General Information Regarding
The Combat Methamphetamine Epidemic Act of 2005
[Title VII of Public Law 109-177]

Drug Enforcement Administration
*May **2006***

The Combat Methamphetamine Epidemic Act of 2005 (Title VII of the USA PATRIOT Improvement and Reauthorization Act of 2005, P.L. 109-177) was signed into law March 9, 2006. All changes go into effect on March 9, 2006, (date the legislation was signed) unless a later effective date is specifically stated. This document discusses those changes made by the Combat Methamphetamine Epidemic Act which primarily affect persons selling products containing the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. Other actions taken by the Combat Methamphetamine Epidemic Act are not discussed here.

Effective March 9, 2006

The Act makes definitional changes to add "scheduled listed chemical product," "regulated seller," "mobile retail vendor," "at retail," and to modify the existing definition of "retail distributor." Definitions are as follows:

"The term *scheduled listed chemical product* means,…a product that—

(i) contains ephedrine, pseudoephedrine, or phenylpropanolamine; and
(ii) may be marketed or distributed lawfully in the United States under the Federal, Food, Drug, and Cosmetic Act as a nonprescription drug.

Each reference in clause (i) to ephedrine, pseudoephedrine, or phenylpropanolamine includes each of the salts, optical isomers, and salts of optical isomers of such chemical."

"The term *regulated seller* means a retail distributor (including a pharmacy or a mobile retail vendor), except that such term does not include an employee or agent of such distributor."

"The term *mobile retail vendor* means a person or entity that makes sales at retail from a stand that is intended to be temporary, or is capable of being moved from one location to another, whether the stand is located within or on the premises of a fixed facility (such as a kiosk at a shopping center or an airport) or whether the stand is located on unimproved real estate (such as a lot or field leased for retail purposes)."

"The term *at retail*, with respect to the sale or purchase of a scheduled listed chemical product, means a sale or purchase for personal use, respectively."

"The term *retail distributor* means a grocery store, general merchandise store, drug store, or other entity or person whose activities as a distributor relating to pseudoephedrine or

phenylpropanolamine products are limited almost exclusively to sales for personal use, both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales."

Effective April 8, 2006

a. The change to 21 U.S.C. § 830 that adds a new subsection (d) SCHEDULED LISTED CHEMICALS; RESTRICTIONS ON SALES QUANTITY; REQUIREMENTS REGARDING NONLIQUID FORMS:

i. This sets the daily sales limit of ephedrine base, pseudoephedrine base, or phenylpropanolamine base at 3.6 grams per purchaser, regardless of the number of transactions.

ii. Affects regulated sellers and persons required to submit mail order reports under 21 U.S.C. 830(b)(3).

iii. Requires all nonliquid forms (including gel caps) to be in 2-unit blister packs (with exception when blister pack is not technically feasible, the product may be in unit dosage packets or pouches).

b. The change to 21 U.S.C. § 830 that adds (2) MAIL-ORDER REPORTING; VERIFICATION OF IDENTITY OF PURCHASER; 30-DAY RESTRICTION ON QUANTITIES FOR INDIVIDUAL PURCHASES:

i. This requires the mail-order seller to confirm the identity of the purchaser prior to shipping the product.

ii. Limits such sales to 7.5 grams per customer during a 30-day period.

c. The change to 21 U.S.C. § 844(a) entitled RESTRICTIONS ON QUANTITY PURCHASED DURING 30-DAY PERIOD:

i. This makes it unlawful for any person to knowingly or intentionally purchase at retail more than 9 grams during a 30 day period (of which no more than 7.5 grams can be imported by private or commercial carrier or the Postal Service).

Effective September 30, 2006

Sales limits

a. A mobile retail vendor may not sell more than 7.5 grams of product per customer during a 30-day period.

Product Placement

b. Regulated seller must place product such that customers do not have direct access before the sale is made ("behind the counter" placement) or in a locked cabinet that is located in an area of the facility to which customers do have direct access. Regulated seller must deliver product directly into the custody of the purchaser.

c. A mobile retail vendor must place product in a locked cabinet.

