SUPPORTING STATEMENT FOR
Application for Registration (DEA Form 225)
Application for Registration Renewal (DEA Form 225a)
Affidavit for Chain Renewal (DEA Form 225b)

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).

A. JUSTIFICAITION

1. 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 DEA, and that the businesses and individuals handling controlled substances are accountable.

2. 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 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. Currently, DEA has a system which permits online registration through the secure network application 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. This Final Rule will require 100% online submissions.

Aside from these activities, 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. 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. 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. 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. There are no special circumstances applicable to this information collection.

8. The 60-Day Notice was published in the Federal Register on March 24, 2025, (90 FR 13627). The comment period ended on May 27, 2025. No comments were received.

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. This collection of information does not propose to provide any payment or gift to respondents.

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

12. 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. DEA estimates 7 chains representing 262 individual registrant locations.

Activity	Number of Respondents	Frequency	Total Annual Responses	Time Per Response	Total Annual Burden (Hours)	Hourly Rate*	Monetized Value of Respondent Time
DEA 225 (new)	**2,006**	**1**	**2006**	**0.42 hours (25 mins)**	**843**	**$69.14**	**$ 58,285.02**
DEA 225a (renewal)	**14,547**	**1**	**14547**	**0.17 hours (10 mins)**	**2473**	**$69.14**	**$170,983.22**
DEA 225b (chain renewal)	**7**	**1**	**7**	**1 hour**	**7**	**$69.14**	**$ 483.98**
Total	**16,560**	**1**	**16,560**	**0.20066 hour**	**3,323**	**$69.14**	**$ 229,752**

Hourly Rate*

Estimate hourly wage ($/hour):[1]	$48.69
Load for benefits (percent of labor rate):[2]	42%

1The median hourly wage for occupation code 11-1021 General and Operations Manager. Bureau of Labor Statistics, Occupational and Employment and Wages, May 2023 (http://www.bls.gov/oes/current/oes_nat.htm).

2 Bureau of Labor Statistics, "Employer Costs for Employee Compensation – September 2024" (ECEC) reports that average benefits for private industry is 29.6% of total compensation. The 29.6% of total compensation equates to 42% (29.6% / 70.4%) load on wages and salaries.

13. 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 Annual Labor Cost to Government: $236,502

Labor Category	Number	Annual rate	Load	% of time	Cost
Registration Program Specialists GS - 9	**85**[3]	**$ 79,246**[4]	**1.618**[5]	**2.2%**[6]	**$ 239,771**
Total					**$ 239,771**

15. The change in annual responses and in annual burden hours reflect the increase in DEA's registrant population. The change in annual cost is due to change in method. Previously, the approved 2022 figure represented the "Monetized Value of Respondent Time" calculated in section 12. The new requested annual cost represents the figure from section 13. The table below summarizes the changes since the last renewal of this information collection.

	2022 Approved Burden	2025 New Requested Burden	Difference
Annual respondents	16,338	16,560	222
Annual burden hours	3,253	3,323	70
Annual cost ($)	225,011	0	(225,011)

3 Average number of Registration Program Specialists (RPS) personnel onboard in FY 2024.
4 Based on 2025 OPM pay scale for GS-9, Step 5, Washington, DC locality as estimate for all.
5 Government salary figures include 61.8% load for benefits based on the ECEC for "State and local government." The ECEC does not include figures for the Federal Government.
6 Based on percent 225, 225a, and 225b forms of all registration application forms in FY 2024.

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

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

18. 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.