

**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
(DEA Form 189)
OMB Approval #1117-0006**

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 #1117-0006, Application for Individual Manufacturing Quota for a Basic Class of Controlled Substance and for Ephedrine, Pseudoephedrine, and Phenylpropanolamine (DEA Form 189).

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 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 complete the DEA Form 189 online, for a manufacturing quota for such quantity of such class or List I chemical. 21 U.S.C. 826 and 21 CFR 1303.22 and 1315.22.

2. Needs and Uses:

DEA Form 189 is utilized by registered manufactures of ephedrine, pseudoephedrine, or phenylpropanolamine and who desire to manufacture a quantity of the chemical or who are registered to manufacture any basic class of controlled substance listed in schedule I or II. 21 CFR 1303.22 and 1315.22.

The 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 complete a DEA Form 189 online each year for assignment of a manufacturing quota. 21 U.S.C. 826.

3. Use of Information Technology:

Since September, 2011, DEA Form 189 has been available to be completed and submitted electronically. DEA Form 189 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 the DEA. Currently, 100% of DEA Forms 189 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 189. 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 13828, 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 189, Application for Individual Manufacturing Quota for a Basic Class of Controlled Substance and for Ephedrine, Pseudoephedrine, and Phenylpropanolamine (including Worksheet A), annually. A respondent may submit multiple responses.

DEA Form 189:

Total number of respondents: 34_

Number of responses per respondent per year: Annually/as needed

Total annual responses: 660

Average time per response: 0.5 hour

Total annual hour burden: 330 hours

Average Burden: Per Collection: 0.5

Per Respondent: 9.7 hours

Total responses received on paper: 0

Total responses received online: 660

Percent of responses received online: 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,” (<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 \$26,291.

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:			
Drug Science Specialists – GS-601-12/14	4	18%	\$ 139,484
Supervisory Physical Scientist - GS-1301-14	1	10%	\$ 19,373
Secretaries - GS-318-7	2	19%	\$ 29,533
Diversion Investigator/Executive Assistant– GS-1801-15	1	3%	\$ 6,837
Analysis of Quota Information (List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine):			
Drug Science Specialists – GS-601-12/14	4	1%	\$ 7,749
Supervisory Physical Scientist - GS-1301-14	1	1%	\$ 1,937
Diversion Investigators/Staff Coordinators – GS-1801-14	4	1%	\$ 7,749
Supervisory Physical Scientist - GS-1301-15	1	1%	\$ 2,279
Secretaries - GS-318-7	2	1%	\$ 1,554
Diversion Investigator/Executive Assistant– GS-1801-15	1	1%	\$ 2,279
Total			\$ 241,562

*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 respondents 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	641	660	19
Annual burden hours	321	330	9
Annual burden dollars	\$0	\$26,291	\$26,291

(* 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.