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USA PATRIOT ACT – TITLE VII "COMBAT METHAMPHETAMINE EPIDEMIC ACT OF 2005"

UPDATED SUMMARY

<u>Introduction</u>: On March 9, 2006, President Bush signed into law the USA Patriot Act, Title VII of which is the Combat Methamphetamine Epidemic Act of 2005. Following is a summary of the key Title VII requirements governing the retail sale of all cough and cold products that contain the methamphetamine precursor chemicals ephedrine, pseudoephedrine or phenylpropanolamine, collectively referred to here as PSE or PSE products, for simplicity. (See also, "Products Covered," below).

Requirements Effective April 8, 2006:

- 1. <u>Daily Sales Limit on Retailers</u>: Retail sales may not exceed 3.6 grams PSE per day per purchaser, regardless of the number of transactions. Retailers are *not* required to consult a logbook to determine whether the sales limitation is exceeded in any particular case. (See attached memorandum from Hogan & Hartson)
- 2. <u>30-Day Purchase Limit on Consumers</u>: Individuals are prohibited from purchasing more than 9 g PSE per 30 day period. The federal statute does *not* impose liability on retailers with respect to the monthly purchase limit. (See attached memorandum from Hogan & Hartson)
- 3. <u>Non-Liquid Forms</u>: All non-liquid forms (including gel caps) of PSE products must be sold in blister packs with no more than 2 dosages or in unit dose packets or pouches.
- 4. <u>Mail Order Limits</u>: Mail order companies may not sell more than 7.5 grams to a customer within a 30 day period.

Requirements Effective September 30, 2006:

- 1. **Behind-the-Counter Placement**: All PSE products must be placed behind a counter (any counter) that is not accessible to purchasing consumers or in a locked display case that is located on the selling floor. Retailers must give the product directly to the purchaser.
- 2. <u>Logbook</u>: Retailers must maintain a logbook of information on transactions involving PSE products. The logbook may be maintained in either written or electronic form. (See "Logbook Requirements," below.)
- 3. **Photo ID:** In conjunction with the logbook requirement, retailers will be required to ask for photo identification, issued by either a State or the Federal Government or other appropriate identification.
- 4. <u>Training & Certification</u>: Retailers must train applicable sales personnel to ensure that they understand the requirements of PSE product sales and submit self-certifications to the Attorney General in this regard. (See "Training & Certification Requirements," below).

EXPLANATION OF REQUIREMENTS

<u>Products Covered</u>: All PSE products, including liquids, gel caps and pediatrics, are subject to the provisions of the law. Products reformulated so that they no longer contain these precursors may be sold without regard to the new statutory provisions. Moreover, the Attorney General may grant an exemption for a product if the Attorney General determines that the product cannot be used in the illicit manufacture of methamphetamine.

Logbook Requirements: (Effective September 30, 2006)

- 1. **Information Required:** Logbooks must capture the following information for all PSE products:
 - a. Purchaser's signature;
 - b. Purchaser's name and address;
 - c. Date and time of sale;
 - d. Name of product sold; and
 - e. Quantity sold.
- 2. **False Statements Notice**: Logbooks must provide notice to purchasers that entering false statements or misrepresentations in the logbook may subject purchasers to criminal penalties under 18 U.S.C. Section 1001 and specify the maximum fine and term of imprisonment under that section.

3. **Purchasers' Obligations:**

- a. Sign the logbook and
- b. Enter name, address, and date/time of sale.

4. **Retailers' Obligations:**

- a. Check information entered by purchaser against photo ID and
- b. Enter name of product sold and quantity.
- 5. **Exemption**: Logbook requirements do not apply to purchases of single sales packages that contain no more than 60 mg of pseudoephedrine.
- 6. **Format**: Written or electronic.
- 7. **2-Year Retention Period**: Each entry must be maintained for two (2) years following the date of entry.

8. **Privacy**.

