

**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. Also, by Executive Order of the President, DEA is required to streamline the export/import process and to utilize the International Trade Data System.

The DEA Form 452 is used by regulated persons involved in regulated transactions in tableting or encapsulating machines, allowing DEA to standardize the reports required for domestic regulated transactions in a tableting or encapsulating machine and for import and export of tableting and encapsulating machines.

The DEA Form 107 standardizes the report required to be submitted by regulated persons when there is an unusual or excessive loss or disappearance of a listed chemical. Each regulated person must report to the Special Agent in Charge of the DEA Divisional Office for the area in 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.

2. Needs and Uses:

The information provided on regulated transactions involving a tableting or encapsulating machine and reports loss or disappearance of listed chemicals provides DEA with important, timely intelligence designed to identify suspected traffickers of listed chemicals and certain machines.

Specifically, DEA Form 452 is used by regulated persons to report both domestic regulated transactions, as well as import and export regulated transactions of tableting and encapsulating machines. DEA requires mandatory filing of return information for

the importing and exporting of tableting and encapsulating machines that would be incorporated into the DEA Form 452. 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 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 DEA's Diversion Control Division's 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.

Additionally, DEA Form 107 is used for the reporting of unusual or excessive loss or disappearance of a listed chemical. Pursuant to 21 CFR 1310.05(a), reports of these transactions must be orally reported to the Special Agent in Charge of the DEA Divisional Office at the earliest opportunity possible after becoming aware of the circumstances. After the oral report, the regulated person must also file a written report, using DEA Form 107, within 15 calendar days after becoming aware of the circumstances. Reports 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.

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 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.

DEA requires each regulated person who is involved in the regulated transaction of tableting or encapsulating machines to file an electronic report of such transaction on DEA Form 452. Additionally, DEA requires regulated persons to report unusual or excessive loss or disappearance of a listed chemical, using the DEA Form 107.

The forms are accessed, completed, and submitted to the DEA through DEA Diversion Control Division's 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. 100% of DEA Forms 452 and 107 are submitted electronically.

4. Efforts to Identify Duplication:

DEA has made efforts to identify and prevent duplication of the collection of information. These reports are unique to DEA. DEA Forms 107 and 452 are not duplicative. The collection of this information is unique to DEA.

5. Impact on Small Businesses or Entities:

DEA has considered alternatives for this collection of information and evaluated the impact of this final rule on small entities. DEA has concluded that the rule will not have a significant economic impact on a substantial number of small entities. For more information, see 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," DEA has no discretion to require less frequent collection in these circumstances. 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 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:

DEA solicited public comment in the 60 Day Notice of Information Collection that was published in the *Federal Register* at 85 FR 34238, on June 3, 2020. DEA received no comments concerning this collection.

The 30 Day Notice of Information Collection was published in the *Federal Register* at 85 FR 48268, on August 10, 2020.

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 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, 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:

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 (minutes)	Total Annual Hours
DEA-107*	69	69	20	23
DEA-452	2,262	3,758	20	1,253
Total	2,331	3,827		1,276

* Based on 3 reports per division for each of 23 field divisions. DEA will continue to monitor and analyze the potential burden of this information collection.

Total number of respondents:	2,331	
Number of responses per respondent per year:	1.6418	(average)
Total annual responses	3,827	
Total annual hour burden	1,276	
Average burden, per collection (hrs):	0.3334	

Average burden, per respondent (hrs): 0.5474

Burden dollars:

Estimate hourly wage (\$/hour):¹ \$38.95
 Load for benefits (percent of labor rate):² 42.7%
 Loaded labor rate (\$/hour):³ \$55.58

Burden by form	DEA-107	DEA-452	Total
Number of responses	69	3,758	3,827
Burden per response (hour)	0.3333	0.3333	N/A
Total burden hours	23	1,253	1,276
Burden dollars per response (\$)	18.52	18.52	N/A
Total burden dollars (\$)	1,278	69,598	70,876

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 (\$)*	Load**	% of time	Cost (\$)
Program Analyst - GS-13	1	116,353	1.605	50%	93,373
Total					93,373

*Government salary figures are based on Washington, DC locality pay at step 5 for each grade level.

**Load of 60.5% for benefits based on the ECEC for “State and local government.” The ECEC does not include figures for the Federal Government.

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:

¹ Median hourly wage, Bureau of Labor Statistics, Occupational and Employment and Wages, May 2019, 41-4011 Sales Representatives, Wholesale and Manufacturing, Technical and Scientific Products (http://www.bls.gov/oes/current/oes_nat.htm).

² Bureau of Labor Statistics, “Employer Costs for Employee Compensation – December 2019” (ECEC) reports that average benefits for private industry is 29.9% of total compensation. The 29.9% of total compensation equates to 42.7% (29.9% / 70.1%) load on wages and salaries.

³ \$38.95 x (1 + 0.427) = \$55.58.

There was an error in the 2017 approved burden; based on the approved 2017 approved supporting statement, the correct annual responses, annual burden hours, and annual burden dollars for 2017 are: 4,100; 1,367, and \$71,149, respectively. The decreases in the number of responses, burden hours, and burden dollars, are 273; 91, and \$273, respectively, from the corrected 2017 approved burden to 2020 requested burden. The decreases reflect adjustments related to normal business activity. There have been no statutory or regulatory changes affecting this information collection. The table below summarizes the changes since the last renewal of this information collection.

	2017 Approved Burden	2020 Requested Burden	Difference
Annual responses	63	3,827	3,764
Annual burden hours	21	1,276	1,255
Annual burden dollars (\$)	31	70,876	70,845

16. Plans for Publication:

DEA will not publish the results of the information collected.

17. Expiration Date Approval:

DEA is not seeking approval not to display the expiration date for OMB approval of this information collection.

18. Exceptions to the Certification Statement:

DEA is not seeking an exception to the certification statement for this collection of information.

Part B. Statistical Methods

DEA does not employ statistical methods in this information collection.