

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 an existing collection that was previously approved by OMB – OMB Approval Number 1117-0001, Report of Theft or Loss of Controlled Substances, DEA Form 106.

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.

3. Use of Information Technology

The DEA Form 106 is available electronically on the DEA Diversion Control Program web site at <https://www.deadiversion.usdoj.gov> or a paper form is available by request. The paper form must be completed, signed and mailed to DEA. DEA estimates that DEA Form 106 will be filled 2% paper and 98% 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. Consequence of Less Frequent Collection

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 was solicited in the 60-day Federal Register Notice of Information Collection, 82 FR 22350, published May 15, 2017 and the 30-day Federal Register Notice of Information Collection, 82 FR 32872, published July 18, 2017. The DEA did not receive any 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 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 41 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 (paper)	11,363	501	20	167
DEA Form 106 (electronic)		30,062	20	10,021
Total	11,363	30,563		10,188

* Based on the number of unique respondents. A respondent may submit paper or electronic version of the DEA Form 106. Separately counting the number of respondents for each version of the form would result in multiple counts of the same respondent. Therefore, the number of combined respondents is used.

Total number of respondents: 11,363
 Number of responses per respondent per year: 2.6897 (average)
 Total annual responses: 30,563
 Total annual hour burden: 10,188

Average Burden: Per Collection: 0.3333 hour
 Per Respondent: 0.8966 hour

Total responses received on paper: 501
 Total responses received electronically: 30,062
 Percentage of responses received electronically: 98%

Burden dollars:

Estimate hourly wage (\$/hour): ¹	42.88
Load for benefits (percent of labor rate): ²	43.5%
Loaded labor rate (\$/hour): ³	61.52

	DEA Form 106
Number of responses	30,563
Total annual hours	10,188
Average burden per response (hour)	0.3333
Burden dollars per response (\$)	20.51
Total burden dollars (\$)	626,753

13. Estimated Total Annual Cost Burden

The DEA Form 106 can be submitted on line or to the DEA Field Division Office. Conservatively, the estimated 501 paper responses are assumed to be submitted by mail, incurring additional costs for postage and envelope. The paper DEA Form 106 is provided by the DEA. Other costs, such as printing, address labels, etc., are estimated to be nominal. The DEA estimates the cost of postage and envelopes for the estimated 501 paper responses is \$286 (\$0.49 for postage and \$0.08 for envelop). The DEA expects that many registrants will use other means of submitting the DEA Form 106 at nominal costs.

Total Cost of Burden: \$286

14. Estimated Annualized Cost to the Federal Government

Cost to Federal Government:

Labor Category	Number	Annual rate	Load ⁴	% of time	Cost
Headquarters Employee - GS-14/5	1	\$ 126,958	1.42	1%	\$ 1,809
Contract Support	N/A	N/A	N/A	N/A	\$ 5,665
Total					\$ 7,474

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. May 2016 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 2016" (ECEC) reports that average benefits for private industry is 30.3% of total compensation. The 30.3% of total compensation equates to 43.5% (30.3% / 69.7%) load on wages and salaries.

³ $42.88 \times (1 + 0.435) = \61.52 .

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.

Total Cost to Federal Government: \$7,474

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

The increase in annual responses reflects adjustments related to normal business activity. The increase in annual burden hours and annual burden dollars reflects the increase in annual responses. There are no statutory or regulatory changes related to this information collection.

	2014 Approved Burden	2017 Requested Burden	Difference
Annual responses	25,430	30,563	5,133
Annual burden hours	8,477	10,188	1,711
Annual burden dollars	475,060	627,039	151,979

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.