Supporting Statement for Paperwork Reduction Act Submission
Reports of Regulated Transactions Involving Extraordinary Quantities, Uncommon Methods of Payment, and Unusual/Excessive Loss or Disappearance, and Regulated Transactions in Tableting/Encapsulating Machines
OMB Approval #1117-0024

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 #1117-0024, Reports of Regulated Transactions Involving Extraordinary Quantities, Uncommon Methods of Payment, Unusual/Excessive Loss or Disappearance, and Regulated Transactions in Tableting/Encapsulating Machines.

Part A. Justification

1. Necessity of Information:

The Controlled Substances Act imposes reporting requirements on those who transact business with listed chemicals, tableting machines and encapsulating machines. See 21 U.S.C. 830(b), 21 CFR 1310.03, 21 CFR 1310.05, 21 CFR 1310.06.

Each regulated person is required to report any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, any unusual or excessive loss or disappearance of a listed chemical, and any regulated transaction in a tableting or encapsulating machine, to include any domestic regulated transaction in a tableting or encapsulating machine and any import or export of a tableting or encapsulating machine. 21 U.S.C. 830(b)(1)(A), (C) and (D); 21 CFR 1310.05(a)(1), (3)–(4); 21 CFR 1310.05(c). Regulated persons include manufacturers, distributors, importers, and exporters of listed chemicals, tableting machines, or encapsulating machines, and persons who act as brokers or traders for international transactions involving a listed chemical, tableting machine, or encapsulating machine. 21 U.S.C. 802(38). The items subject to control are used in the clandestine manufacture of controlled substances.

2. Needs and Uses:

The information provided on regulated transactions involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, any unusual or excessive loss or disappearance of a listed chemical, and any regulated transaction in a tableting or encapsulating machine provides the DEA with important, timely intelligence designed to identify suspected traffickers of listed chemicals and certain machines. Reports of all of these transactions, except the import or export of a tableting or encapsulating machine, are provided to the Special Agent in Charge of the Divisional 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 the DEA to respond quickly based on local circumstances, trends and other relevant information. Written reports of these transactions must subsequently be filed within 15 days. 21 CFR 1310.05(b). Written reports of the proposed import or export of a tableting or encapsulating machine shall be filed with the Import/Export Unit of the DEA Office of Diversion Control on or before the date of importation or exportation. 21 CFR 1310.05(c).

3. Use of Information Technology:

Automated, online, mechanical, or other technological collection methods are not used extensively for this collection of information. As explained above, notification to the DEA shall be made orally at the earliest practicable opportunity after the regulated person becomes aware of the circumstances, and subsequently in writing within 15 days. However, written reports of the proposed import or export of a tableting or encapsulating machine may be filed via fascimile. 21 CFR 1310.05(c).

4. Efforts to Identify Duplication:

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

5. Impact on Small Businesses or Entities:

This is a routine renewal of the information collection. The DEA does not anticipate any additional impact on small businesses or other small entities since the initial approval of this information collection. The 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 information requested is mandated by federal law and reporting is only required when the specified circumstances occur. The CSA requires a report "at the earliest practicable opportunity after the regulated person becomes aware of the circumstances involved" with respect to regulated transactions involving an extraordinary quantity of a listed chemical or an uncommon method of payment or delivery. 21 U.S.C. 830(b)(1). As the information collection is required by statute "at the earliest practicable opportunity," the DEA has no discretion to require less frequent collection in these circumstances. The DEA, by regulation, requires reports of any unusual or excessive loss or disappearance of a listed chemical, and reports of any domestic regulated transactions in a tableting machine or an encapsulating machine "at the earliest practicable opportunity after the regulated person becomes aware of the circumstances involved." 21 CFR 1310.05(b). To require such reporting any less frequently would cause confusion with respect to reporting regulated transactions involving an extraordinary quantity of a

listed chemical or an uncommon method of payment or delivery, and would impede the DEA's ability to ensure that listed chemicals and certain machines are not diverted to the illicit manufacture of controlled substances. Regulated persons who import or export a tableting or encapsulating machine are required to report the information on or before the date of the importation or exportation. 21 CFR 1310.05(c). To require such reporting any less frequently would frustrate the DEA's ability to prevent the unlawful manufacture of controlled substances.

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, 80 FR 6766, published February 6, 2015 and the 30-day Federal Register Notice of Information Collection, 80 FR 18256, published April 3, 2015. 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 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:

Number of Respondents: 63
Frequency of Response: As Needed
Average time per response: 20 minutes
Total annual responses: 63

Total annual burden: 21 hours*

(* Includes all notifications: oral and written reports regarding listed chemicals and written reports of the proposed import or export of a tableting or encapsulating machines.)

The 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' 2014 Occupational Employment Statistics, the median hourly wage for a transportation, storage, and distribution manager is $41.06 (http://www.bls.gov/oes/current/oes_nat.htm). Based on the BLS report, "Employer Costs for Employee Compensation – September 2014," (http://www.bls.gov/news.release/ecec.nr0.htm) an additional 43.3% load for "private industry" is added to the labor rate to account for benefits. Therefore, the estimated labor cost of burden hours is $1,236.

13. Estimate of Cost Burden:

Mailing costs: 63 responses * $0.49 per response = $31

14. Estimated Annualized Costs to the Federal Government:

Estimated annual cost to the Federal Government: $19,389

To process the reports, the DEA estimates four hours of GS-13 time for each response. The 2015 hourly wage for GS-13, step 5 is $49.32. Based on the BLS report referenced above, an additional 56.0% load for "State and local government" is added to the labor rate to account for benefits. Therefore, the estimated cost to the Federal Government is $19,389. (Note: Load for Federal government employees is not included in "Employer Cost of Employee Compensation," thus the figures for "State and local government" were used as estimate. The hourly wage is conservatively based on Washington, DC locality pay.)

All costs to the government for operation of the Diversion Control Program, including the above costs, are recovered by the DEA from registrants through registration fees, as required by 21 U.S.C. 886a.

15. Reasons for Change in Burden:

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

16. Plans for Publication:

The DEA will not publish the results of 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:

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.