February 18, 2011

Self-Certification, Training, and Logbooks for Regulated Sellers and Mail-Order Distributors 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 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 DEA, through DEA's Web site. 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 to DEA that all affected employees have been trained and that the regulated seller or mail-order distributor is in compliance with all CMEA and MEA provisions. Finally, 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: Regulated sellers and mail-order distributors are required to self-certify with DEA to sell scheduled listed chemical products at retail. Such self-certification is required for DEA to enforce the Controlled Substances Act (CSA).

3. Use of Technology: CMEA and MEA specifically require 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 and MEA.

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 the CSA. The CSA requires that regulated sellers and mail-order distributors 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.

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

10. Assurance of Confidentiality: The disclosure of information regarding sensitive business information pertaining to listed chemicals is governed by the Administrative Procedure Act (APA), Department of Justice (DOJ) Regulations, and the CSA. 5 U.S.C. 552; 28 CFR 16.8; 21 U.S.C. 830.

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 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, DEA will give written notice to the submitter to allow an opportunity to object within a reasonable time prior to disclosure by DEA.

More specifically, information related to listed chemicals which is obtained pursuant to 21 U.S.C. 830 is generally not disclosable. Circumstances which allow for disclosure include government personnel engaged in carrying out controlled substance or chemical laws, investigations or proceedings related to the CSA or customs laws, or compliance with treaties or international agreements. 21 U.S.C. 830(c)(2). Finally, aggrieved persons harmed by an improper disclosure of information are afforded further protection by the grant of a private right of action. 21 U.S.C. 830(c)(4)

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 applying for a new self-certification takes 30 minutes and renewing an existing self-certification requires 15 minutes each year.

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

Regarding mail-order distributors, the nine affected firms range in size from 5 employees to more than 800. DEA assumes that the smallest firms will train half their employees and the two large firms will train 20 percent, based on the percentage of retail sales persons, order clerks, and order fillers to total employment in the retail mail order sector. Therefore, DEA estimates that the nine affected mail-order distributors will train 228 employees.

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

[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.

$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.

Activity	**Unit Burden Hour**	**Number of Activities**	**Total Burden Hours**
Training record	0.05 hour (3 minutes)	410,228	20,511.4
Self-certification (regulated sellers)	0.25 hour (15 minutes)	64,000	16,000
Self-certification (mail-order distributors)	0.5 hours (30 minutes)	9	4.5
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			**1,736,515.9**

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] For mail-order distributors, DEA assumes a $20 hourly wage rate for order fillers and a $40 hourly wage rate for the person who completes the self-certification. 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 (regulated sellers)	0.25	$14.68	$941,500
Certification (mail-order distributors)	0.5	$20	$180

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

Training record (regulated sellers)	0.05	$2.94	$188,300
Training record (mail-order distributors)	0.05	$2	$18
Seller Transaction	0.03	$0.52	$13,142,600
Public Transaction	0.03	$0.68	$17,314,500
Total			$31,587,098

For the 64,009 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))

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 MEA amends the CSA to change the regulations for selling scheduled listed chemical products—nonprescription products that contain ephedrine, pseudoephedrine, and phenylpropanolamine, their salts, optical isomers, and salts of optical isomers. The law requires that each regulated person making

sales at retail of a scheduled listed chemical product who is required under Title 21 of the United States Code (21 U.S.C) 830(b)(3) to submit monthly reports of sales transactions to the Attorney General (referred to as mail-order distributors) may not sell any scheduled listed chemical product at retail unless such regulated person has submitted to the Attorney General a self-certification. Sales at retail are those sales intended for personal use; mail-order distributors that sell scheduled listed chemical products not intended for personal use, e.g., sale to a university, are not affected by the new law. The requirement of self-certification becomes effective April 10, 2011. Mail-order distributors must be self-certified before they can sell scheduled listed chemical products. Such self-certification must be consistent with the criteria established for certifications of regulated sellers of scheduled listed chemical products.

As noted previously, DEA estimates that nine persons are affected by the requirements of MEA. DEA estimates that the changes made by this new statute increase the burden by 15.9 hours.

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.