Logbook Provisions

d. Seller maintains written or electronic list (logbook) of sales that identifies:

(1) Products by name;

(2) Quantity sold;

(3) Names and addresses of purchasers; and,

(4) Date and time of the sales.

The logbook requirement does not apply to any purchase by an individual of a single sales package that contains not more than 60 mg. of pseudoephedrine.

e. Seller may not sell the product unless prospective purchaser presents a photographic identification card issued by a State or the Federal Government, or a document considered acceptable for purposes of 8 CFR § 274a.2(b)(1)(v)(A) or (B).

f. Purchaser must sign the logbook and enter his or her name, address, and date and time of sale.

g. Seller must determine that the name entered into the logbook corresponds to the name provided on such identification and that the date and time entered are correct.

h. Seller must enter into the logbook the name of the product and the quantity sold.

i. The logbook must contain a notice to purchasers that entering false statements or misrepresentations in the logbook may subject the purchaser to criminal penalties under 18 U.S.C. § 1001 and such notice must specify the maximum fine ($250,000.00) and term of imprisonment (5 years).

j. Seller must maintain each entry in the logbook for not fewer than two years after the date on which the entry is made.

k. The Attorney General will issue regulations establishing restrictions on disclosure of information in logbooks. Disclosure to the Attorney General and to State and local law enforcement agencies will be authorized. Accessing, using, or sharing the logbook

information for any purpose other than to comply with the Controlled Substances Act or to facilitate a product recall to protect public health and safety will be prohibited.

l. Regulated seller who in good faith releases logbook information to Federal, State or local law enforcement authorities is immune from civil liability for such release unless the release constitutes gross negligence or intentional, wanton, or willful misconduct.

Self-Certification and Training

m. Self-certification and training.

(1) Seller must self-certify to the Attorney General that each individual who is responsible for delivering such products into the custody of purchasers, or who deals directly with purchasers by obtaining payment for the products, has undergone training provided by the seller to ensure that the individual understands the requirements that apply to the sale of these products.

(2) Regulated seller may not sell any scheduled listed chemical product at retail unless the self-certification has been submitted to the Attorney General.

(3) Seller must maintain a copy of such self-certification and records demonstrating that individuals have undergone such training.

(4) The certification is not effective unless, in addition to provisions regarding the training of individuals, the certification includes a statement that the seller understands each of the requirements regarding transactional limits, blister-packs, “behind the counter” placement, photo identification, and logbook also apply and agrees to comply with the requirements.

(5) The Attorney General will issue regulations to establish the criteria for self-certifications and employee training. Separate certification is required for each place of business at which a regulated seller sells such products at retail.

(6) The Attorney General will establish a program that will:

(a) be carried out through an Internet site of the Department of Justice;
(b) inform regulated sellers that 18 U.S.C. § 1001 applies to such certifications;
(c) make available to sellers the criteria for certification and training;
(d) be designed to permit submission of certifications through the Internet site; and
(e) be designed to automatically provide the explanation of the criteria for certification and training and an acknowledgment that the Department of Justice has received a certification, without requiring direct interaction of regulated sellers with staff of the Department of Justice.

(7) Copies of certifications shall be made available to appropriate State and local officials.

Equivalency Charts

The following is not found within DEA law or regulations; DEA provides this for informational purposes only:

A. Effective April 8, 2006, the daily sales limit of ephedrine base, pseudoephedrine base, or phenylpropanolamine base is 3.6 grams per purchaser, regardless of number of transactions.

Ingredient	Number of Tablets [as 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	The Food and Drug Administration issued a voluntary recall of this ingredient as being unsafe for human consumption. Veterinary use is by prescription only.

Ingredient	Number of Milliliters (ml) [as base]
6.25 mg/5 ml Ephedrine HCl	3515
15 mg/1.6 ml Pseudoephedrine HCl	468
7.5 mg/5 ml Pseudoephedrine HCl	2929
15 mg/5 ml Pseudoephedrine HCl	1464
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	The Food and Drug Administration issued a voluntary recall of this ingredient as being unsafe for human consumption. Veterinary use is by prescription only.