- a. DEA will issue regulations governing the release of logbook information. The regulations will provide for the following:
 - i. Information may be disclosed to federal, state and local law enforcement agencies;
 - ii. Logbook information disclosure is only permitted to ensure compliance with this title or to facilitate a product recall to protect public health or safety.
- b. **Immunity.** A retailer who releases logbook information in good faith to federal, state or local law enforcement authorities is immune from civil liability.

Retailer Training and Certification: (Effective September 30, 2006)

1. Training:

- a. **Individuals to be trained.** Retailers must train all individuals who deliver PSE-products to purchasers and cashiers who receive payments for PSE-products to ensure that these persons understand the requirements that apply.
- b. Criteria. DEA will issue regulations on the training criteria.

2. **Training Certification:**

- a. Retailers must certify that all retail store employees who conduct PSE sales transactions have been trained.
- b. Retailers must maintain certifications and records to confirm employee training.

- c. Certifications must state that the retailer understands the legal requirements and agrees to comply with them.
- d. Separate certifications are required for each place of business.
- e. DEA will establish certification criteria through the regulatory process, but must provide for self-certifications.
- f. State and local officials will have access to certifications.
- 3. **Implementation:** Retailers will be able to submit self-certifications over an internet website to be established by DEA and receive an acknowledgement of that submission

<u>Consequences</u>: The Attorney General may prohibit persons who sell products in violation of the sales restrictions or the logbook, training, and certification requirements from selling any scheduled listed chemical products.

Job Applicant Screening: Retail stores may take *reasonable measures* to guard against employing individuals who may present a risk with respect to the theft and diversion of PSE products, including asking job applicants whether they have been convicted of any crime involving or related to PSE products or controlled substances.

Mail Order: As of April 8, 2006, mail order sales of PSE products will be limited to 7.5 grams PSE per customer during a 30-day period. Prior to shipping, the seller must verify the identity of the purchaser in accordance with regulations to be issued by the Department of Justice. Mail orders that must be reported to the Attorney General are not subject to the logbook, training or certification requirements. Retail distributors who are otherwise exempt from the current AG reporting requirement must, however, report transactions related to PSE products.

<u>Pre-emption</u>: The Combat Methamphetamine Epidemic Act of 2005 **does not** provide for federal pre-emption, so state laws that are more restrictive than the federal law will remain in effect. This is an area that is likely to generate intense debate as those who operate in states with their own sales restrictions attempt to determine which law controls. DEA has advised that they are evaluating the state laws and would like to take the position that, in each instance, either the state law in its entirety or the federal law in its entirety controls, rather than "patchworking" different provisions from the state and federal law together. As of this writing, no definitive position has been adopted by the federal government. However, even once the federal government has rendered an interpretation, state governments may take a contrary view. Accordingly, it will be important for retailers to monitor closely developments on the federal, state and local levels with respect to these laws.

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MEMORANDUM

March 30, 2006

BY ELECTRONIC MAIL

TO: Deborah R. White

Food Marketing Institute

FROM: Joseph A. Levitt

Jaime T. Gallimore

RE: Retailer Liability under the Combat Methamphetamine

Epidemic Act of 2005

I. Introduction

You have asked us to review and analyze the scope of retailer liability in the Combat Methamphetamine Epidemic Act of 2005 ("Combat Meth Act"), which was enacted as Section VII of the USA Patriot Improvement and Reauthorization Act of 2005 (Pub. L. No. 109-177) (Mar. 9, 2006).

In relevant part, the Combat Meth Act contains sales and purchase restrictions on FDA-approved, nonprescription "scheduled listed chemical products" that contain ephedrine, pseudoephedrine, or phenylpropanolamine. This new legislation amends various sections of the existing Controlled Substances Act, 21 U.S.C. 801 et seq., the comprehensive federal law regulating the manufacture and distribution of controlled substances and chemicals to prevent abuse or diversion into illicit channels of commerce.

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This memorandum only addresses federal statutory standards for over-the-counter products containing ephedrine, pseudoephedrine, or phenylpropanolamine. It is important to note that the Combat Meth Act does not pre-empt state laws regulating listed chemicals or controlled substances that are more restrictive than the federal law. Many states have passed their own statutes imposing limitations on the retail sales of these products. These state laws may have different or more restrictive rules and/or penalties. Retailers should be aware of both the federal and any applicable state or local laws.

