

**Supporting Statement for Paperwork Reduction Act Submissions
Application for Registration under Domestic Chemical
Diversion Control Act of 1993 (DEA Form 510)
Renewal Application for Registration under Domestic Chemical Diversion Control
Act of 1993 (DEA Form 510A)
OMB Approval #1117-0031**

The Drug Enforcement Administration (DEA) seeks approval by the Office of Management and Budget (OMB) for an existing collection of information that was previously approved by OMB – OMB Control No.1117-0031, Application for Registration under Domestic Chemical Diversion Control Act of 1993 (DEA Form 510) and Renewal Application for Registration under Domestic Chemical Diversion Control Act of 1993 (DEA Form 510A).

Part A. Justification

1. Necessity of Information:

The DEA implements the Controlled Substances Act (CSA) which requires that every person who manufactures or distributes a list I chemical shall annually obtain a registration for that purpose. 21 U.S.C. 822 and 823. Additionally, the Controlled Substances Import and Export Act (CSIEA) requires that persons who import or export list I chemicals must obtain a registration prior to conducting such activities. 21 U.S.C. 957 and 958.

2. Needs and Uses:

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. This information is also used by the 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 the DEA's enforcement of the CSA and CSIEA pursuant to 21 U.S.C. 822, 823 957, and 958, and in accordance with 21 CFR 1309.21 and 1309.32.

3. Use of Information Technology:

The DEA permits online registration and renewal of registration through the secure network application on the DEA Office of Diversion Control Web site <http://www.deadiversion.usdoj.gov>. Applicants may complete and submit DEA Forms 510 and 510A online along with credit card payment. Approximately 89% of applications for initial registration and renewal registration were submitted online during calendar year 2015.

4. Efforts to Identify Duplication:

The DEA has made efforts to identify and prevent duplication of the collection of information. The existing DEA Forms 510 and 510A are not duplicative of any other DEA forms. The collection of this information is unique to the DEA.

5. Impact on Small Businesses or Entities:

This is a routine renewal of DEA Forms 510 and 510A. The DEA does not anticipate any additional impact on small businesses or other small entities since the last approval of this form. The collection will not have a significant economic impact on small businesses or other small entities within the meaning and intent of the Regulatory Flexibility Act, 5 U.S.C. 601–612.

6. Consequences of Less Frequent Collection:

DEA Form 510 is utilized on an “as needed” basis by applicants desiring to manufacture, distribute, import, or 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 the DEA’s enforcement activities and violate 21 U.S.C. 822, 823, 957, and 958 of the CSA and CSIEA. 21 U.S.C. 822(a) requires persons who manufacture or distribute, or propose to manufacture or distribute, any list I chemical to register annually. 21 U.S.C. 958(e) requires persons who import or export, or propose to import or export, any list I chemical to register annually. DEA registrants and applicants 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 applicable to this information collection.

8. Consultation with persons outside the Agency:

Public comment was solicited in the 60-day Federal Register Notice of Information Collection, 81 FR 2240, published January 15, 2016 and the 30-day Federal Register Notice of Information Collection, 81 FR 16215, published March 25, 2016. The DEA did not receive any comments concerning this collection.

The DEA meets regularly with affected industry to discuss policies, programs, and regulations. These meetings provide an open forum to discuss matters of mutual concern with representatives of those entities from whom the information is obtained.

9. Payment or Gift to Claimants:

This collection of information does not propose to provide any payment or gift 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 the 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 as confidential business information per 28 CFR 16.8(c) and Exemption 4 of FOIA, the DEA will give written notice to the submitter to allow an opportunity to object within a reasonable time prior to any disclosure by the DEA.

11. Justification for Sensitive Questions:

This collection of information does not ask any questions of a sensitive nature.

12. Estimate of Hour Burden:

DEA Form 510 is submitted on an as-needed basis by persons seeking to become registered. DEA Form 510A is submitted on an annual basis thereafter.

