

Supporting Statement for Paperwork Reduction Act Submissions
Record Requirements for Chemical Distributors

OMB Approval # 1117-

Part A. Justification

1. Necessity of Information:

Title 21, United States Code, Section 830, and Title 21, Code of Federal Regulations (CFR), part 1314 require that any person who is a regulated seller of scheduled listed chemical products to self-certify to DEA that it has trained its staff in the requirements for selling scheduled listed chemical products and is in compliance with DEA's regulations. To ensure that persons distributing scheduled listed chemical products sell only to regulated sellers who are eligible to sell them, DEA is requiring distributors to collect and retain the certification number DEA issues to regulated sellers when they self-certify.

2. Needs and Uses:

This information collection will assist distributors and other registrants that sell to regulated sellers in determining that their customers are legitimate purchasers of the products. The requirement to determine the legitimacy of the purchaser is part of the existing rules that govern distributors, manufacturers, and importers of listed chemicals.

3. Use of Technology:

This requirement would neither require nor bar the use of technology. Records of the self-certification number of regulated sellers purchasing scheduled listed chemical products may be maintained as part of usual and customary business records.

4. Efforts to Identify Duplication:

This requirement involves no duplication. DEA law and regulations require that regulated sellers of scheduled listed chemical products self-certify to DEA. DEA law and regulations also require that distributors of listed chemicals maintain certain usual and customary business records regarding distribution transactions.

5. Methods to Minimize Burden on Small Businesses:

This collection does not have a significant impact upon small entities within the meaning and intent of the Regulatory Flexibility Act, 5 U.S.C. 601 et seq.

6. Consequences of Less Frequent Collection:

Without this collection, distributors who distribute scheduled listed chemical products to regulated sellers would have to take other actions to ensure the legitimacy of the purchasers.

7. Special Circumstances Influencing Collection:

None of the circumstances in Item 7 apply to this collection.

8. Reasons for Inconsistencies with 5 CFR 1320.6:

There are no inconsistencies with 5 CFR 1320.6. DEA sponsors and participates in training seminars, industry meetings, and conferences, with the regulated industry (manufacturers, importers and exporters). These meetings are held regularly and provide an open forum to discuss matters of mutual concern.

9. Payment or Gift to Claimants:

There are no such gifts or payments to respondents.

10. Assurance of Confidentiality:

Information requested in this collection would not be confidential business information.

11. Justification for Sensitive Questions:

This collection does not include questions of a sensitive nature.

12. Estimate of Hour Burden:

Number of Respondents:	38,926
Frequency of Response:	Annual
Average annual responses:	38,926
Average time per response:	2 minute
Total annual burden:	1,298 hours

DEA estimated the number of respondents as follows:

As of August 6, 2007, 75,721 regulated sellers had self-certified with DEA. Of those, 39,917 certifications were filed by 103 chains. There were, therefore, 36,804 regulated sellers who filed as individual regulated sellers. For sellers who belonged to chains that filed certifications for their stores, DEA assumed that the chain held the master list and would provide the self-certification number to distributors from whom the chain orders scheduled listed chemical products. Thirty of the self-certified chains are also registered as chemical or controlled substance distributors; these chains, therefore, do not need to take any additional action to provide information to the distributor. The number of regulated sellers who would need to provide the self-certification number to a distributor is the 36,804 individual regulated sellers plus the 73 chains that do not serve as their owner distributors. In addition, DEA assumed that 2,049 controlled substance and chemical distributors would have to collect the information. This estimate is conservative because not all of these distributors handle scheduled listed chemical products.

Cost to respondents:

Number of Responses x	Time per Response	x	per hour	=	Total Industry Costs
36,877	x 0.03 hours	x	\$40.78	=	\$50,124
2,049	x 0.03 hours	x	\$60.26	=	<u>\$4,115</u>
					\$54,240 (rounded)

Because wage rates are higher in the wholesale industry, median wage rate for drug wholesaler administrative services managers was used for distributors. A weighted wage rate for retailer general managers was used based on the number of certifiers in grocery, discount, pharmacy, and convenience store sectors. Both wage rates were loaded with fringe at 50 percent. Wage rates were based on the BLS May 2006 National Industry-Specific Occupational Employment and Wage Estimates. Fringe rate is based on BLS *Employer Costs for Employee Compensation*.

13. Estimate of Cost Burden:

There are no operations and maintenance or capital costs associated with the requirement. The certification number can be maintained electronically as part of the purchase order.

14. Estimated Annualized Costs to Federal Government:

This is a recordkeeping requirement. There are no costs to the Federal government.

15. Reasons for Change in Burden:

This is a new information collection.

16. Plans for Publication:

There are no plans to publish the information collected.

17. Expiration Date Approval:

There is no form, so an expiration date for the form is not needed.

18. Exceptions to the Certification Statement:

There are no exceptions to the certification statement.

Part B. Statistical Methods

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