

**SUPPORTING STATEMENT FOR
Report of Theft or Loss or Disappearance of Controlled Substances and Listed Chemicals**

A. JUSTIFICATION

1. In accordance with the Controlled Substance Act (CSA), every DEA registrant must make a biennial inventory and maintain, on a current basis, a complete and accurate record of each controlled substance manufactured, received, sold, delivered, or otherwise disposed of. 21 U.S.C. 827 and 958. These records must be maintained separately from all other records of the registrant or, alternatively, in the case of non-narcotic controlled substances, be in such form that required information is readily retrievable from the ordinary business records of the registrant. 21 U.S.C. 827(b)(2). The records must be kept and be available for at least two years for inspection and copying by officers or employees of the United States authorized by the Attorney General. 21 U.S.C. 827(b)(3). The records must be in accordance with and contain such relevant information as may be required by regulations promulgated by the DEA. 21 U.S.C. 827(b)(1). These record requirements help to deter and detect diversion of controlled substances and ensure that registrants remain accountable for all controlled substances within their possession and/or control.

2. In accordance with current 21 CFR 1301.74, a DEA registrant must notify the Field Division Office of the Administration in writing, of any theft or significant loss of any controlled substance within one business day of discovery of the theft or loss, and must complete and send to the DEA a DEA Form 106 upon determination of a theft or significant loss. The DEA Form 106 is designed to provide a uniform method of reporting and recording thefts and losses of controlled substances as required by 21 U.S.C. 827, 21 CFR 1301.74(c) and 1301.76(b). The form is entitled "Report of Theft or Loss of Controlled Substances" and it is used by the DEA to help determine the quantities and types of controlled substances that are stolen or lost. It may also serve as a record of the theft or loss for the registrant.

The DEA Form 106 is a complete registrant record for the theft and loss of controlled substances, including collected substances. DEA regulations require all registrants to account for all theft and losses of controlled substances, including sealed inner liners and returned mail-back packages. These requirements help the DEA to fulfill its mission to enforce United States controlled substances laws and regulations.

The DEA Form 106 is being revised to mirror the DEA Form 107 ("Reports of Loss or Disappearance of Listed Chemicals," 1117-0024), as they both are for reporting thefts or losses, but for different types of substances. Due to the similarities of the Forms, the DEA wants to remove the information collection for the DEA Form 107 from its current collection (1117-0024) and place it under OMB Approval # 1117-0001, along with the DEA Form 106.

3. The DEA Forms 106 and 107 are available electronically on the DEA Diversion Control Program web site at <https://www.deadiversion.usdoj.gov>. Both forms will now be exclusively submitted 100% electronically.

4. The DEA has made efforts to identify and prevent duplication of the collection of information. The existing DEA Form 106 is not duplicative and was revised for consistency with the new regulations on disposal. DEA Form 106 was revised to account for theft and loss of controlled substances collected from ultimate users and other non-registrants pursuant to the Disposal Act. This particular aspect of the collection of information is associated with new statutory authority and new implementing regulations that do not already exist. The DEA does not believe there is duplication of an existing collection of information.

5. The DEA has concluded that the collection will not have a significant economic impact on small entities within the meaning and intent of the Regulatory Flexibility Act, 5 U.S.C. 601-612. There is no significant impact on small business or other private entities.

6. The collection information must take place upon each occurrence of theft or loss to ensure accountability within the closed system of distribution of controlled substances. If the collection of information is not conducted or is conducted less frequently, there will be an increased risk of diversion. The information collected on DEA Form 106 is vital to the enforcement of the Controlled Substances Act, ensures accountability, and helps to deter and detect the diversion of controlled substances outside of legitimate channels into the illicit market. Furthermore, the information collected, in accordance with the Disposal Act, helps to prevent controlled substances from being diverted during the disposal process. In implementing the Disposal Act, the DEA was required to issue disposal regulations that prevent the diversion of controlled substances. 21 U.S.C. 822(g)(1).

