SUPPORTING STATEMENT FOR
Registration for Controlled Substances Act Data-Use Request

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 #1117-0059, Registration for Controlled Substances Act Data-Use Request.

A. JUSTIFICATION

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, and 957. Once registered, the person becomes a DEA registrant and has the means to conduct DEA registration verifications at any time via the DEA Diversion Website. On the website, registrants can use their registration information for access to the Controlled Substance Database system (CSA Dataset). The CSA Dataset gives one access to the list of DEA-registrants and their registration status.

Non-registrants do not have an obligation to register under the CSA because they do not handle controlled substances. However, they do have obligations to the healthcare sector to do things such as: conducting verifications before hiring a practitioner, verifying that a practitioner has an active registration when an insurance company is paying for a controlled substance prescriptions that could be covered by Medicaid or Medicare, or a prescription paper printing company conducting a verification that a practitioner has an active registration when ordering prescription pads. States use the CSA information to ensure practitioners are prescribing controlled substances within the scope of their professional practice. There are many other instances where a non-registrant has an obligation to verify the registration status of a DEA registrant.

2. From the late 1980's until November 17, 2020, the Department of Commerce (NTIS) and a third party vendor has been the primary source for dissemination of the information from the CSA Dataset. NTIS approached this dissemination as a come-one come-all approach, selling the information to all that would pay a fee. This has resulted in many criminal cases involving the use of the data in criminal endeavors. This in turn resulted in the DEA terminating the relationship with NTIS and bringing the access and distribution of the CSA dataset in-house. As of November 17, 2020, NTIS no longer had access to the CSA Dataset.

This collection will be used by all non-registrants who need to verify the registration status of a DEA registrant by way of the CSA Dataset. In order to provide a secure uninterrupted solution for efficient access to the CSA dataset by non-registrants, this form is necessary to ensure a proper vetting process of those non-registrant entities wishing to use the CSA Datasets to conduct Primary Source Verification of those registered with the DEA. Non-registrants will be required to complete the form in order to get official approval to conduct a vetting of those non-registrants that are expressing a need for access to the CSA Dataset. Failure to be able to

conduct this vetting process will result in a severe interruption in commerce within the health sector.

Non-registrants will be required to complete this form and submit it to DEA annually. They will be required to create a new password with each submission. The annual completion of this form will ensure that the non-registrants, along with the change of passwords, will help to decrease the risks of diversion and ensure that the data is not being used in criminal endeavors.

3. The submissions would be 100% electronic. The registration form will be emailed to the applicant upon their request. They will return the form back to DEA by way of email.

4. There is no duplication of information requested as a part of this collection. DEA has no other collection that gathers this information from non-registrants.

5. The DEA expects 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. If this information is not collected annually, there is a risk that the CSA Dataset will be accessed by criminals and used in criminal endeavors.

7. There are no special circumstances applicable to this information collection.

8. Public comment has been solicited in the 60 Day Notice of Information Collection published in the *Federal Register* at 89 FR 77895, on September 24, 2024. No comments were received. Public comment was also solicited in the 30 day Notice of Information Collection published in the *Federal Register* at 89 FR 94763, on November 29, 2024.

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, the 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. Estimate of Hour Burden:

Activity	Number of Annual Respondents	Number of Annual Responses	Average Time per Response (Minutes)	Total Annual Hours	Hourly Rate ($)	Monetized Value of Repsondent Time ($)
Registration CSA Data-Use Request	9,000	9,000	15	250	51.75	12.94
Total	**9,000**	**9,000**		**250**		

Based on the number of unique respondents. A respondent submits one information collection.

Total Number of respondents: 9,000
Number of responses per respondent per year: 1
Total annual responses: 9,000
Total annual hour burden: 2250 hours
Average Burden: Per Collection: 0.25 hour
Per Respondent: 0.25 hour

Total responses received: 9,000

Burden dollars:

Estimated hourly wage($/hour):[1]
36.38
Load for benefit (percent of labor rate):[2]
42.25%
Loaded labor rate ($/hour):[3]
51.75

1 Hourly median wage, 13-1041 Compliance Officer. Bureau of Labor Statistics, Occupational Employment and Wages, May 2023, https://www.bls.gov/oes/2023/may/oes131041.htm .
2 Average benefits for private industry are 29.7% of total compensation. Bureau of Labor Statistics, Employer Costs for Employee Compensation – March 2024 (ECEC), https://www.bls.gov/news.release/archives/ecec_06182024.pdf. The 29.7% of total compensation equates to 42.25% (29.7% / 70.3%) load on wages and salaries.
3 $36.38 x (1 + 0.4225) = $51.75.

	DEA Information collection
Number of responses	9,000
Total annual hours	2250
Average burden per response (hour)	0.25
Burden dollars per response ($)	12.94
Total burden dollars ($)	**116,460**

13. 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 Costs to Federal Government:

There is no cost to the Federal government.

15. Reasons for Change in Burden:

	2021 Approved Burden	**2024 Requested Burden**	**Difference**
Annual responses	1,000	9,000	8,000
Annual burden hours	250	2250	2,000
Annual burden dollars ($)	11,860	116,460	104,600

Previously, the Department of Commerce had approximately 1,000 customers that were purchasing access to the data from them on an annual basis. This was the basis of our initial estimate from 2021.

The change in annual responses is due to the implementation of multi-factor authentication to strengthen the security of the CSA registration system. This highlighted that some users were logging into the system using the registration credentials of the registrant they were validating. Multi-factor authentication stopped this practice, forcing these individuals to register through the Registrant Dataset Access (RDA) system, increasing the number of responses from 1,000 to 9,000.

Changes in annual burden dollars are primarily driven by the change in annual responses but has also increased due to an increase in the estimated hourly rate of respondent time.

16. Plans for Publication:

DEA will not publish the results of the information collected.

17. Expiration Date Approval:

DEA is not seeking approval not to display the expiration date for OMB approval of this information collection.

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

The Drug Enforcement Administration will not be employing statistical methods in this information collection.