

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 Approval #1117-0012

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 Approval #1117-0012, Application for Registration (DEA Form 225), Application for Registration Renewal (DEA Form 225a), and Affidavit for Chain Renewal (DEA Form 225b).

Part A. Justification

1. Necessity of Information:

The Controlled Substances Act (CSA) (21 U.S.C. 801–971) requires all persons that manufacture, distribute, dispense, conduct research with, import, or export any controlled substance to obtain a registration issued by the Attorney General. 21 U.S.C. 822, 823, 957. This includes persons that reverse distribute, or conduct research or chemical or other laboratory analysis of any controlled substance (including canine handlers). See 21 CFR 1301.13. The CSA also requires all persons who manufacture, distribute, import, or export any list I chemical to obtain a registration from the Attorney General. 21 U.S.C. 822, 957. Generally, any person who is registered may apply to be reregistered no more than 60 days before the expiration date of their registration. 21 CFR 1301.13(b). However, a bulk manufacturer of a schedule I or II controlled substance or an importer of a schedule I or II controlled substance may apply to be reregistered no more than 120 days before the expiration date of their registration. 21 CFR 1301.13(b).

Any person who is required to be registered, but is not so registered, must make an application for registration. Registration is a necessary control measure that helps to detect and prevent diversion by ensuring the closed system of distribution of controlled substances and listed chemicals can be monitored by the DEA, and that the businesses and individuals handling controlled substances and listed chemicals are qualified to do so and are accountable.

2. Needs and Uses:

DEA Form 225 is utilized by applicants seeking to become registered to manufacture, distribute, reverse distribute, import, export, or conduct research (including canine handling) or laboratory analysis with controlled substances. These controlled substance registration applicants may also seek to become registered to import or manufacture the following list I chemicals by utilizing the DEA Form 225: ephedrine, phenylpropanolamine, and/or pseudoephedrine. DEA Form 225a is utilized for renewals of such registrations on an annual basis. DEA Form 225b may be utilized by chain registrants to renew multiple registrations. The information submitted is used to identify

persons seeking registration and provide information so that the DEA can determine whether registration would be in accordance with the CSA. See 21 U.S.C. 823, 824, 958. The purpose of registration or reregistration is to ensure the persons handling controlled substances and list I chemicals are qualified and have the experience necessary to handle these substances. The purpose is to also ensure the integrity of the closed system distribution as well as track/monitor the movement of controlled substances and listed chemicals.

3. Use of Information Technology:

The DEA has a system which permits online registration. Currently, the referenced forms are available on the DEA Office of Diversion Control web site (<http://www.deadiversion.usdoj.gov>). Applicants may complete and submit the form online, along with credit card payment. Approximately 90.8% (12,344 of 13,589) applications for initial registration and renewal registration were submitted online during CY 2014.

Aside from these activities, the DEA currently permits chain distributors and analytical laboratories to renew by submitting to DEA an affidavit and a list of all registrations sought to be renewed on data storage media (e.g., a computer disc). Currently, five businesses renew their registrations utilizing the DEA Form 225b, representing registrations for 138 individual registered locations.

4. Efforts to Identify Duplication:

The DEA has made efforts to identify and prevent duplication of the collection of information. The existing DEA Forms 225, 225a, and 225b 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 225, 225a, and 225b. The DEA does not anticipate any additional impact on small businesses or other small entities since the initial 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:

The CSA requires those who manufacture or distribute any controlled substance or list I chemical to obtain a registration on an annual basis. 21 U.S.C. 822(a). It also states that no registration to import or export a controlled substance or list I chemical shall be issued for a period in excess of one year. 21 U.S.C. 958(e). Accordingly, DEA has no discretion with respect to less frequent collection in these instances. The CSA states that registrations for practitioners (e.g., researchers and analytical laboratories) shall not be “issued for less than one year nor for more than three years.” 21 U.S.C. 822(a)(2).

Researchers (including canine handlers) and analytical laboratories are required to register on an annual basis, because requiring registration less frequently (e.g., every three years) would compromise the closed system of distribution of controlled substances. For example, researchers must submit a statement with their application for registration describing the protocols to be used in the research. DEA must be vigilant in reviewing these research protocols, which routinely change, to ensure that research activities do not shift into manufacturing activities that require a separate registration.

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, 80 FR 5137, published January 30, 2015 and the 30-day Federal Register Notice of Information Collection, 80 FR 18257, published April 3, 2015. The DEA did not receive any comments concerning this collection.

