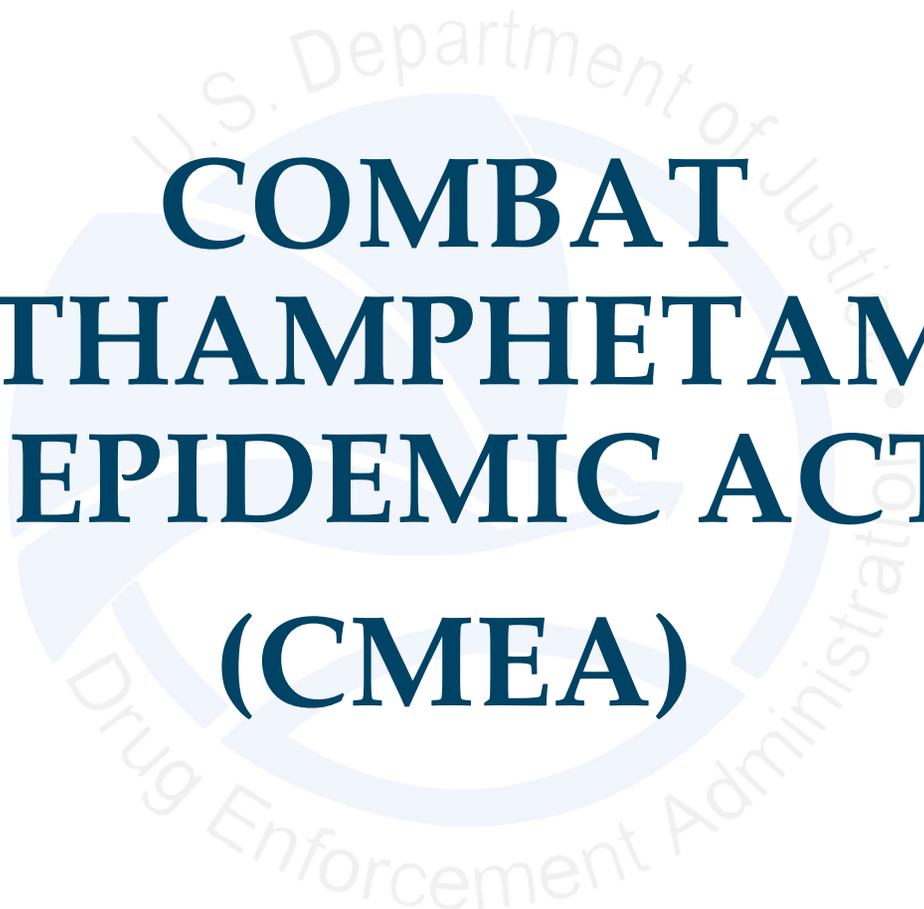


Combat Methamphetamine Epidemic Act of 2005

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**
 - Once an application has been submitted to DEA, print out a certificate.
 - Alternatively, you can request that a certificate be mailed to you.

Availability of Self-Certification Information

- **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.

Product Packaging and Placement

- **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.

Display of Warning Notice

- 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 Notice Text

- **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.

Disclosure of Logbook Information

- **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.**

Daily Sales Limit

- 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.

Ingredient	# of Tablets (base)
25 mg Ephedrine HCl	175
25 mg Ephedrine Sulfate	186
30 mg Pseudoephedrine HCl	146
60 mg Pseudoephedrine HCl	73
120 mg Pseudoephedrine HCl	36
30 mg Pseudoephedrine Sulfate	155
60 mg Pseudoephedrine Sulfate	77
120 mg Pseudoephedrine Sulfate	38
Phenylpropanolamine	FDA issued a voluntary recall on this ingredient. Veterinary use is by Rx only.

CMEA: Point-of-Sale Requirements

● Effective April 8, 2006:

- Daily sales limit 3.6 grams per day per customer.
- Liquid quantities.

