Supporting Statement for Paperwork Reduction Act Submissions
Reporting and Recordkeeping for Digital Certificates
OMB Approval #1117-0038

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 #1117-0038, Reporting and Recordkeeping for Digital Certificates.

Part A. Justification

1. Necessity of information:

The Controlled Substances Act (CSA) (21 U.S.C. 801 et seq.) requires the DEA to establish a closed system of distribution for controlled substances that have a potential for abuse. 21 U.S.C. 828 requires the DEA provide a form to registrants to be used to purchase schedule I and II controlled substances. No person may distribute a schedule I and II controlled substance except pursuant to an order issued on the DEA-provided form.

DEA's regulations implementing section 828 are in 21 CFR part 1305. The DEA's regulations allow registrants to issue orders for schedule I and II controlled substances electronically provided that the electronic order is signed using a digital certificate issued by the DEA Certification Authority. A digital certificate, issued as part of a public key infrastructure (PKI), is necessary to meet the standards of authentication, nonrepudiation, and record integrity that the DEA adopted to ensure that the mandated closed system of distribution continues. At present, only PKI systems meet the standards. The use of digital signatures allows registrants to create, sign, transmit, and store records electronically. Reports to the DEA are also electronic.

Because the CSA mandates that the DEA issue the form, the DEA operates the Certification Authority. The digital certificate serves as the equivalent of the paper DEA Form 222 (U.S. Official Order Forms – Schedules I & II), because the data that the DEA preprints on the form are included as extension data on the digital certificate. Registrants or their staff who have power of attorney to sign orders are required to apply for a digital certificate, which the DEA issues when it has determined that the applicant is eligible to sign orders for schedule I and II controlled substances.

2. Needs and Uses:

The application for a digital certificate is required to ensure that the person applying for the certificate is either a DEA registrant or someone who has power of attorney from a DEA registrant to sign orders for schedule I and II substances. The DEA Certification Authority uses the information to verify the person's identity and eligibility to hold a DEA-issued digital certificate.

3. Use of Information Technology:

The initial applications must include one or more original signatures that are collected on paper. Currently, 100% of digital certificates are issued electronically.

4. Efforts to Identify Duplication:

Digital certificates must be provided only to eligible parties. The DEA has made efforts to identify and prevent duplication of the collection of information. The collection of this information is unique to the DEA.

5. Impact on Small Businesses or Entities:

This information 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:

For the application for a digital certificate, DEA must have sufficient information to verify the identity and registration status of the applicant. Because the validity of the certificate is based on an active DEA registration, the digital certificate must expire at the same time as the registrant's DEA registration. Most registrations expire every three years. DEA does not require resubmission of information until the third renewal of a certificate.

If the information collection is not conducted, DEA registrants would not be authorized to issue orders for Schedule I and II substances electronically. The paper-based system imposes substantial costs on the regulated community both because it requires the use of a special form and because virtually all other ordering is done electronically. The use of digital certificates makes it possible to integrate these orders into existing systems and reduce the costs of ordering.

7. Special Circumstances Influencing Collection:

Some respondents report monthly, others quarterly. Respondents decide how frequently they will submit these voluntary reports. Less frequent reporting would reduce the DEA's ability to monitor actual and relative abuse potential of drugs. Other special circumstances in item 7 of the supporting statement are not 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, 84 FR 5720, published February 22, 2019, and the 30-day Federal Register

Notice of Information Collection, 84 FR 20166, published May 8, 2019. 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 information collection 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 information collection does not ask any questions of a sensitive nature.

12. Estimate of Hour Burden:

DEA Forms 251, 252, 253 and 254 are available to be completed and submitted in connection with this information collection.

Number of Respondents:	10,064
Frequency of Response:	2.68 average (as needed)
Total annual responses:	26,959
Average time per response:	1.5 hours
Total annual burden:	40,439 hours
Average burden:	
Per collection (hour):	1.5
Per respondent (hour):	4.02

Burden dollars:

Estimate hourly wage ($/hour):[1]	$58.52
Load for benefits (percent of labor rate):[2]	43.7%
Loaded labor rate ($/hour):[3]	$84.09
Total annual burden dollar:	$3,400,473
Average burden dollars per collection:	$126.135

13. Estimate of Cost Burden:

Respondents are not estimated to incur any additional start-up cost or capital expenditure as a result of this information collection. However, respondents are expected to incur shipping costs.

The application packages are signed, notarized, and mailed to DEA. Assuming the cost of notarizing the package is nominal, the estimated cost burden is $8.15 per package (based on FedEx One Rate, Envelope, Zone 3, National, 3 days). While a package may contain multiple forms for batch applications, a conservative estimate of one package per form is used in this analysis.

Estimated annual cost burden: $219,716.

14. Estimated Annualized Cost to Federal Government:

Estimated Annual Labor Cost to Government:

Labor Category	Number	Annual rate	Load[4]	% of time	Cost
Information Technology Specialist – GS-14	1	$ 133,689	1.43	100%	$ 191,258
Total					$ 191,258

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

15. Reasons for Change in Burden:

1 Hourly median wage, Bureau of Labor Statistics, Occupational and Employment and Wages, May 2017, 29-1051 Pharmacists (http://www.bls.gov/oes/current/oes).
2 Bureau of Labor Statistics, "Employer Costs for Employee Compensation – June 2018" (ECEC) reports that average benefits for private industry is 30.4% of total compensation. The 30.4% of total compensation equates to 43.7% (30.4% / 69.6%) load on wages and salaries.
3 $58.52 x (1 + 0.437) = $84.09.
4 Government salary figures include 43% load for benefits based on the ECEC for "State and local government" (adjusted for paid leave). The ECEC does not include figures for the Federal Government.

Changes to the annual burden estimate are a result of the increase in the number of annual responses. There have been no statutory or regulatory changes affecting this information collection. The table below summarizes the changes since the last renewal of this information collection.

	2016 Approved Burden	2019 Requested Burden	Difference
Annual responses	19,868	26,959	7,091
Annual burden hours	29,802	40,439	10,637
Annual burden dollars	2,680,690	3,620,189	939,499

16. Plans for Publication:

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

17. Expiration Date Approval:

The DEA does not use a form for this information collection. Therefore, this question is not applicable.

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.