Paperwork Reduction Act Supporting Statement Report of Theft or Loss of Controlled Substance – DEA Form 106 OMB Approval # 1117-0001

The Drug Enforcement Administration (DEA) seeks approval by the Office and Management and Budget (OMB) for a revision of an existing collection that was previously approved by OMB – OMB Approval # 1117-AB57 Amending Regulations Regarding Reporting of Theft or Significant Loss of Controlled Substances

A. JUSTIFICATION

1. Necessity of Information

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. Needs and Uses

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 Chimcials,"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. The current collection for DEA Form 107 would still exist because currently two information collection requests are under that number and the second (DEA Form 452) would remain.

3. <u>Use of Information Technology</u>

The DEA Form 106 is available electronically on the DEA Diversion Control Program web site at https://www.deadiversion.usdoj.gov. DEA Form 106 will now be exclusively submitted electronically.

4. Efforts to Identify Duplication

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. Impact on Small Businesses or Entities

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.

6. <u>Consequence of Less Frequent Collection</u>

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. Special Circumstances Influencing Collection

There are no special circumstances applicable to this information collection.

8. Consultations With Persons Outside the Agency

Public comment has been solicited in the notice of proposed rulemaking (NPRM), published on July 29, 2020, 85 FR 45547. During the 60-day comment period, DEA did receive comments concerning this collection amending the regulations for reporting theft of significant losses of controlled substances to implement the requirement of electronic submissions for reporting the thefts or significant losses of controlled substances to clarify that all such reports must be submitted electronically within 45 days of discovery of the circumstances requiring the report. The comments have been responded in the final rule published June 22, 2023, 88 FR 40707.

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 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.

11. Justification for Questions of a Sensitive Nature

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

12. Estimated Hour Burden of the Collection of Information

DEA Form 106 is completed on an as-needed basis by registrants reporting a theft or loss of controlled substances or collection receptacles.

Activity	Number of Annual Respondents	Number of Annual Responses	Average Time per Response (minutes)	Total Annual Hours
DEA Form 106 (electronic)	10,693	37,047	20	12,349
Total	10,693	37,047		12,349

Total number of respondents: 10,693

Number of responses per respondent per year: 3.4646 (average)

Total annual responses: 37,047 Total annual hour burden: 12,349

Average Burden: Per Collection: 0.3333 hour

Per Respondent: 1.1549 hour

Burden dollars:

Estimated hourly wage (\$/hour): ¹	45.54
Load for benefits (percent of labor rate): ²	<u>42.7%</u>
Loaded labor rate (\$/hour): ³	64.96

	DEA Form 106
Number of responses	37,047
Total annual hours	12,348
Average burden per response (hour)	0.3333
Burden dollars per response (\$)	21.65
Total burden dollars (\$)	802,245

13. Estimated Total Annual Cost Burden

There is no cost burden associated with this information collection.

14. Estimated Annualized Cost to the Federal Government

Cost to Federal Government:

Labor Category	Number	Ar	nual rate	Load ⁴	% of time	Cost
Headquarters Employee - GS-14/5	1	\$	137,491	29.4%	1%	\$ 1,779
Contract Support	N/A		N/A	N/A	N/A	\$ 5,665
Total						\$ 7,444

Total Cost to Federal Government: \$7,444

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. Reasons for Change in Burden

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 for all registrant types. September 2019 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 – 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.

 $^{^{3}}$ \$45.54 x (1 + 42.7%) = \$64.96

⁴ Government salary figures are based on Washington, DC locality pay at step 5 for each grade level and include 41% 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.

The change in annual cost burden is due to change in method. Previously, the approved 2020 figure represents the annual labor burden hours calculated in section 12. The requested 2023 figure represents the annual cost burden calculated in section 13 is due to a change in the way DEA now calculates the annual cost burden dollars. There are no statutory or regulatory changes related to this information collection.

	2020 Approved Burden	2023 Requested Burden	Difference
Annual responses	37,047	37,047	0
Annual burden hours	12,349	12,348	-1
Annual cost burden	802,245	0	-802,245

16. Plans for Publication

The DEA does not anticipate that this collection of information will have results that will be published.

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

The DEA is not seeking an exception to the certification statement "Certification for Paperwork Reduction Act Submissions" for this collection of information.

B. STATISTICAL METHODS

The DEA does not employ statistical methods in this Information Collection.