Combat Methamphetamine Epidemic Act Update

DEA Chemical Industry Conference
September 17 – 18, 2008
Atlanta, Georgia

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Liaison and Policy Section
Office of Diversion Control
## Self-Certification Status
### as of 8/20/2008

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Merchandise Stores</td>
<td>331</td>
</tr>
<tr>
<td>Convenience Stores</td>
<td>5,541</td>
</tr>
<tr>
<td>Discount Department Stores</td>
<td>1,758</td>
</tr>
<tr>
<td>Gas Stations</td>
<td>8,666</td>
</tr>
<tr>
<td>Grocery Stores</td>
<td>4,646</td>
</tr>
<tr>
<td>Other Health &amp; Personal Care</td>
<td>175</td>
</tr>
<tr>
<td>Pharmacy and Drug Stores</td>
<td>28,957</td>
</tr>
<tr>
<td>Specialty Food Stores</td>
<td>14</td>
</tr>
<tr>
<td>Warehouse Clubs &amp; Superstores</td>
<td>4,376</td>
</tr>
</tbody>
</table>

**Total 54,375 Regulated Sellers**
## Self-Certification Status
as of 8/20/2008

### Top Ten States by Total Number

<table>
<thead>
<tr>
<th>State</th>
<th>Total Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Florida</td>
<td>4,026</td>
</tr>
<tr>
<td>California</td>
<td>3,518</td>
</tr>
<tr>
<td>Texas</td>
<td>3,150</td>
</tr>
<tr>
<td>Pennsylvania</td>
<td>2,738</td>
</tr>
<tr>
<td>Georgia</td>
<td>2,650</td>
</tr>
<tr>
<td>New York</td>
<td>2,598</td>
</tr>
<tr>
<td>North Carolina</td>
<td>2,557</td>
</tr>
<tr>
<td>Indiana</td>
<td>2,436</td>
</tr>
<tr>
<td>Michigan</td>
<td>2,195</td>
</tr>
<tr>
<td>Virginia</td>
<td>1,860</td>
</tr>
</tbody>
</table>
Self-Certification Status  
as of 8/20/2008

Top Ten States by Total Number
CMEA Interim/Final Rules

- **Retail Provisions**
  - Effective September 2006

- **Spot Market**
  - Effective June 2007

- **Import and Production Quotas**
  - Effective July 2007
CMEA Interim/Final Rules

• Elimination of Exemption for Chemical Mixtures, Ephedrine & Pseudoephedrine
  - Effective July 2007

• Assessment of Annual Need
  - Effective December 2007
Retail Provisions

- Self-certification
- Employee training & maintenance of records of training
- Daily/Monthly sales/purchase limits
- Product packaging & placement
- Logbook (written or electronic)
- Warning notice
- Customer ID
Spot Market

- Importers, exporters, brokers and traders must provide additional information to DEA on the person(s) to whom chemicals proposed to be transferred.

- After transaction completed, must provide return declaration to DEA with actual information on shipment/distribution.

- Applies to all listed chemicals.
Import and Production Quotas

- Established system for manufacturing, import, and procurement quotas for ephedrine, pseudoephedrine, and phenylpropanolamine

- Annual application process

- Applicant must be registered to handle the chemical to obtain quota

- Separate quota must be obtained for each chemical
Elimination of Exemption for Chemical Mixtures

• Removed prior exemptions for chemical mixtures containing ephedrine and/or pseudoephedrine with concentration at or below five percent

• Consistent with regulatory controls for domestic production and import of ephedrine and pseudoephedrine products
Assessment of Annual Need

- DEA published amounts for legitimate medical, scientific, research, and industrial needs of the United States

<table>
<thead>
<tr>
<th>Chemical</th>
<th>2008 Assessment (kgs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eph (for sale)</td>
<td>11,500</td>
</tr>
<tr>
<td>Eph (for conversion)</td>
<td>128,760</td>
</tr>
<tr>
<td>Pse (for sale)</td>
<td>511,100</td>
</tr>
<tr>
<td>Ppa (for sale)</td>
<td>5,545</td>
</tr>
<tr>
<td>Ppa (for conversion)</td>
<td>85,470</td>
</tr>
</tbody>
</table>
CMEA Pending Provisions

• **Self Certification Fee**
  - Proposed October 2007

• **Removal of Thresholds for PSE, PPA**
  - Proposed November 2007

• **Record Requirements for Chemical Distributors**
  - Proposed September 2007
CMEA Pending Provisions

• Registration Requirements for Imp & Man of RX drugs containing Eph, Pse, & Ppa
  ○ Proposed January 2008

• Foreign Chain of Distribution
  ○ Proposed May 2008
Self-Certification Fee

• Notice of Proposed Rulemaking to require regulated sellers to pay fee for self-certification

• Comment period closed 11/30/2007 - Seven comments received

• DEA registered pharmacies to be exempt from fee.

• Under review by DOJ
Removal of Thresholds

• NPRM to ensure DEA all transactions of importation and manufacturing involving ephedrine, pseudoephedrine, and phenylpropanolamine, are captured

• Comment period closed 01/2008 - Two comments received

• Reduce thresholds for ephedrine, pseudoephedrine, and phenylpropanolamine to zero

• Under review at DEA
Record Requirements for Chemical Distributors

- NPRM to require that manufacturers, distributors, and importers obtain and maintain the certification number issued by DEA to regulated sellers in their records of sales
- Comment period closed 11/20/2007 - Two comments received
- Under review at DEA
Registration Requirements
Imp. & Man. of RX Drugs

• NPRM proposes to amend regulations to ensure that every location that manufactures or imports ephedrine, pseudoephedrine, or phenylpropanolamine is a DEA registered manufacturer or importer.

• Comment period closed 5/30/2008 - Three comments received.

• Make possible the system of quotas and assessment of annual needs

• Under review at DEA
Foreign Chain of Distribution

- NPRM - importers to provide DEA all information known on the foreign chain of distribution from the manufacturer to the US importer

- Comment period closed 5/30/2008 - Two comments received.

- Applies to imports of ephedrine, pseudoephedrine, and phenylpropanolamine

- Under review at DEA
For Additional Information

DEA Diversion Website

www.DEAdiversion.usdoj.gov or www.dea.gov