Supporting Statement for Paperwork Reduction Act Submissions

Application for Registration (DEA Form 225); Application for Registration Renewal (DEA Form 225a); Affidavit for Chain Renewal (DEA Form 225B)

Part A. Justification

1. Necessity of Information:

The Controlled Substances Act requires all firms and individuals who manufacture, distribute, import, export, conduct research with, or dispense controlled substances to register with DEA (21 U.S.C. 822, 21 CFR 1301.11). Registration provides a closed system of distribution to control the flow of controlled substances through the distribution chain.

2. Needs and Uses:

DEA Form 225 is utilized by applicants seeking to become registered to manufacture, distribute, import, export, conduct research, and laboratory analysis with controlled substances. DEA Form 225a is utilized for renewal of such registrations on an annual basis. The DEA Form 225B renews registrations for chain registrants (currently distributor and analytical laboratory). The information submitted is used to identify person's seeking registration and provide information to determine whether registration would be consistent with the public interest.

3. Use of Technology:

DEA has a system which permits fully electronic registration using a credit card. Currently, the referenced forms are available on the DEA Diversion Control Program web site (http://www.deadiversion.usdoj.gov). Applicants complete the form online, and submit the form electronically, along with credit card payment. Aside from these activities, DEA currently permits chain distributors and analytical laboratories to register through the use of an affidavit and a computerized listing of all registrants. Currently, 4 persons participate in this program (DEA Form 225B), holding registrations for 82 individual registrants.

4. Efforts to Identify Duplication:

The federal requirement of registration to handle controlled substances is unique to DEA. This type of information is specific to the applicant's use of controlled substances and is not available from other sources.

5. Methods to Minimize Burden on Small Businesses:

Although some of the registrants affected may be classified as small businesses according to the Small Business Administration, the information collected is maintained as a normal course of business. Therefore, this collection does not have a significant impact upon small entities within the meaning and intent of the Regulatory Flexibility Act, 5 U.S.C. 601, et seq.

6. Consequences of Less Frequent Collection:

The Controlled Substances Act requires that registration for these activities be issued on an annual basis. Not collecting this information, i.e., not registering manufacturers, distributors, importers, exporters, researchers and analytical laboratories, would compromise DEA's mission of ensuring a closed system of distribution of controlled substances, as mandated by the Controlled Substances Act.

7. Special Circumstances Influencing Collection:

There are no special circumstances applicable to this information collection.

8. Reasons for Inconsistencies with 5 CFR 1320.6:

There are no circumstances that require the collection of data that would be inconsistent with the guidelines set forth in 5 CFR 1320.6. 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, including application and registration procedures, with representatives of those from whom the information is obtained.

DEA did not receive any comments for this collection.

9. Payment or Gift to Claimants:

There are no payments or gifts 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 this information collection.

12. Estimate of Hour Burden:

DEA Form 225 is submitted on an as-needed basis by persons seeking to become registered, DEA Form 225a is submitted on an annual basis thereafter, and DEA Form 225B is submitted annually for renewals of chain (distributor and analytical laboratory) registrants

DEA Form 225: Electronic Form
Number of respondents: 1,397
Average time per response: 0.17 hours (10 minutes)
Annual Burden Hours: 232.8 hours

DEA Form 225: Paper Form
Number of respondents: 725
Average time per response: 0.5 hours (30 minutes)
Annual Burden Hours: 362.5 hours

DEA Form 225a: Electronic Form
Number of respondents: 5,948
Average time per response: 0.17 hours (10 minutes)
Annual Burden Hours: 991.3 hours

DEA Form 225a: Paper Form
Number of respondents: 5,481
Average time per response: 0.5 hours (30 minutes)
Annual burden hours: 2,740.5 hours

DEA-225b
Number of respondents: 4
Average time per response: 1 hours
Annual burden hours: 4 hours

