

**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).

This information collection request is associated with DEA’s notice of proposed rulemaking (NPRM), “Amending Regulations to Require Online Submission of Applications for and Renewal of DEA Registration,” RIN 1117-AB58. DEA is proposing to revise the regulations for application and renewal by requiring all DEA registrants to apply for registration online using the agency’s secure portal. This will eliminate the need for paper forms and payments, streamline the registration process, and save time and expense for both the agency and registration population.

Part A. Justification

1. Necessity of Information:

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 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 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:

Currently, DEA permits online registration and renewal of registration through the secure network application on the DEA Diversion Control Division web site (<http://www.deadiversion.usdoj.gov>). Applicants may complete and submit DEA Forms 510 and 510A online, along with credit card payment. This proposed rulemaking would require 100% online submissions.

4. Efforts to Identify Duplication:

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:

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 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 is being solicited in the NPRM associated with this collection, which was published in the *Federal Register*, 86 FR 1030, on January 7, 2021. The NPRM will have a 60 day comment period.

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 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, DEA will give written notice to the submitter to allow an opportunity to object within a reasonable time prior to any disclosure by 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 Hours |
|--------------|-------------------------------------|----------------------------------|---------------------------|
| DEA-510 | 99 | 0.33 hours (20 minutes) | 33 |
| DEA-510A | 902 | 0.17 hours (10 minutes) | 150 |
| Total | 1,001 | | 183 |

Total number of respondents: 1,001

Number of responses per respondent per year: 1

Total annual responses: 1,001

Total annual hour burden: 183

Average Burden: Per Collection: 0.182817 hour
Per Respondent: 0.182817 hour

Total registration applications received on paper: 0

Total registration applications received online: 1,001

Percentage of applications received electronically: 100%

Burden dollars:

| | |
|---|--------------|
| Estimated hourly wage (\$/hour): ¹ | 48.45 |
| Load for benefits (percent of labor rate): ² | <u>42.7%</u> |
| Loaded labor rate (\$/hour): ³ | 69.14 |

| | DEA Form 510 | DEA Form 510A | Combined |
|------------------------------------|--------------|---------------|---------------|
| Number of responses | 99 | 902 | 1,001 |
| Total annual hours | 33 | 150 | 183 |
| Average burden per response (hour) | 0.3 333 | 0.1667 | 0.182817 |
| Burden dollars per response (\$) | 23.04 | 11.53 | 12.668 |
| Total burden dollars (\$) | 2,281 | 10,400 | 12,681 |

Thus, the labor cost of this information collection is \$12,681 annually.

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 Labor Cost to Government:

| Labor Category | Number ⁴ | % of time ⁵ | Cost ⁶ |
|---|---------------------|------------------------|-------------------|
| Registration Program Specialists – GS-963-9 (Field) | 69 | 0.2% | \$ 14,946 |
| Total | | | \$ 14,946 |

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

1 Average of median hourly wages for 11-1021 General and Operations Manager is used to represent the occupation of persons completing the DEA Form 510 and 510A. May 2019 National Occupational Employment and Wage Estimates United States. http://www.bls.gov/oes/current/oes_nat.htm.

2 Bureau of Labor Statistics, “Employer Costs for Employee Compensation – December 2019” (ECEC) reports that average benefits for private industry is 29.9% of total compensation. The 29.9% of total compensation equates to 42.7% (29.9% / 70.1%) load on wages and salaries.

3 $48.45 \times (1 + 42.7\%) = 69.14$.

4 Based on number of allocated positions, February 19, 2020.

5 Based on percent 510 and 510A forms of all registration application forms.

6 Government salary figures include 60.5% load for benefits based on the ECEC for “State and local government.” The ECEC does not include figures for the Federal Government.

15. Reasons for Change in Burden:

The regulatory change affecting this information collection, requiring all forms be submitted online, is expected to lower burden. However, the increase in burden hours is a result of adjusting up, the average burden hours per response. Additionally, the increase in annual responses, burden hours, and annual cost reflects the increase in DEA’s registrant population and a small increase in average burden per response. The table below summarizes the changes since the last renewal of this information collection.

| | 2019 Approved Burden | New Requested Burden | Difference |
|---------------------|-----------------------------|-----------------------------|-------------------|
| Annual respondents | 996 | 1,001 | 5 |
| Annual burden hours | 77 | 183 | 106 |
| Annual cost (\$) | 6,469 | 12,681 | 6,212 |

16. Plans for Publication:

DEA will not publish the results of the information collected.

17. Expiration Date Approval:

DEA does not object to OMB displaying the expiration date.

18. Exceptions to the Certification Statement:

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

DEA does not employ statistical methods in this information collection.