October 5, 2009

Self-Certification, Training, and Logbooks for Regulated Sellers of Scheduled Listed Chemical Products
DEA Form 597
1117-0046

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 DEA, through DEA's Web site. The regulated seller is also responsible to train any employee who will be involved in selling scheduled listed chemical products, document the training, and self-certify to DEA that all affected employees have been trained and that the regulated seller is in compliance with all CMEA provisions. Finally, CMEA mandates that each sale at retail 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: Regulated sellers are required to self-certify with DEA to sell scheduled listed chemical products at retail. Such self-certification is required for DEA to enforce CMEA.

3. Use of Technology: CMEA specifically requires that self-certification to DEA occur through a Web site operated by DEA. At this time, all self-certifications must be filed electronically through the DEA Web site: www.deadiversion.usdoj.gov

4. Efforts to Identify Duplication: There is no duplication of this collection of information since this is a collection necessitated by CMEA.

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

6. Consequences of Less Frequent Collection: If the collection is not conducted or conducted less frequently, DEA would not have sufficient data to enforce CMEA. CMEA requires that regulated sellers selling scheduled listed chemical products must self-certify with 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. Reasons for Inconsistencies with 5 CFR 1320.6: There are no circumstances 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 received one comment for this collection. In response to the 30-day notice (74 FR 42690) the American Pharmacists Association (APhA) submitted a comment.

I. The APhA expressed concern with the lack of burden estimates and information related to maintaining the paper or electronic logbooks, and physically storing and maintaining access to those records. The APhA stated that some pharmacies are burdened with keeping two sets of records, one at a centralized storage location for electronic files within the company and one at the pharmacy to comply with access standards. The APhA recommended that DEA, for electronic records, accept centralized storage systems that may not be physically located in the pharmacy as a means to meet the information access standard for those pharmacies that utilize such systems. The APhA asserted that this would alleviate a significant burden on some pharmacies.

DEA Response: DEA regulations regarding recordkeeping for retail transactions do not require pharmacies to maintain two sets of records. Pharmacies, upon notification to the Special Agent in Charge of the local DEA Divisional Office, may store such records in a single, central location.

> A record under this section must be kept at the regulated seller's place of business where the transaction occurred, except that records may be kept at a single, central location of the regulated seller if the regulated seller has notified the Administration of the intention to do so. Written notification must be submitted by registered or certified mail, return receipt requested, to the Special Agent in Charge of the DEA Divisional Office for the area in which the records are required to be kept. (21 CFR 1314.30(h))

Furthermore, pharmacies that store such records at a single, central location must comply with the requirement for the records to be readily retrievable and available for inspection and copying by authorized employees of the Administration under the provisions of 21 U.S.C. 880 (21 CFR 1314.30(i)). Accordingly, given that DEA does not require records to be kept at two separate locations, DEA will not include this as an additional burden for this information collection.

II. The APhA also expressed concern that DEA's estimates for the burdens associated with activities for transaction records (2 minutes per hour) and customer time

(2 minutes per hour) may be too low. APhA stated that their members report that pharmacies that do not have the electronic infrastructure to capture electronic log data during a sales transaction may spend significantly more time processing paperwork than DEA's estimate suggests. APhA stated that their members also report that the time spent on complying with CMEA requirements impacts the amount of time that pharmacists can spend providing direct patient care for prescription and non-prescription products.

DEA Response: The estimated burden hours for these activities are based on information available to DEA regarding pharmacies that maintain an electronic logbook and pharmacies that maintain a paper logbook. The estimated burden hours are an average of the estimated time to complete these transactions in both paper and electronic form and serve as DEA's conservative estimate based on available information for tracking product sales under the CMEA. DEA has received no additional data to support a change in the estimated burden hours for these activities and the APhA provided no alternative estimates. Consequently, DEA will retain the current burden estimates for this information collection.

III. The APhA expressed concern that the lack of interconnectivity between the different tracking systems (paper and electronic) used by different pharmacies may minimize the program's full, potential benefit. The APhA stated that their members report that the significant amount of time that pharmacy staffs spend explaining and collecting the required information is not fully optimized because there is not a national, centralized system that captures real-time, point-of-sales data.

