

**Supporting Statement for Paperwork Reduction Act Submissions
Annual Reporting for Manufacturers of Listed Chemicals
OMB Approval #1117-0029**

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 #1117-0029, Annual Reporting for Manufacturers of Listed Chemicals.

Part A. Justification

1. Necessity of Information:

This information collection permits the DEA to monitor the volume and availability of domestically manufactured listed chemicals. These listed chemicals may be subject to diversion for the illicit production of controlled substances. This information collection is authorized by Title 21 United States Code, Section 830(b) (21 U.S.C. § 830(b)(2)).

2. Needs and Uses:

The DEA uses this information from businesses and other for-profit entities which manufacture listed chemicals domestically. The collection of this information enables the DEA to monitor the domestic manufacture and availability of listed chemicals. This reporting is mandated by the Domestic Chemical Diversion Control Act of 1993. Failure to collect such information would impede the DEA's enforcement of the Controlled Substances Act.

3. Use of Information Technology:

Each year, businesses domestically manufacturing listed chemicals are required to submit the amount of each chemical produced. Manufacturers create accounts which are available to be completed and submitted electronically on the DEA Office of Diversion Control Web site (<http://www.deadiversion.usdoj.gov>). The accounts are used to submit reports and update contact information. Currently, 100% of DEA annual reports are submitted electronically.

4. Efforts to Identify Duplication:

The DEA has made efforts to identify and prevent duplication of the collection of information. The collection of this information is unique to the DEA.

5. Impact on Small Businesses or Entities:

This information 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. Consequences of Less Frequent Collection:

This information collection is required by law on a yearly basis. This yearly reporting requirement permits the DEA to carry out its policies and programs as they relate to the diversion of listed chemicals for the illicit manufacture of controlled substances. Businesses and other for-profit entities manufacturing listed chemicals maintain the requested data as part of usual and customary business practice.

7. Special Circumstances Influencing Collection:

There are no special circumstances applicable to this information collection. Respondents submit yearly reports in which the requested information is maintained as a usual and customary business practice.

8. Consultation with persons outside the Agency:

Public comment was solicited in the 60-day Federal Register Notice of Information Collection, 81 FR 1443, published January 12, 2016 and the 30-day Federal Register Notice of Information Collection, 81 FR 15351, published March 22, 2016. The DEA did not receive any comments concerning this collection.

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.

Estimated Annual Production Cost to Government:

Production Costs to Government: \$0

Estimated Annual Labor Cost to Government:

| Labor Category | Number | % of time | Cost⁴ |
|-------------------------|---------------|------------------|-------------------------|
| Program Analyst – GS-14 | 1 | 20% | \$ 38,746 |
| Total | | | \$ 38,746 |

*Figures are rounded.

Total costs to Government: \$38,746

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

15. Reasons for Change in Burden:

Changes to the annual burden hours reflect chemical registrant population adjustments and greater use of online applications, which take less time to complete. Although there is a decrease in annual burden hours there is an increase in annual burden dollars due to a change in calculation method.* There have been no statutory or regulatory changes affecting this information collection. The table below summarizes the changes since the last renewal of this information collection.

| | 2012 Approved Burden | 2015 Requested Burden | Difference |
|-----------------------|-----------------------------|------------------------------|-------------------|
| Annual responses | 100 | 100 | 0 |
| Annual burden hours | 98 | 25 | (73) |
| Annual burden dollars | \$0 | \$1,992 | \$1,992 |

(* In prior information collection requests, the estimated annual burden dollars was implied to be a usual and customary business expense not directly associated with this information collection. The DEA believes the estimated annual burden associated with this information collection should be included. This change in calculation method is employed in this and future information collection requests.)

16. Plans for Publication:

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

17. Expiration Date Approval:

The DEA does not use a form for this information collection. Therefore, this question is not applicable.

⁴ Government salary figures include 57% load for benefits based on the ECEC for “State and local government.” The ECEC does not include figures for the Federal Government.

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.