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

The Drug Enforcement Administration (DEA) seeks the Office of Management and Budget (OMB) approval of an existing collection of information that was previously approved by OMB – OMB Approval Number 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. These reporting requirements provide one mechanism for the DEA to track controlled substances through the closed system of distribution, and enable the DEA to meet the United States international treaty obligations pertaining to the Single Convention on Narcotic Drugs, 1961, and the Convention on Psychotropic Substances, 1971. The implementing regulations are found at 21 CFR 1304.33.

2. Needs and Uses:

Collection of information on each sale, delivery, or other disposal of controlled substances is statutorily mandated. 21 U.S.C. 827(d)(1). The information is used by the DEA to monitor selected substances from point of manufacture to point of sale, to distribution, or other disposition to the dispensing (consumption) level. The consumption figures are provided as ancillary data to the International Narcotics Control Board (INCB) to fulfill international treaty obligations, and they are used by the DEA to identify potential diversion of controlled substances.

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 the acceptance of a number of electronic media — electronic data interchange (EDI), CD-ROM, and disk - as an alternative to the standard reporting form. Currently, electronic reporting makes up 93 % of the data collected. Of those participants that provide responses electronically, the vast majority do so through EDI.

4. Efforts to Identify Duplication:

The DEA has made efforts to identify and prevent duplication of the colleciton of information. The existing DEA Form 333 is not duplicative. The collection of this information is unique to the DEA.

5. Impact on Small Businesses or Entities:

This is a routine three-year renewal of DEA Form 333. The DEA does not anticipate any additional impact on small businesses or other small entities since the initial approval of this form, accordingly, 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 the collection is not conducted or 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 obligations. Since this system is the only one of its kind in the United States, the aggregated information cannot be obtained anywhere else. The information collected by DEA Form 333 is vital to the enforcement of the CSA.

7. Special Circumstances Influencing Collection:

There are no special circumstances appilcable 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, 79 FR 21954-21955, published on 04/18/2014 and the 30 day Federal Register Notice of Information Collection, 79 FR 35573-35574, published on 06/23/2014. 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. Estimated Hour Burden:

DEA Form 333:

Number of Respondents:	1,265
Frequency of Response:	Quarterly/Monthly
Average time per response:	1 Hour
Total annual responses:	7,932

Total annual burden: 7,932 hours

Paper: 7% (555 Hours)
Electronic: 93% (7,377 Hours)

13. Estimated Cost of Burden:

The DEA assumes that a transportation, storage, and distribution manager (SOC 11-3071) will complete the form on behalf of the registrant. The median hourly wage for that position according to the Bureau of Labor Statistics' 2013 Occupational Employment Statistics is $40.33 (http://www.bls.gov/oes/current/oes_nat.htm). Applying 42.25% load for benefits, the loaded median hourly wage is $57.37. Therefore, the overall cost of burden hours is $455,046.

Mailing costs for paper forms is estimated at $0.49 per form, or $272 for 555 forms which represents the total mailing costs. Electronic/automated responses are handled via secure Internet and no longer require the mailing of media.

Total estimated cost of burden is $455,318 ($455,046 + $272).

14. Estimated Annualized Cost to the Federal Government:

Estimated annual cost to Government:

Data Support: $150,000

TOTAL COST TO GOVERNMENT: $150,000

There is no actual cost to the Federal Government for this activity as all costs are recovered from the registrants through registration fees, as required by 21 U.S.C. 886a.

15. Reasons for Change in Burden:

There has been no program change. Changes in the number of respondents and responses vary depending on the number of controlled substance transactions reported to the DEA.

16. Plans for Publication:

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

17. Expiration Date of 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 does not employ statistical methods in this information collection.