

Supporting Statement for Paperwork Reduction Act Submission
Report of Suspicious Orders or Theft/Loss of Listed Chemicals/Machines

OMB Approval Number 1117-0024

Part A. Justification

1. Necessity of Information:

The Chemical Diversion and Trafficking Act of 1988 (Public Law 100-690) levies reporting requirements on those who transact business with List I and List II chemicals, tableting machines and encapsulating machines. These persons include manufacturers, distributors, importers, and exporters of listed chemicals, tableting machines, or encapsulating machines, or persons who serve as brokers or traders for international transactions involving a listed chemical, tableting machine, or encapsulating machine (21 CFR 1300.02(b)(25)). The items subject to control are used in the clandestine manufacture of controlled substances. Part 1310 of Title 21, Code of Federal Regulations sets these controls. These regulations require that suspicious orders and thefts or losses be reported to the Drug Enforcement Administration (DEA).

2. Needs and Uses:

The information provided on suspicious orders and thefts provides DEA with important, timely intelligence designed to identify suspected traffickers of the listed chemicals and machines. Reports are provided to the Special Agent in Charge of the Divisional Field office for the area in which the regulated person making the report is located (21 CFR 1310.05(a)). Oral contact should be made "at the earliest practicable opportunity after the regulated person becomes aware of the circumstances involved" (21 CFR 1310.05(b)). This allows DEA to respond based on local circumstances, trends and information.

3. Use of Technology:

Notification of suspicious orders and thefts does not occur using a form. Notification is provided in writing.

4. Efforts to Identify Duplication:

The reports on suspicious orders and thefts or losses are unique to DEA. There is no other system of its kind in the Federal Government.

5. Methods to Minimize Burden on Small Businesses:

This collection does not have a significant economic impact upon 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 information required is kept to the minimum necessary to fulfill the requirements of the law. Reports occur as needed. Not collecting this information would impede DEA's investigative ability and its ability to ensure that chemicals and machines are not diverted for the illicit manufacture of controlled substances.

7. Special Circumstances Influencing Collection:

Reports are collected as needed, when circumstances warrant reporting of suspicious transactions, thefts and losses. It is possible that reports could be submitted more frequently than quarterly. There are no other special circumstances in Item 7 of the supporting statement applicable to this information collection.

8. Reasons for Inconsistencies with 5 CFR 1320.6:

There are no inconsistencies with the Paperwork Reduction Act. DEA meets regularly with the affected industry to discuss policies, programs and regulations.

Comment: The Office of Management and Budget received one comment regarding this information collection from the Healthcare Distribution Management Association. The comment was provided to DEA for response.

The commenter did not disagree with DEA's estimate that it takes 15 minutes for registrants to complete the report of a suspicious order or theft/loss of a listed chemical or tableting machine. However, the commenter claimed that the burden for the collection is significantly greater due to the need for registrants to determine whether a report should be filed in the first place. The commenter claimed that "DEA registrants were required to develop means to identify what constituted 'extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation' of the Controlled Substances Act." The commenter asserted that "[t]hese efforts often include monitoring of wholesale distributors' customer's ordering patterns, making inquiries of customers regarding their business operations, reacting to changes in business operations or ordering patterns, and/or developing information technology capabilities and tracking systems to record and maintain associated data." The commenter estimated that it could take a registrant from one hour to more than three hundred hours for each report when the respondent's information collection and monitoring activities in support of the reports are factored in.

DEA Response: Through the Controlled Substances Act (CSA), Congress established a closed system with respect to controlled substances and listed chemicals. DEA is charged with implementing and enforcing the CSA. Registrants and chemical handlers under the CSA, such as those represented by the commenter, are individuals and entities found to meet the legal requirements under the CSA and to assume the responsibilities encompassed in being authorized to operate within such a closed system of controlled substances and listed chemicals. As the participants most directly involved and equipped with information necessary to enforce the closed system, DEA registrants and chemical handlers are under a statutory duty to report suspicious transactions. Contrary to the comment, the 2005 CMEA did not alter this

longstanding duty. This statutory duty would include the types of activities described on page 2 of the comment:

“DEA registrants were required to develop means to identify what constituted ‘extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation’ of the Controlled Substances Act. These efforts often include monitoring of wholesale distributors’ customer’s ordering patterns, making inquiries of customers regarding their business operations, reacting to changes in business operations or ordering patterns, and/or developing information technology capabilities and tracking systems to record and maintain associated data.”