DEA Response: The CMEA requires a regulated seller to be self-certified, to train and self-certify that all affected employees have been trained, and to document each sale in a written or electronic logbook to be retained for two years. DEA has no statutory authority to mandate the interconnectivity of tracking systems regarding the sale of ephedrine, pseudoephedrine, or phenylpropanolamine and is unable to address this recommendation.

9. Payment or Gift to Claimants: There are no such payments or gifts to respondents.

10. Assurance of Confidentiality: Information requested in this collection is not confidential.

11. Justification for Sensitive Questions: Questions of a sensitive nature are not included in this collection of information.

12. Estimate of Hour Burden:

Reporting is required on DEA Form 597 for Self-Certification. The form is completed online and must be renewed annually. The information required, however, is limited: 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. DEA estimates that updating the form will require 15 minutes each year. There are currently approximately 64,000 locations that have self-certified.

DEA Form 597:

Number of respondents:	64,000
Frequency of response:	annual
Average annual responses:	64,000
Average time per response:	0.25 Hrs (15 minutes) [note that this is for the form only]
Total Annual burden:	16,000 hours

Regulated sellers will need to maintain a record of employee training and maintain a logbook of transactions. 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 on the annual job turnover rate at retail establishments (approximately 50 percent), DEA estimates that 410,000 employees will be trained each year. [1]

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 two minutes per transaction. Based on latest data on sales of OTC cold and allergy medications, DEA estimated that total retail sales of scheduled listed chemical products were at most $500 million in 2007.[2] Import data from the U.S. International Trade Commission indicate a continuing decline in imports of both ephedrine and pseudoephedrine. To be conservative, DEA used an estimate of $500 million in sales. The existing products retail for $9 to $30; 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 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 U.S. population. DEA assumes that the number of transactions is proportionate to the population. The table below presents the burden hour calculations including the certification burden.

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[1] BLS data indicate a total separation rate of 54.9% and total hire rate of 51.3% in 2008 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 two 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.

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)	64,000	16,000
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			**1,736,500**

Cost to Respondent:
To estimate labor costs, DEA used weighted averages based on the assumption that in stores with pharmacies (47,250 of the 64,000), pharmacists would sign the certification and pharmacy technicians would handle the logbook. At other retail stores (16,750), the general manager would sign the certification and retail sales clerks would maintain the logbook. Based on BLS May 2007 National Industry-Specific Occupational Employment and Wage Estimates for drug stores and gas stations and BLS Employer Costs of Employee Compensation – December 2008 for benefit rates at retail stores, DEA developed weighted wages of $58.72 for certifications and $15.76 for transactions.[3] In addition, DEA assumed a wage rate for the public of $20.37 based on the BLS average civilian wage rate for December 2008. The table below presents the unit and total cost for each element.

	Unit Time	Unit cost	Total Cost
Certification	0.25	$14.68	$941,500
Training record	0.05	$2.94	$188,300
Seller Transaction	0.03	$0.52	$13,142,600
Public Transaction	0.03	$0.68	$17,314,500
Total			$31,587,000

For the 64,000 business respondents, the average annual burden is 13.85 hours.

TOTAL COST TO RESPONDENT: $239 ($14.68+2.94*6.39(average number of trainees) +$205(398 transactions))

[3] Inflated to December 2008 dollars and loaded with fringe benefits.

13. Estimate of Cost Burden: 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). DEA expects that many retail sellers will use existing computer systems and signature capture devices to meet the requirement, which will reduce the costs. DEA expects that training records will be maintained electronically on existing computer systems.

14. Estimated Annualized Cost to Federal Government:

Estimated annual cost to Government:

DESCRIPTION	**2009**
Professional/Admin	$ 21,713
DI	$ 8,397
Attorney	$ 38,909
Call Center, Finance, Mail Room, Printing	$ 306,874
Maintenance	$ 38,728
Enhancements	
Total	**$ 414,620**

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 (64,000) than the number DEA estimated in 2006 (92,000). The number of trainees is slightly higher based on actual data submitted by regulated sellers. The number of transactions is lower (25.5 million versus 67.25 million) based on a decline in the number of scheduled listed chemical products being marketed, the replacement of pseudoephedrine in most cold and allergy medications, and the higher cost of the remaining products containing pseudoephedrine.

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

17. Expiration Date Approval: DEA is not seeking approval not to list 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 does not employ statistical methods in this information collection.