Supporting Statement for Paperwork Reduction Act Submissions
U.S. Official Order Forms for Schedules I and II Controlled Substances
(DEA Form 222)

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 # 1117-0010, U.S. Official Order Forms for Schedules I and II Controlled Substances (DEA Form 222).

A. JUSTIFICATION

1. The Controlled Substances Act (CSA) (21 U.S.C. 801–971) establishes a closed system of distribution for controlled substances. To this end, controlled substances are closely monitored and tightly regulated as they are distributed through the supply chain. One tool that helps maintain the closed system of distribution is the CSA provision that states "It shall be unlawful for any person to distribute a controlled substance in schedule I or II to another except in pursuance of a written order of the person to whom such substance is distributed, made on a form to be issued by the Attorney General in blank in accordance with subsection (d) of this section." 21 U.S.C. 828(a). The regulations implementing this provision are contained in 21 CFR part 1305 and 21 CFR part 1311, subpart B.

Pursuant to the CSA, the DEA provides authorized registrants (purchasers) with DEA Forms 222 for ordering schedules I and II controlled substances. Registrants are prohibited from distributing schedules I or II controlled substances except pursuant to a written order made on a DEA Form 222. In certain circumstances, suppliers must submit copies of DEA Forms 222 to the DEA. These processes help maintain the closed system of distribution because each registrant in the transaction serves as a check against the other.

Since 2005, registrants have also been permitted to issue orders for schedules I and II controlled substances electronically, provided that the electronic order is signed using a digital certificate issued by the DEA Certification Authority. This electronic ordering system is called the Controlled Substances Ordering System (CSOS). The regulations governing the creation, transmission, and storage of electronic orders are contained in 21 CFR part 1311, subpart B.

2. The DEA Form 222, or its electronic equivalent, provides the DEA with oversight and control over the distribution of schedules I and II controlled substances. The form is the only document that can authorize the distribution of schedules I and II controlled substances within the closed system of distribution. To ensure distribution is restricted only to authorized registrants, each DEA Form 222 is serially numbered and pre-printed with the date the order form was issued, the registrant's name, registered address, and DEA registration number, the type of registrant, and the schedules of controlled substances the registrant is authorized to handle.

The DEA Form 222 must be signed by a person authorized to sign an application for registration or reregistration on behalf of the registrant, or a person authorized to sign the DEA Form 222 by a properly executed power of attorney. Upon execution of an order form, the purchaser makes and retains a copy and sends the original to the supplier. The supplier fills out the original with the date and quantity shipped, and retains the original. If the supplier is not required to report acquisition/distribution transactions to the Automation of Reports and Consolidated Orders System, the supplier submits a copy of the original DEA Form 222 to DEA headquarters. Upon receipt of the order, the purchaser is required to complete its copy of the DEA Form 222 with the date and quantity received. As mandated by 21 U.S.C. 828(c), the purchaser and supplier must make DEA Forms 222 available for inspection for a period of two years. These requirement ensure that only authorized registrants can order schedules I and II controlled substances, that these orders are delivered to the registrant at the registered location, and protects against diversion.

To ensure the security of orders obtained pursuant to CSOS, registrants must obtain a CSOS digital certificate from the DEA Certification Authority to sign electronic orders for controlled substances. The requirement of a digital signature also helps to ensure that only authorized registrants can order schedules I and II controlled substances.

In addition to restricting the distribution of schedules I and II controlled substances only to authorized registrants, the DEA uses the information to ensure accountability of controlled substances and to detect diversion.

3. The DEA allows, but does not require, registrants to utilize electronic orders for the distribution of schedules I and II controlled substances rather than the DEA Form 222. 21 CFR part 1305, subpart C. Once a registrant, or someone authorized to sign electronic orders for the registrant, obtains a digital certificate issued by the DEA Certification Authority, the registrant may issue orders for schedules I and II controlled substances and maintain records of those orders electronically.

Approximately 3.3 million DEA Forms 222 and 2.05 million electronic orders were submitted. Thus, for the period used for this supporting statement, electronic orders represented approximately 38.3% of all orders.

4. The DEA has made efforts to identify and prevent duplication of the collection of information. The existing DEA Form 222 and CSOS are not duplicative. The collection of this information is unique to the DEA.

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. The frequency of orders is driven by the needs of purchasers, not by the regulation. 21 U.S.C. 828 requires that the DEA provide the order forms and that registrants maintain copies of executed order forms for a period of two years. 21 U.S.C. 828(c). The DEA does not have the authority to reduce the period of recordkeeping.

7. If a supplier is not required to report acquisition/distribution transactions to the Automation of Reports and Consolidated Orders System (ARCOS), it instead must submit a copy of each executed DEA Form 222 to the DEA at the close of the month during which the order is filled. The supplier receives the original from the purchaser, fills in the date and quantity shipped, retains the original, and sends a copy to the DEA. This copy provides the DEA with information on the distribution of schedules I and II controlled substances so that potential diversion can be identified and investigated in a timely manner. With respect to electronic orders pursuant to CSOS, suppliers are required to forward to the DEA either a copy of the electronic order or an electronic report of the order within two business days. Because the DEA provides to registrants pre-printed, sequentially numbered DEA Forms 222, the DEA knows how many forms are printed and who holds them. In contrast, with CSOS, the DEA has no information on orders being issued until reported to the DEA. The DEA determined that reviewing electronic orders at the end of the month would unreasonably frustrate the identification and investigation of diversion. Because these reports are generated automatically and transmitted electronically, the decreased reporting time does not impose an unreasonable burden on reporters, particularly when weighed against the need to prevent and detect the diversion of the most dangerous controlled substances—substances in schedules I and II.

Other special circumstances are not applicable to this information collection.

