Regulatory Update

13th Pharmaceutical Industry Conference
Houston, Texas
September 11-12, 2007

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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
Questions?