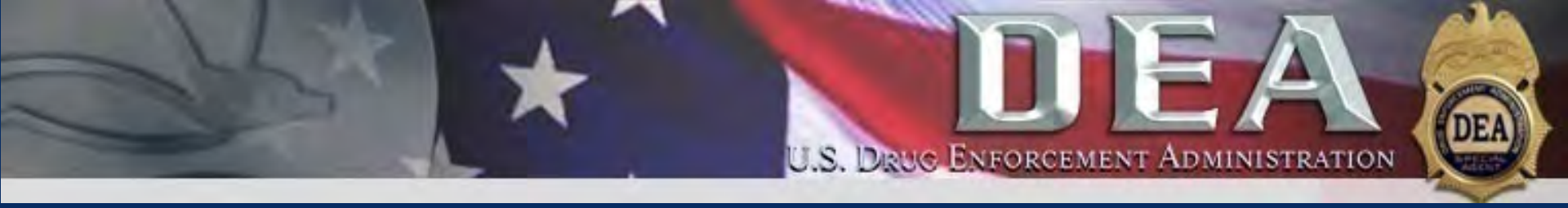

Researcher Training Conference

Procedures for Campus Registration, Compounding Drug Issues, and Destruction

Lynnette Wingert, Unit Chief
Policy Section

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Course Objectives

- Discuss Campus Registration.
- Discuss Compounding Drug Issues.
- Discuss Destruction Requirements.

Registration

- **“[a] separate registration is required for each principal place of business…at one general physical location where controlled substances are manufactured, distributed, imported, exported, or dispensed by a person.”**

21 CFR § 1301.12(a)

Campus Registration

A campus registration is NOT an exemption, exception, or a waiver to registration.

A campus registration IS an inclusion of specific locations under the DEA registration.

Who can request a campus registration?

- Schedule II – V Researchers YES
- Schedule I Researchers NO

REASON: A Schedule I Researcher registration is issued pursuant to a project-specific protocol with an identified investigator(s).

Details of required information is found under: 21 C.F.R. § 1301. 18

What does the DEA look at?

- Considers each request on a **case-by-case** basis.
- Some, but not all factors the DEA considers are:
  - Is the company operating **a single business activity** in more than one building?
  - How **close** are the buildings to each other?
  - If granting a campus registration would in any way **diminish the security of the controlled substances** within the registrant's possession or control?
  - Are there any field **on-site inspection concerns**?

Additional items to consider and provide

- Campus map showing the locations
- Campus security details
- Street descriptions
- Fences/boundary identification/description
- Access to buildings/laboratories information
- Law enforcement patrol information

Work with your local DEA Diversion Group

Security Requirements

"All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in §§ 21 C.F.R 1301.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion."

21 C.F.R. § 1301.71(a)

Procedure for Request

Currently

- **Letter**

  John J. Martin

  Assistant Administrator

  Diversion Control Division

  8701 Morrissette Drive

  Springfield, Virginia 22152

  Email to ODLP@usdoj.gov

- **DEA Notification**

Procedure for Request

Future

- § **Indicate on initial or renewal application**
- § **Modify your DEA registration www.DEAdiversion.usdoj.gov**
  - **Request additional locations**
  - **Remove locations**
- ü **DEA Notification**

Compounding Drug Issues

A pharmacy may dispense a controlled substance only to an "ultimate user", or member of the ultimate user's household in response to a valid prescription issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice.

21 C.F.R. Part 1306 and 21 U.S.C. § 802

Compounding Drug Issues

“Ultimate User” means a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household.