Ingredient	# of Milliliters (base)
6.25 mg / 5 ml Ephedrine HCl	3,515
15 mg / 1.6 ml Pseudoephedrine HCl	468
7.5 mg / 5 ml Pseudoephedrine HCl	2,929
15 mg / 5 ml Pseudoephedrine HCl	1,464
15 mg / 2.5 ml Pseudoephedrine HCl	732
30 mg / 5 ml Pseudoephedrine HCl	732
30 mg / 2.5 ml Pseudoephedrine HCl	366
60 mg / 5 ml Pseudoephedrine HCl	366
Phenylpropanolamine	FDA issued a voluntary recall on this ingredient. Veterinary use is by Rx only.

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.

Verification of Identities

- 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.

Monthly Mail Order Report

- **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.

Ingredient	Tablets (3.6 gm)(base)	Tablets (7.5 gm)(base)
25 mg Ephedrine HCl	175	366
25 mg Ephedrine Sulfate	186	389
30 mg Pseudoephedrine HCl	146	305
60 mg Pseudoephedrine HCl	73	152
120 mg Pseudoephedrine HCl	36	76
30 mg Pseudoephedrine Sulfate	155	324
60 mg Pseudoephedrine Sulfate	77	162
120 mg Pseudoephedrine Sulfate	38	81
Phenylpropanolamine	FDA issued a voluntary recall on this ingredient. Veterinary use is by Rx only.	

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.

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

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*)

Ingredient	Tablets (7.5 gm)(base)	Tablets (9.0 gm)(base)
25 mg Ephedrine HCl	366	439
25 mg Ephedrine Sulfate	389	466
30 mg Pseudoephedrine HCl	305	366
60 mg Pseudoephedrine HCl	152	183
120 mg Pseudoephedrine HCl	76	91
30 mg Pseudoephedrine Sulfate	324	389
60 mg Pseudoephedrine Sulfate	162	194
120 mg Pseudoephedrine Sulfate	81	97
Phenylpropanolamine	FDA issued a voluntary recall on this ingredient. Veterinary use is by Rx only.	

Purchaser 30-Day Limit (*liquid*)

Ingredient	# of Milliliters (7.5 gm)(base)	# of Milliliters (9.0 gm)(base)
6.25 mg / 5 ml Ephedrine HCl	7,323	8,788
15 mg / 1.6 ml Pseudoephedrine HCl	976	1,171
7.5 mg / 5 ml Pseudoephedrine HCl	6,103	7,323
15 mg / 5 ml Pseudoephedrine HCl	3,051	3,661
15 mg / 2.5 ml Pseudoephedrine HCl	1,525	1,830
30 mg / 5 ml Pseudoephedrine HCl	1,525	1,830
30 mg / 2.5 ml Pseudoephedrine HCl	762	915
60 mg / 5 ml Pseudoephedrine HCl	762	915
Phenylpropanolamine	FDA issued a voluntary recall on this ingredient. Veterinary use is by Rx only.	

DEA's Diversion Control Program Website (www.DEAdiversion.usdoj.gov)

U.S. DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
OFFICE OF DIVERSION CONTROL

HOME PRIVACY POLICY CONTACT US WHAT'S NEW HOT ITEMS SITEMAP SEARCH

DIVERSION PROGRAMS
APPLICATIONS & ON-LINE FORMS
ARCOS
CHEMICALS
CONTROLLED SUBSTANCE SCHEDULES
IMPORT AND EXPORT
HELIS
QUOTAS
REGISTRATION SUPPORT
REPORTS REQUIRED BY 21 CFR

RESOURCES
CAREER OPPORTUNITIES
DRUGS/CHEMICALS OF CONCERN
E-COMMERCE INITIATIVES
FEDERAL REGISTER NOTICES
MEETINGS & EVENTS
OFFICES & DIRECTORIES
PROGRAM DESCRIPTION
PUBLICATIONS
QUESTIONS & ANSWERS
REGULATIONS & CODIFIED CSA

LINKS
FEDERAL AGENCIES & RELATED INDUSTRY RELATED
PUBLIC INTEREST

REGISTRATION VALIDATION

CASES AGAINST DOCTORS

REGULATIONS.GOV

DEA.COM.GOV CSOS Controlled Substance Ordering System

To view PDF documents
Adobe Get Acrobat

External links included in this website should not be construed as an official endorsement of the views contained therein.

