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

The Drug Enforcement Administration (DEA) seeks approval by the Office of Management and Budget (OMB) for an existing collection of information that was previously approved by OMB – OMB Approval #1117-0007, Registrant Record of Controlled Substances Destroyed, DEA Form 41.

Part 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.

2. Needs and Uses:

Registrants that destroys a controlled substance pursuant to 21 CFR 1317.95(d), or causes the destruction of a controlled substance pursuant to 21 CFR 1317.95(c), shall maintain a record of distruction 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.

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 from the Special Agent in Charge (SAC) in their area, they must submit one copy, to the SAC, pursuant to 21 CFR 1317.05(4)(i).

DEA Form 41 will 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 currently, 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 collection of this information is unique to the DEA.

5. Impact on Small Businesses or Entities:

This is a routine renewal of existing collection of Registrant Record of Controlled Substances Destroyed. The DEA does not anticipate any additional impact on small businesses or other small entities since the initial approval of this form. The collection will not have a significant economic impact on small business or other small entities within the meaning and intent of the Regulatory Flexibility Act, 5 U.S.C 601 –612.

6. Consequences 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.

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. Consultation with persons outside the Agency:

Public comment was solicited in the 60-day Federal Register Notice of Information Collection, 85 FR 44927, published on July 24, 2020 and the 30-day Federal Register Notice of Information Collection, 85 FR 69647, published on November 3, 2020.

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 requested in this collection 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 (FOIA). Submitters who are required to furnish commercial or financial information to the government are protected from the competitive disadvantages that could result from disclosure of such information. The information is protected by DEA through secure storage, limited access, and federal regulatory and DEA procedures. In the event a FOIA request is made to obtain information that has been designated as confidential business information per 28 CFR 16.8(c) and Exemption 4 of FOIA, DEA will give written notice to the submitter to allow an opportunity to object within a reasonable time prior to any disclosure by DEA.

11. Justification for Sensitive Questions:

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

12. Estimate of Hour Burden:

DEA Form 41 is completed on an as-needed bassis by registrants destroying controlled substances. The forms are prepared, completed and maintained by DEA registrant. Therefore, DEA does not have a strong basis to estimate the number of DEA Forms 41 that are completed each year. DEA's estimate of 90,629 respondents represents the total number of registrants in business activities that are most likely to destroy controlled substances: manufacturer, distributor, reverse distributor, retail pharmacy, hospital/clinic, and narcotic treatment program. The table below lists the number of registrations for each of these business activities.

Business Activity	Number of registrations

Manufacturer	579
Distributor	679
Reverse Distributor	72
Retail Pharmacy	68,882
Hospital/Clinic	18,614
Narcotic Treatment Program	1,803
Total	**90,629**

Source: DEA, May 2020

Again, DEA does not have a strong basis to estimate the frequency of responses. Therefore, for the purposes of this analysis, DEA assumes each respondent will complete one DEA Form 41 each year. Some registrants will complete more than one per year and others may complete none. However, DEA believes this is a reasonable "order-of-magnitude" estimate.

Activity	Number of Annual Respondents	Number of Annual Responses	Average Time per Response (minutes)	Total Annual Hours
DEA Form 41	90,629	90,629	30	45,315
Total	**90,629**	**90,629**		**45,315**

Total number of respondents: 90,629
Number of responses per respondent per year: 1
Total annual responses: 90,629
Total annual hour burden: 45,315 hours

Average Burden: Per Collection: 0.5 hour
Per Respondent: 0.5 hour

Burden dollars:

Estimate hourly wage ($/hour):[1]	$15.60
Load for benefits (percent of labor rate):[2]	42.7%
Loaded labor rate ($/hour):[3]	$22.25

	DEA Form 41
Number of responses	90.629
Total annual hours	45,315
Average burden per response (hour)	0.50

1 Used average of median hourly wages for 53-0000 Transportation and Material Moving Occupations to represent the occupation of persons completing the DEA Form 41 for all registrant types. May 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 $15.60 x (1 + 0.427) = $22.25.

	DEA Form 41
Burden dollars per response ($)	11.1269 572
Total burden dollars ($)	**1,008,425**

13. Estimate of Cost Burden:

The estimated annual cost burden is zero. Respondents are not estimated to incur any a) additional start-up cost or capital expenditure, or b) additional operation and maintenance costs or purchase services as a result of this information collection.

14. Estimated Annualized Costs to 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:

The decrease in annual responses and corresponding decrease in annual burden hours reflect the decrease in the number of registrations related to normal business activity. The increase in annual burden dollars reflects the increase in estimated labor rate for the occupation estimated to complete the form. There are no statutory or regulatory changes related to this information collection.

	2017 Approved Burden	2020 Requested Burden	Difference
Annual responses	92,924	90,629	-2,295
Annual burden hours	46,462	45,315	-1,148
Annual burden dollars	985,234	1,008,425	23,191

16. Plans for Publication:

DEA will not publish the results of the information collected.

17. Expiration Date Approval:

DEA is not seeking approval not to display the expiration date for OMB approval of this information collection.

18. Exceptions to the Certification Statement:

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

Part B. Statistical Methods

The Drug Enforcement Administration will not be employing statistical methods in this information collection.