Update on EPA’s Study of Unused Pharmaceuticals from the Health Care Industry

Stakeholder Outreach Meeting
September 18, 2008
OVERVIEW

- Meeting Objectives
- Background:
  - Clean Water Act (CWA)
  - Effluent Guidelines
  - Effluent Guidelines Planning
  - Paperwork Reduction Act (PRA)
- Health Care Industry Survey
  - Scope
- Health Care Industry (HCI) Study
  - Activities and Schedule
- EPA Contacts
- Questions/Comments
MEETING OBJECTIVES

- Introduce the HCI Survey and Clean Water Program
- Provide Background
- Encourage Participation, Comments and Suggestions in the Development of the HCI Survey
  - Feedback on Scope of Study
  - Facilities Under Study – Are the right organizations included?
  - Questions Included in Survey – Are the questions phrased correctly to collect reliable consistent data?
BACKGROUND – Clean Water Act

• Is the major environmental law governing surface water discharges.
• Implemented by EPA, in part, through publication of effluent guidelines regulations and discharge permits for point sources of wastewater pollution.
  • Regulations can impose discharge limits or require the use of best management practices (BMPs)
BACKGROUND - Effluent Guidelines

Effluent Guidelines (ELGs) regulate indirect and direct dischargers.
BACKGROUND – ELGs Planning

- EPA Conducts a Planning Process on a Biennial Basis:
  - Review existing regulations
  - Study potential new categories for possible regulation
- EPA Identified the Health Care Industry
  - Based on comments received as part of the 2006 planning cycle
- EPA 2008 Planning Cycle
  - Studied the discharge of dental amalgam from dentist offices and the disposal of unused medications from hospitals and long term care facilities
- EPA Finalized the 2008 Plan
  - Included two reports summarizing our study of the disposal of unused medications
  - EPA has posted a pre-publication copy of the most recent plan on its website at http://epa.gov/guide/304m/
BACKGROUND – Paperwork Reduction Act

- Requires each Federal Agency to seek and obtain Office of Management Budget (OMB) approval before any information can be collected from 10 or more persons.

- Goals:
  - Minimize the burden on respondents
  - Ensure data collection meets a specific agency need
  - Not unnecessarily duplicate available information

- Process:
  - Two opportunities for public comments
    - First Federal Register Notice
      - Published on August 12, 2008
      - 90 Day Comment Period – November 10, 2008
BACKGROUND – Paperwork Reduction Act

• Process (Cont):
  • What happens in between Federal Register Notices?
    • EPA will address public comments
    • Tailor the survey according to the feedback provided
  • Second Federal Register Notice
    • 30 Day Comment Period
    • Publish at the time Information Collection Request (ICR) package is submitted to OMB for approval
HEALTH CARE INDUSTRY SURVEY

• Purpose
  • How much unused, expired and unwanted pharmaceuticals are being disposed and to where?
    • Interest: Disposed to Municipal Wastewater Treatment Plants from Hospitals, Long-term Care Facilities, Hospices and Veterinary Facilities
  • Identify Current Industry Practices, Guidance and Regulatory Requirements
  • Identify Best Management Practices (BMPs)
  • Determine the amount of unused pharmaceuticals disposed of, not just down the drain
HEALTH CARE INDUSTRY SURVEY

- Want to work directly with industry associations and health care industry representatives
- Coordinating with Federal, State and local governments
- **Scope of Study**
  - Hospitals, hospices, long-term care facilities, and veterinary hospitals
  - Should EPA Include in the Study?
    - Veterinary clinics
    - Medical and dental offices
    - University and prison health clinics
HEALTH CARE INDUSTRY SURVEY

- Method for Collecting a Nationally Representative Data
  - Identify national population
    - Welcome suggestions for listing of companies/organizations
  - Identify characteristics that define key differences
    - Example: Location (urban vs. rural)
  - Draw sample of facilities based on key characteristics
HEALTH CARE INDUSTRY SURVEY

- Overview of Question Categories
  - What are the options for disposing of unused pharmaceuticals other than down the drain or toilet?
  - What factors influence disposal decisions?
  - What Best Management Practices (BMPs) could facilities implement to reduce the generation of unused pharmaceuticals?
  - How do you dispose of your unused pharmaceuticals?
  - Which pharmaceuticals are being disposed of, in what quantities, and at what cost?
HEALTH CARE INDUSTRY STUDY

Activities – Accomplished

- Identified Data Needs
  - No national data exists to quantify:
    - Amount of unused, expired, unwanted pharmaceuticals disposed of
    - Methods of disposal
- Developed Draft of ICR
  - Includes a questionnaire for medical facilities and another questionnaire for veterinary facilities
- Published First Federal Register Notice in Accordance with PRA on August 12, 2008
- Initiated Site Visits
Activities – Current

- Meeting with Stakeholders and Industry Experts on the Survey
  - Directly affected facilities/organizations
    - September 11, 2008 (1-3 pm ET)
    - September 16, 2008 (1-3 pm ET)
  - All interested parties
    - September 18, 2008 (1-3 pm ET)
  - Identify other avenues for feedback
- Review Comments and Suggestions Provided for HCI Study
- Perform Site Visits to Health Care Facilities
  - Long-term care facility
  - Veterinary hospital
Activities – Next Steps

- Address Comments and Suggestions Provided in Response to the First Federal Register Notice
- Ongoing Communication with Stakeholders and Industry Experts
- Publish a Second Federal Register Notice for Review and Comments
- Submit ICR to OMB
- OMB Approves Survey
- Conduct Nationwide Survey of HCI Facilities
HEALTH CARE INDUSTRY STUDY

SCHEDULE

• Calendar Year 2008
  • Stakeholders Teleconference
    • September 18, 2008 (1-3pm ET)
  • November 10, 2008 - Deadline for Public Comments for First Federal Register Notice
  • Health Care Facility Site Visits
SCHEDULE – Continued

• **Calendar Year 2009**
  • Health Care Facility Site Visits
  • Publish Second Federal Notice for Public Review
  • Obtain approval from OMB
  • Conduct Nationwide Survey of Facilities In Scope

• **Calendar Year 2010**
  • Develop national estimates of pharmaceutical disposal from survey responses
  • Identify Possible Best Practices for Pollutant Source Control and Associated Costs
  • October 2010 - Development of Final Report to be Published with the 2010 Plan
FOR MORE INFORMATION….

Please contact us if you would like to be included in our study.

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