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).

This information collection request includes changes associated with the DEA's Management of Quotas for Controlled Substances and List I Chemicals rulemaking, RIN 1117-AB49. The DEA is proposing to formally implement the use of subcategories to facilitate the issuance of procurement quotas and provide a more accurate calculation of the aggregate production quotas for the United States. The DEA proposes the addition of the following five subcategories for quota: (1) Quota for Commercial Sales; (2) Quota for Transfer; (3) Quota for Product Development; (4) Quota for Replacement; and (5) Quota for Packaging/Repackaging and Labeling/Relabeling. All types of quota could be requested using the same application and format registrants are accustomed to using, in an online form. Manufacturers of schedules I and II controlled substances and list I chemicals would continue to receive manufacturing and procurement quotas appropriate to their manufacturing and inventory requirements, and the DEA would retain greater control over the amount of these controlled substances and listed chemicals produced, thereby reducing the amount of inventories at risk of diversion.

Part A. Justification

1. Necessity of Information:

Any person that desires to use any basic class of controlled substances listed in schedules 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 or List I chemical. 21 U.S.C. 826; 21 CFR 1303.12(b), 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(a).

2. Needs and Uses:

The DEA uses DEA Form 250 to determine the estimated legitimate need for schedule I and II controlled substances and ephedrine, pseudoephedrine, and phenylpropanolamine, and to establish quotas for persons who use such controlled substances and List I chemicals for purposes of manufacturing. Persons who manufacture schedule I and II controlled substance and ephedrine, pseudoephedrine, and phenylpropanolamine products must apply on DEA Form 250

each year for a procurement quota for such controlled substance or List I chemical. 21 U.S.C. 826; 21 CFR 1303.12(b), 1315.32.

3. Use of Information Technology:

DEA Form 250 is available to be completed and submitted electronically on the DEA Diversion Control Web site, at https://www.deadiversion.usdoj.gov. Currently, 100% of DEA Form 250 applications are submitted electronically.

4. Efforts to Identify Duplication:

Controlled substance and listed chemical quotas are unique to DEA. Therefore, there is no duplication of information requested as part of this collection.

5. Impact on Small Businesses or Entities:

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 were not conducted or conducted less frequently, the DEA would not have sufficient data to set procurement quotas and would be unable to determine the amounts necessary to meet medical, scientific, and other legitimate needs.

7. Special Circumstances Influencing Collection:

There are no special circumstances applicable to this information collection.

8. Consultation with persons outside the Agency:

Public comment will be solicited in the notice of proposed rulemaking (NPRM) associated with this collection. The NPRM will have a 60-day comment period.

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:

Total number of respondents: 344
Average number of responses per respondant per year: 8.9128 (calculated)
Total annual responses: 3,066
Average burden per response: 0.50 hours
Average burden per respondant: 4.46 hours
Total annual burben hours: 1,533 hours

Percent of responses received electronically: 100%

Hour burden cost:

Estimate hourly wage ($/hour):[1]	$61.94
Load for benefits (percent of labor rate):[2]	43.5%
Loaded labor rate ($/hour):[3]	$88.88
Average burden per response (hour):	0.5
Burden cost per response:	$44.44
Number of annual responses:	3,066
Total annual burden dollar:	$136,253

1 Hourly median wage, 11-3061 Purchasing Managers for North American Industry Classification System code 325400 – Pharmaceutical and Medicine Manufacturing. Bureau of Labor Statistics, *Occupational and Employment and Wages, May 2017*, https://www.bls.gov/oes/2017/may/naics4_325400.htm.

2 Average benefits for private industry are 30.3% of total compensation. Bureau of Labor Statistics, *Employer Costs for Employee Compensation – September 2018* (ECEC), https://www.bls.gov/news.release/archives/ecec_12142018.pdf. The 30.3% of total compensation equates to 43.5% (30.3% / 69.7%) load on wages and salaries.

3 $61.94 x (1 + 0.435) = $88.88.

13. Estimate of Cost Burden:

The estimated annual cost burden is zero. Respondents are estimated to not incur any additional start-up costs or capital expenditures, or additional operation and maintenance costs, or to purchase services as a result of this information collection.

14. Estimated Annualized Costs to Federal Government:

Estimated Annual Labor Cost to Government:

Labor Category[4]	**Number**	**% of time**	**Cost**[5]
Section Chief/Supervisory Physical Scientist – GS-1301-15	1	10%	$ 24,481
Analysis of quota information (Schedule I and II controlled substances):			
Drug Science Specialists – GS-601-14	4	69%	$ 574,433
Supervisory Physical Scientist - GS-1301-14	1	42%	$ 87,413
Supervisory Physical Scientist - GS-1301-15	1	5%	$ 12,241
Secretaries - GS-318-7	2	55%	$ 91,847
Diversion Investigator/Executive Assistant– GS-1801-15	1	5%	$ 12,241
Analysis of Quota Information (List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine):			
Drug Science Specialists – GS-601-14	4	10%	$ 83,251
Supervisory Physical Scientist - GS-1301-14	1	6%	$ 12,488
Diversion Investigators/Staff Coordinators – GS-1801-14	4	14%	$ 116,552
Supervisory Physical Scientist - GS-1301-15	1	5%	$ 12,241
Secretaries - GS-318-7	2	9%	$ 15,029
Diversion Investigator/Executive Assistant– GS-1801-15	1	1%	$ 2,448
Total			**$1,044,655**

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:

There are no changes in burden for this information collection request. The proposed changes to this collection would formally implement the use of subcategories, and would not change the amount of time needed for respondents to complete responses. The table below summarizes the changes since the last renewal of this information collection.

4 All government labor costs are rounded to the nearest dollar. Costs are based on the Office of Personnel Management's 2018 general schedule locality pay tables for the Washington-Baltimore-Arlington area (https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2018/DCB.pdf) for the grade listed, step 5.

5 Figures are rounded. Government salary figures include 60.26% load for benefits based on the ECEC for State and local government. The ECEC does not include figures for the Federal government.

	2019 Approved Burden	New Requested Burden	Difference
Annual responses	3,066	3,066	0
Annual burden hours	1,533	1,533	0
Annual burden dollars	$136,253	$136,253	$0

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.