

EPA Regulations for Hazardous Waste Pharmaceuticals

Briefing for DEA Registered Reverse Distributors

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Outline

- ▶ Examples of HW Pharmaceuticals
- ▶ RCRA HW that are also DEA Controlled Substances
- ▶ Household Hazardous Waste Exemption
- ▶ DEA Authorized Collection Receptacles
- ▶ State Considerations

Examples of HW Pharmaceuticals

▶ Listed hazardous wastes

- ▶ P-listed (acute HW): Warfarin, Nicotine, etc.
- ▶ U-listed: Mitomycin C, Chloral hydrate, Lindane, Selenium sulfide, Cyclophosphamide, etc.

▶ Characteristic hazardous wastes

- ▶ Ignitable (D001): Preparations with >24% alcohol
- ▶ Toxicity (D004-D043): if present above certain concentrations in the leachate during TCLP test
 - ▶ m-Cresol (preservative in insulin)
 - ▶ Mercury (preservative thimerosal)
 - ▶ Selenium (multi-vitamins)
 - ▶ Chromium (multi-vitamins)
 - ▶ Silver (burn creams)

Examples of HW Pharmaceuticals

- ▶ The chemical names on the P- and U-list are different than the drugs' brand names and generic names, for example -
 - ▶ If you are a pharmacist: Brand name Trisenox
 - ▶ If you speak RCRA: Arsenic trioxide = P012
- ▶ The characteristic hazardous wastes (D001-D043) are descriptive:
 - ▶ Do not give any indication which specific drugs might exhibit a characteristic and
 - ▶ Can vary for different forms of the same drug, for example -
 - ▶ Fentanyl sublingual spray is dissolved in alcohol – D001 (ignitable)
 - ▶ Other forms of fentanyl are not hazardous waste

RCRA & DEA Overlap

- ▶ There are a few RCRA hazardous wastes that are also DEA controlled substances
 - ▶ Chloral hydrate (U034)
 - ▶ Fentanyl sublingual spray (D001)
 - ▶ Phenobarbital (D001)
 - ▶ Testosterone gels (D001)
 - ▶ Valium injectable (D001)
- ▶ EPA is in the final stages of developing a proposed rule that will eliminate the dual regulation for RCRA hazardous wastes that are also controlled substances
- ▶ EPA will request comment in the proposed rule on whether this list is complete and accurate

Household Hazardous Waste Exemption

- ▶ Hazardous waste generated at residences is exempt from RCRA regulation
 - ▶ “Household hazardous waste” = HHW
 - ▶ 40 CFR 261.4(b)(1)
 - ▶ The exemption continues to apply even when the HHW is collected

DEA Authorized Collection Receptacles

- ▶ Since the the waste collected in a DEA authorized collection receptacle is from a residence (ultimate user), EPA would consider it to be exempt from RCRA as HHW
- ▶ Pharmacies can not use the collection receptacles for their own hazardous waste pharmaceuticals
- ▶ Pharmacies must manage their own hazardous waste pharmaceuticals separately

States May be Different

- ▶ State hazardous waste regulations may still apply for collected HHW
 - ▶ States can be more stringent
- ▶ State solid waste regulations may apply for collecting waste
 - ▶ States may require licensing or permitting to be a solid waste collector