

Supporting Statement for Paperwork Reduction Act Submissions

Annual Reporting for Manufacturers of Listed Chemicals

[OMB control number 1117-0029]

A. Justification

1. Necessity of information: This information collection permits the Drug Enforcement Administration 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, § 830(b) (2).
2. Needs and Uses: This information is collected from businesses and other for-profit entities which manufacture listed chemicals domestically. Collection of this information enables the Drug Enforcement Administration 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 DEA's enforcement of the Controlled Substances Act.
3. Use of Technology: Each year, businesses domestically manufacturing listed chemicals are required to submit the amount of each chemical produced. In 2012, DEA began accepting these reports electronically. Manufacturers create accounts through the OD website. The accounts are used to submit reports and update contact information. The ability to report online reduces paper, time typing letters, and report time.
4. Efforts to Identify Duplication: This reporting requirement is unique to the Drug Enforcement Administration. To the extent that the information required to be reported to DEA may be contained in reports made to other agencies, respondents may submit such other reports, in lieu of creating a new report for DEA.
5. Methods to Minimize Burden on Small Businesses: This collection of information does not impact small businesses or small entities.
6. Consequences of Less Frequent Collection: This information collection is required by law on a yearly basis. This yearly reporting requirement permits the Drug Enforcement Administration 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: This information collection involves none of the listed criteria. Respondents submit yearly reports in which the requested information is maintained as a usual and customary business practice.

8. Reasons for Inconsistencies with 5 CFR 1320.6: DEA meets regularly with the regulated industry to discuss DEA regulations, policies and procedures and to solicit comments from the regulated industry.

DEA received no comments to this collection of information.

9. Payment or Gift to Claimants: No gifts or remunerations are given to respondents.

10. Assurance of Confidentiality: Confidentiality is protected under the Freedom of Information Act (5 U.S.C. 552) and the Controlled Substances Act (21 U.S.C. 830(c) which states that any information obtained by the Attorney General which is exempt under 5 U.S.C. 552 is confidential and may not be disclosed to any person.

11. Justification for Sensitive Questions: This information collection does not request information of a sensitive nature.

12. Estimate of Hour Burden:

Number of Respondents: 100
Number of Responses per Respondent: 1
Total Annual Responses: 100
Estimated Time per Response: 1 hours
Total Burden Hours: 100 hours

Average Time to Complete Responses:

Paper: 1 Hour
Electronic: 15 minutes

Time for Responses:

Paper: 97 respondents at 1 hour per response, 1 response per year = 97 hours
Electronic: 3 respondents at 15 minutes, 1 response per year = 45 minutes.

Cost:

Cost per hour: 97.75 burden hours at \$10 per hour = \$977.50

This estimate is based on the population the regulated industry manufacturing listed chemicals domestically. Data collected are available as a part of usual and customary business practice. Each year, businesses domestically manufacturing listed chemicals are required to submit the amount of each chemical produced. In 2012, DEA began accepting these reports electronically. Manufacturers create accounts through the OD website (www.DEAdiversion.usdoj.gov). The accounts are used to submit reports and update contact information. The ability to report online reduces paper, time spent typing letters, and report time.

13. Estimate of Cost Burden:

Mailing costs: No mailing costs incurred. No form is used for this collection; in previous years, the information was either mailed or faxed to DEA pursuant to 21 C.F.R. § 1310.05(d). In 2011, DEA began encouraging registrants to submit responses electronically (via DEA website interface) or via facsimile. In 2012, DEA received 3% of responses electronically; DEA expects the number of electronic responses to increase dramatically due to the implementation of the new interface website.

14. Estimated Annualized Cost to Federal Government:

Costs to Government: \$0

Compilation and reporting of information:

1 GS-14 Program Analyst (20% of work year): \$30,525

Total costs to Government: \$30,525

15. Reasons for Change in Burden: Adjustments made to this information collection are a result of the agency adopting electronic reporting and new estimated reporting times. This adjustment reduced overall burden hours from 4,000 to 97.75. The estimated reporting burden was reduced from 4 hours to 1 hour per paper response; electronic responses were reported to take 15 minutes.

16. Plans for Publication: The results of this information collection will not be published.

17. Expiration Date Approval: No form is used for this information collection. Therefore, this question is not applicable.

18. Exceptions to the Certification Statement: There are no exceptions to the certification statement.

Part B. Collections of Information Employing Statistical Methods:

The Drug Enforcement Administration does not employ statistical methods in this information collection.