21 C.F.R. Part 1306 and 21 U.S.C. § 802

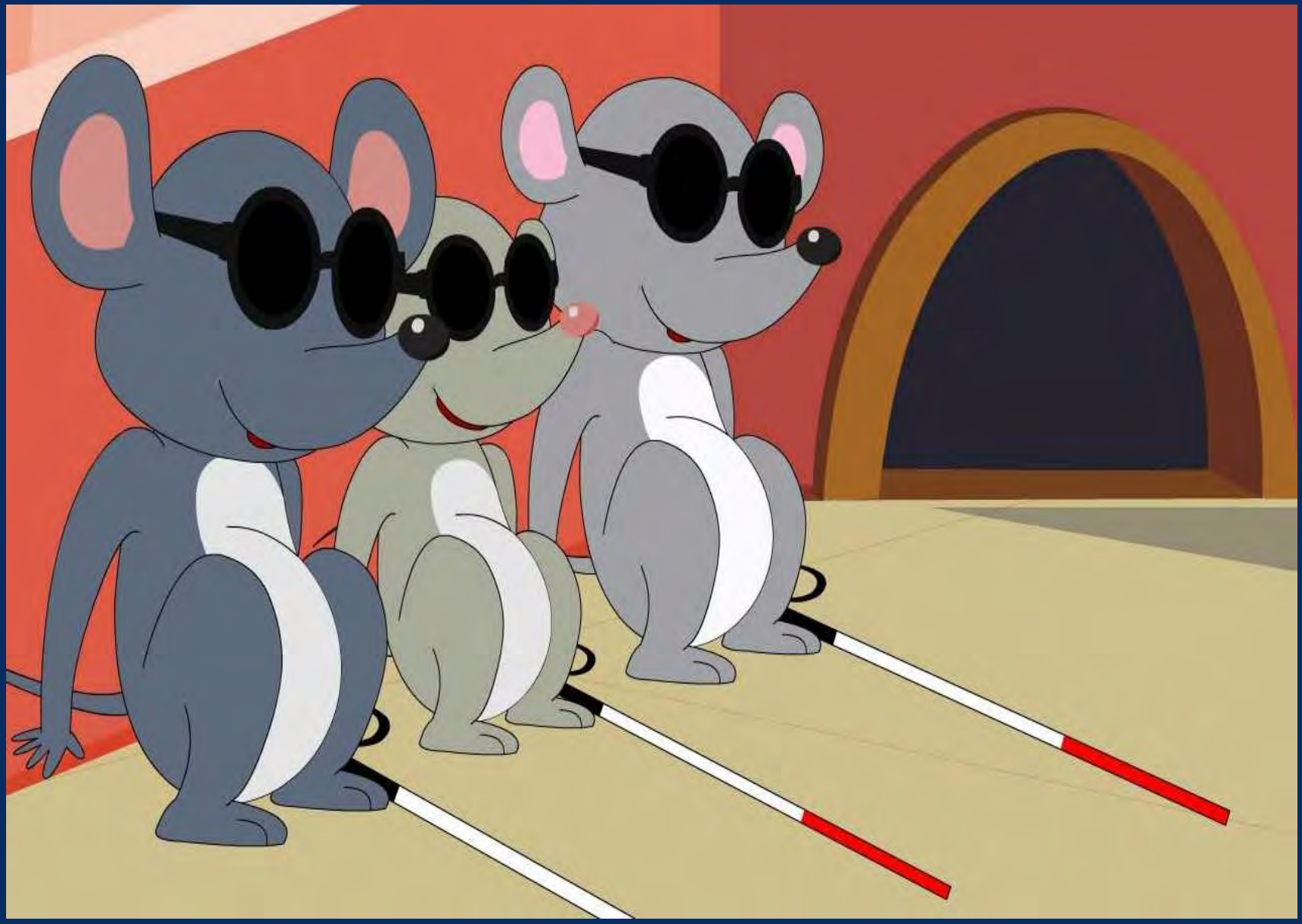
Compounding Drug Issues

A DEA-registered pharmacy may compound a controlled substance without obtaining a separate DEA registration as a manufacturer, if said compounding is pursuant to a valid patient specific prescription.

21 C.F.R. Part 1306 and 21 U.S.C. § 802

Prescription - Animals

- A veterinarian with a valid **vet-client-patient relationship** may **issue a prescription** for the controlled substance to the **animal or "herd of animals"** and give it to the **owner or caretaker** of the animal or herd.
- Under Food and Drug Administration (FDA) veterinarian guidelines, the **"herd" is the patient.**
- **The caretaker could be the researcher.**

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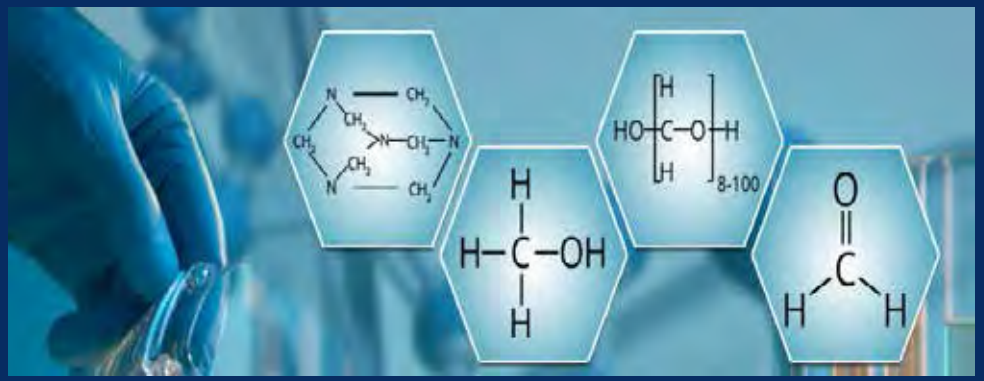
DISPOSAL FOR THE RESEARCHER (Practitioner)

Non-Retrievable

- A controlled substance is considered "non-retrievable" when it cannot be transformed to a physical or chemical condition or state as a **controlled substance or controlled substance analogue…**