8. Public comment was solicited in the Federal Register on June 30, 2023, 88 FR 51368. DEA received no comments concerning this collection.

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

12. DEA Form 222, or its electronic equivalent, is used for ordering schedules I and II controlled substances. The DEA provides pre-printed order forms to purchasers. Upon execution of an order form, the purchaser makes and retains a copy and sends the original to the supplier. The supplier fills in the original with the date and quantity shipped, retains the original, and, if the supplier is not an ARCOS filer, forwards a copy to the DEA (in batches, usually monthly). Upon receipt of the order, the purchaser fills in its copy with the actual date and quantity received.

Manufacturers and distributors are generally both purchasers and suppliers. Importers may only act as suppliers. All other listed registrants are purchasers. Only suppliers that do not file with ARCOS file order forms with the DEA.

Registrant Type	**Number of Registrants***
Manufacturers	205
Distributors	334
Importers	0
Exporters	67
Reverse Distributors	39
Hospitals/Clinics, Emergency Medical Service (EMS) Agency	12,123
Pharmacies	64,113
Teaching Institutions	39
Narcotic Treatment Programs, Researchers, Analytical Labs	2,829
Practitioners/Mid-Level Practitioners	37,318
TOTAL	**117,067**

* Number of registrants that ordered schedules I or II controlled substances in 2022.

	Number of Annual Respondents	**Number of Annual responses***	**Average Time per Response (minutes)****	**Total Annual Hours**
DEA-222 (paper)	117,067	468,212	15	117,053

DEA-222/CSOS (online)		2,345,115	6	234,512
Total	**117,067**	**2,813,327**		**351,565**

* Number of annual responses for "paper" is estimated by counting the number of DEA Forms 222 printed and shipped to registrants. Number of annual responses for "online" is estimated by dividing the number of transaction items by 20. This normalization is required to accurately compare the number of responses on paper versus online. Some pre-printed DEA Forms 222 are anticipated to go unused, in cases where the registrant information has changed or discontinues operation, etc., overestimating the number of paper responses. However, the amount of unused forms is not anticipated to be excessive, and any overestimate is not significant.
** The burden estimate includes initial execution of DEA Form 222, subsequent annotations by the supplier and purchaser, and submission to DEA by the supplier.

Total number of respondents: 117,067
Number of responses per respondent per year: 24.031768 (average)
Total annual responses: 2,813,327
Total annual hour burden: 351,565

Average Burden: Per Collection: 0.124964 hour
Per Respondent: 3.003105 hour

Total responses received on paper: 468,212
Total responses received electronically: 2,345,115
Percentage of responses received electronically: 83%

Burden dollars:

Estimate hourly wage ($/hour):[1]	$63.82
Load for benefits (percent of labor rate):[2]	41.8%
Loaded labor rate ($/hour):[3]	$90.50
Number of responses	2,813,327
Total annual hours	351,565
Total burden dollars	**$ 31,816,587**

13. Respondents are not estimated to incur any additional start-up cost or capital expenditure as a result of this information collection. While the copy retained by the purchaser may be in paper or electronic form, the majority are expected to retain copies in electronic form. Therefore, any cost associated with making and retaining copies of DEA Form 222 is nominal ($0).

[1] The median hourly wages for 29-1051 Pharmacists was used for simplicity to represent all registrant types. Bureau of Labor Statistics, Occupational and Employment and Wages, May 2022 (https://www.bls.gov/oes/current/oes_nat.htm).
[2] The Bureau of Labor Statistics' "Employer Costs for Employee Compensation – March 2023" (ECEC) reports that average benefits for private industry are 30.4% of total compensation. The 30.4% of total compensation equates to a 41.8% (29.5% / 70.5%) load on wages and salaries.
[3] $63.82 x (1 + 0.418) = $90.50.

14. Estimated annual production cost to the Federal government for the DEA Form 222 system:

Government Employees	$	2,577
Contract Employees	$	96,092
Cost of Forms	$	55,517
Mailing (Postage)	$	241,378
Custom Envelopes	$	10,682
Total	$	406,246

Estimated annual labor cost to the Federal government for the DEA Form 222 system:

Labor Category	Number	Loaded Annual rate*	% of time	Cost
Unit Chief - GS-14	1	$ 242,726	20%	$ 48,545
Technical Information Specialist - GS-14	1	$ 242,726	20%	$ 48,545
Import/Export Specialist - GS-13	3	$ 205,403	100%	$ 616,210
Secretary - GS-7	1	$ 97,379	5%	$ 4,869
Total				$ 718,170

*Loaded annual rate is based on the annual rate plus load for benefits. The annual rate is based on 2023 OPM pay scale for the Washington, DC locality at Step 5. Load is based on ECEC for State and local government workers, as estimate for Federal government employees.

Total annualized production and labor costs: $1,124,416.

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

15. The change in annual responses and burden hours is due to a large decrease in the use of paper forms. The change in annual cost burden is due to change in method. Previously, the approved 2020 figure represents the annual labor burden hours calculated in section 12. The requested 2023 figure represents the annual cost burden calculated in section 13 is due to a change in the way DEA now calculates the annual cost burden dollars. There are no statutory or regulatory changes related to this information collection.

	2020 Approved Burden	2023 Requested Burden	Difference
Annual responses	5,350,000	2,813,327	-2,536,673
Annual burden hours	1,030,000	351,565	-678,435
Annual burden dollars	85,376,700	0	-85,376,700

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

17. Due to the administrative burdens related to replacing expired forms when no information on those forms has been changed, the DEA is seeking approval not to display the expiration date on any paper forms printed by the agency.

18. The DEA is not seeking an exception to the certification statement "Certification for Paperwork Reduction Act Submissions" for this collection of information.

B. COLLECTIONS OF INFORMATON EMPLOYING STATISTICAL METHODS.

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