DEA Chemical Regulatory Actions

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

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Agenda

1. Implementation of the Combat Methamphetamine Epidemic Act of 2005
2. Other chemical regulatory actions
Implementation of CMEA

- Retail sales/regulated sellers
- “Spot market” & foreign chain of distribution
- Quotas
- Others
Retail Sales/Regulated Sellers

- Interim Final Rule with Request for Comment 71 FR 56008, September 26, 2006
- Comment period ends November 27, 2006
Regulated Seller Requirements

- Self-certification
- Employee training & maintenance of records of training
- Daily sales limit
- Product packaging & placement
- Logbook requirements
- Warning notice
- Privacy protection
Self Certification

As of 10/24/2006

- 49,102 Regulated Sellers
  - 497 General Merchandise Stores
  - 2,687 Convenience Stores
  - 2,863 Discount Department Stores
  - 4,642 Gas Stations w/ Convenience Store
  - 5,974 Grocery Stores
  - 91 Other Health and Personal Care
  - 29,482 Pharmacy and Drug Stores
  - 7 Specialty Food Stores
  - 2,858 Warehouse Clubs and Superstores
Self Certification
As of 10/24/2006

Top Five States

- 3,966 Florida
- 3,001 California
- 2,755 Texas
- 2,464 New York
- 2,052 Georgia

Regional Interest

- 1,067 Kentucky
- 1,367 Indiana
Mail Order Distributor Requirements

- Verification of identity of purchaser and recipient
- Monthly mail order reports to DEA
- Daily sales limit
- 30-day sales limit
“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.
Foreign Chain of Distribution

- Importers must provide to DEA all information known to the importer on the foreign chain of distribution from the manufacturer to the US importer.
- Attorney General may seek other information from foreign manufacturers.
- Applies to imports of ephedrine, pseudoephedrine, and phenylpropanolamine.
Quotas

- CMEA requires establishment of production quotas for ephedrine, pseudoephedrine, phenylpropanolamine

- CMEA establishes import quotas for ephedrine, pseudoephedrine, phenylpropanolamine

- DEA must publish regulations to implement procedures for issuance of individual manufacturing and import quotas

- Publication of proposed Assessment of Annual Needs
DEA must ensure that all persons who will need to apply for quota are registered with DEA to handle ephedrine, pseudoephedrine, phenylpropanolamine
To ensure that DEA is aware of all importation and manufacturing involving ephedrine, pseudoephedrine, and phenylpropanolamine, all transactions must be captured.

Thresholds for ephedrine, pseudoephedrine, and phenylpropanolamine must be removed – reduced to zero.
Other Regulatory Activities

- Sodium permanganate
- Iodine
Sodium Permanganate

- Final Rule 71 FR 60823, October 17, 2006
- Effective December 18, 2006
- Controls sodium permanganate as a List II chemical
Sodium Permanganate

- 55 kg threshold for domestic transactions
- 500 kg threshold for import, export, international transactions
- Chemical mixtures with concentration limits greater than 15% subject to control
Iodine

- Notice of Proposed Rulemaking 71 FR 46144, August 11, 2006
- Comment period closed October 10, 2006
Proposed moving iodine from List II to List I

Proposed reducing threshold from 0.4 kg to zero kg – no threshold

Proposed addition of import, export, international transaction controls

Proposed chemical mixtures with concentration limits greater than 2.2% be subject to control