Supporting Statement for Paperwork Reduction Act Submissions

Application for Registration under Domestic Chemical Diversion Control Act of 1993 and Renewal Application for Registration under Domestic Chemical Diversion Control Act of 1993

DEA Forms 510 & 510A

1117-0031

Part A. Justification

1. Necessity of Information: The Controlled Substances Act (21 U.S.C. §§ 822 and 823) require that every person who manufactures or distributes a list I chemical shall annually obtain a registration for that purpose. Additionally, the Controlled Substances Import and Export Act (21 U.S.C. §§ 957 and 958) require that persons who import or export List I chemicals must obtain a registration prior to conducting such activities. DEA is required to fund the costs of the Diversion Control Program through the charging of fees. “Fees charged by the Drug Enforcement Administration under its diversion control program shall be set at a level that ensures the recovery of the full costs of operating the various aspects of that program.” (21 U.S.C. § 886a). Title 21 Code of Federal Regulations § 1309.21 outlines the procedures and requirements for submission of applications for registration by those persons required to be registered. DEA Form 510 is utilized by applicants desiring to manufacture, distribute, import, and export List I chemicals. DEA Form 510a is utilized for renewal of the registration on an annual basis.

2. Needs and Uses: The information provided on the application is necessary to register a person to conduct specific activities with List I chemicals, which are regulated by DEA. This information is also used by DEA investigators in evaluating the applicant to determine if the requirements for registration have been met. Failure to collect such information would prevent evaluation of the applicant prior to registration and would impair DEA’s enforcement of the Controlled Substances Act.

3. Use of Technology: Currently, the DEA Form 510 may be submitted electronically through the DEA Diversion Control Program web site at http://www.deadiversion.usdoj.gov. New applicants complete this form online and submit it to DEA electronically. Currently, 1,165 respondents (64.5%) submit reports electronically. DEA is taking steps to encourage more respondents to respond electronically.

4. Efforts to Identify Duplication: The Federal requirement of registration to handle list I chemicals is unique to DEA.

5. Methods to Minimize Burden on Small Businesses: The collection of information does not have a significant impact on small business entities.

6. Consequences of Less Frequent Collection: DEA Form 510 is utilized as an “as needed” basis by applicants desiring to manufacture, distribute, import, and export List I chemicals. DEA Form 510a is utilized for the renewal of registration on a yearly basis. Failure to collect the information would impair DEA’s enforcement activities and violate Section 822 and 823 of the Controlled Substances Act. Businesses and other for-profit entities participating in this information collection maintain the requested data as part of usual and customary business practice.

7. Special Circumstances Influencing Collection: There are no special circumstances in item 7 of the supporting statement 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 1320.8(d). DEA meets regularly with the affected industry to discuss policies, programs and regulations.

As part of its Notice of Proposed Rulemaking entitled “Registration Requirements for Importers and Manufacturers of Prescription Drug Products Containing Ephedrine, Pseudoephedrine, or Phenylpropanolamine” [Docket No. DEA-294, RIN 1117-AB09] (73 FR 3432, January 18, 2008), DEA discussed the revision of this information collection. DEA did not receive any comments regarding the information collection aspects of that rulemaking. Accordingly, DEA is revising this collection as proposed.

9. Payment or Gift to Claimants: There are no such 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. There are also restrictions under the Freedom of Information Act regarding disclosure of investigative files. Further, disclosure of information regarding activities of registrants is addressed in 21 U.S.C. § 830.

11. Justification for Sensitive Questions: Questions of a sensitive nature are not included in the reporting requirements.

12. Estimates of Hour Burden:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Respondents** | **Burden (minutes)** | **Total Hour Burden** | **@ $10/hour =** |
| DEA-510 (paper) | 60 | 0.5 hours | 30 | $ 300.00 |
| DEA-510 (electronic) | 325 | 0.25 hours | 81.25 | $ 812.50  |
| DEA-510a (paper) | 580 | 0.5 hours | 290 | $ 2,900  |
| DEA-510a (electronic) | 840 | 0.25 hours | 210 | $ 2,100 |
| Total | 1,805 |  | 611.25 | $ 6,112.50 |

Total percentage electronic: 64.5%

Reporting is required on DEA Forms 510 and 510a.

