

**SUPPORTING STATEMENT FOR
Application for Import Quota for Ephedrine, Pseudoephedrine, and Phenylpropanolamine
(DEA Form 488)**

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 #1117-0047, Application for Procurement Quota for Ephedrine, Pseudoephedrine, and Phenylpropanolamine (DEA Form 488).

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 import quotas and provide a more accurate calculation of the assessment of annual needs 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 can be requested using the same application and format registrants are accustomed to using, in an online form. Importers of list I chemicals will continue to receive import quotas appropriate to their manufacturing and inventory requirements, and DEA will retain greater control over the amount of these listed chemicals produced, thereby reducing the number 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. Pursuant to 21 U.S.C. 952 and 21 CFR 1315.34, any person who desires to import the List I chemicals Ephedrine, Pseudoephedrine, or Phenylpropanolamine during the next calendar year must apply on DEA Form 488 for an import quota for each such List I chemicals. DEA is required to limit the importation of ephedrine, pseudoephedrine, and phenylpropanolamine to the amounts "necessary to provide for medical, scientific, or other legitimate purposes." 21 U.S.C. 952.

2. DEA uses DEA Form 488 to determine the estimated need for ephedrine, pseudoephedrine, and phenylpropanolamine and to establish import quotas for persons importing these List I chemicals. Persons importing ephedrine, pseudoephedrine, and phenylpropanolamine must apply on DEA Form 488 each year for an import quota for each such List I chemical. 21 CFR 1315.34.

3. DEA Form 488 is available to be completed and submitted electronically on the DEA Diversion Control Program website, at <https://www.deadiversion.usdoj.gov>. Currently, 100% of DEA Form 488 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 with the 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 was 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.

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. This collection of information does not 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 488	49		126	30 mins	63
Unduplicate d Totals	49	N/A	126	30 mins	63 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:	126
Total annual burden dollar:	\$5,599

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 (List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine):			
Drug Science Specialists – GS-601-14	1	29%	\$ 60,357
Supervisory Physical Scientist - GS-1301-14	1	10%	\$ 20,813
Secretary - GS-318-7	1	19%	\$ 15,864
Total			\$121,516

Total cost to the Federal Government: \$121,516.

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

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.

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.

	2022 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. 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 INFORMATION EMPLOYING STATISTICAL METHODS.

This collection does/does not contain statistical data.