

Supporting Statement for Paperwork Reduction Act Submission
ARCOS Transaction Reporting
DEA Form 333

OMB Approval Number 1117-0003

Part A. Justification

1. Necessity of Information:

Title 21 U.S.C. 827 requires controlled substances manufacturers and distributors to make periodic reports to DEA regarding sales, deliveries and other disposals of certain controlled substances. These reporting requirements provide one mechanism for DEA to track controlled substances through the closed system of distribution, and allow DEA to meet United States international treaty obligations pertaining to the Single Convention on Narcotic Drugs, 1961, and the Convention on Psychotropic Substances, 1971. These treaties require information on the manufacture and consumption of certain controlled substances. The implementing regulations are found at 21 CFR 1304.33.

2. Needs and Uses:

The information is used by DEA to track selected substances from point of manufacture to point of sale, 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 treaty obligations, and they are used by DEA to identify potential diversion of controlled substances. Since this system is the only one of its kind in the United States, the information cannot be obtained anywhere else should the collection of the information not be conducted. Consequently, the information would not be available to fulfill United States' treaty obligations or identify actual registrants or potential areas of drug diversion.

3. Use of Technology:

Since the reporting requirement is applied on 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 collection of this information is unique to DEA.

5. Methods to Minimize Burden on Small Businesses:

Although some reporting manufacturers are small businesses, the burden is minimal.

6. Consequences of Less Frequent Collection:

Failure to collect the data would make it impossible for DEA to meet the Government's international treaty obligations. These collections are mandated by the Controlled Substances Act.

7. Special Circumstances Influencing Collection:

Persons are required to submit reports quarterly. Persons may request and be granted permission to submit reports more frequently than quarterly, but not more often than monthly, depending on the number of transactions being reported. Other special circumstances in item 7 of the supporting statement are not applicable to this information collection.

8. Reasons for Inconsistencies with 5 CFR 1320.6:

There are no inconsistencies with the Paperwork Reduction Act. DEA meets regularly with the affected industry to discuss policies, programs and regulations. DEA did not receive any comments concerning this collection.

9. Payment or Gift to Claimants:

There are no such gifts or payments 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 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:

Questions of a sensitive nature are not included in reporting requirements.

12. Estimate of Hour Burden:

DEA Form 333:

Number of Respondents: 1,090
Frequency of Response: Quarterly/Monthly
Average time per response: 1 Hour
Total annual responses: 6,856

Total annual burden: 6,856 hours

Paper: 7% (496 Hours)
Electronic: 93% (6,360 Hours)

Estimated time (hours) to complete response:

Paper :

Monthly (1 hour per form x 17 respondents x 12 months): 204
Quarterly (1 hour per form x 73 respondents x 4 Qtrs): 292

Subtotal: 496

Electronic:

Monthly (1 hour per form x 295 respondents x 12 months): 3,540
Quarterly (1 hour per form x 705 respondents x 4 Qtrs): 2,820

Subtotal: 6,360

Total Hours: 6,856

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' 2009 Occupational Employment Statistics is \$38.22 (http://www.bls.gov/oes/current/oes_nat.htm). Therefore, the cost of burden hours is \$262,036.32.

13. Estimate of Cost Burden:

Mailing costs for paper forms is estimated at \$0.44 per form, or \$218.24 for 496 forms which represents the total mailing costs. Electronic/automated responses are handled via secure Internet and no longer require the mailing of media.

14. Estimated Annualized Costs to Federal Government:

Estimated annual cost to Government:

Personnel costs:

Data Support: \$150,000

TOTAL COST TO GOVERNMENT: \$150,000

All costs to the government for operation of the Diversion Control Program, including the above costs, are recovered by DEA from registrants through registration fees, as required by the Department of Justice and Related Agencies Appropriations Act.

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 substances transactions and with the number of thefts and losses reported to DEA.

16. Plans for Publication:

There are no plans to publish the information collected.

17. Expiration Date Approval:

It would be an administrative burden to replace existing forms in all field locations when nothing of substance changed except Date of Expiration, therefore, approval is requested not to list Date of Expiration on the form.

18. Exceptions to the Certification Statement:

There are no exceptions to the certification statement.

Part B. Statistical Methods

The Drug Enforcement Administration does not employ statistical methods in this information collection.