

**Supporting Statement for Paperwork Reduction Act Submission  
Reports of Loss or Disappearance of Listed Chemicals –DEA Form 107, and  
Regulated Transactions in Tableting/Encapsulating Machines – DEA Form 452  
OMB Approval #1117-0024**

The Drug Enforcement Administration (DEA) seeks approval by the Office of Management and Budget (OMB) for a revision of an existing collection of information that was previously approved by OMB—OMB Approval # 1117-0024, Reports of Loss or Disappearance of Listed Chemicals – DEA Form 107, and Regulated Transactions in Tableting/Encapsulating Machines – DEA Form 452.

**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.

As part of the implementation of the International Trade Data System (ITDS), the DEA is establishing a new DEA Form 452 to be used by regulated persons involved in regulated transactions<sup>1</sup> in tableting or encapsulating machines. The DEA would standardize the current report required in the previous § 1310.05(a)(4) for domestic regulated transactions in a tableting or encapsulating machine as well as the report required in the previous § 1310.05(c) for import and export of tableting and encapsulating machines. DEA Form 452 would be required to be accessed, completed, and submitted to the DEA through the DEA Office of Diversion Control secure network application. Furthermore, the DEA is mandating filing of return information for the import and export of tableting and encapsulating machines which will be electronically submitted as part of the DEA Form 452.

Additionally, as part of the implementation of the ITDS, the DEA is establishing a new DEA Form 107 to be used by regulated persons involved in reporting unusual or excessive loss or disappearance of a listed chemical. The DEA would standardize the current report required to be filed in the previous § 1310.05(a)(3). Each regulated person must report to the Special Agent in Charge of the DEA Divisional Office for the area in

<sup>1</sup> The CSA defines a “regulated transaction” as being: (1) with certain enumerated exceptions—a distribution, receipt, sale, or importation, or exportation of, or an international transaction involving shipment of, a listed chemical, or if the Attorney General establishes a threshold amount for a specific listed chemical, a threshold amount including a cumulative threshold amount for multiple transactions (as determined by the Attorney General, in consultation with the chemical industry and taking into consideration the quantities normally used for lawful purposes), of a listed chemical; and (2) a distribution, importation, or exportation of a tableting machine or encapsulating machine. 21 U.S.C. 802(39).

which the regulated person making the report is located any unusual or excessive loss or disappearance of a listed chemical under the control of the regulated person.

The existing collection of information is affected by the new regulations that update regulations for the import and export of tableting and encapsulating machines, and the loss and disappearance of listed chemicals. The amendments clarify certain policies and reflect current procedures and technological advancements as well as allow for the implementation of the President's Executive Order on streamlining the export/import process and requiring the government-wide utilization of the International Trade Data System (ITDS).

## 2. Needs and Uses:

The information provided on regulated transactions involving in a tableting or encapsulating machine or reports loss or disappearance of listed chemicals 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). Moreover, under both the current and revised regulation, each regulated person must orally report any domestic regulated transaction in a tableting machine or an encapsulating machine to the Special Agent in Charge of the DEA Divisional Office for the area in which the regulated person making the report is located, although the DEA imposed that the report must be made when the order is placed with the seller. The regulated person must subsequently file a written report of the domestic regulated transaction (on DEA Form 452) with the Administration through the DEA Office of Diversion Control secure network application within 15 calendar days after the order has been shipped by the seller. A report (on DEA Form 452) may contain multiple line entries for more than one transaction.

Specifically, the DEA mandated a new DEA Form 452, "Reports for Regulated Machines." The DEA Form 452 will be used by regulated persons to report both domestic regulated transactions as well as import and export regulated transactions of tableting and encapsulating machines. The DEA is requiring mandatory filing of return information for the importing and exporting of tableting and encapsulating machines that would be incorporated into the DEA Form 452. Additionally, the DEA revised existing information collection 1117-0024 by establishing a new form for the reporting of unusual or excessive loss or disappearance of a listed chemical. Regulated persons would report this information on new DEA Form 107, "Reports of Loss or Disappearance of Listed Chemicals."

## 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.

Previously, written reports of the proposed import or export of a tableting or encapsulating machine may be filed via facsimile. However, the DEA revised this existing regulation each regulated person who is involved in the regulated transaction of tableting or encapsulating machines must file an electronic report of such transaction on DEA Form 452. Also, the DEA is requiring mandatory filing of return information for the import and export of tableting and encapsulating machines which will be electronically submitted as part of the DEA Form 452.

Additionally, the DEA established a new form for the reporting of unusual or excessive loss or disappearance of a listed chemical. Regulated persons would report this information electronically on new DEA Form 107, "Reports of Loss or Disappearance of Listed Chemicals." The DEA estimates that 100% of DEA Form 452 and 107 will be submitted electronically.

#### 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 new DEA Forms 107 and 452 are not duplicative. These are brand new forms. The collection of this information is unique to the DEA.

