

Combat Methamphetamine Epidemic Act Update

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



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Self-Certification Status

as of 8/20/2008

General Merchandise Stores	331
Convenience Stores	5,541
Discount Department Stores	1,758
Gas Stations	8,666
Grocery Stores	4,646
Other Health & Personal Care	175
Pharmacy and Drug Stores	28,957
Specialty Food Stores	14
Warehouse Clubs & Superstores	4,376

Total 54,375 Regulated Sellers

Self-Certification Status

as of 8/20/2008

Top Ten States by Total Number

Florida	4,026
California	3,518
Texas	3,150
Pennsylvania	2,738
Georgia	2,650
New York	2,598
North Carolina	2,557
Indiana	2,436
Michigan	2,195
Virginia	1,860

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

Chemical	2008 Assessment (kgs)
Eph (for sale)	11,500
Eph (for conversion)	128,760
Pse (for sale)	511,100
Ppa (for sale)	5,545
Ppa (for conversion)	85,470

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

DEA Diversion Website

The screenshot shows the homepage of the DEA Office of Diversion Control. At the top, it features the U.S. Department of Justice Drug Enforcement Administration logo and the text "OFFICE OF DIVERSION CONTROL". Below this is a navigation bar with links for HOME, PRIVACY POLICY, CONTACT US, WHAT'S NEW, HOT ITEMS, SITEMAP, and SEARCH.

The main content area is divided into three columns:

- Left Column:** Contains a "DIVERSION PROGRAMS" menu with links to APPLICATIONS & ON-LINE FORMS, ARCOS, CHEMICALS, CONTROLLED SUBSTANCE SCHEDULES, IMPORT AND EXPORT, IFLIS, QUOTAS, REGISTRATION SUPPORT, and REPORTS REQUIRED BY 21 CFR. Below this is a "RESOURCES" section with links to CAREER OPPORTUNITIES, DRUGS/CHEMICALS OF CONCERN, e-COMMERCE INITIATIVES, FEDERAL REGISTER NOTICES, MEETINGS & EVENTS, OFFICES & DIRECTORIES, PROGRAM DESCRIPTION, PUBLICATIONS, QUESTIONS & ANSWERS, and REGULATIONS & CODIFIED CSA. A "LINKS" section follows with links to FEDERAL AGENCIES & RELATED, INDUSTRY RELATED, and PUBLIC INTEREST. At the bottom of the left column are two boxes: "REGISTRATION VALIDATION" and "CASES AGAINST DOCTORS".
- Middle Column:** Features a "WELCOME TO THE DIVERSION CONTROL PROGRAM" message with the registration number and toll-free number (1-800-882-9539). Below this is a "REGISTRATION SUPPORT" section with a "SAVE TIME" graphic and text encouraging on-line applications. A "NEW REGISTRATION FEE EFFECTIVE NOVEMBER 1, 2006" notice is also present. At the bottom of the middle column is a "WHAT'S NEW" section with a list of updates: "To Apply for Renewal Applications for Registration On-Line", "To Apply for New Applications for Registration On-Line", "To Apply for Registration by Mail", "For Registration Changes (Address, Drug Codes, Name, Schedules)", "Duplicate Certificates", and "Order Forms".
- Right Column:** Contains several promotional boxes: "RENEWAL Apply On-Line REGISTRATION APPLICATIONS Renewal Applications", "NEW APPLICATIONS FOR REGISTRATION New Registration Applications", "DEA FORM 104 ONLINE REPORT THEFT OR LOSS OF CONTROLLED SUBSTANCES", and "Sales of Ephedrine & Pseudoephedrine Products COMBAT METH ACT 2005 Combat Methamphetamine Epidemic Act 2005".

For Additional Information

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

Comments / Questions?

