

**Supporting Statement for Paperwork Reduction Act Submissions**  
**ARCOS Transaction Reporting -- DEA Form 333**  
**OMB Approval # 1117-0003**

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 # 1117-0003, ARCOS Transaction Reporting, DEA Form 333.

**Part A. Justification**

1. Necessity of Information:

Title 21 U.S.C. 827 requires controlled substance manufacturers and distributors to make periodic reports to the DEA regarding the sale, delivery, and other disposal of certain controlled substances. The implementing regulations are found at 21 CFR 1304.33. The Single Convention on Narcotic Drugs, 1961, and the Convention on Psychotropic Substances, 1971, impose certain reporting obligations on the United States, and aggregate data from Form 333s are provided to the International Narcotics Control Board to meet those obligations.

2. Needs and Uses:

The information collected in Form 333 is used by the DEA to monitor controlled substances through the closed system of distribution and identify potential diversion of controlled substances. Selected substances are tracked from point of manufacture to point of sale, distribution, or other disposition to the dispensing (consumption) level. In addition to providing an important enforcement mechanism for the DEA, the consumption figures are used to fulfill the United States' international treaty obligations.

3. Use of Information Technology:

Since the reporting requirement is applied to an industry, the overall burden is controlled by the number of firms in the industry and the amount of business conducted. The burden is eased by reporting options provided by automation of data exchange through an online application and/or electronic data interchange, as an alternative to the standard manual reporting form. Currently, electronic reporting makes up 97% of the data collected.

4. Efforts to Identify Duplication:

The DEA has made efforts to identify and prevent duplication of the collection of information. DEA Form 333 has been reviewed for possible duplication, and been determined not to be duplicative. The collection of the information in Form 333 is unique to the DEA; this reporting system is the only one of its kind in the United States, and the aggregated information cannot be obtained anywhere else.

5. Impact on Small Businesses or Entities:

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 businesses 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:

The DEA uses the information collected to monitor the movement of certain controlled substances. If collection were not conducted, or were conducted less frequently, the DEA would lose this valuable method of identifying potential areas of diversion, and would be severely restricted from complying with international treaty obligations. The regular collection of the information in DEA Form 333 is vital to the enforcement of the Controlled Substances Act (CSA).

7. Special Circumstances Influencing Collection:

There are no special circumstances applicable to this information collection.

8. Consultation with persons outside the Agency:

Public comment was solicited in the 60-day Federal Register Notice of Information Collection, 82 FR 37613, published on August 11, 2017 and the 30-day Federal Register Notice of Information Collection, 82 FR 47580, published on October 12, 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 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 the 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, the DEA will give written notice to the submitter to allow an opportunity to object within a reasonable time prior to any disclosure by the DEA.

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 Annual Respondents	Number of Annual Responses	Average Hours per Response	Total Annual Hours
DEA-333 (paper)	70	379	1	379
DEA-333 (electronic)	1,552	11,777	0.1667 (10 minutes)	1,963
<b>Total</b>	<b>1,622</b>	<b>12,156</b>		<b>2,342</b>

Average burden per response: 0.1927 hour

Hour burden cost:

Estimated hourly wage <sup>1</sup>	\$42.88
Load for benefits (percent of labor rate) <sup>2</sup>	47.1%
Loaded labor rate <sup>3</sup>	\$63.08
Average burden per response (hour)	0.1927
Burden cost per response	\$12.16
Number of annual responses	12,156
<b>Total hour burden cost</b>	<b>\$147,817</b>

13. Estimate of Cost Burden:

Respondents are not estimated to incur any additional start-up costs or capital expenditures as a result of this information collection. Any costs associated with retention is nominal. However, respondents are estimated to incur shipping costs for paper responses.

Number of paper responses	379
Shipping cost per paper response	\$0.49
<b>Total shipping cost</b>	<b>\$186</b>

1 Median hourly wage for a transportation, storage, and distribution manager (SOC 11-3071). *May 2016 National Occupational Employment and Wage Estimates, United States*, BUREAU OF LABOR STATISTICS, [http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm) (last visited July 14, 2017).

2 Average benefits for civilian workers are 32% of total compensation. *Employer Costs for Employee Compensation – March 2017*, BUREAU OF LABOR STATISTICS, <https://www.bls.gov/news.release/pdf/ecec.pdf> (last visited July 14, 2017). The 32% of total compensation equates to 47.1% (32% / 68%) load on wages and salaries.

3  $42.88 \times (1 + 0.471) = 63.08$ .

14. Estimated Annualized Costs to Federal Government:

Estimated annual cost to the Federal government:

Data Support	\$150,000
<b>Total</b>	<b>\$150,000</b>

All costs are recovered from the registrants through registration fees, as required by the 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 decrease in annual burden hours reflects the adjustment to estimated burden per electronic response, from one hour to ten minutes, and the increase in the portion of total responses that are electronic responses. The 2014 annual burden dollars erroneously excluded labor burden in the annual burden dollars calculation and should have been \$455,046. The increase in 2017 requested annual burden dollars reflects the inclusion of labor burden. If the labor burden had been included in 2014, the 2017 requested annual burden dollars would be a decrease that is consistent with the decrease in annual burden hours. There are no statutory or regulatory changes related to this information collection.

	2014 Approved Burden	2017 Requested Burden	Difference
Annual responses	7,932	12,156	4,224
Annual burden hours	7,932	2,342	(5,590)
Annual burden dollars	272	147,817	147,545

16. Plans for Publication:

The DEA will not publish the results of the information collected.

17. Expiration Date Approval:

The DEA does not object to OMB displaying the expiration date.

18. Exceptions to the Certification Statement:

The 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.