Supporting Statement for Paperwork Reduction Act Submissions
DEA Form 189
Application for Individual Manufacturing Quota for a Basic Class of Controlled Substance and for Ephedrine, Pseudoephedrine, and Phenylpropanolamine
[OMB 1117-0006]

Part A. Justification

1. Necessity of Information: 21 U.S.C. 826 and 21 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. DEA anticipates making a fillable fileable form available within the next two years.

4. Efforts to Identify Duplication: Controlled substance and List I chemical 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 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 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 payments or gifts 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: DEA reports do 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:	30
Frequency of Response:	Annually/as needed
Total Annual Responses:	465
Average Time Per Response:	.5 hour (30 minutes)
Total Annual Burden:	232.5 hours

List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine:

Number of Respondents:	1
Frequency of Response:	Annually
Total Annual Responses:	3

Average Time Per Response: .5 hour (30 minutes)

Total Annual Burden: 1.5 hours

Combined Number of Respondents: 31

Combined Number of Responses: 468

Cost To Respondents:

Number of Responses	x	Time per Response	x $103.15 per hour	=	Total Industry Costs
468	x	.5 hour	x $103.15	=	$24,137

Total Costs: $24,137

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 189 to DEA by a package service (United States Postal Service Express Mail Flat Rate Envelope).

DEA Form 189 mailing costs:
468 responses x $18.30 per response = $8,564

14. Estimated Annualized Cost to Federal Government:

Personnel Salaries:

Analysis of Quota Information (Schedule I and II Controlled Substances):

1 Drug Science Officer - GS-601-13 step 5 (33% of time)	$37,294
1 Supervisory Drug Science Officer – GS-601-14 step 5 (12% of time)	$16,026
1 Secretary – GS-318-7 step 5 (33% of time)	$17,681

Analysis of Quota Information (List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine):

1 Drug Science Officer - GS-601-13 step 5 (2% of time)	$2,260
1 Supervisory Drug Science Officer – GS-601-14 step 5 (2% of time)	$2,671
1 Secretary – GS-318-7 step 5 (2% of time)	$1,072

Total personnel costs: $77,004

Total Cost to Government: $77,004

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: The adjustments to Items 12 and 14 are due to an increase in the number of U.S. imports. There have been no program changes.

16. Plans for Publication: There are no plans to publish this information.

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 requirement.

Part B. Statistical Methods

The Drug Enforcement Administration will not be employing statistical methods in this information collection.