EPA Comments on the Development of Safe and Effective Drug Collection and Disposal Methods

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Introductory Remarks

- Active Pharmaceutical Ingredients (APIs) have been found in low concentrations in the environment potentially exposing wildlife and humans
- EPA and DEA share a common goal to protect public health
  - DEA works to prevent drug diversion to people
  - EPA works to prevent drug diversion to the environment and thus indirectly to people
- Our agencies can collaborate to prevent diversion to both people and the environment

Introductory Remarks (Cont.)

- Our collaboration should focus on making drug take-back programs available and easy to execute in a safe manner
- EPA is working to stop flushing of drugs where appropriate and drug take back programs can help keep drugs out the environment
- EPA has awarded two grants for take-back programs which we will discuss later and drafted Best Management Practices for Unused Pharmaceuticals at Health Care Facilities

Overview—EPA Recommendations

- Develop a national set of options for take-back programs
- Ensure that collected controlled substances are managed and disposed of in accordance with environmental regulations
- Clarify current destruction/disposal methods and approve additional methods
- Streamline recordkeeping requirements for take-back programs

Development of Take-Back Options

- EPA encourages flexibility in the new DEA regulations to allow for various approaches to drug take-back programs

- Providing a choice of take-back options will help communities overcome obstacles that their geographical locales may present or that their individual residents may experience

- Some options include but are not limited to:
  - Mail-back programs
  - Consumer returns to DEA registrants (including but not limited to reverse distributors)
  - Secured boxes at pharmacies and/or other locations
  - Any combination of the above

- EPA awarded two successful grants to test different approaches for prudent disposal of unwanted pharmaceuticals

EPA Grant: RxMEDS

- RxMEDS - Regional Excess Medication Disposal Service
  - St. Louis Metro Region
- Returns by users to pharmacies
- Collected 244,708 capsules, tablets and suppositories over an 12 month period
- Unable to obtain permission to collect controlled substances
- All collected drugs were incinerated
- No instances of diversion, theft, etc.
- http://www.epa.gov/aging/grants/winners/archs.htm

EPA Grant:
Safe Medicine Disposal for ME

- Mail-back program
  - Univ. of ME, ME DEA, US Postal Service, other partners
  - Collected 2,373 lbs of drugs during the grant period
    - 2,123 lbs – non-controlled substances
    - 250 lbs – controlled substances
  - Take-back program still in operation post-EPA grant
    - 20,000 mailers available at approx. 150 sites
    - Collecting over 100 lb a week
    - Funding in place through 2011
  - No instances of diversion, theft, etc
  - Secure delivery to Maine Drug Enforcement Agency for data collection & destruction
    - All non-controlled drugs are incinerated as HWs
    - Controlled drugs are witness-incinerated as municipal solid waste at a waste-to-energy facility
  - Final report issued in April 2010: www.safemeddisposal.com

Environmental Regulations

- Once collected, unwanted controlled substances and other unwanted pharmaceuticals must be managed in accordance with all applicable federal, state, and local environmental regulations

- Federal environmental regulations lay out the baseline standards
  - States may have more stringent or broader regulations than federal EPA

- EPA comments focus upon the federal regulations as they apply to disposal of household (ultimate user) pharmaceutical waste
  - Resource Conservation and Recovery Act (RCRA)
  - Clean Air Act (CAA)

RCRA

- Non-hazardous wastes, such as municipal solid waste, are regulated under Subtitle D of RCRA (local and state level)

- Hazardous wastes are regulated under Subtitle C of RCRA

Are Pharmaceuticals HW Under RCRA?

- A waste is hazardous if:
  - It is specifically listed by EPA; or
  - It exhibits a characteristic of HW
- Only a very small percentage of pharmaceuticals are regulated HW
  - 3 listed hazardous wastes are also DEA controlled substances
- The regulations applicable to HW pharmaceuticals depends on the type of generator
  - Household, conditionally-exempt small quantity generator, small quantity generator or large quantity generator

Applying RCRA to Households

- Household hazardous wastes (HHWs) are exempt from federal Subtitle C regulations (40 CFR 261.4(b)(1))
  - When Congress enacted RCRA, it indicated that HW regulations should NOT apply to households
  - Exemption applies even when HHWs are collected
  - Some states do have more stringent requirements and regulate HHW once collected and consolidated (e.g., PA)
  - EPA recommends that collected pharmaceutical HHWs be managed and disposed of as HW

CAA

- No air standards apply directly to the ultimate user (i.e., household) who disposes controlled substances

- Certain CAA regulations may apply if the controlled substances are disposed of in landfills or incinerated
  - EPA has issued emission standards for:
    - Hazardous waste incinerators (under section 112(d) of the CAA)
    - Solid waste incinerators (under section 129 of the CAA)
      - Hospital, medical and infectious waste incinerators
      - Municipal Waste Combustors (large and small)
      - Other solid waste incinerators
    - Municipal solid waste landfills (under sections 111 and 112 of the CAA)

Additional Destruction and Disposal Methods

- EPA suggests DEA:
  - Discourage the sewering of household controlled substances **except** in the few instances where FDA recommends flushing
    - FDA recommends sewering for a short list of drugs that are extremely dangerous to those for whom the drug has not been prescribed (e.g., children and pets)
  - Define what constitutes destruction and identify DEA-approved methods
    - Destruction methods must also be in accordance with all federal, state and local environmental regulations

Expand Disposal Options for Non-DEA Registrants

- It is EPA's understanding that long-term care facilities (LTCFs) often dispose of unwanted controlled substances by sewering
  - LTCFs employees are typically not DEA-registrants, and as a result they cannot:
    - Return controlled substances to the LTCF pharmacy;
    - Transfer controlled substances to a reverse distributor; or
    - Transfer to a DEA-registrant for disposal

- EPA recommends that DEA allow LTCFs to become DEA-registrants or authorize them to return/transfer controlled substances in order to expand their disposal options

Recordkeeping Requirements

- EPA recommends that DEA
  - Streamline or modify the recordkeeping requirements for take-back programs

- Current recordkeeping requirements could present obstacles to take-back organizers because inventory and recordkeeping requirements for controlled substances are applied in various ways
  - Pill-by-pill identification
  - Separation and tracking prior to disposal

Summary

- In development of regulations, EPA recommends that DEA:
  - Develop a set of flexible options for pharmaceutical take-back programs
  - Ensure destruction/disposal of pharmaceuticals is in accordance with all federal, state, and local environmental regulations
  - Define allowed additional destruction methods and disposal options
  - Streamline recordkeeping requirements for take-back programs

Conclusion

- Thank you for inviting us to comment
- We look forward to working together on this issue
- For more information, please contact Lisa Lauer at 703-308-7418