

Regulatory Update

13th Pharmaceutical Industry Conference

Houston, Texas

September 11-12, 2007



*Mark W. Caverly, Chief
Liaison and Policy Section
Office of Diversion Control*

Combat Methamphetamine Epidemic Act of 2005

- **Title VII of USA Patriot Improvement and Reauthorization Act of 2005, March 2006 (Public Law 109-177)**
- **Purpose:**
 - To provide greater controls of OTC products containing ephedrine, pseudoephedrine, and phenylpropanolamine.
- **Retail Provisions became fully effective on September 30, 2006**

CMEA Retail Rule

- **Self-Certification**
- **Employee Training**
- **Maintain Records of Training**
- **Product Packaging (blister-packs)**
- **Product Placement**
- **Logbook (Manual or Electronic option)**
 - Logbook information disclosed only as permitted
- **Daily and 30-Day Sales/Purchase Limits**

CMEA “Spot Market” Rule

- **Applies to All List I and List II chemicals**
- **Interim Final Rule – April 9, 2007**
- **Effective June 8, 2007**
- **New DEA-486**
 - **Transferee and quantity of chemical to be transferred**
 - **Return declaration**

Additional CMEA Rules

- **Assessment of Annual Need**
 - **Circulating within DEA for signature**
- **Import and Production Quotas for Certain List I Chemicals**
 - **Published and effective 7/10/07**
- **Elimination of Exemption for Chemical Mixtures containing Ephedrine and/or Pseudoephedrine**
 - **Published 7/25/07, effective 8/24/07**

Additional CMEA Rules

- **Record Requirements for Chemical Distributors**
 - Cleared to publish, circulating for signature
- **Foreign Chain of Distribution**
 - Accepted by OMB 8/1/07

Multiple CII Prescription Rule

- **Permit practitioners to issue multiple prescriptions for C II substances to allow patients up to a 90-day supply.**
- **Provide greater control to physicians for prescribing Schedule II medications.**
- **Rule finalized within DEA, sent to OMB in June 2007**

Controlled Substances Reexport Rule

- **Controlled Substances Export Reform Act of 2005 authorizes export of controlled substances from US to another country for subsequent export to one or more other countries**
- **Schedules I, II, narcotic controlled substances in Schedules III, IV**
- **Final Rule sent to OMB in August 2007**

Single Sheet DEA Form 222

- **Rule proposes a new format for Official Order Form, DEA 222**
- **Single, pre-printed form**
- **Special paper, security features**
- **Rule sent to OMB for review on April 6, 2007**

Multi-State Practice Clarification

- **Amended registration regulations to clarify requirement that when an individual practitioner practices in more than one state, a separate DEA registration for each State (21 CFR 1301.12)**
- **Final Rule published December 1, 2006, became effective January 2, 2007**

Iodine and Chemical Mixtures

- **Moves Iodine from a List II chemical to List I**
- **Controls chemical mixtures over 2.2%**
- **Reduces thresholds for regulated transactions to zero**
- **Adds import/export regulatory controls**
- **Final Rule published on 7/2/07, Effective on 8/1/07**

Pending Regulations/Policies

- **Policy Working Group**
 - **Locum Tenens**
 - **Reverse Distributors**
 - **Agent of a Practitioner**
 - **Telepharmacy, Telemedicine, and Remote Dispensing Sites**
 - **“Medical Bag” Supply**
 - **Emergency Kits in LTCFs**

A large, faint watermark of the Drug Enforcement Administration (DEA) logo is centered on the page. The logo consists of a circular border containing the text "U.S. Department of Justice" at the top and "Drug Enforcement Administration" at the bottom, separated by a small dot. In the center of the circle is a stylized eagle with its wings spread, perched on a globe.

Questions?