Being Prepared for a DEA Inspection at Your Institution

Gary L. Borkowski, DVM, DACLAM
Pre-Test

- Which is more difficult to comprehend?
  a) DEA Regulations
  b) Rocket Science

- Buprenorphine is in which Schedule for controlled substances?
  a) V
  b) III

- Define the term “name”.
  The term name means the official name, common name, or usual name, chemical name, or brand name of a substance.
Outline

- Definitions
- Registration
- Forms
- Fees
- USDA
- AAALAC
- Hearings
- Security & Employee Screening
- Questions & Discussion
Definitions

- 21 CFR 1300
- Practitioner
  - Individual
  - Institutional
  - Mid-Level
- Dispenser
- Manufacturer
- Diversion
- Reverse Distributor (Registered Disposer)
- CSA = Controlled Substances Act
Registration

- Who needs to register?
  - “Every person who manufactures, distributes, dispenses, imports or exports any controlled substance or who proposes to engage in the manufacture, distribution, dispensing, importation or exportation of any controlled substance shall obtain a registration…” (21 CFR 1301.11)

- “A separate registration is required for each principal place of business..”
Registration & Fees

- Manufacturing
- Distributing
- Dispensing
- Research

- Fees
  - Federal - $130/yr (recent increase)
  - State – variable

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- State – variable
Compliance & Inspections

- The Code of Federal Regulations provides penalties for non-compliance:
  - Civil
  - Criminal
  - Fines, loss of registration, imprisonment

- The DEA conducts unannounced inspections
Security

- “All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.” (21 CFR 1301.71)
- Are you a practitioner or non-practitioner?
  - 21 CFR 1301.72 – 21 CFR 1301.74
  - 21 CFR 1301.75 & 21 CFR 1301.76
- Quantity, Schedule, Environment, etc
Security

- Securely locked, substantially constructed cabinet
- Don’t leave material “at-risk”
- Don’t leave key accessible (e.g. under shelf)
Theft or Significant Loss

- NPRM – July 8, 2003
- Theft
- Loss
- Explained Loss
- Form 106
Employee Screening

- 21 CFR 1301.90
- “Within the past 5 years, have you been convicted of a felony or within the past 2 years, of any misdemeanor…?”
- “In the past 3 years, have you knowingly used any narcotics, amphetamines or barbiturates, other than those prescribed to you by a physician?”
USDA

- USDA Policy 3
  - Pharmaceutical Grade Compounds in Research
  - Expectation that Rx grade be used when available, even in acute procedures.
AAALAC

- Program Description
- Site Visit
- Annual Report
Welcome to the Diversion Control Program

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

Please Read this Privacy and Security Statement

http://www.deadiversion.usdoj.gov/
## Classification

<table>
<thead>
<tr>
<th>Class</th>
<th>Abuse Potential</th>
<th>Therapeutic Value</th>
<th>Misc</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>High</td>
<td>No</td>
<td>Excl.</td>
<td>LSD, cocaine, proheptazine</td>
</tr>
<tr>
<td>II</td>
<td>High</td>
<td>Yes</td>
<td>Form 222</td>
<td>Pentobarbital, phenylacetone</td>
</tr>
<tr>
<td>III</td>
<td>Moderate</td>
<td>Yes</td>
<td></td>
<td>Ketamine(7285), buprenorphine</td>
</tr>
<tr>
<td>IV</td>
<td>Moderate</td>
<td>Yes</td>
<td></td>
<td>Alprazolam, diazepam</td>
</tr>
<tr>
<td>V</td>
<td>Low</td>
<td>Yes</td>
<td></td>
<td>Pyrovalerone</td>
</tr>
</tbody>
</table>
# List of Controlled Substances

<table>
<thead>
<tr>
<th>Alphabetical Order</th>
<th>By Schedule</th>
<th>Scheduling Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>A - B</td>
<td>Schedule I</td>
<td>Actions from 1971-1979</td>
</tr>
<tr>
<td>C</td>
<td>Schedule II</td>
<td>Actions from 1980-1984</td>
</tr>
<tr>
<td>D</td>
<td>Schedule III</td>
<td>Actions from 1985-1989</td>
</tr>
<tr>
<td>E - F</td>
<td>Schedule IV</td>
<td>Actions from 1990-present</td>
</tr>
<tr>
<td>G - L</td>
<td>Schedule V</td>
<td></td>
</tr>
<tr>
<td>M</td>
<td></td>
<td></td>
</tr>
<tr>
<td>N - Q</td>
<td></td>
<td></td>
</tr>
<tr>
<td>P</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q - Z</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

[View Defined Abbreviations]
## Updates/Hot Items

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Date</th>
<th>Approval Date</th>
<th>Approval Status</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>KETAMINE</td>
<td>04-09-99</td>
<td>07-13-99</td>
<td>8/12/99</td>
<td>III</td>
</tr>
<tr>
<td>ZALEPLON</td>
<td>05-05-99</td>
<td>09-15-99</td>
<td>9/15/99</td>
<td>IV</td>
</tr>
<tr>
<td>GAMMA HYDROXYBUTYRIC ACID (GHB)</td>
<td>PL 106-172</td>
<td>03-13-00</td>
<td>3/13/00</td>
<td>I</td>
</tr>
<tr>
<td>GAMMA HYDROXYBUTYRIC ACID (GHB) FDA approved drug products</td>
<td>PL 106-172</td>
<td>03-13-00</td>
<td>3/13/00</td>
<td>III</td>
</tr>
<tr>
<td>DIHYDROETORPHINE (thebaine derivative)</td>
<td>11-17-00</td>
<td>11/17/00</td>
<td>clarification of CII control</td>
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</tr>
<tr>
<td>DICHLORALPHENAZONE (chloral hydrate compound)</td>
<td>12-11-00</td>
<td>08-16-01</td>
<td>08/16/01</td>
<td>clarification of CIV control.</td>
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<tr>
<td>FENFLURAMINE</td>
<td>05-06-97</td>
<td>pending</td>
<td>IV -&gt; O</td>
<td></td>
</tr>
<tr>
<td>BUPRENORPHINE</td>
<td>03-21-02</td>
<td>10-7-02</td>
<td>10/7/02</td>
<td>V -&gt; III</td>
</tr>
</tbody>
</table>
Records & Reports

- Ordering (Form 222 for I & II)
- Receipt
- Storage
- Use
- Disposal
- Import
- Export
Inventories

- 21 CFR 1304.11 – “Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location.”
List(ed) Chemicals

- 21 CFR 1310.02 – Substances Covered
- Class I (examples)
  - Phenylacetic Acid
  - Phenylpropanolamie
  - Pseudoephedrine
- Class II (examples)
  - Iodine
  - Acetone
  - Ethyl Ether
Summary

- 21 CFR 1300
- Be familiar with State regulations too
- Review your program
  - Resolve gaps identified
  - Don’t forget the chemists!
- Inventories
- Monitor DEA website for changes
  - Comment period
A class V controlled substance has a higher abuse potential than a class I.  

If a DEA Agent says “I’m from the government, and I’m here to help,” you should be worried.

If USDA and AAALAC didn’t cite your institution for Controlled Substance problems, that’s sufficient.
Questions & Discussion