

**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, 83 FR 64368, published December 14, 2018 and the 30-day Federal Register Notice of Information Collection, 84 FR 5719, published February 22, 2019. 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.

	<b>Number of Annual Respondents</b>	<b>Average Time per Response</b>	<b>Total Annual Burden Hours</b>
DEA-510 (paper)	6	0.20 hours (12 minutes)	1.20
DEA-510 (electronic)	88	0.17 hours (8 minutes)	11.73
DEA-510A (paper)	28	0.2 hours (10 minutes)	4.67
DEA-510A (electronic)	874	0.07 hours (4 minutes)	58.27
Total	996		76.87

Total number of respondents: 996

Number of responses per respondent per year: 1

Total annual responses: 996

Total annual hour burden: 76.87

Average Burden: Per Collection: 0.08 hour

Per Respondent: 0.08 hour

Total registration applications received on paper: 34

Total registration applications received online: 962

Percentage of applications received electronically: 96.6%

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/2017/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) 2017 National Occupational Employment and Wage Estimates for NAICS 424600 is \$59.35. Based on the BLS report, “Employer Costs for Employee Compensation – June 2018,” (ECEC) (<http://www.bls.gov/news.release/pdf/ecec.pdf>) an additional 43.7% load (for “private industry”) is added to the wage rate to account for benefits.

Thus, the labor cost of this information collection is \$6,469 annually. (The average cost per response is \$6.50.)

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:

<b>Production Item</b>	<b>Cost (\$) *1</b>
Contract Employees	8
Cost of Paper	21
Mailing (Postage)	4
Return Envelopes	94
Mailing Envelopes	3
Equipment Maintenance	3
Equipment Cost	12
<b>Total</b>	<b>161</b>

\*Figures are rounded.

Estimated Annual Labor Cost to Government:

---

1 Based on percent paper 510 and 510a forms of total paper forms.

<b>Labor Category</b>	<b>Number</b>	<b>Cost (\$)*</b>
Registration Program Specialists – GS-11 (Field) <sup>2</sup>	54	8,624
Legal Instrument Examiners – GS-9 (HQ) <sup>3</sup>	1	328
Legal Instrument Examiner – GS-11 (HQ) <sup>4</sup>	1	396
<b>Total</b>		<b>9,348</b>

\*Figures are rounded.

**Grand Total:** **\$9,509**

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 a lower estimated average time per response. Changes to the annual responses reflect the decrease in applications. 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.

	<b>2015 Approved Burden</b>	<b>2019 Requested Burden</b>	<b>Difference</b>
Annual responses	1,054	996	(58)
Annual burden hours	90	76	(14)
Annual burden dollars	6,736	6,469	(267)

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**

<sup>2</sup> Based on percent 510 and 510a forms of all registration application forms.

<sup>3</sup> Based on percent paper 510 and 510a forms of total paper forms.

<sup>4</sup> Based on percent paper 510 and 510a forms of total paper forms.

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