Total number of respondents: 13,555
Total annual burden hours: 4331.1 hours

Percent Electronic (DEA-225) – 66%
Percent Electronic (DEA-225a) – 52%

Hourly cost to respondent:
(DEA 225 - Electronic) – 1,397 respondents x 0.17 hours per response x $10 = $ 2,328
(DEA 225 - Paper) – 725 Respondents x .5 hours per response x $10 = $ 3,625
(DEA 225a – Electronic) – 5,948 Respondents x 0.17 hours per response x $10 = $ 9,913
(DEA 225a - Paper) – 5,481 Respondents x .5 hours per response x $10 = $ 27,405
(DEA 225b) – 4 Respondents x 1 hour per response x $10 = $ 40
Total $ 43,311

This cost is a usual and customary business expense not directly associated with this information collection.

13. Estimate of Cost Burden:

The annual fees vary by business activity. Annual cost to respondents was calculated as follows:

(Respondents - Exempt Respondents) x Fee = Annual Fee Cost to Respondents

Business Activity	Number of Respondents	Exempt Respondents	Non-Exempt Respondents	Annual Fee	Annual Cost to Respondents
Researcher	9,315	5,205	4,110	$ 184	$ 756,240
Analytical Laboratories	1,851	788	1,063	$ 184	$ 195,592
Distributors	1,141	157	984	$ 1,147	$ 1,128,648
Manufacturers	649	6	643	$ 2,293	$ 1,474,399
Importers	283	1	282	$ 1,147	$ 323,454
Exporters	316	4	312	$ 1,147	$ 357,864
TOTAL	13,555	6,161	7,394		$ 4,236,197

Total Registrants Represented:

Respondents - DEA Form 225	2,122
Respondents - DEA Form 225a	11,429
Registrants in Chain Renewal Process - DEA Form 225B	
(Note: 4 Respondents complete DEA Form 225B)	
Distributors	39
Analytical Laboratories	43
Total	13,633

Mailing cost: 6,288 x $0.42 = $2,640.96

Annual Fee Cost to Respondent + mailing cost = Annual Cost to Respondents

$4,236,197 + $2,641 = $ 4,238,838

There are 6,161 respondents who are exempt from paying the fee because they are affiliated with a Federal, State, or local government agency (21 CFR 1301.21).

14. Estimated Annualized Cost to Federal Government:
Cost to Federal Government:

Estimated Annual Cost to the Government:

Postage	$3,000
Rent, Equipment, etc.	$208,725
Printing	$1000
Automatic Data Processing	$1860
Total:	$214,585

Project Manager
Unit Chief (Registration Unit) - GS-301-14 (HQ); (5% of time) = $ 7,111

Review and Notification
46 Registration Assistants - GS-963-9 (Field); (10% of time) = $ 321,043

7 Registration Assistants - GS-963-9 (HQ); (10% of time) = $ 48,854

1 Registration Assistants - GS-963-11(HQ); Team Leaders; (10% of time) = $ 8,444
483 Diversion Investigators - GS-1801-12 (Field) (15% of time) = $ 7,332,450
4 Program Analyst GS-343-13 (HQ) (35% of time) = $ 168,493
21 Government Contractor Employees from ASRC (25% of time) = $ 414,309
(25% of average contract cost x 21)
Scanning
1 Computer Assistant – GS-335-9 (HQ) (2 % of time) = $ 1,396

Fee Processing
4 Government Contractor Employees from ASRC (25% of time) = $ 93,284
(25% of average contract cost x 4)

Total: $ 8,395,384

TOTAL COST: $ 8,609,969

There is no actual cost to the Federal Government for these activities as all costs are recovered from registrants through registration fees, as required by the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act of 1993.

15. Reasons for Change in Burden:

Changes reflect population adjustments and time it takes to complete the forms.

16. Plans for Publication:

There are no plans to publish this 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 the Date of Expiration; therefore, approval is requested not to list the Date of Expiration.

18. Exceptions to the Certification Statement:

There are no exceptions to the certification requirement.

Part B. Statistical Methods
The Drug Enforcement Administration will not be employing statistical methods in this information collection.