

Supporting Statement for Paperwork Reduction Act Submissions

**Application for Registration under Domestic Chemical Diversion Control Act of 1993 and  
Renewal Application for Registration under Domestic Chemical Diversion Control Act of  
1993**

**DEA Forms 510 & 510A**

**[OMB number 1117-0031]**

Part A. Justification

1. Necessity of Information: The Controlled Substances Act (21 U.S.C. 822 and 823) require that every person who manufactures or distributes a list I chemical shall annually obtain a registration for that purpose. Additionally, the Controlled Substances Import and Export Act (21 U.S.C. 957 and 958) require that persons who import or export List I chemicals must obtain a registration prior to conducting such activities. DEA is required to fund the costs of the Diversion Control Program through the charging of fees. “Fees charged by the Drug Enforcement Administration under its diversion control program shall be set at a level that ensures the recovery of the full costs of operating the various aspects of that program.” (21 U.S.C. 886a). 21 CFR 1309.21 outlines the procedures and requirements for submission of applications for registration by those persons required to be registered. DEA Form 510 is utilized by applicants desiring to manufacture, distribute, import, and export List I chemicals. DEA Form 510a is utilized for renewal of the registration on an annual basis.

2. Needs and Uses: The information provided on the application is necessary to register a person to conduct specific activities with List I chemicals, which are regulated by DEA. This information is also used by DEA investigators in evaluating the applicant to determine if the requirements for registration have been met. Failure to collect such information would prevent evaluation of the applicant prior to registration and would impair DEA’s enforcement of the Controlled Substances Act.

3. Use of Technology: Currently, the DEA Form 510 may be submitted electronically through the DEA Diversion Control Program web site at <http://www.deadiversion.usdoj.gov>. New applicants complete this form online and submit it to DEA electronically. Currently, 1,039 respondents (98.5%) submit reports electronically.

4. Efforts to Identify Duplication: The Federal requirement of registration to handle list I chemicals is unique to DEA.

5. Methods to Minimize Burden on Small Businesses: The collection of information does not have a significant impact on small business entities.

6. Consequences of Less Frequent Collection: DEA Form 510 is utilized on an “as needed” basis by applicants desiring to manufacture, distribute, import, and export List I chemicals. DEA Form 510a is utilized for the renewal of registration on a yearly basis. Failure to collect the

information would impair DEA’s enforcement activities and violate 21 U.S.C. 822, 823, 957, and 958 of the Controlled Substances Act. Businesses and other for-profit entities participating in this information collection maintain the requested data as part of usual and customary business practice.

7. Special Circumstances Influencing Collection: There are no special circumstances influencing 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 1320.8(d). DEA meets regularly with the affected industry to discuss policies, programs and regulations.

9. Payment or Gift to Claimants: There are no such payments or gifts 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 disclosure by DEA. Further, disclosure of information regarding activities of registrants is addressed in 21 U.S.C. 830.

11. Justification for Sensitive Questions: Questions of a sensitive nature are not included in the reporting requirements.

12. Estimates of Hour Burden:

	<b>Respondents</b>	<b>Burden (minutes)</b>	<b>Total Hour Burden</b>	<b>@ \$50.14/hour =</b>
DEA-510 (paper)	17	0.5 hours	8.5	\$448.80
DEA-510 (electronic)	143	0.25 hours	35.75	\$1,887.60
DEA-510a (paper)	158	0.5 hours	79	\$4,171.20
DEA-510a (electronic)	896	0.25 hours	224	\$11,827.20
<b>Total</b>	<b>1,054</b>		<b>347.25</b>	<b>\$18,334.80</b>

Total percentage electronic: 98.5%

Estimates are based on the population of the regulated industry participating in this business activity. DEA assumes that a general and operations manager (SOC 11-1020, 2010 Standard Occupational Classification) ([http://www.bls.gov/soc/2010/soc\\_alph.htm](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' 2009 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 424600 – Chemical and Allied Products Merchant Wholesalers ([http://www.bls.gov/oes/current/naics4\\_424600.htm#11-0000](http://www.bls.gov/oes/current/naics4_424600.htm#11-0000)) is \$50.14. This is a usual and customary business expense not directly associated with this information collection.

13. Estimate of Cost Burden: As noted previously, persons applying for a new registration and persons applying to renew registrations pay a registration application fee based on their business category. Fees associated with this application are as follows:

<b>Business Activity</b>	<b># Registrants</b>	<b>Fee</b>	<b>Total</b>
Manufacturer	197	\$3,047	\$600,259
Distributor	511	\$1,523	\$778,253
Importer	192	\$1,523	\$292,416
Exporter	154	\$1,523	\$234,542
Total	1,054		\$1,904,470

Mailing cost for applications: 170 responses @ \$0.45 per response = \$76.50

TOTAL RESPONDENT COST: \$1,904,546.50

14. Estimated Annualized Cost to Federal Government:

COST TO FEDERAL GOVERNMENT:

Printing and Mailing (DEA estimates combined printing and mailing costs to average \$0.50 per registrant annually): \$527.00

Personnel costs:

1 GS-7 (10% of time): \$6,303.48

1 GS-9 (100% of time): \$74,894.08

1 GS-13 (40% of time): \$51,622.85

Total Personnel Costs: \$93,487.85

TOTAL COSTS: \$132,860.41

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: There have been no programmatic changes to this collection. The changes in burden are due to a decrease in chemical registrant population. Additionally, the

cost of obtaining a DEA registration increased.

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

17. Expiration Date Approval: All forms contain the date of expiration.

18. Exceptions to the Certification Statement: There are no exceptions to the certification statement.

#### Part B. Statistical Methods

The Drug Enforcement Administration will not be employing statistical methods in this information collection.