II. Summary of Key Points

- The Combat Meth Act contains **separate** provisions for: (a) retailers; and (b) consumer purchasers.
 - o The **3.6 gram daily** sales limitation is a **retailer** limitation.
 - The 9 grams per 30 day limitation is a consumer purchaser limitation.

These provisions are independent of each other and carry different penalties.

- The requirement for the **logbook** is solely a recordkeeping requirement for access by governmental law enforcement officials. Retailers are expressly **not** required to consult the logbook for purposes of implementing the 3.6 gram daily sales limitation.
- Civil and criminal penalties on retailers are tied to **knowing** or **reckless** violations of the **statutory provisions**.

III. Relevant Provisions of the Combat Meth Act

A. Retailer Sales Restrictions

Two particular sections of the Combat Meth Act apply to retailers or "regulated sellers" of scheduled listed chemical products. Section 711(b)(1) requires that: (1) retail sales to any purchaser must not exceed a daily amount of 3.6 grams of a product with a base of ephedrine, pseudoephedrine, or phenylpropanolamine; and (2) all non-liquid forms (including gel caps) of scheduled listed chemical products must be sold in blister packs with no more than 2 dosage units or in unit dose packets or pouches. 21 U.S.C. 830(d)(1), (2). Both of these provisions take effect thirty days after the March 9, 2006 passage date, or April 8, 2006.

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Section 711(b)(1) also adds a new paragraph (e) to Section 310 of the Controlled Substances Act, which is entitled "Regulation of listed chemicals and certain machines." 21 U.S.C. 830. Paragraph (e) sets various restrictions on retail transactions of scheduled listed chemical products. Some of these restrictions include: (1) placement of products "behind-the-counter" away from direct consumer access; (2) creation and maintenance of logbooks detailing each transaction and purchaser of scheduled listed chemical products; (3) photo identification confirmation prior to purchase; (4) privacy protection of logbook information; and (5) personnel training and related self-certifications to the Attorney General. These provisions apply as of September 30, 2006.

B. <u>Consumer Purchase Restrictions</u>

In addition to the 3.6 grams daily quantity sales restriction, the law also restricts the quantity that consumers may purchase at retail during a 30-day period to 9 grams of a product with a base of ephedrine, pseudoephedrine, or phenylpropanolamine.

This restriction, which is contained in Section 711(e), is completely separate from the retailer provisions in Section 711(b), and it amends a different section of the Controlled Substances Act (Section 404(a)), entitled "Penalties for simple possession." 21 U.S.C. 844(a). This provision is effective thirty days after the March 9, 2006 passage date, or April 8, 2006.

IV. Enforcement and Penalties

A. Retailer Restrictions

A separate section of the Combat Meth Act -- Section 711(f) entitled *Enforcement of Requirements for Retail Sales* -- sets forth the civil and criminal penalties attendant to the retail sales restrictions described above. This section amends Section 402(a) of the Controlled Substances Act (21 U.S.C. 842(a) ("Prohibited Acts" and applicable "Penalties") to add to its list of unlawful acts, the specific restrictions on daily sales limits of 3.6 grams, blister packaging for non-liquid forms, and retail transaction requirements, including behind-the-counter placement, logbooks, and training/certifications. Specifically, under Section 402(a) as amended, it is unlawful for regulated sellers to:

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- (1) sell at retail a scheduled listed chemical in violation of the 3.6 grams daily maximum, "knowing at the time of the transaction (independent of consulting the logbook) that the transaction is a violation;"
- (2) knowingly or recklessly sell at retail a non-liquid form of a scheduled listed chemical that is not in blister packs or unit dose packets;
- (3) knowingly or recklessly sell at retail a scheduled listed chemical in violation of the requirements in Section 310(e) (e.g., behind-the-counter placement, logbooks, and training/ certifications).