7. There are no special circumstances.

Under 21 CFR 1310.05(b)(1), in addition to certain other specified reporting requirements, a regulated person must file a complete and accurate DEA Form 107 in accordance with 21 CFR 1310.06(d), with DEA through DEA's Diversion Control Division secure network application within 15 calendar days after becoming aware of the circumstances requiring the report.

This final rule sets forth in 21 CFR 1301.74(c) and 1301.76(b) that DEA registrants will have a 45-day calendar period (instead of the proposed 15-day calendar period), upon discovery of the theft or significant loss of any controlled substances, to submit DEA Form 106.

Additionally, non-practitioners and practitioners preliminarily notify their local DEA Field Division Office, in writing, of the theft or significant loss of any controlled substances within one business day of discovering such theft or loss.

8. The 60-Day Notice was published in the Federal register on September 20, 2023 (88 FR 64928). The comment period ended on November 20, 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. No government funds will be used as payment or for gifts to respondents.

10. Information provided pursuant to the requirements of the disposal rule and to 21 U.S.C. 827(b)(3) 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. The information is protected by the DEA through secure storage, limited access, and federal regulatory and DEA procedures. Confidentiality is not required in the processing of this information collection.

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 Annual Respondents	Frequency of Reporting	Number of Annual Responses	Average Time per Response (minutes)	Total Annual Hours
DEA Form 106 (electronic)	10,377	3.115737	32,332	20 min	10,777
DEA Form 107 (electronic)	170	1.835294	312	20 min	104
Total	10,547	N/A	32,644		10,881

Monetized value of respondent time: \$736,317

Total number of respondents: 10,547

Number of responses per respondent per year: 3.0951 (average)

Total annual responses: 32,644

Total annual hour burden: 10,881

Average Burden: Per Collection: 0.3333 hour
Per Respondent: 1.0316678 hour

10,881 (total annual burden hours) x \$67.67 (loaded labor rate)

Estimated hourly wage (\$/hour): ¹	47.39
Load for benefits (percent of labor rate): ²	<u>42.8%</u>

¹ Average of median hourly wages for 11-3071 Transportation, Storage, and Distribution Managers is used to represent the occupation of persons completing the DEA Form 106/107 for all registrant types. May 2023 National Occupational Employment and Wage Estimates United States. http://www.bls.gov/oes/current/oes_nat.htm.

² Bureau of Labor Statistics, "Employer Costs for Employee Compensation – March 2023" (ECEC) reports that

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Loaded labor rate (\$/hour): ³	67.67
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	DEA Form 106	DEA Form 107	Total
Number of responses	32,332	312	32,644
Total annual hours	10,777	104	10,881
Average burden per response (hour)	0.3333	.3333	.3333
Burden dollars per response (\$)	22.5 5815	22.55815	22.55815
Total burden dollars (\$)	729,350	7,038	736,317

13. There are no start-up costs associated with this collection.

14. Cost to Federal Government:

Labor Category	Number	Loaded Annual rate ⁴	% of time	Cost
Headquarters Employee - GS-14/5	1	\$ 261,247.60	1%	\$2,612
Contract Support	N/A	N/A	N/A	\$5,665
Total				\$8,277

Total Cost to Federal Government: \$8,277.

All costs to the Federal Government for these activities are recovered from registrants through registration fees, as required by the Controlled Substance Act (CSA). 21 U.S.C. 886a.

15. The decrease in annual responses, burden hours, and burden dollars reflect adjustments related to normal business activity. There are no statutory or regulatory changes related to this information collection.

	2020 Approved Burden	2023 Requested Burden	Difference
Annual responses	37,047	32,644	-4,403

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.

³ \$47.39 x (1 + 42.8%) = \$67.67

⁴ Government salary figures are based on 2003 Washington, DC locality pay at step 5 for each grade level and include 42.6% load for benefits based on the ECEC for “State and local government” (adjusted for paid leave). The ECEC does not include figures for the Federal Government.

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Annual burden hours	12,348	12,349	-1,467
Annual burden dollars	802,245	736,317	-65,928

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 INFORMATION EMPLOYING STATISTICAL METHODS.

This collection does/does not contain statistical data.