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)

OMB number 1117-0012

Part A. Justification

1. Necessity of Information:

Purpose of collection: The Controlled Substances Act requires all firms and individuals who manufacture, distribute, import, export, and conduct research and laboratory analysis with 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. Registration is needed for control measures over legal handlers of controlled substances and is used to monitor their activities.

2. Needs and Uses:

Intended uses: Registration is needed for control measures over legal handlers of controlled substances and is used to monitor their activities. 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. DEA Form 225b renews registrations for chain registrants (currently distributors). The information submitted is used to identify persons 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 85 individual registrants.

Accounting for those applications individually submitted online as well as those applications submitted electronically as part of a chain renewal, 11,368 of the 13,178 applications for registration and registration renewal were submitted electronically, or approximately 86%.

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 handling 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 economic 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 5CFR 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:

Opportunities for consent: Applicants and registrants must register with DEA in order to handle controlled substances and List I chemicals. Failure to provide the requested

information precludes processing of the application. The parameters for consent and the use and sharing of the information collected are conveyed to applicants and registrants whether they are using the online forms or paper forms.

Each form in the information collection states the purposes for which DEA will use the information and whether disclosure of the information is voluntary or mandatory. Each form in the information collection also states that DEA will disclose the information without prior written consent only when DEA has legal authority to do so.

Information requested in this collection may be considered confidential business information if marked as such pursuant to 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.

System of Records notice: The System of Records Notice for this information collection is the Controlled Substances Act Registration Records (DEA-005). The publication of the complete notice may be found at 52 FR 47208, December 11, 1987; modified at 66 FR 8425, January 31, 2001; modified at 72 FR 3410, January 25, 2007.

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 to renew existing registrations, and DEA Form 225b is submitted annually for renewals of chain (distributor and analytical laboratory) registrants.

	Number of Annual Respondents	**Average Time per Response**	**Total Annual Hours**
DEA-225 (paper)	465	0.5 hours (30 minutes)	232.5
DEA-225 (electronic)	1,562	0.17 hours (10 minutes)	260.33
DEA-225a (paper)	1,345	0.5 hours (30 minutes)	672.5
DEA-225a (electronic)	9,721	0.17 hours (10 minutes)	1,620.17
DEA-225b (chain renewal)*	4	1 hour	4
Total	13,097		2,789.5

* In total, 4 chains represent 85 individual registrant locations.

Total registration applications received on paper: 1,810

Total registration applications received electronically: 11,368

Percentage of applications received electronically: 86%

Estimates are based on the population of the regulated industry participating in this business activity. DEA assumes that a general and operations manager (SOC 11-1021, 2010 Standard Occupational Classification) (http://www.bls.gov/soc/2010/soc_alph.htm) will complete the form on behalf of the applicant or registrant. The median hourly wage for that position according to the Bureau of Labor Statistics' 2010 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 424200 –Drugs and Druggist Sundries (http://www.bls.gov/oes/current/naics5_424200.htm is $57.53. Thus the labor cost of this information collection is $160,479.93 annually.

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**
Researchers	9,460	5,376	4,084	$ 244	$996,496
Analytical Laboratories	1,556	699	857	$ 244	$209,108
Distributors	1,026	127	899	$ 1,523	$1,369,177
Manufacturers	561	13	548	$3,047	$1,669,756
Importers	292	8	284	$ 1,523	$432,532
Exporters	283	2	281	$ 1,523	$427,963
TOTAL	13,178	6,225	6,953		$5,105,032

Mailing cost: 1,810 x $0.45 = $814.50

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

$5,105,032+ $814.50 = $5,105,846.50

There are 6,225respondents that 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:

Estimated Annual Production Cost to Government:

Government Employees:	$ 0.00	
Contract Employees:		$728.22
Cost of Paper:		$104.00
Mailing (Postage):		$4,572.00
Custom Envelopes:		$23.00
Mailing Envelopes:		$208.00
Equipment Maintenance:		$211.49
Equipment/10 years:		$229.51
Per Print Charges:		$274.35
Total:		**$6,350.57**

Estimated Annual Labor Cost to Government:

Section Chief – GS-301-15 (10% of time)	$14,026
Deputy Section Chief – GS1801-14 (10% of time)	$11,924
<u>Review & Notification</u>	
54 Registration Program Specialists - GS-963-9 (Field); (10% of time)	$315,960
3 Legal Instrument Examiners - GS-963-9 (HQ); (5% of time)	$8,777
1 Legal Instrument Examiner Sup - GS-963-11 (HQ); (5% of time)	$3,540
461 Diversion Investigators - GS-1801-12 (Field) (5% of time)	$1,955,908
1 Program Analyst GS-343-13 (HQ) (40% of time)	$40,362
2 Program Analyst GS-343-13 (HQ) (20% of time)	$40,362
21 Government Contractor Call Center Employees, 3 Supervisors, and 1 Task Manager (10% of time for an average annual contract cost x 25)	$202,322.
<u>Fee Processing and Mail Room</u>	
6 Government Contractor Employees (2.5% of time for average annual contract cost x 6)	$12,630
<u>Scanning</u>	
1 Computer Assistant – GS-335-9 (HQ) (2% of time)	$1,171
Total:	**$2,613,331**

All labor costs are rounded up to the nearest dollar. Costs are calculated by using the DC-Baltimore pay tables for the grade listed, step 5.

All costs to the Federal Government for these activities 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:

The decrease in hour burden is related to more applications for and renewals of registration being conducted electronically. For this collection overall, electronic responses increased from 54% during the previous renewal to 86% for this renewal. Other changes reflect population adjustments. The table below summarizes the changes since the last renewal of this information collection.

	2009 Approved Burden	**2012 Requested Burden**	**Difference**
Annual respondents	13,555	13,097	(458)
Annual burden hours	4,331	2,789.5	(1,541.5)
Annual cost	$4,238,838	$5,105,846.50	$867,008.50

16. Plans for Publication:

There are no plans to publish this information.

17. Expiration Date Approval:

DEA is not requesting such approval.

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.