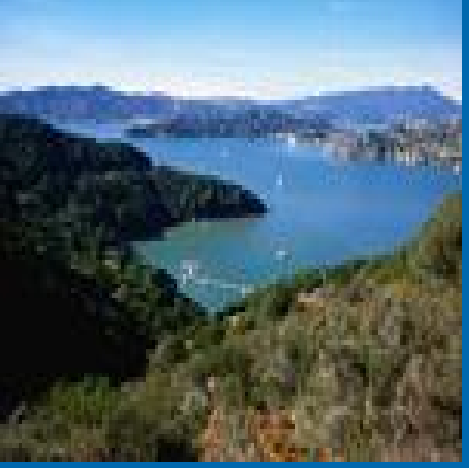

Environmental Stewardship of Waste Pharmaceuticals from a Hospital Perspective

August 24th, 2005

Las Vegas, NV

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The Hospital Perspective

- Today's comments based on PharmEcology's interaction with the healthcare industry:
  - **Conducted on-site risk assessments for over 30 hospitals in the past 3 years**
  - **Analyzed the drug formularies of over 35 hospital pharmacies**
  - **Conducted over 70 seminars in the past 5 years to healthcare professionals on this topic**
  - **Worked closely with EPA and state environmental regulatory authorities in the area of pharmaceutical waste**
  - **Involved with an EPA-funded grant to Hospitals for a Healthy Environment to develop an Rx management blueprint**

If the Shoe Doesn't Fit….

- The only federal regulation to deal with pharmaceutical waste generated in healthcare facilities is the Resource Conservation and Recovery Act
- RCRA was drafted for industrial settings and bulk chemicals, not for healthcare settings and pharmaceuticals in finished dosage forms (tablets, capsules, injectables, etc.)
- RCRA is only starting to be enforced in healthcare facilities; much education and "encouragement" is needed
- Many drugs currently causing concern are not captured at all under RCRA and certain RCRA drugs should be re-evaluated to determine their actual environmental risk

Beginning at the End…

- Current RCRA regulations need to be clarified and enforced uniformly
- A new paradigm for regulating pharmaceutical waste needs to be developed at the federal level
- Regulatory hurdles to consumer take-back programs need to be included in the dialog
- Resources need to be committed towards this effort from the air, water, and solid waste offices of EPA
- A dialog needs to be facilitated between state and federal regulatory agencies, pharmaceutical supply chain and healthcare organizations, and non-profit stakeholders

Back to the Beginning….What's Happening in Healthcare?

- Very little awareness of the impact of pharmaceutical waste disposal
- No training in the Resource Conservation and Recovery Act as it applies to waste drugs
- Little understanding of the concept of endocrine disruption
- No corporate mission involving waste disposal until fairly recently
- Hospitals for a Healthy Environment (H2E)

Hospitals for a Healthy Environment

2004 Champion for Change Award

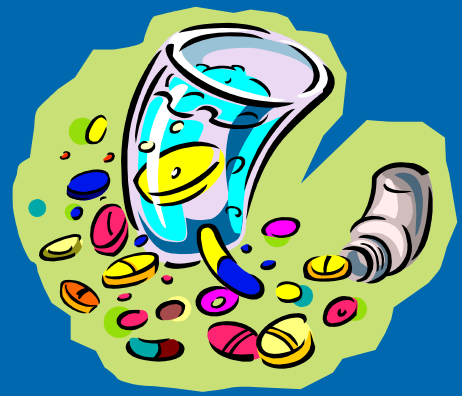
- Enhanced focus on hazardous waste and pharmaceutical waste
  - http://www.h2e-online.org/tools/chem-hwm.htm
  - http://www.h2e-online.org/tools/chem-pharm.htm
- EPA grant to H2E to develop a pharmaceutical waste management blueprint
- EPA grant to H2E to train JCAHO inspectors on environmental issues
- www.h2e-online.org

Hospitals for a Healthy Environment™

- Healthcare Environmental Resource Center
- Funded by EPA Office of Enforcement and Compliance Assistance and H2E
- Launched in April, 2005
- Environmental Compliance and Improvement Guide
  - "To improve compliance with JCAHO Environment of Care Standards"
  - http://www.hercenter.org/regsandstandards/jcahointro.html
- Hazardous waste determination
  - http://www.hercenter.org/hazmat/hazdeterm.html

How is Pharmaceutical Waste Generated at the Healthcare Facility?

