SUPPORTING STATEMENT FOR
Procurement Quota Certification and Recordkeeping Requirements

The Drug Enforcement Administration (DEA) seeks approval by the Office of Management and Budget (OMB) for a new collection of information– OMB Approval #1117-0055, Procurement Quota for Certification and Recordkeeping Requirements.

This information collection request includes is associated with DEA's Management of Quotas for Controlled Substances and List I Chemicals rulemaking, RIN 1117-AB49. DEA is finalizing revisions to the regulations for procurement quota certification by requiring all DEA registrants supplying schedules I and II controlled substances or list I chemicals to DEA manufacturers to obtain certification of the manufacturer's procurement quota before completing the transaction. This will prevent manufacturers from purchasing active pharmaceutical ingredients from distributors, rather than other manufacturers, without including a quota certification. Current DEA regulations stipulate that a procurement quota certification is only required to be given when a person is ordering from entities registered as importers, manufacturers, or bulk manufacturers. Manufacturers procuring schedules I and II controlled substances or list I chemicals must maintain a copy of the certification they provide with their order for a period of two years from the date of the certification. Under this final rule, this recordkeeping requirement would apply to certifications included with orders for schedules I and II controlled substances or list I chemicals to all registrants, including distributors.

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 to whom a procurement quota has been issued, authorizing that person to procure and use a quantity of a basic class of controlled substances listed in Schedules I or II and ephedrine, pseudoephedrine, phenylpropanolamine during the current calendar year, shall, at or before the time of giving an order to another registrant requiring the distribution of a quantity of such basic class and the chemical, certify in writing to such other registrant that the quantity of such basic class and list I chemical ordered does not exceed the person's unused and available procurement quota of such basic class and chemical for the current calendar year. Registrants shall not fill an order from a person required to apply for a procurement quota unless the order is accompanied by such a certification. 21 U.S.C. 826; 21 CFR 1303.12(f), 1315.32(h).

2. The third-party disclosure and recordkeeping requirements of this collection ensure that manufacturers must include a quota certification with all orders for schedules I and II controlled substances and list I chemicals, regardless of whether a manufacturer orders from other manufacturers or from distributors. Requiring quota certifications with orders helps prevent diversion and assure that a registrant is not exceeding their allotted procurement quota for that calendar year.

3. The certification letters will be submitted together with DEA Form 222. If the purchaser submits DEA Form 222 electronically, using the Controlled Substances Ordering System, the certification will also be 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 expects this collection will not have a significant economic impact on a substantial number of 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. Respondents will submit qouta certification letters to suppliers for review before an order for a quantity of a basic class of controlled substances listed in Schedules I or II and ephedrine, pseudoephedrine, phenylpropanolamine may be filled, using information maintained as part of usual and customary business practice.

Estimated Annualized Respondent Cost and Hour Burden

Activity	Number of Respondents	Frequency	Total Annual Responses	Time Per Response	Total Annual Burden (Hours)
Procurement Quota Certification and Recordkeeping	500		3,000	15 mins	750
Unduplicated Totals	***500***	***N/A***	***3,000***	***15 mins***	***750 hrs***

Percent of responses received electronically: 100%

Hour burden cost:

Estimate hourly wage ($/hour):[1]	$32.63
Load for benefits (percent of labor rate):[2]	43.7%
Loaded labor rate ($/hour):[3]	$46.99
Average burden per response (hour):	0.25
Burden cost per response:	$11.72
Number of annual responses:	3,000
Total annual burden dollar:	$35,160

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

14. Estimated Annual Labor Cost to Government: $0

Estimated Annual Production Cost to Government: $0

Estimated Annual Labor Cost to Government: $0

Total cost to the Federal Government: $0.

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

15. This is a new collection being created as a part of DEA's Management of Quotas for Controlled Substances and List I Chemicals rulemaking, RIN 1117-AB49.

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

[1] Hourly median wage, 13-1041 Compliance Officer. Bureau of Labor Statistics, *Occupational Employment and Wages, May 2017*, https://www.bls.gov/oes/2017/may/oes131041.
[2] Average benefits for private industry are 30.4% of total compensation. Bureau of Labor Statistics, *Employer Costs for Employee Compensation – June 2018* (ECEC), https://www.bls.gov/news.release/archives/ecec_09182018.pdf. The 30.4% of total compensation equates to 43.7% (30.4% / 69.6%) load on wages and salaries.
[3] $32.63 x (1 + 0.437) = $46.99.

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.