Supporting Statement for Paperwork Reduction Act Submissions
Procurement Quota Certification and Recordkeeping Requirements
OMB Approval #1117-New

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

This information collection request is associated with the DEA's Management of Quotas for Controlled Substances and List I Chemicals rulemaking, RIN 1117-AB49. The DEA is proposing to revise 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 would 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 the proposed 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.

Part A. Justification

1. Necessity of Information:

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. Needs and Uses:

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. Use of Information Technology:

The certification letters will be submitted together with the DEA Form 222. If the purchaser submits the DEA Form 222 electronically, using the Controlled Substances Ordering System, the certification will also be 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 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. Consequences of Less Frequent Collection:

If quota certifications were not included with every order for schedules I and II controlled substances and list I chemicals, there would not be a method for ensuring that a registrant is not exceeding their procurement quota for that year, risking the chance for the occurrence of diversion.

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 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.

Total annual respondents: 500
Total annual responses: 3,000
Total annual burden hours: 750 hours
Average burden per response: 0.25 hour

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. 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:

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.

Estimated Annual Production Cost to Government: $0

Estimated Annual Labor Cost to Government: $0

Total costs to Government: $0

15. Reasons for Change in Burden:

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

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 displaying the expiration date for this collection.

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.