The registrant is provided maximum flexibility in how suspicious transactions are reported. The reporting requirements contained in 21 CFR 1310.05(a)-(b) and 1310.06(c) require that only a minimal amount of information be provided sufficient to inform DEA of the existence of a suspicious transaction: for example, names, date, quantity, registration number and a brief description. DEA’s regulations specifically state that normal business records are sufficient provided they include the relevant information and are readily retrievable. 21 CFR 1310.06(b). DEA is looking into an online reporting mechanism to provide industry with even more flexibility and ease in reporting suspicious transactions.

Employees who are familiar with the regulated person’s sales/distributions will recognize when a sale appears to be an outlier, that is, when the quantity sold seems to far exceed the norm, when the method of payment does not match the typical method of payment accustomed to being seen by a particular regulated person for a particular type of sale, etc. DEA believes that many of the items necessary to be monitored in support of this information collection are routinely tracked as aspects of normal good operational practices and procedures by any company doing business.

DEA further believes that some of the systems which the commenter described have already been built on a one-time basis. As this has been a longstanding collection and requirement, DEA questions the high end of the commenter’s estimate – more than three hundred hours (more than 7.5 person weeks) involved for every report submitted to DEA.

Finally, DEA notes the availability of certain information to all DEA registrants which can facilitate some of the monitoring the commenter discusses. DEA provides all registrants the ability to search the DEA registration database for information regarding other registrants – name, address, DEA registration number, chemicals authorized to be handled. This means that no registrant is required to maintain or retain such information themselves, but instead can search DEA resources. DEA will be making available a similar system for persons self-certified to distribute drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine in the future.

For these reasons, and after carefully considering all comments, DEA believes the best estimate of time for this information collection is 15 minutes.

9. Payment or Gift to Claimants:

There are no such gifts or payments 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 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 business information per 28 CFR 16.8(c) and Exemption 4 of FOIA, DEA will give written notice to the submitter to allow an opportunity to object within a reasonable time prior to disclosure by DEA.

11. Justification for Sensitive Questions:

Questions of a sensitive nature are not included in reporting requirements.

12. Estimate of Hour Burden:

Number of Respondents:	1,200
Frequency of Response:	As Needed
Average time per response:	15 minutes
Total annual responses:	300

Total annual burden: 75 hours

DEA assumes that a transportation, storage, and distribution manager (SOC 11-3071) will file the report on behalf of the registrant. According to the Bureau of Labor Statistics' 2009 Occupational Employment Statistics, the median hourly wage for a transportation, storage, and distribution manager is \$38.22 (http://www.bls.gov/oes/current/oes_nat.htm). Therefore, the labor cost of burden hours is \$2,866.50.

13. Estimate of Cost Burden:

Mailing costs: 300 responses * \$0.44 per response = \$132

14. Estimated Annualized Costs to Federal Government:

Estimated annual cost to the Federal government

2 full-time GS 12 positions:	\$217,228.80
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Total Cost to Federal Government:	\$217,228.80
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All costs to the government for operation of the Diversion Control Program, including the above costs, are recovered by DEA from registrants through registration fees, as required by the Department of Justice and Related Agencies Appropriations Act of 1993.

15. Reasons for Change in Burden:

There are no program changes. Changes are due to population adjustments as fewer entities have registered as chemical handlers.

16. Plans for Publication:

There are no plans to publish the information collected.

17. Expiration Date Approval:

Registrants report information using their own documents. No form is used for this information collection.

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.