#### 5. Impact on Small Businesses or Entities:

The DEA has considered alternatives for this collection of information and evaluated the impact of this final rule on small entities. The DEA has concluded that the rule will not have a significant economic impact on a substantial number of small entities. For more information, see the DEA's Regulatory Flexibility Act analysis included in the Final rule.

#### 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 must file DEA Form 452 at least one business day before the date of importation or exportation. In order to facilitate the importation or exportation of any tableting machine or encapsulating machine and implement the purpose of the CSA, regulated persons may report to the Administration as far in advance as possible. A separate report must be filed for each import and export 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:

The notice of proposed rulemaking on the Revision of Import and Export Requirements for Controlled Substances, Listed Chemicals, and Tableting and Encapsulating Machines, Including Changes To Implement the International Trade Data System; Revision of Reporting Requirements for Domestic Transactions in Listed Chemicals and Tableting and Encapsulating machines; and Technical Amendments (RIN 1117-AB41) was published in the Federal Register at 81 FR 63576, on September 15, 2016. The DEA received no comments concerning this collection.

The final rulemaking on the Revision of Import and Export Requirements for Controlled Substances, Listed Chemicals, and Tableting and Encapsulating Machines, Including Changes To Implement the International Trade Data System; Revision of Reporting Requirements for Domestic Transactions in Listed Chemicals and Tableting and Encapsulating machines; and Technical Amendments (RIN 1117-AB41) was published in the Federal Register at 81 FR 96992, on December 30, 2016. The DEA received no 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 Annual Respondents	Number of Annual responses	Average Time per Response	Total Annual Hours
DEA-107*	63	63	20	21
DEA-452	130	4,037	20	1,346
<b>Total</b>	<b>193</b>	<b>4,100</b>		<b>1,367</b>

\* Initial estimate based on 3 reports per division for each of 21 field divisions.

\*\* Initial estimate based on 70 import/export respondents submitting 917 responses, 60 domestic transaction respondents submitting weekly responses totaling 3,120.

The DEA will continue to monitor and analyze the potential burden of this information collection.

Total number of respondents:	193	
Number of responses per respondent per year:	21.24	(average )
Total annual responses	4,100	
Total annual hour burden	1,367	
Average burden, per collection (hrs):	0.33	
Average burden, per respondent (hrs):	.1	

Burden dollars:

Estimate hourly wage (\$/hour): <sup>2</sup>	\$36.13
Load for benefits (percent of labor rate): <sup>3</sup>	44.1%

<sup>2</sup> Median hourly wage, Bureau of Labor Statistics, Occupational and Employment and Wages, May 2014, 41-4011 Sales Representatives, Wholesale and Manufacturing, Technical and Scientific Products ([http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm)).

<sup>3</sup> Bureau of Labor Statistics, "Employer Costs for Employee Compensation – December 2014" (ECEC) reports that average benefits for private industry is 30.2% of total compensation. The 30.6% of total compensation equates to 44.1% (30.6% / 69.4%) load on wages and salaries.

Loaded labor rate (\$/hour): <sup>4</sup>	\$52.06		
	<u>DEA 107</u>	<u>DEA 452</u>	<u>Total</u>
Number of responses:	63	4,037	4,100
Burden per response (hours):	0.33	0.33	
Burden dollars per response (\$):	17.3535	17.3535	
Total burden dollars	<b>1,093</b>	<b>70,056</b>	<b>71,149</b>

13. Estimate of Cost Burden:

The estimated annual cost burden is zero. Respondents are estimated to not incur any a) additional start-up cost or capital expenditure, or b) additional operation and maintenance costs or purchase services as a result of this information collection.

14. Estimated Annualized Cost to Federal Government:

Estimated Annual Labor Cost to Government:

Labor Category	Number	Annual rate (\$) <sup>5</sup>	Load <sup>6</sup>	% of time	Cost (\$)
Program Analyst - GS-13	1	104,431	1.41	50%	73,751
<b>Total</b>					<b>73,751</b>

All costs are recovered from registrants through registration fees, as required by the CSA. 21 U.S.C. 886a.

15. Reasons for Change in Burden:

The increase in the number of responses, burden hours, and burden dollars is due to an updated estimate of number of responses for domestic transactions in tabulating and encapsulating machines. There have been no statutory changes affecting this information collection. The main regulatory change affecting this information collection is the mandatory use of online DEA Forms 107 and 452 as part of the implementation of ITDS. The table below summarizes the changes since the last renewal of this information collection.

	2015 Approved Burden	2016 Requested Burden	Difference
Annual responses	63	4,100	4,037
Annual burden hours	21	1,367	1,346
Annual burden dollars (\$)	31	71,149	71,118

<sup>4</sup> \$36.13 x (1 + 0.441) = \$52.06.

<sup>5</sup> Government salary figures are based on Washington, DC locality pay at step 5 for each grade level.

<sup>6</sup> The ECEC does not include figures for the Federal Government, 41% load for benefits based on the ECEC for "State and local government" (adjusted for paid leave).

16. Plans for Publication:

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

17. Expiration Date Approval:

The DEA is not seeking approval not to display the expiration date for OMB approval of 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.