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).

This information collection request is associated with the DEA's rulemaking titled Controls to Satisfy the Requirements of the Controlled Substances Act and the Single Convention on Narcotic Drugs, 1961, Relating to Cannabis; DEA Docket No. 506, RIN 1117-AB54. The DEA is proposing to amend its regulations governing applications by persons seeking to become registered with DEA to grow marihuana as bulk manufacturers, in order to more precisely conform with the requirements of the Controlled Substances Act and the Single Convention on Narcotic Drugs, 1961, relating to cannabis.

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. 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 that the closed system of distribution of controlled substances can be monitored by the DEA, and that the businesses and individuals handling controlled substances 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. 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 and reregistration is to ensure the integrity of the closed system distribution and to track/monitor the movement of controlled substances.

3. Use of Information Technology:

The DEA has a system which permits online registration. Currently, the referenced forms are available on the DEA Diversion Control Division web site (https://www.deadiversion.usdoj.gov). Applicants may complete and submit the form online, along with credit card payment. Based on data from CY 2018, approximately 97% of applications for registration and reregistration were submitted online.

Aside from these activities, the DEA currently permits chain distributors 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).

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 collection will not have a significant economic impact on a substantial number of 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 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 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 will be solicited in the notice of proposed rulemaking (NPRM) associated with this collection. The NPRM will have a 60-day comment period.

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. 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 distributors that maintain separate registrations at multiple locations and may renew all their registrations using a single DEA Form 225b. The below table presents information regarding the number of respondents, responses, and associated burden hours.

	Number of Annual Respondents	Average Time per Response	Total Annual Hours
DEA-225 (paper)	261	0.33 hours (20 minutes)	87
DEA-225 (online)	1996	0.17 hours (10 minutes)	333
DEA-225a (paper)	211	0.25 hours (15 minutes)	53
DEA-225a (online)	13,829	0.12 hours (7 minutes)	1,613
DEA-225b (chain renewal)*	4	1 hour	4
Total	16,301		2,090

* In total, 4 chains represent 83 individual registrant locations.
Figures are rounded.

Total number of respondents: 16,301
Number of responses per respondent per year: 1
Total annual responses: 16,301
Total annual hour burden: 2,090
Average burden per response: 0.1282 hours

Hour burden cost:

Estimate hourly wage ($/hour):[1]	$48.52
Load for benefits (percent of labor rate):[2]	42.7%
Loaded labor rate ($/hour):	$69.24
Average burden per response (hour):	0.1282
Burden cost per response	$8.88
Number of annual responses	16,301
Total burden hour cost (annually):	**$144,753**

13. Estimate Cost of 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.

1The median hourly wage for occupation code 11-1021 General and Operations Manager. Bureau of Labor Statistics, Occupational and Employment and Wages, May 2018 (http://www.bls.gov/oes/current/oes_nat.htm).

2 Bureau of Labor Statistics, "Employer Costs for Employee Compensation – March 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.

14. Estimated Annualized Cost to the Federal Government:

Estimated Annual Labor Cost to Government:

Review & Notification	
61 Registration Program Specialists - GS-963-9/11 (Field)[3]	$179,264
1 Legal Instrument Examiner - GS-963-9 (HQ)[4]	$ 5,072
Total:	**$184,336**

Estimated Annual Production Cost to Government:[5]

Government Employees:	$ 114
Contract Employees:	$ 308
Cost of Paper:	$ 61
Mailing (Postage):	$ 1,408
Return Envelopes:	$ 48
Mailing Envelopes:	$ 51
Equipment Maintenance:	$ 174
Equipment/10 years:	$ 258
Total:	**$ 2,422**
Grand Total Cost to Government ($184,336 + $2,422):	**$186,758**

(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 responses and burden hours reflects the increase in the DEA's registrant population. The decrease in annual cost is due to a lower estimated hourly rate for employees completing the responses. The table below summarizes the changes since the last renewal of this information collection.

3 Based on percent 225 and 225a forms of all registration application forms.
4 Based on percent paper 225 and 225a forms of total paper forms.
5 *See* note 4.

	2018 Approved Burden	2019 Requested Burden	Difference
Annual responses	15,919	16,301	382
Annual burden hours	2,076	2,090	14
Annual cost	$175,109	144,753	-30,356

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.