	Number of Annual Respondents	Average Time per Response	Total Annual Burden Hours
DEA-510 (paper)	14	0.20 hours (12 minutes)	2.80
DEA-510 (electronic)	116	0.17 hours (8 minutes)	15.47
DEA-510A (paper)	97	0.2 hours (10 minutes)	16.17
DEA-510A (electronic)	827	0.07 hours (4 minutes)	55.13
Total	1,054		89.57

Total number of respondents: 1,054

Number of responses per respondent per year: 1

Total annual responses: 1,054

Total annual hour burden: 89.57

Average Burden: Per Collection: 0.08 hour

Per Respondent: 0.08 hour

Total registration applications received on paper: 111

Total registration applications received online: 943

Percentage of applications received electronically: 89.5%

Estimates are based on the population of the regulated industry participating in this business activity. The DEA assumes that a “general and operations manager” (SOC 11-1021, 2010 Standard Occupational Classification) (<http://www.bls.gov/soc/2010/soc111021.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’ (BLS) 2014 National Occupational Employment and Wage Estimates for NAICS 424600 – Chemical and Allied Products Merchant Wholesalers industry (http://www.bls.gov/oes/current/oes_nat.htm) is \$52.41. Based on the BLS report, “Employer Costs for Employee Compensation – September 2015,” (ECEC) (<http://www.bls.gov/news.release/pdf/ecec.pdf>) an additional 43.5% load (for “private industry”) is added to the wage rate to account for benefits. Thus, the labor cost of this information collection is \$6,736 annually. (The average cost per response is \$6.39.)

13. Estimate of Cost Burden:

The estimated annual cost burden is zero. Respondents are not estimated to incur any a) additional start-up cost or capital expenditure, or b) additional operation and maintenance costs or purchase services as a result of this information collection.

14. Estimated Annualized Cost to Federal Government:

Estimated Annual Production Cost to Government:

Production Item	Cost (\$)*
Contract Employees	98
Cost of Paper	15
Mailing (Postage)	371
Return Envelopes	11
Mailing Envelopes	11
Equipment Maintenance	66
Equipment Cost	97
Total	669

*Figures are rounded.

Estimated Annual Labor Cost to Government:

Labor Category	Number	Cost (\$)*
Section Chief – GS-15	1	402
Deputy Section Chief – GS-14	1	190
Project Manager/Unit Chief – GS-14	1	342
Registration Program Specialists – GS-11 (Field)**	52	8,802
Legal Instrument Examiners – GS-9 (HQ)	6	839
Legal Instrument Examiner – GS-11 (HQ)	1	181
Diversion Investigators – GS-12 (Field)	468	6,330
Program Analysts – GS-13 (HQ)	7	1,464
Computer Assistant – GS-9 (HQ)	1	177
Government Contractor Call Center Employees, 3 Supervisors and 1 Task Manager	25	3,237
Fee Processing and Mail Room, 6 Government Contractor Employees	6	960
Total		22,924

*Figures are rounded. Cost is 0.2% of production cost determined for OMB# 1117-0014 in 2015. Information collection activities are performed by the same activity center for both OMB# 1117-0014 and this information collection. Based on the number of responses, this information collection requires approximately 0.2% of resources as required by OMB# 1117-0014. **Cost for Registration Program Specialists (Field) was estimated for GS-9 for OMB# 1117-0014. For this information collection, the cost was updated for GS-11.

Grand Total: \$23,593

All costs are recovered from registrants through registration fees, as required by the CSA. 21 U.S.C. 886a.

15. Reasons for Change in Burden:

Changes to the annual burden hours reflect greater use of online applications, which take less time to complete, and lower estimated average time per response. Although there is a decrease in annual burden hours there is an increase in annual burden dollars due to a change in calculation method.* There have been no statutory or regulatory changes affecting this information collection. The table below summarizes the changes since the last renewal of this information collection.

	2012 Approved Burden	2015 Requested Burden	Difference
Annual responses	1,054	1,054	0
Annual burden hours	347	90	(257)
Annual burden dollars	0	6,736	6,736

(* In prior information collection requests, the estimated annual burden dollars was described as “a usual and customary business expense not directly associated with this information collection.” The DEA believes the estimated annual burden associated with this information collection should be included. This change in calculation method is employed in this and future information collection requests.)

16. Plans for Publication:

The DEA will not publish the results of the information collected.

17. Expiration Date Approval:

The DEA does not object to OMB displaying the expiration date.

18. Exceptions to the Certification Statement:

The DEA is not seeking an exception to the certification statement “Certification for Paperwork Reduction Act Submissions” for this collection of information.

Part B. Statistical Methods

The DEA does not employ statistical methods in this information collection.