Combat Methamphetamine Epidemic Act of 2005

DEA Chemical Industry Conference
October 31 – November 1, 2006
Louisville, Kentucky

Mark W. Caverly, Chief
Liaison and Policy Section
Office of Diversion Control
COMBAT METHAMPHETAMINE EPIDEMIC ACT (CMEA)
Combat Methamphetamine Epidemic Act

**Title VII of USA PATRIOT Improvement and Reauthorization Act of 2005 (Public Law 109-177)**

**Purpose:**

To provide greater controls of “Scheduled Listed Chemical Products” containing ephedrine, pseudoephedrine, and phenylpropanolamine that are used in the illicit production of methamphetamine.
CMEA: Key Definitions

Scheduled Listed Chemical Product –
- Non-prescription drug containing ephedrine, pseudoephedrine, or phenylpropanolamine.

Regulated Seller –
- Retail distributor (including pharmacy, grocery store, convenience store, or mobile retail vendor)
  - Does not include employee or agent.

Mobile Retail Vendor –
- A person who makes retail sales from a temporary stand (kiosk) / cart –
  - Located in a shopping center / mall, or
  - Can be moved to different locations (i.e., an unimproved lot, or a field during an outdoor event).
CMEA: Retail Provisions

Who May Sell “Scheduled Listed Chemical Products”:

- Regulated Sellers
- Mobile Retail Vendors
- Mail Order Sellers
Requirements for Regulated Sellers

- Self-Certification
- Employee Training
- Maintain Records of Training
- Product Packaging
- Product Placement
- Logbook
  - Logbook information disclosed only as permitted
- Daily and 30-Day Sales Limits
Self-Certification: Regulated Sellers

- **Must self-certify.**
  - May **not** sell any Scheduled Listed Chemical Product at retail unless their self-certification has been submitted to DEA.

- **Self-certification is location specific, not employee specific.**

- **Application is available on Diversion’s website at** [www.DEAdiversion.usdoj.gov](http://www.DEAdiversion.usdoj.gov)
  - Once an application has been submitted to DEA, print out a certificate.
  - Alternatively, you can request that a certificate be mailed to you.
DEA has developed a database containing self-certification records that is available to State and local law enforcement agencies.

- This database is available through FBI’s LEO.

Privacy restrictions on data in logbooks

- Good Faith Protection
Employee Training

Regulated sellers must train employees who:

- Deliver scheduled listed chemical product to custody of purchasers, or
- Who obtain payment for scheduled listed chemical product purchases.

Record of training must be maintained by the regulated seller.

- Record not required to be sent to Attorney General.
Non-liquid Scheduled Listed Chemical Products must be packaged in blister packs, each blister containing not more than 2 dosage units.

All Scheduled Listed Chemical Products (liquid, non-liquid, pediatric, gel caps, etc.) must be stored behind the counter, or in a locked cabinet.
Logbook Information

Contains a written or electronic list of sales of Scheduled Listed Chemical Products.

Seller must write, or enter in the logbook the name of the drug product and the quantity sold.

Purchaser must write, or enter in the logbook their name and address, and the date and time of the sale.

Purchaser must sign the logbook.

Seller must maintain logbook two years from date of sale.
Identification and Verification

- Purchasers **must** provide regulated seller photo identification issued by a State or the Federal government.

- If this identification not available, alternate forms of identification are permissible.

- Regulated sellers **must** verify that the purchaser’s name on the ID corresponds to the name s/he wrote in logbook.

- Regulated sellers **must** verify that date and time of the sale that the purchaser entered in logbook are correct.
The “logbook” **must** contain a notice to purchasers that false statements or misrepresentations in the logbook is a criminal offense.

If not feasible to display notice within the logbook, the “notice” must be prominently displayed where purchasers will see it when purchasing Scheduled Listed Chemical Products.

- Prominently displayed sign on the counter or wall, near the logbook.
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.
Exemption for 60 mg PSE Products

Individual sales transactions in which purchaser purchases a single package containing not more than 60 mgs of pseudoephedrine* (i.e., 1 x 60 mg tablet, or 2 x 30 mg tablets) are exempt from:

- Logbook requirements.
- Verification of identification.

