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

Part A. Justification

1. Necessity of Information:

Title 21, United States Code (U.S.C.), Section 826, and Title 21, Code of Federal Regulations (CFR), §§ 1303.12(b) and 1315.32 require that United States companies who 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. DEA is required by statute (21 U.S.C. 826(c)) 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."

2. Needs and Uses:

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.

3. Use of Technology:

Currently DEA Form 250 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 anticipates making a fully interactive version of this form which could be completed and submitted electronically available within the next two years.

4. Efforts to Identify Duplication:

Quotas are unique to DEA, therefore there is no duplication of information requested as part of DEA Form 250, Application for Procurement Quota for Controlled Substances and 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 the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. The Controlled Substances Act requires DEA to set annual production limits for controlled substances and for ephedrine, pseudoephedrine, and phenylpropanolamine, a requirement which must be satisfied through the use of quotas.

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 (manufacturers of controlled substances and listed 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. DEA has procedures in place to protect this information, including secure storage, limited access, and protection against release pursuant to laws, regulations and agency procedures.

11. Justification for Sensitive Questions:

This collection does not include questions of a sensitive nature.

12. Estimate of Hour Burden:

Respondents complete DEA Form 250, Application for Procurement Quota for Controlled Substances and Ephedrine, Pseudoephedrine, and Phenylpropanolamine, annually. A respondent may submit multiple responses.

DEA Form 250:

Schedule I and II controlled substances:

Number of Respondents:	255
Frequency of Response:	Annually
Total annual responses:	2,077
Average time per response:	1 hour

Total annual burden: 2,077 hours

List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine:

Number of respondents:	165
Frequency of Response:	Annually
Total annual responses:	271
Average time per response:	1 hour

Total annual burden: 271 hours

Total number of respondents: 420
Combined Annual Public Burden: 2,348 hours

Cost to respondents:

DEA Form 250 Number of Responses x Time per Response x $103.15 per hour for a purchasing manager = Total Industry Labor Costs

2,348	x	1 hours	x	$103.15	=	$242,196

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

13. Estimate of Cost Burden:

Respondents are assumed to submit their Form 250 to DEA by a package service (standard overnight package of less than 8 ounces).
DEA Form 250 mailing cost:
2,348 responses x $18.30 per response = $42,968

14. Estimated Annualized Costs to Federal Government:

Estimated annual cost to Federal government:

Personnel Salaries:

Analysis of quota information (Schedule I and II controlled substances):
- 1 Drug Science Officer - GS-601-14 step 5 (67% of time) $102,259
- 1 supervisory Drug Science Officer - GS-601-14 step 5 (12% of time) $18,315
- 1 Secretary - GS-318-7 step 5 (67% of time) $41,026

Analysis of quota information (List I chemicals ephedrine, pseudoephedrine, phenylpropanolamine):
- 1 Drug Science Officer - GS-601-13 step 5 (49% of time) $63,287
- 1 supervisory Drug Science Officer - GS-601-14 step 5 (12% of time) $18,315
- 1 Secretary - GS-318-7 step 5 (49% of time) $30,004

Total Cost: $273,206

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 been no program changes. The adjustment is due to increased number of responses received and increased mailing fees.

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.