

**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:

Pursuant to 21 U.S.C. 830(b)(2) and 21 CFR 1310.05(d), manufacturers of listed chemicals must file annual reports of manufacturing, inventory, and use data for the listed chemicals they manufacture. These reports allow the DEA to monitor the volume and availability of domestically manufactured listed chemicals, which may be subject to diversion for the illicit production of controlled substances.

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:

Respondents may submit reports electronically on the DEA's Diversion Control Division web site (<http://www.deadiversion.usdoj.gov>), or in writing on company letterhead. 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 information related to domestic listed chemical production 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:

The Controlled Substances Act requires this collection be conducted annually. 21 U.S.C. 830(b) (2). This annual reporting requirement allows 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. Respondents 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.

8. Consultation with persons outside the Agency:

Public comment was solicited in the 60-day Federal Register Notice of Information Collection, 83 FR 64366, published on December 14, 2018, and the 30-day Federal Register Notice of Information Collection, 84 FR 5719, published on February 22, 2019. 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.

11. Justification for Sensitive Questions:

This collection of information does not ask any questions of a sensitive nature.

12. Estimate of Hour Burden:

Respondents submit reports on an annual basis, using information maintained as part of usual and customary business practice.

	Number of Annual Respondents	Average Time per Response (hours)	Total Annual Burden Hours
Paper	-	N/A	-
Electronic	50	0.25	12.50
Total	50		12.50

Total number of respondents: 50

Total number of responses per respondent per year: 1

Total annual responses: 50

Total annual burden hours: 12.5 hours

Average burden per response: 0.25 hour

Total responses received on paper: 0

Total responses received online: 100

Percent of responses received online: 100%

Hour burden cost:

Estimate hourly wage (\$/hour): ¹	\$61.94
Load for benefits (percent of labor rate): ²	43.7%
Loaded labor rate (\$/hour): ³	\$89.01
Average burden per response (hour):	0.25
Burden cost per response:	\$22.25
Number of annual responses:	50
Total annual burden dollar:	\$1,113

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, 11-3061 Purchasing Manager for North American Industry Classification System code 325400 – Pharmaceutical and Medicine Manufacturing. Bureau of Labor Statistics, *Occupational Employment and Wages, May 2017*, https://www.bls.gov/oes/2017/may/naics4_325400.htm.

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 \$61.94 x (1 + 0.437) = \$89.01.

Estimated Annual Production Cost to Government: \$0

Estimated Annual Labor Cost to Government:

Labor Category	Number	Annual rate ⁴	Load ⁵	% of time	Cost
Program Analyst – GS-14	1	\$ 129,869.00	1.603	20%	\$ 41,636
Total					\$ 41,636

*Figures are rounded.

Total costs to Government: \$41,636

All costs to the federal government for these activities are recovered from registrants through registration fees, as required by the Departments of Commerce, Justice, State, the Judiciary, and Related Agencies Appropriations Act of 1993. 21 U.S.C. 886a.

15. Reasons for Change in Burden:

Changes to the annual burden hours reflect changes in the chemical registrant population and manufacturing activity. 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.

	2016 Approved Burden	2019 Requested Burden	Difference
Annual responses	100	50	-50
Annual burden hours	25	12.5	-12.5
Annual cost	\$1,992	\$1,113	-\$879

16. Plans for Publication:

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

17. Expiration Date Approval:

There is no form associated with this information collection.

18. Exceptions to the Certification Statement:

⁴ 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 Government salary figures include 60.3% (37.6% / 62.4%) load for benefits based on the ECEC data for State and local government. The ECEC data does not include figures for the Federal government.

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.