WELCOME TO THE DIVERSION CONTROL PROGRAM

Registration Number
Toll Free: 1-800-882-9539

REGISTRATION SUPPORT

Save time by applying for and/or renewing your DEA Registration on-line. Data will be entered through a secure connection to the ODWIF on-line web application system. Minimum requirements: Credit Card and a web browser that supports 128-bit encryption.

NEW REGISTRATION FEE EFFECTIVE NOVEMBER 1, 2006

- 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
- Order Forms

For Registration Matters
1-800-882-9539

WHAT'S NEW

As of October 4, 2006

- Proposed Rule - Authorized Sources of Narcotic Raw Materials

As of September 29, 2006

- Stepan Company
- Organix Inc.
- Mallinckrodt Inc.
- Lilly Del Caribe, Inc.
- Abbott Laboratories
- Johnson Matthey Inc.
- Dakota Pharmaceutical Packaging
- Cambridge Isotope Lab
- Cambrex Charles City, Inc.
- Cambrex Charles City, Inc.
- Aptuit

As of September 26, 2006

- Interim Final Rule - Retail Sales of Scheduled Listed Chemical Products; Self-Certification of Regulated Sellers of Scheduled Listed Chemical Products

As of September 19, 2006

- Combat Methamphetamine Epidemic Act 2005 (Q&A's) Questions and Answers
- Interim Rule - Retail Sales of Scheduled Listed Chemical Products; Self-Certification of Regulated Sellers of Scheduled Listed Chemical Products
- News Release - DEA Issues Regulations to Implement the Combat Methamphetamine Epidemic Act of 2005

RENEWAL
Apply On-Line
REGISTRATION APPLICATIONS
Renewal Applications

NEW APPLICATIONS FOR REGISTRATION
New Registration Applications

DEA FORM 106 ONLINE
REPORT THEFT OR LOSS OF CONTROLLED SUBSTANCES

Sales of Ephedrine & Pseudoephedrine Products
COMBAT METH ACT 2005
Combat Methamphetamine Epidemic Act 2005

ORDER FORMS ON-LINE
Order Forms

DUPLICATE CERTIFICATE
REQUEST ADDITIONAL *REPLACED* *ILLEGIBLE* OR *DESTROYED* ORIGINALS
Duplicate Certificate

Report Suspicious Internet Pharmacies
1-877-RXABUSE
1-877-792-2873

Some Internet sites facilitate the illegal sale of prescription drugs. Find out if you are **ILLEGALLY** purchasing prescription drugs.



DEA Diversion's CMEA Webpage



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FEDERAL REGISTER NOTICES
MEETINGS & EVENTS
OFFICES & DIRECTORIES
PROGRAM DESCRIPTION
PUBLICATIONS
QUESTIONS & ANSWERS
REGULATIONS & CODIFIED CSA

LINKS
FEDERAL AGENCIES & RELATED INDUSTRY RELATED
PUBLIC INTEREST



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](#)
- [\(O&A's\) Questions and Answers](#)
- [Interim Final Rule - Retail Sales of Scheduled Listed Chemical Products; Self-certification of Regulated Sellers of Scheduled Listed Chemical Products](#)
- [News Release - DEA Issues Regulations to Implement the Combat Methamphetamine Epidemic Act of 2005 \(September 19, 2006\)](#)
- [Alternate Forms of Identification](#)

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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 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)

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LAW ENFORCEMENT

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



Questions?