Universal Waste Rule for Pharmaceuticals
62-730.186 F.A.C.

What Is ‘Universal Waste’?
- Generated in large quantities
- Found in variety of industries
- 40 CFR Part 273

Examples
- Fluorescent lamps
- Mercury thermostats
- Batteries
- Recalled pesticides

Why Drugs?
- Wide variety of generators:
  - Fire stations
  - Small drugstores
  - Warehouses
  - Large hospitals

How does it work?
- Alternative set of standards
- Regulatory flexibility vs. 40 CFR Parts 260-272...

Reduces barriers to collection
- Small quantity handler: 5000 kg
- SQG: 1000 kg
- Longer accumulation time
Reduces complexities

- Waste Management
- Accumulation time
- Off-site shipments
- Tracking

Reduces cost of compliance

- Increased accumulation times
- Relaxed standards

A look at the Rule...

- Applies to H/W drugs ("viable")
- Requires *documented credit*
  - Mfg
  - RD
  - Charities

Handler requirements

- Small quantity: \( \leq 5000 \text{ kg/mth} \)
  - Accumulate 1 year
- Large quantity: \( > 5000 \text{ kg/mth} \)
  - Accumulate 6 mos
- Amounts are cumulative
- EPA ID number
- Proper container mgmt. (label, compatible)
- Training

Reverse Distributors

- H/W Generators
- Begin waste determination w/in 24 hrs
- Complete process in 10 days
- Keep record
  - Date of receipt
  - Date determined hazardous waste

Documentation is key!
Labpacks

- Handler may:
  - Sort/mix compatible drugs
  - Consolidate
  - Remove drugs from consumer packaging
  - Manage any resulting wastes

Employee Training

- Waste mgmt. relevant to position
- Contingency Plan
- 3-month window
- Annual review
- Document (3 years)

Off-site shipments

- Destination facility (40 CFR 273.9)
- RD: permitted HW disposal facility
- Self-transport
- DOT requirements
- Documentation (3 years)

Acceptance of shipments

- Written agreement w/ destination facility
- Rejected shipments:
  - Receive waste back, or
  - Alternate facility
- Receipt of non-UW haz waste:
  - Notify DEP
  - Manage pursuant to Ch 62-730 F.A.C.

Comments...

- No prior knowledge of final disposition
- Mfg. policies vary widely
  - Don’t always cover returns
  - Deduct from invoice vs credit return
- Current wording increases waste

“Viable”
Definitions

- “Container”
  - Not intended for ingestion, absorption, etc.
- “Consumer packaging”
  - Intended for retail/household environment

Waste determination

- 24 hrs/10 days
  - Allow for business fluctuation
  - 20 days; no start time

What’s next?

- Workshop in early February
  - Public notice in January
- Final Rule in April
- Effective in July

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