It is also unlawful for a regulated seller or an employee or agent to disclose information in transaction logbooks for any purpose other than to ensure compliance with the statute or to facilitate a product recall to protect public health and safety. Retailers will be required to provide the logbook information to law enforcement authorities under certain circumstances.

The statute does not define knowingly or recklessly.

Because all of these restrictions are inserted as unlawful acts in Section 402(a) of the Controlled Substances Act, 21 U.S.C. 842(a), the penalties provided in Section 402 apply to the Combat Meth Act restrictions on retailers. Violations of any of these provisions are subject to a civil penalty of up to \$25,000. See 21 U.S.C. 842(c). If a trier of fact finds that a violation was knowingly committed, the penalty is increased to imprisonment of up to one year, a fine of up to \$25,000, or both. *Id.* Repeat offenses can be subject to a prison term of up to two years, a \$50,000 fine, or both. *Id.*

B. <u>Prohibition on Sales</u>

In addition, the Combat Meth Act amendments allow the Attorney General to issue an order prohibiting a retailer from selling any scheduled listed chemical products if the retailer violates the retail sales restrictions (e.g., 3.6 grams daily quantity or blister pack requirement for non-liquid forms) or the attendant requirements regarding retail transactions (e.g., behind-the-counter, logbooks, identification, training/certifications). 21 U.S.C. 842(c)(4)(A).

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C. Consumer Purchase Restrictions

Section 711(e) of the Combat Meth Act amends the unlawful acts listed under the "Penalties for simple possession" in Section 404(a) of the Controlled Substances Act. 21 U.S.C. 844(a). Under the Controlled Substances Act as amended, it is now unlawful for a person to knowingly or intentionally purchase more than 9 grams of a scheduled listed chemical with a base of ephedrine, pseudoephedrine, or phenylpropanolamine during a 30-day period.

The penalties for violation of this subsection—applicable only to the consumer purchaser—include a minimum fine of \$1,000, a prison sentence of up to one year, or both. *See* 21 U.S.C. 844(a). A repeat conviction is subject to imprisonment for not less than fifteen days and up to two years, and a minimum fine of \$2,500. *Id.* Penalties escalate for a third conviction and carry a prison term of 90 days to three years and a minimum fine of \$5,000. *Id.*

V. Analysis

It is our interpretation that the individual purchaser liability section at 711(e) of the Combat Meth Act is separate and distinct from the sections that apply to retailer responsibilities and penalties (711(b) and 711(f)). The statute does not require retailers to take actions to limit 30-day purchases to less than 9 grams, nor does it impose any liability on the retailer if an individual violates the monthly purchase limit. The Combat Meth Act applies the monthly quantity restrictions to individual purchasers (any person who knowingly or intentionally purchases at retail during a 30 day period more than 9 grams) rather than to retail sellers. This provision amends the section of the Controlled Substances Act for simple possession penalties, and drug possession liability falls upon the purchaser, not the seller.

A different section of the Combat Meth Act entitled, *Enforcement of Requirements for Retail Sales – Civil and Criminal Penalties*, addresses all of the retailer restrictions and the penalties, which are listed in a different section of the Controlled Substances Act for prohibited acts and applicable penalties. There are no cross-references in the retailer-related sections to the monthly purchase limits.

Retailers are prohibited from selling more than 3.6 grams per day per purchaser as of April 8, 2006. The Combat Meth Act does not identify specific actions or minimum standards necessary to limit daily sales to this amount. However, for retail sellers, it is only a violation to sell greater than 3.6 grams of scheduled listed chemical products "knowing at the time of the transaction involved (independent of consulting the logbook . . .) that the transaction is a violation." A

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mistake made in good faith would not impose liability because of the "knowing" requirement. The statute specifically says that retailers do not have to check a logbook to meet this obligation.¹

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We hope you find this information useful. Please contact us if we can be of further assistance.

¹ This conclusion is further supported by the timing of the effective dates. Retailers need not have transactional logbooks in place until September 30, 2006, and the daily quantity limit takes effect on April 8, 2006; therefore, the statute clearly does not contemplate a retailer consulting a logbook immediately following the April implementation date, when the 3.6 gram daily sales limitation takes effect.