September 2014

Supporting Statement for Paperwork Reduction Act Submissions
Self-Certification, Training, and Logbooks for Regulated Sellers and Mail-Order Distributors of Scheduled Listed Chemical Products -- DEA Form 597
OMB Approval # 1117-0046

The Drug Enforcement Administration (DEA) seeks Office of Management and Budget (OMB) approval of an existing collection of information that was previously approved by OMB – OMB Approval Number 1117-0046, Self-Certification, Training, and Logbooks for Regulated Sellers and Mail-Order Distributors of Scheduled Listed Chemical Products, DEA Form 597.

Part A. Justification

1. Necessity of Information:

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), requires that on and after September 30, 2006, a regulated seller must not sell at retail over-the-counter (nonprescription) products containing the List I chemicals ephedrine, pseudoephedrine, or phenylpropanolamine (referred to here as "scheduled listed chemical products"), unless it has self-certified to the DEA, through the DEA's website. The Combat Methamphetamine Enhancement Act of 2010 (Pub. L. 111-268) (MEA) requires that on and after April 10, 2011, a regulated person that sells scheduled listed chemical products at retail and uses or attempts to use the U.S. Postal Service or a private or commercial carrier to deliver the product to the customer (referred to as a "mail-order distributor"), must not sell those products unless it has self-certified to the DEA, through the DEA's website. The Methamphetamine Production Prevention Act of 2008 (MPPA) (Pub. L. 110-415) was enacted in 2008 to clarify the information entry and signature requirements for electronic logbook systems permitted for the retail sale of scheduled listed chemical products. The MPPA expressly permits the regulated seller to capture information regarding the name of the product and the quantity sold through bar code, electronic data capture, or similar technology.

The regulated seller or mail-order distributor is also responsible to train any employee who will be involved in selling scheduled listed chemical products, document the training, and self-certify annually to the DEA that all affected employees have been trained and that the regulated seller or mail-order distributor is in compliance with all the CMEA and MEA provisions. Finally, the CMEA mandates that each sale at retail by a regulated seller be documented in a written or electronic logbook and that the logbooks be retained for two years from the date of the transaction.

2. Needs and Uses:

The logbooks are used, as mandated by the Controlled Substance Act (CSA), to track the sale of scheduled listed chemical products. It is also needed and used for regulated sellers and mail-order distributors to retain a record of employee training, and complete a

self-certification for verifying the training and compliance with CMEA provisions regarding retail sales of scheduled listed chemical products. Regulated sellers and mail-order distributors are required to self-certify with the DEA to sell scheduled listed chemical products at retail. Such self-certification is required for the DEA to enforce the CSA.

3. Use of Information Technology:

The CMEA and MEA specifically require that self-certification to the DEA occur through a website operated by the DEA. At this time, all self-certifications must be filed electronically through the DEA website: www.DEAdiversion.usdoj.gov.

The CMEA allows each retail sale by a regulated seller be documented in a written or electronic logbook. Each regulated seller has the option to choose the technology/format that is best suited for its individual situation.

4. Efforts to Identify Duplication:

The DEA has made efforts to identify and prevent duplication of the collection of information. The existing DEA Form 597 is not duplicative. This specific information is only required by CMEA and MEA, therefore, no similar information is being collected.

5. Impact on Small Businesses or Entities:

This is a routine three-year renewal of DEA Form 597. 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.
The DEA has concluded that the collection will not have a significant economic impact on small entities within the meaning and intent of the Regulatory Flexibility Act, 5 U.S.C. 601-612.

6. Consequences of Less Frequent Collection:

If the collection is not conducted or conducted less frequently, the DEA would not have sufficient data to enforce the CSA. The information collected by DEA Form 597 is vital to the enforcement of the CSA, which mandates that regulated sellers of scheduled listed chemical products maintain a written or electronic logbook of sales. The CSA requires that regulated sellers and mail-order distributors selling scheduled listed chemical products must self-certify with the DEA. Collection of information on each sale is statutorily mandated.

7. Special Circumstances Influencing Collection:

There are no special circumstances 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 79 FR 12705 published on 03/06/2014 and the 30 day Federal Register Notice of Information Collection 79 FR 28553 on 05/16/2014. The DEA did not receive any comments concerning this collection.

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 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 disclosure by the DEA.

11. Justification for Sensitive Questions:

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

12. Estimate of Hour Burden

Reporting self-certification is required on DEA Form 597. The form is completed online and must be renewed annually. The required information is limited: the DEA number (where applicable), taxpayer ID, business address, point of contact information, number of employees trained, total employees at the location, scheduled listed chemical products sold (by chemical), and the type of establishment. The DEA estimates that applying for a new self-certification takes 30 minutes and renewing an existing self-certification requires 15 minutes each year. Since the vast majority of self-certifications are renewals, 15 minutes per self-certifications is used for estimating hour burden. The DEA estimates there will be 60,043 self-certifications per year.

