

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 Office and Management and Budget (OMB) approval for revision to an existing collection of information that was previously approved by OMB – OMB Approval Number 1117-0001, Report of Theft or Loss of Controlled Substances, DEA Form 106.

The existing DEA Form 106, which expires on August 31, 2014, and was approved by OMB on August 24, 2011, will remain in effect and should be used by all registrants until the effective date of the Disposal of Controlled Substances final rule.

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.

The existing collection of information is affected by the new regulations that implement the Secure and Responsible Drug Disposal Act of 2010. (Disposal Act) (Pub. L. 111-273). The Disposal of Controlled Substances final rule (RIN 1117-AB18), expands disposal options for ultimate users, reorganizes and consolidates existing regulations on the disposal of controlled substances, and establishes a comprehensive regulatory framework for the collection and destruction of controlled substances consistent with the Controlled Substances Act.

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 existing DEA Form 106 must include the signature of the person completing the form, in addition to information about the controlled substances stolen or lost, and an itemized list of the controlled substances being reported as stolen or lost. Registrants may collect pharmaceutical controlled substances from ultimate users for the purpose of destruction in accordance with the Disposal of Controlled Substances final rule. Accordingly, registrants are required to report the theft or loss of sealed inner liners and returned mail-back packages to the DEA on DEA Form 106. DEA is revising the existing DEA Form 106 to include information regarding the theft or loss of sealed inner liners and returned mail-back packages. The revised DEA Form 106 will include an additional page for the signature of the person completing the form and information columns for an itemized list of all sealed inner liners and returned mail-back packages being reported as lost or stolen. The revised DEA Form 106 will also require an authorized retail pharmacy or hospital/clinic with an on-site pharmacy reporting a theft or loss of a long-term care facility inner liner, to include the name and address of the long-term care facility. The DEA Form 106 has previously been approved by OMB and was assigned OMB control number 1117-0001.

The DEA is revising DEA Form 106 to be 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

DEA Form 106 is available online for printing. The form can be printed and completed manually. Additionally, the form may be completed online and submitted electronically via the DEA Office of Diversion Control website at <http://www.DEAdiversion.usdoj.gov>. The DEA estimates that 5% of DEA Form 106s will be submitted on paper and 95% will be 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 is being revised for consistency with the new regulations on disposal. DEA Form 106 is also being 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 considered alternatives for this collection of information and evaluated the impact of this proposed 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. 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). Accordingly, the disposal final rule requires thefts or losses of collected substances to be reported to the DEA on a DEA Form 106.

7. Special Circumstances Influencing Collection

The DEA does not foresee any special circumstances that would cause an information collection to be conducted in a particular manner, e.g., requiring respondents to report information to the agency more than quarterly; requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it; requiring respondents to submit more than an original and two copies of any document; requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records, for more than three years; in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study; requiring the use of a statistical data classification that has not been reviewed and approved by OMB; that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or requiring respondents to submit proprietary trade secrets, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Consultations With Persons Outside the Agency

On January 19 and 20, 2011, the DEA held a public meeting to receive comments regarding the implementation of the Disposal Act (75 FR 80536, December 22, 2010).¹ This meeting allowed all interested persons – the general public, including ultimate users, pharmacies, law enforcement personnel, reverse distributors, and other third parties – to express their views regarding safe and effective methods of disposal of controlled substances consistent with the

¹ The transcript of this public meeting can be found on the DEA website at: http://www.DEAdiversion.usdoj.gov/drug_disposal/non_registrant/meeting_010511.htm.

CSA. Representatives of various industries as well as various federal, state, and local agencies spoke at the meeting and provided information and suggestions on the implementation of the Disposal Act. The DEA has met with other federal agencies, the Office of National Drug Control Policy, congressional staffs, and pharmacy and reverse distributor representatives to discuss and receive feedback on both the proposed rule and the final rule.

The Notice of Proposed Rulemaking on the Disposal of Controlled Substances (RIN 1117-AB18) was published in the Federal Register on December 21, 2012, with a request for public comment. (77 FR 75784). The comments the DEA received regarding DEA Form 106 addressed a variety of topics; including which records must be kept, when the form must be used, and form requirements.

The DEA responded that the records that registrants are required to maintain pursuant to law are a vital component of the DEA's enforcement and oversight responsibilities – such records ensure accountability and help to deter and detect diversion. The DEA is requiring registrants involved in the destruction of controlled substances to report certain information. DEA Form 106 has previously been approved by OMB and assigned OMB control number 1117-0001.

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

Number of respondents: 9,655 registrants

Note: DEA Form 106 is completed by registrants reporting a theft or loss of controlled substances.

Frequency of response: Varies.

The DEA estimates that the frequency of response will vary because, in accordance with 21 U.S.C. 827(a), registrants maintain, on a current basis, a complete and accurate record of each controlled substance manufactured, received, sold, delivered, or otherwise disposed of.

Total annual responses: 25,430 (24,189 electronic/1,241 paper)

Average time per response: 20 minutes

Total Annual burden: 8,477 hours

13. Estimated Total Annual Cost Burden

Estimated Total Annual Cost Burden: \$475,060

The total cost is based on cost estimates for labor and materials.

The DEA used the median hourly wage of \$39.34 for occupation code 11-3071 Transportation, Storage, and Distribution Managers from the Bureau of Labor Statistics May 2012 Occupational Employment and Wages data and applied a 42.25% load for taxes and benefits. Therefore, the estimated cost of burden hours is \$474,364.

Like the current DEA Form 106, the revised form can be submitted on line or to the DEA Field Division Office. For the estimated 1,241 paper responses, the respondents are estimated to incur additional costs for postage, paper, and envelope. Other costs, such as printing, address labels, etc., are estimated to be nominal. The DEA estimates the cost of postage, paper, and envelopes for the estimated 1,241 paper responses is \$696. In total, the DEA estimates the total annual cost burden to be \$475,060. The table below summarizes the cost estimates.

<u>Cost Associated with Responses</u>	
Total annual responses	25,430
<i>Electronic responses</i>	24,189
<i>Paper responses</i>	1,241
Average time for response (minutes)	20
Total annual burden (hours)	8,477
11-3071 Transportation, Storage, and Distribution Managers (\$/hour)	\$ 39.34
Load for taxes and benefits	<u>42.25%</u>
Total annual labor burden (\$)	\$ 474,364
Postage, first class	\$ 0.49
Paper	\$ 0.01
Envelope	<u>\$ 0.06</u>
Material cost per paper response	\$ 0.56
Total cost of postage/paper/envelope	\$ 696

Total annual cost burden	\$ 475,060
<u>Cost to Federal Government</u>	
GS-14/5, Washington DC, annual wage	\$ 120,429
Load for benefits	27.39%
% of time	<u>0.50</u>
Cost of Federal Government employee	\$ 76,706
Contract support	\$ 22,080
Total Cost to Federal Government	\$ 98,786
Total Cost to Respondents and Federal Government	
	\$ 573,846

14. Estimated Annualized Cost to the Federal Government

Estimated Annualized Costs to the Federal Government: \$98,786

To process the DEA Form 106, the DEA estimates that 50% of a GS-14 headquarters employee and \$22,080 of contract support is required. See table above for cost estimate.

15. Reasons for Change in Burden

Any program changes or adjustments reported result from the proposed revisions to DEA Form 106, as described above.

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

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

