DEA Interim Final Regulation: Ephedrine, Pseudoephedrine, and Phenylpropanolamine Requirements

On September 20, 2006, the Drug Enforcement Administration (DEA) released an interim final regulation to implement new restrictions for over-the-counter (OTC) products that contain ephedrine, pseudoephedrine, and phenylpropanolamine (PPA). The new restrictions for these products, which were created by the Combat Methamphetamine Epidemic Act of 2005, are intended to deter access to products that can be used to manufacture the illegal drug methamphetamine.

Under the Combat Methamphetamine Act of 2005, OTC drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine are subject to sales and purchase restrictions, storage requirements, and record-keeping requirements. Under the law, these new requirements are to be implemented in phases. In the first phase, retailers of these products had until **April 8, 2006** to adopt new sales and purchase restrictions. The second phase of implementation must be completed by September 30, 2006. As of **September 30, 2006**, all ephedrine, pseudoephedrine, and PPA* products must be kept behind a counter or in a locked cabinet; retailers must maintain a logbook of all product sales; retailers must train their employees on the new restrictions; and retailers must self-certify to the Federal government.

Following is a summary outlining the steps a retailer must take in order to comply.

Retailers must comply with the requirements by the September 30th deadline. However, the DEA is still soliciting comments on the interim final regulation. Comments must be submitted by mid-November 2006 (The exact comment deadline is not yet available).

Comments may be emailed to dea.diversion.policy@usdoj.gov, submitted online at http://www.regulations.gov, or mailed to:

Deputy Administrator
Drug Enforcement Administration
Washington, DC 20537
Attention: DEA Federal Register Representative/ODL

All comments must reference “DEA-2911”.

A copy of the rule is available on the DEA website at http://www.deadiversion.usdoj.gov/meth/irule.htm.

* Note that phenylpropanolamine is only available as a prescription veterinary product.

Combat Methamphetamine Epidemic Act

GENERAL REQUIREMENTS

Products Involved
The following requirements apply to all over-the-counter sales of products that contain ephedrine, pseudoephedrine, and phenylpropanolamine, their salts, optical isomers, and salts of optical isomers.

Under the law, these products are placed in a new category of "scheduled listed products". These products are List 1 chemicals because they are used in the illegal manufacture of methamphetamine, although they do have a legitimate medical purpose.

Retailers Involved
The following requirements apply to all retailers of ephedrine, pseudoephedrine, and phenylpropanolamine. This includes pharmacies, grocery stores, discount stores, warehouse clubs, convenience stores, variety stores, mail order stores, gas stations, etc.

April 8, 2006
Retailers had until April 8, 2006, to implement the following sales and purchase restrictions:

- 3.6 gram daily sales limit
- 9.0 gram 30-day purchase limit
- All non-liquid forms must be sold in blister packs or unit dose packages
- Mail service retailers must verify the purchaser's identification before shipping
- 7.5 gram 30-day sales limit for mail service retailers

September 30, 2006
Retailers have until September 30, 2006 to implement the following requirements related to storage, employee training, and record-keeping:

- Products must be placed in a locked cabinet or behind a counter
- Retailers must maintain a written or electronic logbook of product purchases
- Customers must present a photo identification (with a few limited exceptions) and sign the logbook
- Retailers must train employees on the new requirements and self-certify to the DEA that the training has occurred
- 7.5 gram 30-day sales limit for mobile sellers (such as kiosks in airports)

A detailed explanation of these requirements follows.

SALES / PURCHASE LIMITS

Sales Limits
A retailer may not sell more than **3.6 grams** of ephedrine, pseudoephedrine, or phenylpropanolamine products to any one individual in a single day. The DEA has defined a single day as one 24-hour period – from midnight to midnight.

Mail order retailers may not sell more than 7.5 grams of ephedrine, pseudoephedrine, or phenylpropanolamine products in a 30-day period. The 30-day period is not based on a calendar month; the DEA has defined the 30-day period as a "rolling calendar" based on the sales to the customer in the past 30 days.