21 CFR § 1300.05



Non-Retrievable

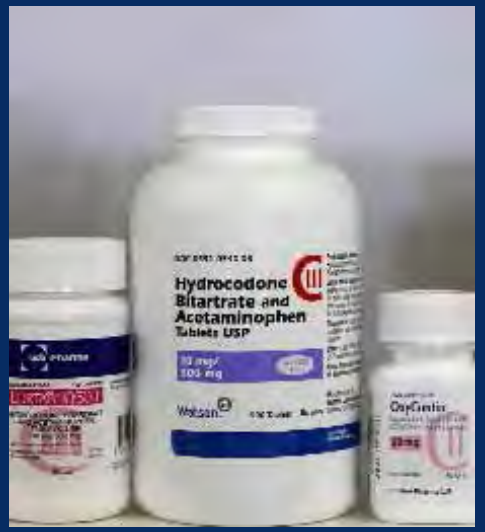
The purpose of this destruction standard is to:

- **Permanently render the controlled substance(s) to a non-retrievable state and thus prevent diversion of any such substance to illicit purposes.**

These methods do not meet the standard

21 CFR § 1300.05

Disposal of Practitioner Controlled Substance Inventory and Controlled Substance Waste



U.S. Drug Enforcement Administration
Diversion Control Division

Disposal of Controlled Substance Inventory

Practitioner options to dispose of inventory are:

- **Prompt on-site destruction if proper method.**
- **Prompt delivery to a DEA registered reverse distributor by common carrier or reverse distributor pick-up.**

21 C.F.R. § 1317.05(a) and (b)

Record for On-Site Disposal

- **DEA Form 41 shall be used to record the destruction of all controlled substances using an on-site method that renders the controlled substances non-retrievable.**

- **DEA Form 41 shall include the names and signatures of the two employees who witnessed the destruction.**
  21 CFR § 1317.95(d)

Record for delivery to a DEA Registered Reverse Distributor

Exceptions for DEA Form 41:

- **Transfers by registrant to a reverse distributor must be recorded in accordance with § 1304.22(c), and such record need not be maintained on a Form 41.**

21 C.F.R. § 1304.21(e)

Disposal of Controlled Substance Waste

DEA allows disposal of controlled substance waste if:

- **It is authorized under your states laws… and**
- **It is the remaining portion of used needles, syringes, or other injectable products in a practitioner environment (hospital, clinic, physicians office, researcher, etc.)**

Records for disposal of waste

Recordkeeping for disposal of controlled substance waste:

- **No DEA Form 41 required.**
- **Recommended that two employees witness the handling and the destruction of the controlled substance waste.**


U.S. DEPARTMENT OF JUSTICE – DRUG ENFORCEMENT ADMINISTRATION
REGISTRANT RECORD OF CONTROLLED SUBSTANCES DESTROYED
FORM DEA-41
A. REGISTRANT INFORMATION
B. ITEM DESTROYED
1. Inventory

21 C.F.R. § 1317.95(c) and (d)

21 C.F.R. § 1304.21(e)

Disposal of Controlled Substance Waste

Record of waste disposal must include:

- **Name of Substance**
- **Form**
- **Quantity**
- **Date of Disposal**
- **Manner of Disposal**

21 CFR § 1304.22(c)

Returned or Recalled controlled substance inventory

Returned or Recalled Controlled Substances

- **Prompt delivery by common or contract carrier or pick-up at the registered location by:**
  - **Registrant from whom it was *obtained.***
  - **Registered *manufacturer* of the substance.**
  - **Another registrant authorized by the manufacturer to accept returns or recalls *on the manufacturers behalf*.**

21 C.F.R. § 1317.05(a) and (b)

Disposal of Controlled Substance Inventory (special circumstances)

- A practitioner may also request assistance from the Special Agent in Charge.

21 C.F.R. § 1317.05(a) and (b)

Products That Advertise They are Non-Retrievable

- **DEA is aware that there are companies that claim that their products can render controlled substance inventories non-retrievable, and have DEA approval.**

- **DEA has not approved any such products for the disposal of practitioner inventory.**

21 CFR § 1300.05

No disposal of controlled substance inventory at:

- Controlled substance practitioner inventory **cannot** go to a collector (Take Back Days, Law Enforcement Collections, Pharmacy Collection Boxes, etc.)

- Collectors can **only** receive controlled substances from the "ultimate users."

21 C.F.R. § 1317.05(a) and (b) 21 C.F.R. § 1317.75(c)

Disposal

Requirements that apply to all controlled substance records required to be kept:

- **Must be complete and accurate.**
  21 C.F.R. § 1304.21(a)
- **Must be stored at the registered location.**
  21 C.F.R. § 1304.21(b)
- **Must be kept for two years.**
  21 C.F.R. § 1304.04(a)

Thank-you for your time and attention!