Supporting Statement for Paperwork Reduction Act Submissions
Application for Individual manufacturing Quota for a Basic Class of Controlled Substance and for Ephedrine, Pseudoephedrine, and Phenylpropanolamine
OMB Approval # 1117-0006

Part A. Justification

1. Necessity of Information:

Title 21, United States Code, Section 826, and Title 21, Code of Federal Regulations (CFR) §§ 1303.22 and 1315.22 require that any person who is registered to manufacture any basic class of controlled substances listed in Schedule I or II and who desires to manufacture a quantity of such class, or who desires to manufacture using the List I chemicals ephedrine, pseudoephedrine, or phenylpropanolamine, must apply on DEA Form 189 for a manufacturing quota for such quantity of such class or List I chemical.

2. Needs and Uses:

DEA uses this information to determine the estimated legitimate need for Schedule I and II controlled substances and for the List I chemicals 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 substances and the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine must apply on DEA Form 189 each year for an assignment of a manufacturing quota.

3. Use of Technology:

Currently the referenced form 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.

4. Efforts to Identify Duplication:

Quotas are unique to DEA, therefore there is no duplication of information.

5. Methods to Minimize Burden on Small Businesses:

This collection does not have a significant 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 legitimate needs. The Controlled Substances Act requires DEA to set annual production limits.

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 sponsors and participates in training seminars, industry meetings, and conferences, with the regulated industry (manufacturers, importers and exporters). These meetings are held regularly and provide an open forum to discuss matters of mutual concern, including quota application procedures, with industry representatives. DEA consults 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. Its release is governed by laws, regulations, and agency procedures.

Confidentiality is assured pursuant to 21 U.S.C. 830(c).

11. Justification for Sensitive Questions:

This collection does not include questions of a sensitive nature.

12. Estimate of Hour Burden:

Respondents report on DEA Form 189. A respondent may submit multiple responses.

Controlled Substances:

Number of Respondents: 36
Frequency of Response: Annually
Average annual responses: 297
Average time per response: 0.5 hours (30 minutes)

Total annual burden: 148.5 hours

List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine:

Number of respondents: 1
Frequency of Response: Annually
Average annual responses: 1
Average time per response: 0.5 hours (30 minutes)

Total annual responses: 0.5 hours

Combined number of respondents: 37
Combined number of responses: 298

Total Annual Public Burden: 149 hours

Cost to respondents:

Number of Responses	x	Time per Response	x	$99.83 per hour	=	Total Industry Costs
298	x	0.5 hour	x	$99.83	=	$14,875

Total Costs: $14,875

13. Estimate of Cost Burden:

Respondents are assumed to submit their Form 189 to DEA by a package service (standard overnight package of less than 8 ounces).
DEA Form 189 mailing costs:
298 responses x $12.7 per response = $3,785

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 (33% of time)	$43,758
1 supervisory Drug Science Officer - GS-601-14 step 5 (12% of time)	$15,912
1 Secretary - GS-318-7 step 5 (33% of time)	$17,554

Analysis of Quota Information (List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine):

1 Drug Science Officer – GS-601-13 step 5 (2% of time)	$2,244
1 supervisory Drug Science Officer - GS-601-14 step 5 (2% of time)	$2,652
1 Secretary - GS-318-7 step 5 (2% of time)	$1,064

Total Cost: $83,184

There is no actual cost to the Government for this activity as all costs are recovered from the registrants through registration fees, as required by the Departments of Commerce, Justice and State, the Judiciary, and Related Agencies Appropriations Act of 1993.

15. Reasons for Change in Burden:

No adjustments were made to this information collection.

16. Plans for Publication:

There are no plans to publish the information collected.

17. Expiration Date Approval:

Due to the administrative burdens related to replacing expired forms when no information on those forms has been 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.