Frequency of Response:	Annually/as needed
Total annual responses:	278
Average time per response:	0.5 hours

Total annual burden: 139.0 hours

Combined

Total number of respondents: 417

Total annual responses: 2,960

Total annual burden hours: 1,480 hours

Average Burden: Per Collection: 0.50 hour

Per Respondent: 3.55 hour

Total registration applications received on paper: 0

Total registration applications received online: 417

Percentage of applications received electronically: 100%

Based on the population of the regulated industry participating in this business activity. The 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' (BLS) 2014 National Occupational Employment and Wage Estimates for 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 – September 2015," (ECEC) (http://www.bls.gov/news.release/pdf/ecec.pdf) an additional 43.5% 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 $117,912.

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:

Estimated Annual Labor Cost to Government:

Labor Category	**Number**	**% of time**	**Cost**
Section Chief/Supervisory Physical Scientist – GS-1301-15	1	10%	$ 22,788
Analysis of quota information (Schedule I and II controlled substances):			
Drug Science Specialists – GS-601-12/14	4	69%	$ 534,690
Supervisory Physical Scientist - GS-1301-14	1	42%	$ 81,366
Supervisory Physical Scientist - GS-1301-15	1	5%	$ 11,394

Secretaries - GS-318-7	2	55%	$ 85,489
Diversion Investigator/Executive Assistant– GS-1801-15	1	5%	$ 11,394
Analysis of Quota Information (List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine):			
Drug Science Specialists – GS-601-12/14	4	10%	$ 77,491
Supervisory Physical Scientist - GS-1301-14	1	6%	$ 11,624
Diversion Investigators/Staff Coordinators – GS-1801-14	4	14%	$ 108,488
Supervisory Physical Scientist - GS-1301-15	1	5%	$ 11,394
Secretaries - GS-318-7	2	9%	$ 13,989
Diversion Investigator/Executive Assistant– GS-1801-15	1	1%	$ 2,279
Total			**$ 972,387**

*Figures are rounded. Government salary figures include 57% load for benefits based on the ECEC for "State and local government." The ECEC does not include figures for the Federal Government.

All Government labor costs are rounded to the nearest dollar. Costs are based on the DC-Baltimore 2016 pay tables for the grade listed, step 5.

All costs are recovered from registrants through registration fees, as required by the CSA. 21 U.S.C. 886a.

15. Reasons for Change in Burden:

Changes reflect a small increase in the number of responses per respondent and a change in calculation method.* There have been no statutory or regulatory changes affecting this information collection. The table below summarizes the changes since the last renewal of this information collection.

	2012 Approved Burden	2015 Requested Burden	Difference
Annual responses	2,716	2,960	244
Annual burden hours	1,358	1,480	122
Annual burden dollars	$0	$117,912	$117,912

(* In prior information collection requests, the estimated annual burden dollars was implied to be usual and customary business expense not directly associated with this information collection. The DEA believes the estimated annual burden associated with this information collection should be included. This change in calculation method is employed in this and future information collection requests.)

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.