- IV Preparation
- General Compounding
- Spills/Breakage
- Partially Used Vials
- Partially Used Syringes/IVs
  - If Contaminated, Biohazardous
- Discontinued, Unused Preparations
- Unused Repacks (Unit Dose)
- Patients' Personal Medications
- Outdated Pharmaceuticals



When is an Outdated Drug a Waste?

- At the time and place the decision is made to discard it
- Two EPA guidance letters to the industry:
  - Merck & Co., 1981
  - BFI Pharmaceutical, 1991
- Has enabled shipping of potentially creditable outdates to a reverse distributor as product
- PROHIBITS the shipping of waste-like items, such as unused IVs, partial vials, expired repacks, samples
- Hospital is liable for using due diligence in selecting a vendor
- New interpretations in EPA Region 2 and the State of Minnesota regarding the shipment of outdated drugs that will become hazardous waste when disposed

Demographics of DEA Registered Reverse Distributors: 39 Facilities in 21 States*

- **Illinois** 5
- **Florida** 6
- **Georgia** 4
- **Tennessee** 2
- **Arizona** 2
- **New Jersey** 1
- **New York** 2
- **North Carolina** 1
- **Indiana** 2
- **Iowa** 1
- **Oklahoma** 1
- **Michigan** 1
- **Minnesota** 1
- **Missouri** 1
- **Washington** 1
- **Pennsylvania** 2
- **Wisconsin** 1
- **California** 1
- **Texas** 1
- **Ohio** 1
- **Utah** 2

* 2003 DEA FOIA List of Registrants

The Major Players
85% of Market

- Capital Returns, Inc.
- Carolina Logistics
  - USF Processors
  - Med-Turn
- EXP Pharmaceutical Waste Management, Inc.
- Guaranteed Returns
- Stericycle (new entry)
  - Direct Returns
  - Rx Automation, Inc.
- Universal Rx

Reverse Distribution Generally Works

- Centralizes outdated drugs into a finite number of warehouses which can be monitored for compliant hazardous waste disposal procedures
- Returns millions of dollars to the healthcare industry from pharmaceutical manufacturers each year
- Removes outdated drugs from the market in a systematic fashion, thereby reducing diversion possibilities
- Could provide the infrastructure for national consumer take-back programs in the future
- Causes some heartburn with respect to a strict interpretation of the RCRA regulations
- Making pharmaceuticals “Universal Waste” could ease the regulatory misfit

Universal Waste: One Approach to Regulatory Reform

- Enacted in December, 2004, in Michigan
- Final draft stages in Florida
- Has limited impact when done on a state-by-state basis
- Still only deals with RCRA hazardous waste
- Some benefits to the generator and handler but does not solve the pollution prevention problems for 95% of the drugs on the market

