Supporting Statement for Paperwork Reduction Act Submissions Controlled Substances Import/Export Declaration DEA Form 236 OMB Approval # 1117-0009

The Drug Enforcement Administration (DEA) seeks the Office of Management and Budget (OMB) approval of an existing collection of information that was previously approved by OMB – OMB Approval Number 1117-0009, Controlled Substances Import/Export Declaration, DEA Form 236.

Part A. Justification

1. Necessity of Information:

DEA Form 236 provides the DEA with oversight and control over the importation and exportation of controlled substances. 21 CFR part 1312, promulgated pursuant to 21 U.S.C. 952 and 21 U.S.C. 953, requires registrants who desire to import non-narcotic substances in Schedules III, IV, and V or to export non-narcotic substances in Schedules III and IV and any other substance in Schedule V, to furnish a controlled substances import declaration/controlled substances export invoice on a DEA Form 236 (if those activities are not otherwise subject to import/export permit requirements). In addition, Article 12 of the Convention on Psychotropic Substances of 1971 (Convention) requires a system of export declarations for certain substances controlled under the Convention.

2. Needs and Uses:

DEA Form 236 enables the DEA to monitor and control the importation and exportation of controlled substances. Analysis of these documents provide the DEA with important intelligence regarding the international commerce in controlled substances and assists in the identification of suspected points of diversion. In addition, the compiled data is reported to the International Narcotics Control Board (INCB) annually, as required by Article 16 of the Convention. Failure to require import/export declarations, and the information provided thereon, would violate the requirements imposed by the Controlled Substances Act (CSA) and the United States' international obligations.

3. Use of Information Technology:

The referenced DEA Form 236 is available on the DEA Diversion Control Program website (http://www.DEAdiversion.usdoj.gov). This form is partially interactive and can be completed electronically, printed, signed manually, and sent to the DEA. DEA Form 236 is also available for online completion and submission.

4. Efforts to Identify Duplication:

The DEA has made efforts to identify and prevent duplication of the collection of information. The existing DEA Form 236 is not duplicative. The collection of this information is unique to the DEA.

5. <u>Impact on Small Businesses or Entities:</u>

This is a routine three-year renewal of DEA Form 236. The DEA does not anticipate any additional impact on small businesses or other small entities since the initial approval of this form. The 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:

The DEA uses the information collected to monitor the import and export of controlled substances. Information is provided each time the registrant proposes to import or export controlled substances and therefore cannot be collected less frequently. Failure to collect the information would impair the DEA's enforcement activities and violate the requirements imposed by the CSA and the United States' international obligations.

7. Special Circumstances Influencing Collection:

There are no special circumstances applicable to this information collection.

8. <u>Consultation with persons outside the Agency:</u>

Public comment was solicited in the 60-day Federal Register Notice of Information Collection, 79 FR 29801-29802, published on 05/23/2014 and the 30-day Federal Register Notice of Information Collection, 79 FR 45461-45462, published on 08/05/2014. 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 collection of information 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. <u>Justification for Sensitive Questions:</u>

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

12. Estimate of Hour Burden:

Reporting is required on DEA Form 236.

Controlled Substances:

Number of Respondents:

Paper 304 Online 38 Total Respondents: 342

Frequency of Response: As needed

Average annual responses:

Paper 4,717 Online 347 Total Annual Responses: 5,064

Average time per response:

Paper 0.3 hours (18 minutes) X 4,717 = 1,415.1 Online 0.25 hours (15 minutes) X 347 = 86.75

Total annual burden: 2,282.6 hours

Cost to respondents:

4,717 responses @ 18 minutes (0.3 hours) per response @ \$40.33 per burden hour = \$57,070.98 (paper)

347 responses @ 15 minutes (0.25 hours) per response @ \$40.33 per burden hour = \$3,498.63 (online)

Total cost to respondents: \$60,569.61

13. Estimate of Cost Burden:

DEA assumes that a transportation, storage, and distribution manager (SOC 11-3071) will complete the form on behalf of the registrant. The median hourly wage for that position according to the Bureau of Labor Statistics' 2013 Occupational Employment Statistics is \$40.33 (http://www.bls.gov/oes/current/oes_nat.htm). This is a usual and customary business expense not directly associated with this information collection.

Mailing: 4,717 responses @ \$0.49 per response = \$2,311.33

14. Estimated Annualized Costs to Federal Government:

Estimated Annual Cost to Federal Government:

Printing: Interactive forms and online submissions have eliminated the cost of printing this form.

Mailing: The form is no longer mailed to registrants, as it is available online in both interactive printable format and as an online submission.

Analysis of data:

2 GS-13 (100% of time): \$213,311.80

TOTAL COST TO GOVERNMENT: \$213,311.80

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

15. Reasons for Change in Burden:

Changes reflect an adjustment in Postal Service rates for the mailing of paper forms (submissions by registrants), adjustment of salaries to 2013 rates, and for reduced time for recently developed online forms and submissions. Government expenses for printing and mailing of blank forms has been eliminated due to online availability.

16. Plans for Publication:

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

17. Expiration Date Approval:

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. The DEA will

display the expiration date on the partially interactive electronic form and the online form.

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.