B. Effective April 8, 2006, for mail-order sellers, sales are limited to 7.5 grams per customer during a 30-day period.

Ingredient	Number of tablets [as base]
25 mg Ephedrine HCl	366
25 mg Ephedrine Sulfate	389
30 mg Pseudoephedrine HCl	305
60 mg Pseudoephedrine HCl	152
120 mg Pseudoephedrine HCl	76
30 mg Pseudoephedrine Sulfate	324
60 mg Pseudoephedrine Sulfate	162
120 mg Pseudoephedrine Sulfate	81
Phenylpropanolamine	The Food and Drug Administration issued a voluntary recall of this ingredient as being unsafe for human consumption. Veterinary use is by prescription only.

Ingredient	Number of Milliliters (ml) [as base]
6.25 mg/5 ml Ephedrine HCl	7323
15 mg/1.6 ml Pseudoephedrine HCl	976
7.5 mg/5 ml Pseudoephedrine HCl	6103
15 mg/5 ml Pseudoephedrine HCl	3051
15 mg/2.5 ml Pseudoephedrine HCl	1525
30 mg/5 ml Pseudoephedrine HCl	1525
30 mg/2.5 ml Pseudoephedrine HCl	762
60 mg/5 ml Pseudoephedrine HCl	762
Phenylpropanolamine	The Food and Drug Administration issued a voluntary recall of this ingredient as being unsafe for human consumption. Veterinary use is by prescription only.

C. Effective April 8, 2006, it is unlawful for any person to knowingly or intentionally purchase at retail more than 9 grams during a 30-day period (of which no more than 7.5 grams can be imported by private or commercial carrier or the Postal Service).

Ingredient	Number of tablets (7.5 gm) [as base]	Number of tablets (9 gm) [as 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	The Food and Drug Administration issued a voluntary recall of this ingredient as being unsafe for human consumption. Veterinary use is by prescription only.	

Ingredient	Number of milliliters (ml) (7.5 gm) [as base]	Number of milliliters (9 gm) [as base]
6.25 mg/5 ml Ephedrine HCl	7323	8788
15 mg/1.6 ml Pseudoephedrine HCl	976	1171
7.5 mg/5 ml Pseudoephedrine HCl	6103	7323
15 mg/5 ml Pseudoephedrine HCl	3051	3661
15 mg/2.5 ml Pseudoephedrine HCl	1525	1830
30 mg/5 ml Pseudoephedrine HCl	1525	1830
30 mg/2.5 ml Pseudoephedrine HCl	762	915
60 mg/5 ml Pseudoephedrine HCl	762	915
Phenylpropanolamine	The Food and Drug Administration issued a voluntary recall of this ingredient as being unsafe for human consumption. Veterinary use is by prescription only.	

D. Effective September 30, 2006, for mobile retail vendors, sales are limited to 7.5 grams per customer during a 30-day period.

Ingredient	Number of tablets [as base]
25 mg Ephedrine HCl	366
25 mg Ephedrine Sulfate	389
30 mg Pseudoephedrine HCl	305
60 mg Pseudoephedrine HCl	152
120 mg Pseudoephedrine HCl	76
30 mg Pseudoephedrine Sulfate	324
60 mg Pseudoephedrine Sulfate	162
120 mg Pseudoephedrine Sulfate	81
Phenylpropanolamine	The Food and Drug Administration issued a voluntary recall of this ingredient as being unsafe for human consumption. Veterinary use is by prescription only.

Ingredient	Number of Milliliters (ml) [as base]
6.25 mg/5 ml Ephedrine HCl	7323
15 mg/1.6 ml Pseudoephedrine HCl	976
7.5 mg/5 ml Pseudoephedrine HCl	6103
15 mg/5 ml Pseudoephedrine HCl	3051
15 mg/2.5 ml Pseudoephedrine HCl	1525
30 mg/5 ml Pseudoephedrine HCl	1525
30 mg/2.5 ml Pseudoephedrine HCl	762
60 mg/5 ml Pseudoephedrine HCl	762
Phenylpropanolamine	The Food and Drug Administration issued a voluntary recall of this ingredient as being unsafe for human consumption. Veterinary use is by prescription only.