

SUPPORTING STATEMENT FOR Regulated Transactions in Tableting/Encapsulating Machines – DEA Form 452

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, Regulated Transactions in Tableting/Encapsulating Machines – DEA Form 452.

A. JUSTIFICATION

1. 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 transactions¹ 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.

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. The information provided on regulated transactions involving in a tableting or encapsulating machine provides the DEA with important, timely intelligence designed to identify suspected

¹ 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).

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 moving DEA Form 107, “Reports of Loss or Disappearance of Listed Chemicals” into information collection 1117-0001.

3. 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. The DEA estimates that 100% of DEA Form 452 will be submitted electronically.

4. The DEA has made efforts to identify and prevent duplication of the collection of information. The reports are unique to the DEA. The new DEA Form 452 is not duplicative. The collection of this information is unique to the DEA.

5. 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. 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. There are no special circumstances applicable to this information collection.

8. The 60-Day Notice was published in the Federal Register on September 11, 2023 (88 FR 62398). The comment period ended on November 13, 2023. No comments were received.

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. This collection of information does not propose to provide any payment or gift to respondents.

10. 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. This collection of information does not ask any questions of a sensitive nature.

12.

Estimated Annualized Respondent Cost and Hour Burden

Activity	Number of Respondents	Frequency	Total Annual Responses	Time Per Response	Total Annual Burden (Hours)	Hourly Rate ²	Monetized Value of Respondent Time ³
DEA-452	274	92	25,101	0.33	8,283	67.074667	\$555,601.60
Unduplicated Totals	274		25,101	0.33	8,283		\$555,601.60
Total number of respondents:					274		
Number of responses per respondent per year:					91.609489		(average)
Total annual responses					25,101		
Total annual hour burden					8,283.33		
Average burden, per collection (hrs):					0.333333		
Average burden, per respondent (hrs):					0.333333		

Burden dollars:

Estimate hourly wage (\$/hour):⁴ \$46.97

² Median hourly wage, Bureau of Labor Statistics, Occupational and Employment and Wages, May 2023, 11-3071 Transportation, Storage, and Distribution Managers (https://www.bls.gov/oes/current/oes_nat.htm).

³ Monetized value is based on the loaded wage multiplied by the total annual burden, in hours. Bureau of Labor Statistics, “Employer Costs for Employee Compensation – March 2023” (ECEC) reports that average benefits for private industry is 29.97% of total compensation. The 29.97% of total compensation equates to 42.8% (29.97% / 70.07%) load on wages and salaries. The median wage of \$46.97 times (1 + 0.428) = \$67.08 per hour for the loaded wage.

⁴ Median hourly wage, Bureau of Labor Statistics, Occupational and Employment and Wages, May 2019, 41-4011

Load for benefits (percent of labor rate):⁵ 42.8%
 Loaded labor rate (\$/hour):⁶ \$67.07

Burden by form	DEA-452
Number of responses	25,101
Burden per response (hour)	0.33333
Total burden hours	8,283.3 3
Burden dollars per response (\$)	22.134 64
Total burden dollars (\$)	555,601.60

13. 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. The estimated annual cost to the Federal Government is \$331,615.85. This includes the annual salaries for a GS-13 Import/Export Specialist at 100% of available time, and a GS-13 Program Analyst at 50% of available time, as well as the additional “load” from benefits. There are no other additional costs such as printing, supplies, or equipment.

Labor Category	Number	Annual Rate (\$)*	Load	% of Time	Cost (\$)
Import/Export Specialist - GS-13	1	\$126,949.00	1.74146493	100%	\$221,077
Program Analyst – GS-13	1	\$126,949.00	1.74146493	50%	\$110,539
Total	2				\$331,616

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

**Load of 74.15% for benefits based on the ECEC for “State and Local Government.” The ECEC does not include figures for the Federal Government.

Sales Representatives, Wholesale and Manufacturing, Technical and Scientific Products
 (http://www.bls.gov/oes/current/oes_nat.htm).

⁵ Bureau of Labor Statistics, “Employer Costs for Employee Compensation – December 2019” (ECEC) reports that average benefits for private industry is 29.97% of total compensation. The 29.97% of total compensation equates to 42.8% (29.97% / 70.03%) load on wages and salaries.

⁶ \$46.97 x (1 + 0.428) = \$67.07.

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

15. The increase in the number of responses, burden hours, and burden dollars, are 21,274; 7,007, and \$490,337, respectively, from the 2020 approved burden to 2023 requested burden. The increase reflect adjustments related to an increase in 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.

	2020 Approved Burden	2023 Requested Burden	Difference
Annual responses	3,827	25,101	21,274
Annual burden hours	1,276	8,283	7,007
Annual burden dollars (\$)	70,876	561,213	490,337

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

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

18. This collection of information does not include any exceptions to the certificate statement.

B. COLLECTIONS OF INFORMATON EMPLOYING STATISTICAL METHODS.

This collection does/does not contain statistical data.