SUPPORTING STATEMENT FOR
Application for Individual Manufacturing Quota for a Basic Class of Controlled Substance and for Ephedrine, Pseudoephedrine, and Phenylpropanolamine (DEA Form 189)

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).

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. DEA is formally implementing the use of subcategories to facilitate the issuance of manufacturing quotas and provide a more accurate calculation of the aggregate production quotas for the United States. DEA is adding 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 will 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 who is registered to manufacture any basic class of controlled substances listed in schedule I or II, or the List I chemicals ephedrine, pseudoephedrine, or phenylpropanolamine, and who desires to manufacture a quantity of such class or List I chemical, must apply on DEA Form 189 for a manufacturing quota for such quantity of such class or List I chemical. 21 U.S.C. 826(c); 21 CFR 1303.22, 1315.22.

2. DEA uses DEA Form 189 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 persons manufacturing these substances and chemicals. Manufacturers of schedule I and II controlled substances and the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine must apply on DEA Form 189 each year for assignment of their individual manufacturing quota. 21 U.S.C. 826(c); 21 CFR 1303.22, 1315.22.

3. Since September, 2011, DEA Form 189 has been available to be completed and submitted on the DEA Diversion Control Web site, at https://www.deadiversion.usdoj.gov. Currently, 100% of DEA Forms 189 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 production 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. No government funds will be used as payment or for gifts 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 189	1	1	.6 hrs	1	1hr
DEA Form 189	33	26.0303	859	30 mins	430
Unduplicated Totals	***33***	***NA***	***859***		***430 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
Total annual responses:	859
Total annual hour burden dollars:	$38,174

13. The annual IC cost burden for this collection is $0. Respondents are not estimated to 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. Cost to Federal Government:

Labor Category[4]	Number	% of time	Cost[5]

[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

Section Chief/Supervisory Physical Scientist – GS-1301-15	1	10%	$ 24,481
Analysis of quota information:			
Drug Science Specialists – GS-601-14	4	18%	$ 149,852
Supervisory Physical Scientist - GS-1301-14	1	10%	$ 20,813
Secretaries - GS-318-7	2	19%	$ 31,729
Diversion Investigator/Executive Assistant– GS-1801-15	1	3%	$ 7,344
Analysis of Quota Information (List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine):			
Drug Science Specialists – GS-601-14	4	1%	$ 8,325
Supervisory Physical Scientist - GS-1301-14	1	1%	$ 2,081
Diversion Investigators/Staff Coordinators – GS-1801-14	4	1%	$ 8,325
Supervisory Physical Scientist - GS-1301-15	1	1%	$ 2,448
Secretaries - GS-318-7	2	1%	$ 1,670
Diversion Investigator/Executive Assistant– GS-1801-15	1	1%	$ 2,448
Total			**$ 259,516**

Total Cost to Federal Government: $259,516.

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	859	859	0
Annual burden hours	430	430	0
Annual burden dollars	$38,174	$38,174	$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.

local government. The ECEC does not include figures for the Federal government.