**NOTE:** This does not apply to either ephedrine, or phenylpropanolamine drug products.
Logbook information shall be provided as appropriate to Attorney General and to State and local law enforcement.

Law prohibits accessing, using or sharing information for any purpose other than to ensure compliance with Title 21, U.S. Code, or to facilitate product recall to protect public health and safety.
Regulated sellers **cannot** sell more than 3.6 grams per day to each purchaser of Scheduled Listed Chemical Products, regardless of number of transactions.

**Daily sales limit per chemical.**

Refer to the charts on the next two slides for the amount of tablets or liquids that equals 3.6 grams.
CMEA:
Point-of-Sale Requirements

Effective April 8, 2006:

- Daily sales limit 3.6 grams per day per customer.
- Non-liquids packaged in blister pack only – 2 dosage units / blister pack.

<table>
<thead>
<tr>
<th>Ingredient</th>
<th># of Tablets (base)</th>
</tr>
</thead>
<tbody>
<tr>
<td>25 mg Ephedrine HCl</td>
<td>175</td>
</tr>
<tr>
<td>25 mg Ephedrine Sulfate</td>
<td>186</td>
</tr>
<tr>
<td>30 mg Pseudoephedrine HCl</td>
<td>146</td>
</tr>
<tr>
<td>60 mg Pseudoephedrine HCl</td>
<td>73</td>
</tr>
<tr>
<td>120 mg Pseudoephedrine HCl</td>
<td>36</td>
</tr>
<tr>
<td>30 mg Pseudoephedrine Sulfate</td>
<td>155</td>
</tr>
<tr>
<td>60 mg Pseudoephedrine Sulfate</td>
<td>77</td>
</tr>
<tr>
<td>120 mg Pseudoephedrine Sulfate</td>
<td>38</td>
</tr>
<tr>
<td>Phenylpropanolamine</td>
<td>FDA issued a voluntary recall on this ingredient. Veterinary use is by Rx only.</td>
</tr>
</tbody>
</table>
**CMEA: Point-of-Sale Requirements**

**Effective April 8, 2006:**
- Daily sales limit 3.6 grams per day per customer.
- Liquid quantities.

<table>
<thead>
<tr>
<th>Ingredient</th>
<th># of Milliliters (base)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.25 mg / 5 ml Ephedrine HCl</td>
<td>3,515</td>
</tr>
<tr>
<td>15 mg / 1.6 ml Pseudoephedrine HCl</td>
<td>468</td>
</tr>
<tr>
<td>7.5 mg / 5 ml Pseudoephedrine HCl</td>
<td>2,929</td>
</tr>
<tr>
<td>15 mg / 5 ml Pseudoephedrine HCl</td>
<td>1,464</td>
</tr>
<tr>
<td>15 mg / 2.5 ml Pseudoephedrine HCl</td>
<td>732</td>
</tr>
<tr>
<td>30 mg / 5 ml Pseudoephedrine HCl</td>
<td>732</td>
</tr>
<tr>
<td>30 mg / 2.5 ml Pseudoephedrine HCl</td>
<td>366</td>
</tr>
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<td>366</td>
</tr>
<tr>
<td>Phenylpropanolamine</td>
<td>FDA issued a voluntary recall on this ingredient. Veterinary use is by Rx only.</td>
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</tbody>
</table>
Mail Order Distributors

**Requirements:**
- Verify identification prior to shipping product,
- Monthly mail order reports,
- Daily sales limit of 3.6 grams, and
- 30-day sales limit of 7.5 grams.

**Not Required:**
- Self-certification,
- Employee training, and
- Maintaining a logbook.
Mail order distributors **must** verify identity of purchasers and recipients *(if different than purchaser)*, prior to shipping product.

Identity verified by purchaser providing copy of ID to mail order distributor prior to shipment of product.

- Law / regulations do not stipulate how ID must be provided. Some examples, include:
  - Mailing,
  - Faxing, and
  - Scanning and e-mailing.
Mail order distributors must file **monthly** mail order reports regarding their sales of Scheduled Listed Chemical Products.