Purchase Limits
An individual is restricted from buying more than **9 grams** of ephedrine, pseudoephedrine, or phenylpropanolamine products in a 30-day period.

Not more than 7.5 grams of the 9 grams may be imported through the mail.

PRODUCT PLACEMENT

Behind a Counter or in a Locked Cabinet
The products must be stored behind a counter (not necessarily the pharmacy counter), or in areas where the public has access, in a locked cabinet.

Products stored behind a counter or in a locked cabinet should only be accessible by sales staff.

LOGBOOK REQUIREMENTS

Logbook Requirements
Retailers must maintain a logbook to record sales of these products. The logbook may be kept on paper or electronically.

Logbooks must be kept for a minimum of two years.

Logbooks must contain the following information:

- Quantity of product and form sold (the product UPC code is acceptable)
- Purchaser name and address
- Date and time of sale
- Purchaser's signature

All logbooks must contain a notice on misrepresentation. The notice must inform purchasers that entering false information into the logbook may subject them to criminal penalties.

Retailers are required to use the following language as the notice on misrepresentation:

> **WARNING:** Section 1001 of Title 18, United States Code, states that whoever, with respect to the logbook, knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact, or makes any materially false, fictitious, or fraudulent statement or representation, or makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry, shall be fined not more than $250,000 if an individual or $500,000 if an organization, imprisoned not more than five years, or both.

The notice on misrepresentation must be included on the actual logbook. If that is not possible, the retailer may prominently display the notice where the purchaser will see it when entering or providing the information for the logbook.

Written Logbooks

The purchaser is responsible for entering the following information in the logbook:

- Purchaser name and address
- Date and time of sale
- Purchaser's signature

The retailer is responsible for entering the following information:

- Quantity of product and form sold

Written logbooks must be bound (similar to a Schedule V logbook).

Electronic Logbooks

When a product purchase is entered electronically, the computer system may enter the date and time of the purchase electronically.

The retailer may enter the information on the product sold though a bar code reader.

The purchaser may enter his/her name and address into the electronic system, or if that is not possible, the retailer can ask for the purchaser's name and address and enter it into the system.

Regardless of how the information is entered into the system, the purchaser must sign the logbook. An electronic signature system, such as the one many stores use for credit card purchases, may be used to capture the purchaser's signature for the electronic log.

Information in the logbook must be readily retrievable.

Disclosure of Logbook Information

Disclosure of information in the logbook is restricted to the following:

- As appropriate to the Administration, State and local law enforcement agencies
- To facilitate a product recall to protect public health and safety

A retailer who in good faith releases information in a logbook to Federal, State, or local law enforcement authorities is immune from civil liability for the release unless the release constitutes gross negligence or intentional, wanton, or willful misconduct.

Verification of ID

Retailers must verify the purchaser's identification using a photo ID. The name on the photo identification must match the purchaser's name in the logbook.

Acceptable forms of ID include:

- U.S. passport
- Alien registration receipt card or permanent resident card
- Unexpired foreign passport that contains a temporary I-551 stamp
- Unexpired Employment Authorization Document issued by the Immigration and Naturalization Service which contains a photograph
- In the case of a nonimmigrant alien authorized to work for a specific employer incident to status, an unexpired foreign passport with an Arrival-Departure Record, Form I-94, bearing the same name as the passport and containing an endorsement of the alien's nonimmigrant status, so long as the period of endorsement has not yet expired and the proposed employment is not in conflict with restrictions on limitations identified in the Form I-94

Other forms of acceptable IDs for individuals 16 years or older:

- Driver's license or identification card containing a photograph issued by the State* (*If the driver's license or ID card does not have a photograph, it must contain identifying information such as name, date of birth, sex, height, color of eyes, and address)
- School ID card with photograph
- Voter's registration card
- U.S. military card or draft record
- ID card issued by Federal, State, or local government agencies or entities. If the ID card does not have a photograph, it must contain identifying information such as name, date of birth, sex, height, color of eyes, and address.
- Military dependent's ID card
- Native American tribal documents
- U.S. Coast Guard Merchant Mariner card
- Driver's license issued by a Canadian government authority

For individuals under 18 who are unable to produce an ID form listed above:

- School record or report card
- Clinic, doctor, or hospital record
- Daycare or nursery school record

Verification of ID for Mail Order Sales

Mail order sellers must confirm the identity of the purchaser prior to shipping the product. Mail order sellers must obtain a copy of an ID card that includes a photograph that is issued by a State or Federal Government, or one of the alternative ID forms listed above. A copy of the ID can be obtained through the mail, fax, or scanning and electronically transmitting to the retailer.