The 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 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 225 is only for registration of controlled substance manufacturers, distributors, reverse distributors, importers, exporters, researchers, analytical laboratories, canine handlers, and certain manufacturers and importers of ephedrine, phenylpropanolamine, and pseudoephedrine. DEA Form 225 is submitted on an as-needed basis by persons seeking to become registered, DEA Form 225a is submitted annually thereafter to renew existing registrations, and DEA Form 225b is submitted annually for renewals of chain registrants. Chain registrants are those corporations and laboratories that maintain separate registrations at multiple locations and may renew all their registrations using a single DEA Form 225b.

	Number of Annual Respondents	Average Time per Response	Total Annual Hours
DEA-225 (paper)	369	0.33 hours (20 minutes)	123
DEA-225 (online)	1,865	0.17 hours (10 minutes)	311
DEA-225a (paper)	871	0.25 hours (15 minutes)	218
DEA-225a (online)	10,479	0.12 hours (7 minutes)	1,223
DEA-225b (chain renewal)*	5	1 hour	5
Total	13,589		1,879

* In total, 5 chains represent 138 individual registrant locations. Figures are rounded.

Total number of respondents: 13,589

Number of registration per respondent per year: 1

Total annual responses: 13,589

Total annual hour burden is 1,879

Average Burden: Per Collection: 0.14 hour

Per Respondent: 0.14 hour

Total registration applications received on paper: 1,245

Total registration applications received online: 12,344

Percentage of applications received online: 90.8%

Estimates are based on the population of the regulated industry participating in these business activities. The DEA assumes that a general and operations manager (11-1021, 2013 Standard Occupational Classification) (http://www.bls.gov/soc/soc_2010_definitions.pdf) 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, NAICS 424200 – Drugs and Druggist Sundries

(http://www.bls.gov/oes/current/oes_nat.htm) is \$58.69. Based on the BLS report, “Employer Costs for Employee Compensation – September 2014,” (<http://www.bls.gov/news.release/ecec.nr0.htm>) an additional 43.3% load is added to the labor rate to account for benefits. Thus the estimated cost burden of this information collection to all respondents is \$158,040 annually.

13. Estimate of Cost Burden:

The estimated annual cost burden is zero. Respondents are estimated to not 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 the Federal Government:

Estimated Annual Production Cost to Government:

Government Employees:	\$0
Contract Employees:	\$714
Cost of Paper:	\$52
Mailing (Postage):	\$482
Custom Envelopes:	\$23
Mailing Envelopes:	\$208
Equipment Maintenance:	\$211
Equipment/10 years:	\$230
Per Print Charges:	\$274
Total:	\$2,195

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

Review & Notification

54 Registration Program Specialists - GS-963-9 (Field); (5% of time)	\$157,980
1 Legal Instrument Examiner - GS-963-9 (HQ); (5% of time)	\$2,925
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) (10% of time)	\$10,091

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
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Fee Processing and Mail Room

6 Government Contractor Employees	\$5,052
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(1.0% of time for average annual contract cost x 6)

Scanning

1 Computer Assistant – GS-335-9 (HQ) (2% of time) \$1,171

Total: \$2,364,939

Grand Total cost to government (\$2,195 + 2,364,939): \$2,367,134

(Figures are rounded to whole dollar.)

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

All costs to the government for operation of the Diversion Control Program, including the above costs, are recovered by the DEA from registrants through registration fees, as required by 21 U.S.C. 886a.

15. Reasons for Change in Burden:

The increase in annual respondents reflects the increase in the DEA’s registrant population. The decrease in hour burden is related to an increase in online registration applications and renewals. For this collection overall, online responses increased from 86% to 90.8% since the previous renewal in 2012. Although the decrease in the burden hours contributed to the decrease in the annual cost, the majority of the decrease in annual cost is attributed to a change in calculation method.* The table below summarizes the changes since the last renewal of this information collection.

	2012 Approved Burden	2015 Requested Burden	Difference
Annual respondents	13,097	13,589	492
Annual burden hours	2,789.5	1,879	(910)
Annual cost	\$5,105,846.5	\$158,040	\$(4,947,806)

(* In prior information collection requests, the associated registration fee was included in the cost burden calculation. The DEA believes the registration fee should be excluded from the information collection cost burden because the time and capital expense burden to provide the information is not tied to the registration fee. 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.