Regulated sellers will need to maintain a record of employee training as well as maintain a logbook of transactions. Mail-order distributors will need to maintain a record of

employee training. Completing a roster of employees trained is estimated to take 3 minutes per employee, assuming that the recordkeeping takes one tenth of the time spent on training. Based on information filed by respondents who reported that they had trained about 820,000 employees and the annual on the job turnover rate at retail establishments is approximately 50 percent, the DEA estimates that 410,000 employees will be trained by regulated sellers each year.[1]

The DEA estimates that having the customer enter information and sign the logbook while the sales person checks the photographic identification of the purchaser (as required by CMEA) will take 2 minutes per transaction. Based on latest data on sales of over-the-counter (OTC) cold and allergy medications, the DEA estimated that total retail sales of scheduled listed chemical products were at most $500 million in 2007.[2] Import data from the United States International Trade Commission indicate a continuing decline in imports of both ephedrine and pseudoephedrine. To be conservative, the DEA used an estimate of $500 million in sales. The existing products retail for $9 to $30; the DEA used an average cost of $10 to estimate 50 million transactions. The number of transactions was reduced to 25.5 million to account for the states that imposed requirements for logbooks prior to CMEA; the rule implementing the retail sales provisions of the CMEA and this associated information collection impose no additional burden for the transactions on either purchasers or sellers in those states. Based on Bureau of Census state population numbers for 2005, these states represent 49 percent of the United States population. The DEA assumes that the number of transactions is proportionate to the population. The table below presents the burden hour calculations including the certification burden.

Activity	Unit Burden Hour	Number of Activities	Total Burden Hours
Training record	0.05 hour (3 minutes)	410,000	20,500
Self-certification	0.25 hour (15 minutes)	60,043	15,011
Transaction record	0.033 hour (2 minutes)	25,500,000	850,000
Customer time	0.033 hour (2 minutes)	25,500,000	850,000
Total			**1,735,511**

[1] BLS data indicate a total hire rate of 51.6% in 2013 for the retail sector as a whole. DEA used a 50% rate because pharmacists, pharmacy technicians, and general managers may have lower turnover rates than sales clerks and other retail workers.

[2] Only 2 products in the top 200 OTC products contained pseudoephedrine; their sales value was about $187 million; if private brand cough, cold, and allergy tablets had the same mix of products as brand name, pseudoephedrine product sales would have been about $257 million. The products in the top 200 represent about 75 percent of the cold medication market. DEA has previously estimated the ephedrine market at less than 6 percent of the pseudoephedrine market.

13. Estimate of Cost Burden:

Cost to Respondent:

To estimate labor costs, DEA used weighted averages based on the assumption that in stores with pharmacies (47,250 of the 60,043), pharmacists would sign the certification and pharmacy technicians would handle the logbook. At other retail stores (12,793), the general manager would sign the certification and retail sales clerks would maintain the logbook. Based on the Bureau of Labor Statistics (BLS) May 2013 National Occupational Employment and Wage Estimates for pharmacists, pharmacy technicians, general and operation managers, and cashiers, and BLS Employer Costs of Employee Compensation – September 2013 for benefit rates, DEA developed weighted wages of $78.25 for training records and self-certifications and $18.72 for transactions.[3] In addition, DEA assumed a wage rate for the public of $24.00 based on the BLS median hourly wage rate for all occupations and benefits.[4] The table below presents the unit and total cost for each activity.

Activity	Unit Cost ($/hour)	Total Burden Hours	Total Cost ($)
Training record	78.25	20,500	1,604,086
Self-Certification	78.25	15,011	1,174,563
Transaction record	18.72	850,000	15,908,157
Customer time	24.00	850,000	20,397,582
Total			39,084,388

For the 60,043 business respondents, the average annual burden is 14.75 hours.

TOTAL COST TO RESPONDENT: $311 (($ 1,604,086 + 1,174,563 + 15,908,157) / 60,043)

The CMEA allows each retail sale by a regulated seller be documented in a written or electronic logbook. Each regulated seller has the option to choose the technology/format that is best suited for its individual situation. If every retail seller used bound logbooks, the annual cost of logbooks needed to record 25.5 million transactions would be $218,473 ($47.55 for a bound logbook that has 150 pages and 37 lines/page). The DEA

[3] http://www.bls.gov.
[4] See note 3.

expects that many retail sellers will use existing computer systems and signature capture devices to maintain electronic logbooks and reduce costs. The DEA conservatively estimates the non-wage related cost to respondents is $218,473 per year.

14. Estimated Annualized Cost to Federal Government:

There is no actual cost to the Federal Government for this activity as all costs are recovered from registrants and self-certifiers through registration fees, as required by the Department of Justice and Related Agencies Appropriations Act of 1993.

15. Reasons for Change in Burden:

The number of regulated sellers that have self-certified is lower (60,043) than the number DEA estimated in 2011 (64,000). The number of trainees is slightly lower based on actual data submitted by regulated sellers. The number of transactions is the same. There are no mail-order distributors in 2014 unlike 2011 (9).

16. Plans for Publication:

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

17. Expiration Date Approval:

The DEA has no issues with OMB displaying the expiration date.

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 Drug Enforcement Administration does not employ statistical methods in this information collection.