- Reporting requirement same as before, *except* must now specify method used to verify identity of purchaser and, where applicable, recipient.
Mail Order Sales Limits

**Daily Sales Limit:**
- 3.6 gram per purchaser regardless of the number of transactions.

**30-Day Sales Limit:**
- 7.5 grams per purchaser regardless of the number of transactions.
- 30-day sales limit per chemical product.

Refer to the charts on the next two slides for the amount of tablets or liquids that equals 3.6 and 7.5 grams.
CMEA: Mail-Order Sales (*tablets*)

- Daily sales limit 3.6 grams per day per customer.
- 30-day sales limit 7.5 grams per customer.
- Confirm identity of purchaser prior to shipping.

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Tablets (3.6 gm)(base)</th>
<th>Tablets (7.5 gm)(base)</th>
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<td>175</td>
<td>366</td>
</tr>
<tr>
<td>25 mg Ephedrine Sulfate</td>
<td>186</td>
<td>389</td>
</tr>
<tr>
<td>30 mg Pseudoephedrine HCl</td>
<td>146</td>
<td>305</td>
</tr>
<tr>
<td>60 mg Pseudoephedrine HCl</td>
<td>73</td>
<td>152</td>
</tr>
<tr>
<td>120 mg Pseudoephedrine HCl</td>
<td>36</td>
<td>76</td>
</tr>
<tr>
<td>30 mg Pseudoephedrine Sulfate</td>
<td>155</td>
<td>324</td>
</tr>
<tr>
<td>60 mg Pseudoephedrine Sulfate</td>
<td>77</td>
<td>162</td>
</tr>
<tr>
<td>120 mg Pseudoephedrine Sulfate</td>
<td>38</td>
<td>81</td>
</tr>
<tr>
<td>Phenylpropanolamine</td>
<td>FDA issued a voluntary recall on this ingredient. Veterinary use is by Rx only.</td>
<td></td>
</tr>
</tbody>
</table>
CMEA: Mail-Order Sales (liquid)

- Daily sales limit 3.6 grams per day per customer.
- 30-day sales limit 7.5 grams per customer.
- Confirm identity of purchaser prior to shipping.

<table>
<thead>
<tr>
<th>Ingredient</th>
<th># of Milliliters (3.6 gm)(base)</th>
<th># of Milliliters (7.5 gm)(base)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.25 mg / 5 ml Ephedrine HCl</td>
<td>3,515</td>
<td>7,323</td>
</tr>
<tr>
<td>15 mg / 1.6 ml Pseudoephrine HCl</td>
<td>468</td>
<td>976</td>
</tr>
<tr>
<td>7.5 mg / 5 ml Pseudoephrine HCl</td>
<td>2,929</td>
<td>6,103</td>
</tr>
<tr>
<td>15 mg / 5 ml Pseudoephrine HCl</td>
<td>1,464</td>
<td>3,051</td>
</tr>
<tr>
<td>15 mg / 2.5 ml Pseudoephrine HCl</td>
<td>732</td>
<td>1,525</td>
</tr>
<tr>
<td>30 mg / 5 ml Pseudoephrine HCl</td>
<td>732</td>
<td>1,525</td>
</tr>
<tr>
<td>30 mg / 2.5 ml Pseudoephrine HCl</td>
<td>366</td>
<td>762</td>
</tr>
<tr>
<td>60 mg / 5 ml Pseudoephrine HCl</td>
<td>366</td>
<td>762</td>
</tr>
<tr>
<td>Phenylpropanolamine</td>
<td>FDA issued a voluntary recall on this ingredient. Veterinary use is by Rx only.</td>
<td></td>
</tr>
</tbody>
</table>
30-Day Purchaser Limits

- Individual purchasers may **not** purchase more than 9.0 grams in a 30-day period, and
- Not more than 7.5 grams of the 9.0 grams may be imported through the U.S. Postal Service or private or commercial carrier.
### Purchaser 30-Day Limit (tablets)

