

Supporting Statement for Paperwork Reduction Act Submissions

Application for Registration (DEA Form 224); Application for Registration Renewal (DEA Form 224a); Affidavit for Chain Renewal (DEA Form 224B)

Part A. Justification

1. Necessity of Information:

All firms and individuals who administer, dispense or prescribe controlled substances must register with DEA under the Controlled Substances Act (21 U.S.C. 822, 21 CFR 1301.11). Registration is needed for control measures over legal handlers of controlled substances and is used to monitor their activities.

2. Needs and Uses:

DEA Form 224 is used by applicants seeking to become registered to distribute or dispense any controlled substances. DEA Form 224a is used for renewal of such registrations on a triennial basis. DEA Form 224B is an affidavit used for the renewal of chain registrants, primarily retail pharmacies, on a triennial basis. The information submitted is used to identify person's seeking registration and provide information to determine whether registration would be consistent with the public interest.

3. Use of Technology:

DEA has a system which permits fully electronic registration using a credit card. Currently, the referenced forms are available on the DEA Diversion Control Program web site (<http://www.deadiversion.usdoj.gov>). Applicants complete the form online and submit electronically, along with credit card payment. Aside from these activities, DEA currently permits chain registrants (primarily retail pharmacies) to register through the use of an affidavit and a computerized listing of all registrants. Currently, 16 chains participate in this program, holding registrations for 19,088 individual registrants.

4. Efforts to Identify Duplication:

The federal requirement of registration to handle controlled substances is unique to DEA. The information provided is specific to the applicant's use of controlled substances and is not available from other sources.

5. Methods to Minimize Burden on Small Businesses:

Although many of the registrants affected may be classified as small businesses according to the Small Business Administration, the information collected is maintained as a normal course of business. Therefore, this collection does not have a significant impact upon small entities within the meaning and intent of the Regulatory Flexibility Act, 5 U.S.C. 601, et seq.

6. Consequences of Less Frequent Collection:

The Controlled Substances Act requires that registration for these activities be issued on a triennial basis.

7. Special Circumstances Influencing Collection:

There are no special circumstances applicable to this information collection.

8. Reasons for Inconsistencies with 5 CFR 1320.6:

There are no circumstances that require the collection of data that would be inconsistent with the guidelines set forth in 5 CFR 1320.6. 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, including application and registration procedures, with representatives of those from whom the information is obtained.

DEA did not receive any comments for this collection.

9. Payment or Gift to Claimants:

There are no payments or gifts to respondents.

10. Assurance of Confidentiality:

Confidential business information is protected under Department of Justice regulations, 28 CFR 16.8 and 16.9.

11. Justification for Sensitive Questions:

Questions of a sensitive nature are not included in this information collection.

12. Estimate of Hour Burden:

DEA Form 224 is submitted on an as-needed basis by persons seeking to become registered. DEA Form 224a is submitted on a triennial basis thereafter. DEA Form 224b is submitted triennially for renewals of chain (retail pharmacy) registrants.

DEA-224: Electronic Form

Number of Respondents: 59,283

Average time per response: 0.13 hours (8 minutes)

Annual burden hours: 7,904.4 hours

DEA-224: Paper Form

Number of Respondents: 12,094

Average time per response: 0.2 hours (12 minutes)

Annual burden hours: 2,418.8 hours

DEA-224a Electronic Form:

Number of respondents: 209,535

Average time per electronic response: 0.07 hours (4 minutes)

Annual burden hours: 13,969 hours

DEA-224a Paper Form

Number of respondents: 159,678

Average time per response: 0.2 hours (12 minutes)

Annual burden hours: 31,935.6 hours

DEA-224b

Number of respondents: 16

Average time per response: 5 hours

Annual burden hours: 80 hours

Total number of respondents: 440,606

Total annual burden hours: 56,307.8 hours

Percent Electronic (DEA-224) – 83%

Percent Electronic (DEA-224a) – 57%

Electronic responses to DEA-224:

Approximately 59,283 (DEA 224 electronic) respondents at
0.13 hours per response = 7,904 x \$10 per hour =

\$ 79,040

Paper responses to DEA-224
Approximately 12,094 (DEA 224 paper) respondents at
0.2 hours per response = 2,418.8 x \$10 per hour = \$ 24,188

Electronic responses to DEA-224a
Approximately 209,535 (DEA-224a electronic) respondents at
0.07 hours per response = 13,969 x \$10 per hours = \$ 139,690

Paper response to DEA-224a
Approximately 159,678 (DEA-224a paper) respondents at
0.2 hours per response = 31,935 x \$10 per hour = \$ 319,350

Approximately 16 (DEA 224B) respondents per year at 5
hours per response = 80 hours x \$10 per hour \$ 800

This cost is a usual and customary business expense not directly associated with this information collection.

13. Estimate of Cost Burden:

Note, there are 27,673 respondents who are exempt from paying the fee because they are affiliated with a federal, state, or local government agency (21 CFR 1301.21).

Annual Cost to Respondents:
413,293 @ $\frac{\$551}{3}$ per applicant = \$ 75,908,148

Note that the \$551 registration fee is for a three-year period. Thus, the annual fee is \$184.

71,377 Respondents - DEA Form 224
369,213 Respondents - DEA Form 224a
19,088 Registrants in chain renewal process.
459,678 **Total Registrants represented**
(Note: 16 respondents complete DEA Form 224B)

Mailing cost: 171,772 @ \$0.42 per response = \$ 72,144

Total Cost \$ 75,980,292

14. Estimated Annualized Cost to Federal Government: Cost to Federal Government:

Estimated Annual Cost to the Government:

Printing	\$10,000
Automatic Data Processing	\$182,357
Postage	\$82,000
Equipment, Repair Contracts, Rent and Overhead	\$834,900
Total:	\$1,100,273,339,257

Review and Notification

Project Manager

1 Unit Chief (Registration Unit) - GS-301-14; (90% of time) = \$127,992

Review & Notification

- 46 Registration Assistants - GS-963-9 (Field); (75% of time) = \$2,407,824
- 7 Registration Assistants - GS-963-9 (HQ); (75% of time) = \$366,408
- 1 Registration Assistants - GS-963-11 (HQ Team Leaders); (80% of time) = \$67,550
- 483 Diversion Investigators - GS-1801-12 (Field) (5% of time) = \$2,444,150
- 4 Program Analyst GS-343-13 (HQ) (45% of time) = \$216,634
- 21 Government Contractor Employees from ASRC (75% of time) = \$1,242,927
(75% of average contract cost x 21)

Fee Processing

4 Government Contractor Employees from ASRC (65% of time) = \$242,544
(65% of average contract cost x 4)

Scanning

1 Computer Assistant – GS-335-9 (HQ) (95% of time) = \$66,302

Total: \$ 7,182,331

TOTAL COST: \$ 8,209,670

There is no actual cost to the Federal Government for these activities as all costs are recovered from registrants through registration fees, as required by the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act of 1993.

15. Reasons for Change in Burden:

Changes reflect population adjustments and time it takes to complete the forms.

16. Plans for Publication:

There are no plans to publish this information.

17. Expiration Date Approval:

It would be an administrative burden to replace existing forms in all field locations when nothing of substance changed except the Date of Expiration; therefore, approval is requested not to list the Date of Expiration.

18. Exceptions to the Certification Statement:

There are no exceptions to the certification requirement.

Part B. Statistical Methods

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