Number of respondents: 1,805

Frequency of response: DEA Form 510 as needed &

 DEA Form 510a annually

Estimates are based on the population of the regulated industry participating in this business activity. The $10 hourly charge is a usual and customary business expense not directly associated with this information collection.

13. Estimate of Cost Burden: As noted previously, persons applying for a new registration and persons applying to renew registrations pay a registration application fee based on their business category. Fees associated with this application are as follows:

|  |  |  |  |
| --- | --- | --- | --- |
| **Business Activity** | **# Registrants** | **Fee** | **Total** |
| Manufacturer | 322 | $2,293 | $738,346 |
| Distributor | 1,203 | $1,147 | $1,379,841 |
| Importer | 165 | $1,147 | $189,255 |
| Exporter | 115 | $1,1147 | $131,905 |
| Total | 1,805 |  | $2,439,347 |

Mailing cost for applications: 640 responses @ $0.44 per response = $281.60

TOTAL RESPONDENT COST: $2,439,628.60

14. Estimated Annualized Cost to Federal Government:

COST TO FEDERAL GOVERNMENT:

Printing: $3,354

Mailing: $2,884

Personnel costs:

1 GS-7 (10% of time): $5,978.24

1 GS-9 (100% of time): $73,125.12

1 GS-13 (40% of time): $50,441.22

Total Personnel Costs: $129,544.57

TOTAL COSTS: $135,882.57

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:

On March 9, 2006, the President signed the Combat Methamphetamine Epidemic Act of 2005 (CMEA), which is Title VII of the USA PATRIOT Improvement and Reauthorization Act of 2005 (Pub. L. 109-177). CMEA amended the Controlled Substances Act (CSA) to include ephedrine, pseudoephedrine, and phenylpropanolamine in 21 U.S.C. § 826 (Production quotas for controlled substances) and § 952(a) (Importation of controlled substances). Imports of ephedrine, pseudoephedrine, and phenylpropanolamine are prohibited except for such amounts as the Attorney General (DEA by delegation) finds to be necessary to provide for medical, scientific, or other legitimate purposes. CMEA also mandated the establishment of a total need for ephedrine, pseudoephedrine, and phenylpropanolamine to be manufactured each calendar year to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. These requirements apply equally to products containing these three List I chemicals as they do to the List I chemicals themselves.

The CSA requires that persons must be registered manufacturers to receive manufacturing or procurement quota. Historically, however, firms that manufactured prescription drugs containing ephedrine, pseudoephedrine, and phenylpropanolamine were not required to register because distributions of the prescription products were not regulated. In addition, DEA previously waived the chemical distribution registration requirement for firms that manufacture or distribute drug products containing the three chemicals for any firm that is registered to manufacture, distribute, or dispense a controlled substance.

CMEA requires production quotas for manufacturers handling the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, and authorized DEA to establish import quotas for ephedrine, pseudoephedrine, and phenylpropanolamine. The Controlled Substances Act requires that quotas be issued to registrants. Were DEA not to issue this rule, it would have no mechanism to permit the registration of persons handling prescription products containing ephedrine, pseudoephedrine, or phenylpropanolamine. If these persons were not permitted to register, there would be no mechanism by which they would be permitted to apply for production or import quotas. Therefore, these persons would have no means by which to acquire the List I chemicals ephedrine, pseudoephedrine, or phenylpropanolamine necessary for them to conduct business.

To ensure continued legitimate commerce, DEA must amend this collection of information, as well as its regulations, to permit these persons to register with DEA.

DEA estimates that approximately 200 firms may have to obtain a new DEA registration, 150 manufacturers and 50 importers. DEA assumes that these firms complete the registration application electronically, with each application taking 15 minutes to complete. The receipt of these additional applications increases the hour burden by 50 hours annually.

16. Plans for Publication: There are no plans to publish the information.

17. Expiration Date Approval: All forms contain the date of expiration.

18. Exceptions to the Certification Statement: There are no exceptions to the certification statement.

Part B. Statistical Methods

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