Logbook Exceptions

Retailers do not have to record single package sales of pseudoephedrine that are not more than 60mg (one 60mg tablet or two 30mg tablets).

TRAINING & SELF-CERTIFICATION

Training

Retailers are required to train their employees on the new requirements related to ephedrine, pseudoephedrine, and phenylpropanolamine. The retailer must train every employee who will be involved in the sale of these products – either providing the product to the purchaser or obtaining money for the product.

The DEA has developed a training program that retailers must use to train their employees. The training program consists of approximately 19 "slides" which are available in a PDF format. Retailers must use the content of these materials in the training of their employees. However, a retailer may supplement the content with additional material (such as state-specific material) of their own choosing.

The DEA training materials are available on the DEA website at http://www.deadiversion.usdoj.gov/meth/trg_retail_081106.pdf.

Retailers must provide this training to their employees by **September 30, 2006**.

Each employee who undergoes training must sign an acknowledgment that they received the training. This acknowledgement must be kept in the employee's personnel file.

Self-Certification

By **September 30, 2006,** retailers must self-certify to the Federal government that they have trained their employees on the new product restrictions.

The self-certification process must be completed online at https://www.deadiversion.usdoj.gov/webforms/jsp/cmea/forms/menu.jsp.

The self-certification requires the retailer to confirm the following:

- That they have trained their employees on the new product restrictions
- Records of the training are maintained
- Sales to individuals do not exceed 3.6 grams per day
- Non-liquid forms are packaged as required
- The products are stored behind a counter or in a locked cabinet
- A written or electronic logbook of sales is properly maintained
- The logbook will only be disclosed to Federal, State, or local law enforcement or to facilitate a product recall

Retailers must complete a separate self-certification for each store location.

Upon self-certification, retailers will be assigned an expiration date between 12 and 23 months from the initial filing. After the second self-certification, retailers will be required to self-certify annually.

Employment Measures

A retailer may take reasonable measures to guard against employing individuals who may present a risk with respect to the theft and diversion of these products. The reasonable measures (if acceptable under State law) may include asking applicants for employment whether they have been convicted of any crime involving or related to such products or controlled substances.

MAIL ORDER REQUIREMENTS

Customer Identification

Mail order sellers must confirm the identity of the purchaser prior to shipping the product. Mail order sellers must obtain a copy of an ID card that includes a photograph that is issued by a State or Federal Government, or one of the alternative ID forms listed above. A copy of the ID can be obtained through the mail, fax, or scanning and electronically transmitting to the retailer.

Prior to shipping the product, the retailer must determine that the name and address on the ID match the name and address provided by the purchaser as part of the sales transaction. If the retailer cannot verify a match, the retailer may not ship the product to the purchaser.

Monthly Reports

Mail order sellers must file monthly reports with the DEA. The report must include information on the previous month's sales including the name of the purchaser, quantity and form of the product purchased (product name, dosage form, strength, number of dosage units per package), package type, number of packages, and lot number, the address to which the product was sent, the method used to verify the purchaser's identity, and the date of the shipment.

The report must be submitted to the DEA on company letterhead (or electronically if the retailer receives DEA approval), and must be submitted by the 15th of every month.

RELATIONSHIPS TO STATE LAWS

State Laws

The DEA requirements do not preempt state laws/regulations that are more stringent than the DEA requirements.

Retailers in every state are required to comply with the DEA regulations. However, if the DEA regulations are less stringent than a State law, the retailer must also comply with the stronger State requirements.

If the State requirements are less stringent than the DEA requirements, the DEA requirements supersede the State provisions.