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:

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 allows 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 Section 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—tape, disk--as an alternative to the standard reporting form. Currently, electronic reporting makes up 93 % of the data collected.

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. The 60 and 30 Day notices have been published in the Federal Register. 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:

Confidential business information is protected under Department of Justice regulations, 28 CFR 16.8 and 16.9.

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: 1,173
Frequency of Response: Annually and Quarterly
Average time per response: 1 Hour
Total annual responses: 7,768

Total annual burden: 7,768 hours

Paper: 7% (544 Hours)
Electronic: 93% (7,224 Hours)

Estimated time (hours) to complete response:

Paper :
Monthly (1 hour per form x 9 respondents x 12): 108
Quarterly (1 hour per form x 62 respondents x 4 Qtrs): 248

Subtotal: 356

Electronic:
Monthly (1 hour per form x 381 respondents x 12 months): 4,572
Quarterly (1 hour per form x 710 respondents x 4 Qtrs): 2,840

Subtotal: 7,412

Total Hours: 7,768

13. Estimate of Cost Burden:

Currently data must be mailed to DEA either on electronic media (tape, disk) or on paper. The mailing cost for paper forms is estimated at $0.41 per form or $29.11 for 71 forms; mailing costs for electronic media is estimated at $1.84 per package (U.S. Postal Service, package of up to 2 pounds) or $8,890.88 for 4,832 forms. Total mailing costs therefore are $9,077.36. DEA expects to be able to accept electronic transmission of Form 333 in the future, which will reduce the mailing costs.

14. Estimated Annualized Cost to Federal Government:

Estimated annual cost to Government:

Data Processing: $114,895

TOTAL COST TO GOVERNMENT: $114,895

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. All changes are due to population adjustments.

16. Plans for Publication: There are no plans to publish the information.

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.

18. Exceptions to 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.