Paperwork Reduction Act Supporting Statement
Registrant Record of Controlled Substances Destroyed – DEA Form 41
OMB Approval # 1117-0007

The Drug Enforcement Administration (DEA) seeks Office of Management and Budget (OMB) approval for revision to an existing collection of information that was previously approved by OMB – OMB Approval Number 1117-0007, Registrants Inventory of Drugs Surrendered, DEA Form 41. The revised form is entitled "Registrant Record of Controlled Substances Destroyed, DEA Form 41."

The existing DEA Form 41, which expires on August 31, 2014, and was approved by OMB on August 25, 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 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

The final rule that implements the Disposal Act establishes information that registrants that destroy controlled substances must record, and requires this information to be recorded on DEA Form 41. Revised 21 CFR 1304.21(e) requires any registered person that destroys a controlled substance to maintain a record of the destruction on a DEA Form 41. The records shall be complete and accurate, and include the name and signature of the two employees who witnessed the destruction, in addition to information about the controlled substances destroyed

and the method of destruction utilized. The DEA is revising existing DEA Form 41 to incorporate this additional information. The DEA is also revising DEA Form 41 to reflect information regarding the destruction of controlled substances that have been collected from non-registrants pursuant to the Disposal Act. In particular, the DEA is adding information columns for sealed inner liners and returned mail back packages that are utilized in the collection of ultimate user controlled substances. DEA Form 41 has previously been approved by OMB and was assigned OMB control number 1117-0007.

Currently, in 21 CFR 1307.21, a DEA registrant that desires to dispose of a controlled substance was required to submit three copies of DEA Form 41 to the Special Agent in Charge (SAC) in their area. The DEA is deleting 21 CFR 1307.21 and replacing it with a comprehensive part 1317 on disposal. In an effort to minimize the burden on registrants, and in accordance with the comprehensive part on disposal, registrants that destroy controlled substances will no longer be required to submit three copies of DEA Form 41 to the SAC in their area. Rather, in accordance with the CSA, all registrants that destroy controlled substances will only be required to keep and make available that record, 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). If a DEA registrant asks for assistance for the SAC in their area, they must submit one copy, rather than three copies of DEA Form 41 to the SAC, pursuant to new 21 CFR 1317.05(4)(i).

The DEA is revising DEA Form 41 to be a complete record of the destruction of controlled substances in an effort to strengthen the integrity of the destruction process. Registrants that destroy controlled substances themselves are the last persons to possess such substances and, therefore, must follow specific recordkeeping requirements at the point of destruction, including the names and signatures of the two authorized employees that witnessed the destruction, to ensure accountability and help deter and detect diversion.

3. Use of Information Technology

DEA Form 41 will be available online for printing, at the DEA Office of Diversion Control website at http://www.DEAdiversion.usdoj.gov. The form can be printed and must be completed manually. Registrants that destroy controlled substances will be required to keep and make available that record, 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).

4. Efforts to Identify Duplication

The DEA has made efforts to identify and prevent duplication of the collection of information. The existing DEA Form 41 is not duplicative and is being revised to be consistent with the new regulations on disposal. DEA Form 41 is also being revised to account for destruction 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 that there is a 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. The DEA has considered alternatives for this collection of information and evaluated the impact of the 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. Consequence of Less Frequent Collection

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 41 is vital to the enforcement of the CSA, 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 a record of the destruction of collected controlled substances.

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,

[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.

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 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 41 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 record certain information. The record of destruction must include the names and signatures of the two authorized employees of the registrant that witnessed the destruction, in addition to information about the controlled substance destroyed and the method of destruction utilized. The DEA is revising the existing DEA Form 41 to serve as a record of the destruction of controlled substances that remain in the closed system of distribution and to account for registrant destruction of controlled substances collected from ultimate users and other non-registrants outside the closed system pursuant to the Disposal Act. DEA Form 41 has previously been approved by OMB and assigned OMB control number 1117-0007. In accordance with the CSA, registrants that destroy controlled substances must utilize DEA Form 41 and they are required to keep and make available the information in the specified format, 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).

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 Sensitive Questions

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

12. Estimate of Hour Burden

Number of respondents: 87,736 (Distributors - 829, Reverse Distributors - 60, Manufacturers - 536, Retail Pharmacies - 69,026, Hospitals/Clinics - 15,953, Narcotic Treatment Programs - 1,332)

*Note: DEA Form 41 is completed by registrants destroying controlled substances. The number of respondents (*87,736*) represents the total number of registrants in business activities that are most likely to destroy 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.

Average annual responses: 87,736

Average time per response: 30 minutes

Total Annual burden: 43,868 hours

13. Estimate of Cost Burden

In the disposal final rule, the DEA used the median hourly wage of $15.97 for 53-0000 Transportation and Material Moving Occupations in the Warehousing and Storage Industry from the Bureau of Labor Statistics May 2012 Occupational Employment and Wages data and applied a 32.5% load for taxes and benefits for a labor unit cost of $21.16. Therefore, the estimated cost burden is $928,247.

Estimated Annual Cost Burden: $928,247

14. Estimated Annualized Costs to the Federal Government

The forms are prepared, completed, and maintained by DEA registrants. There is no cost to the federal government.

15. Reasons for Change in Burden

Any program changes or adjustments reported result from the proposed revisions to DEA Form 41, 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.