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Tablets (7.5 gm)(base)</th>
<th>Tablets (9.0 gm)(base)</th>
</tr>
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<tbody>
<tr>
<td>25 mg Ephedrine HCl</td>
<td>366</td>
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</tr>
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<td>76</td>
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</tr>
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<td>324</td>
<td>389</td>
</tr>
<tr>
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<td>162</td>
<td>194</td>
</tr>
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<td>81</td>
<td>97</td>
</tr>
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<tr>
<td>6.25 mg / 5 ml Ephedrine HCl</td>
<td>7,323</td>
<td>8,788</td>
</tr>
<tr>
<td>15 mg / 1.6 ml Pseudoephedrine HCl</td>
<td>976</td>
<td>1,171</td>
</tr>
<tr>
<td>7.5 mg / 5 ml Pseudoephedrine HCl</td>
<td>6,103</td>
<td>7,323</td>
</tr>
<tr>
<td>15 mg / 5 ml Pseudoephedrine HCl</td>
<td>3,051</td>
<td>3,661</td>
</tr>
<tr>
<td>15 mg / 2.5 ml Pseudoephedrine HCl</td>
<td>1,525</td>
<td>1,830</td>
</tr>
<tr>
<td>30 mg / 5 ml Pseudoephedrine HCl</td>
<td>1,525</td>
<td>1,830</td>
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<tr>
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DEA’s Diversion Control Program Website
(www.DEAdiversion.usdoj.gov)

WELCOME TO THE DIVERSION CONTROL PROGRAM

Registration Number
Toll Free: 1-800-482-0539

REGISTRATION SUPPORT

New Registration Fee Effective November 1, 2006

To Apply For Initial Applications for Registration on-Line
To Apply For Renewal Applications for Registration On-Line
For Registration Changes
For Registration Cancellations
Order Forms

For Registration Matters
0-800-482-0539

WHAT’S NEW

As of October 4, 2006:
- Proposed Rule - Authorized Sources of Narcotic Raw Materials

As of September 24, 2008:
- Steinman Company
- Organic Inc.
- Macrocab Inc.
- IIN and Chemicals, Inc.
- IIN and Chemicals, Inc.
- Johnson Biotech Inc.
- Ethanol Pharmaceutical Packaging
- Endo Laboratories
- Endo Laboratories
- Cardinal Charles City Inc.
- Apoll

As of September 26, 2008:
- Informal Final Rule - Retail Sales of Scheduled Listed Chemical Products: Requirements for Certification of Registered Sellers of Scheduled Listed Chemical Products

As of September 19, 2005:
- Central Methylamphetamine Epidemic Act 2005 DEA's Questions and Answers
- Informal Rule - Retail Sales of Scheduled Listed Chemical Products: Requirements for Certification of Registered Sellers of Scheduled Listed Chemical Products
- News Release - DEA Issues Regulations to Implement the Central Methylamphetamine Epidemic Act of 2005
Combat Methamphetamine Epidemic Act 2005
(Title VII of Public Law 109-177)

NOTICE: This is an unofficial version. An official version of this publication may be obtained directly from the Government Printing Office (GPO).

- USA Patriot Improvement and Reauthorization Act 2005 (Public Law 109-177) PDF
- General Information Regarding the Combat Methamphetamine Epidemic Act 2005 PDF Version
- (GSA) Questions and Answers
- Interim Final Rule - Retail Sales of Scheduled Listed Chemical Products: Self-Certification of Regulated Sellers of Scheduled Listed Chemical Products
- Alternate Forms of Identification

October 2006

REQUIRED TRAINING AND SELF-CERTIFICATION

- Retail Vendors
  - Training Required to Sell Drug Products Containing Ephedrine, Pseudoephedrine, and Phenylpropanolamine PDF
  - Self-Certification (Only one certificate per retail store is required)
- Mobile Retail Vendors
  - Mobile Retail Vendor Training Required to Sell Drug Products Containing Ephedrine, Pseudoephedrine, and Phenylpropanolamine by Mobile Retail Vendors PDF
  - Self-Certification (Self-certification required for each location)

LAW ENFORCEMENT

- Law Enforcement Officials should contact the Webmaster at deaersionwebmaster@usdoj.gov for access to the CMEA database.
Questions?