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FAX

Date: 9/23/09

To: DEA Office of Management and Budget
Office of Information and Regulatory Affairs
Attention Department of Justice Desk Officer

Fax: (202)395-5806

From: American Pharmacists Association

Tel: 202-429-7538 (Marcie Bough)

Pages: 3 (including fax cover page)

Re: DEA Information Collection 1117-0046; Self-Certification, Training and Logbooks for Regulated Sellers of Scheduled Listed Chemical Products

Notes: See attached.

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September 23, 2009

Office of Management and Budget
Office of Information and Regulatory Affairs
Attention Department of Justice Desk Officer
Washington, DC 20503

[Submitted via facsimile to (202)395-5806]

Re: DEA Information Collection 1117-0046; Self-Certification, Training and Logbooks for Regulated Sellers of Scheduled Listed Chemical Products

Dear Sir/Madam:

The American Pharmacists Association (APhA) appreciates the opportunity to provide comments to the Drug Enforcement Administration (DEA) Office of Management and Budget on the collection of information related to self-certification, training, and logbooks for regulated retail sellers of scheduled listed products (pseudoephedrine, ephedrine, and phenylpropanolamine). APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 62,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings, and the uniformed services.

Pharmacists are committed to complying with the Combat Methamphetamine Epidemic Act of 2005 (CMEA) that mandates that retail sellers (including pharmacies) of scheduled listed chemical products maintain a written or electronic logbook of sales, retain a record of employee training, and complete an annual self-certification form verifying employee training and compliance of the CMEA provisions for retail sales of these products. While we appreciate efforts to implement the CMEA, we believe that the effectiveness and utility of the CMEA provisions to track product sales may be limited due to inefficiencies in the program. Unfortunately, the administrative burden and time required to comply with the various sales and record keeping requirements impacts pharmacists' time, workflow and ability to provide direct patient care for prescription and non-prescription medications.

APhA is concerned with the lack of burden estimates and information related to the maintaining the paper or electronic logbooks, and physically storing and maintaining access to those records. Additionally, 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. Therefore, APhA recommends that the Agency, 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 (must be able to produce) for those pharmacies that utilize such systems. This would alleviate a significant burden on some pharmacies.

We are also concerned that the Agency's estimates of time burdens associated with activities for transaction records (2 minutes per hour) and customer time (2 minutes per hour) may be too low. Our 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. Our 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.

Finally, we are concerned 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. Our 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. Capturing such data could better ensure tracking of sales data between stores and across states. Until there is an improved process for tracking sales information, individuals that may be purchasing a product for non-medical purposes will likely continue to purchase pseudoephedrine from more than one store and/or from across state lines, thus limiting the effectiveness of the program and the efforts by pharmacy staff to comply with the requirements.

In conclusion, APhA appreciates the steps that the Agency has taken on addressing issues related to CMEA implementation and compliance. However, we believe that more can be done to limit the burden on pharmacists and pharmacy systems using paper or electronic logbooks. In addition, we believe that the Agency could achieve a more efficient and useful system for tracking pseudoephedrine sales by ensuring that a centralized, interconnected data processing system is utilized.

Thank you for the opportunity to provide comments on this important issue, on which we look forward to continuing to work with the Agency. If you have any questions or require additional information, please contact Marcie Bough, Director of Federal Regulatory Affairs, at (202) 429-7538, or at mbough@aphanet.org.

Sincerely,

Thomas E. Menighan

Thomas E. Menighan, RPh, MBA
Executive Vice President and CEO

cc: Kristina E. Lunner, Vice President, Government Affairs
Marcie A. Bough, PharmD, Director, Federal Regulatory Affairs