SUPPORTING STATEMENT FOR
Application for Procurement Quota for Controlled Substance and for Ephedrine, Pseudoephedrine, and Phenylpropanolamine (DEA Form 250)

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 DEA's Management of Quotas for Controlled Substances and List I Chemicals rulemaking, RIN 1117-AB49. DEA is formally implementing 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. 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 will continue to receive manufacturing and procurement quotas appropriate to their manufacturing and inventory requirements, and DEA will retain greater control over the amount of these controlled substances and listed chemicals produced, thereby reducing the amount of inventories at risk of diversion.

A. JUSTIFICATION

1. The Controlled Substances Act requires the Attorney General to establish aggregate production quota and assessment of annual needs years for each basic class of controlled substance listed in schedules I and II and the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. 21 U.S.C. 826. 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. 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. 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. 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. Controlled substance and listed chemical quotas are unique to DEA. Therefore, there is no duplication of information requested as part of this collection.

5. 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. If the collection were not conducted or conducted less frequently, 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. There are no special circumstances applicable to this information collection.

8. Public comment was solicited in the notice of proposed rulemaking for "Management of Quotas for Controlled Substances and List I Chemicals," which published in the *Federal Register* on October 23, 2019 at 84 FR 56712. All comments were addressed in the final rule, published in the *Federal Register* on August 31, 2023, at 88 FR 60117.

9. This collection of information does not propose to provide any payment or gift to respondents.

10. 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 as confidential 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. This collection of information does not ask any questions of a sensitive nature.

12.

Estimated Annualized Respondent Cost and Hour Burden

Activity	Number of Respondents	Frequency	Total Annual Responses	Time Per Response	Total Annual Burden (Hours)
DEA Form 250	344	8.9128	3,066	30 mins	1,533
Unduplicated Totals	***344***	***NA***	***3,066***	***30 mins***	***1,533 hrs***

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

13. The annual IC cost burden for this collection is $0.

14. 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):			

[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.

[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.

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**

Total cost to the Federal Government: $1,044,655.

All costs are recovered from registrants through registration fees, as required by the CSA. 21 U.S.C. 886a.

15. There are no changes in burden for this information collection request. The changes to this collection will formally implement the use of subcategories, and will 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.

	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 (wage rate)	$136,253	$136,253	$0

16. DEA will not publish the results of the information collected.

17. DEA does not object to displaying the expiration date for this collection.

18. DEA is not seeking an exception to the certification statement "Certification for Paperwork Reduction Act Submissions" for this collection of information.

B. COLLECTIONS OF INFORMATON EMPLOYING STATISTICAL METHODS.

This collection does/does not contain statistical data.