Theoretical Hospital Rx Waste Streams

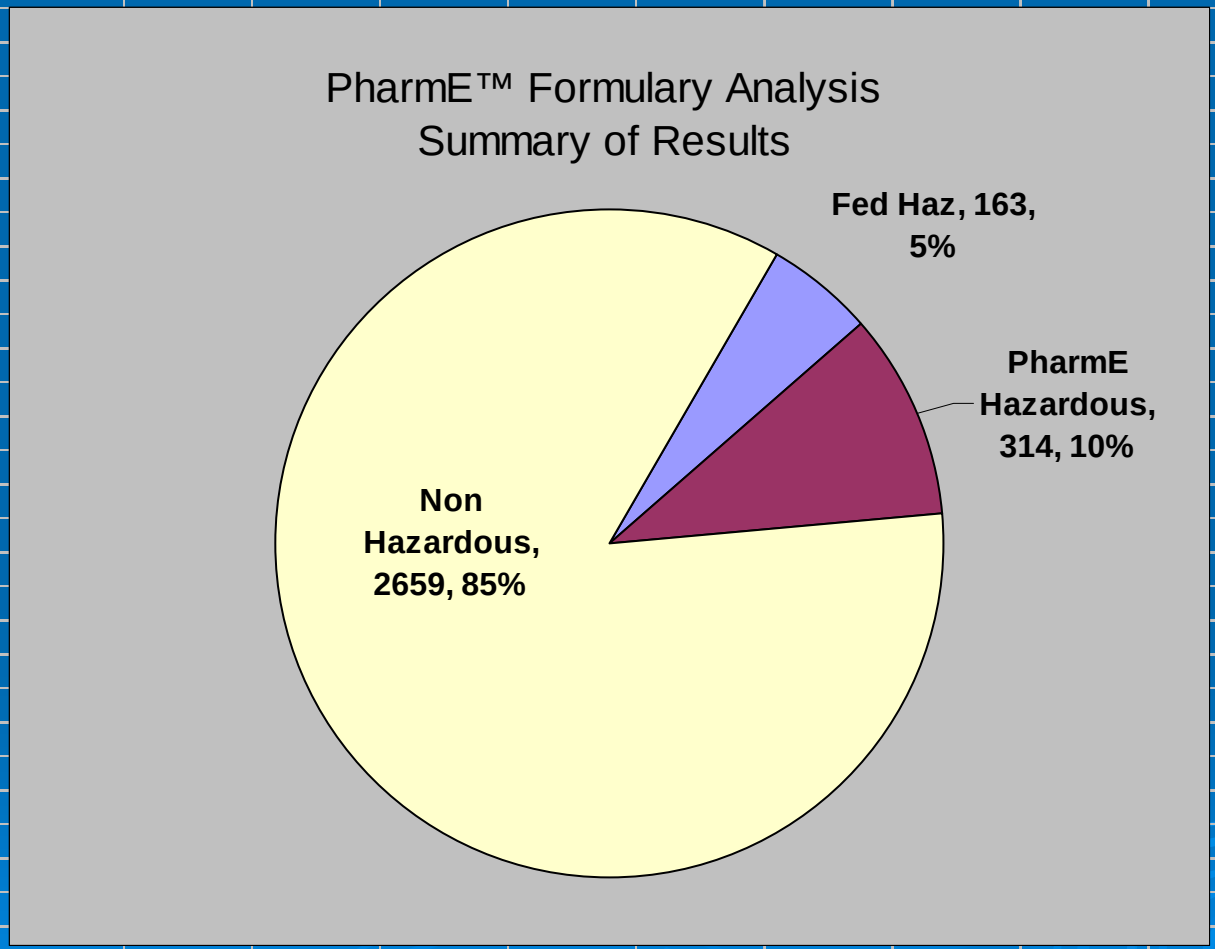
- Hazardous chemical waste
  - Toxic P, U, D listed wastes
  - Ignitable
- Non-RCRA hazardous waste
  - Chemotherapy waste
  - Endocrine disruptors
  - Other equally hazardous pharmaceuticals
- “Non-hazardous” drugs
  - Antibiotics/antimicrobials: Cipro, Levaquin, erythromycin
  - Controlled substances: morphine, Valium
  - Antihypertensives: Inderal
  - Anticholestermics: Lipitor
  - Antidepressants: Prozac, Zoloft
  - Anti-inflammatories: Motrin, Naprosyn

Non-RCRA Hazardous Waste

- Developed as a Best Management Practice by PharmEcology Associates (PharmE Hazardous™)

- Primary criteria:
  - Chemotherapy
  - OSHA and NIOSH Hazardous Drugs
  - Known carcinogen
  - Combination of more than one P or U drug
  - Endocrine disruptors

Memorial Hospital



Detailed Information by Therapeutic Category

		Fed Haz	PharmE Hazardous	Non Hazardous	Total
01	Anti_Infective Agents		30	274	304
17	Biologicals	4		29	33
21	Antineoplastic Agents	27	89	5	121
22	Endocrine and Metabolic Drugs	13	54	144	211
31	Cardiovascular Agents	29	2	340	371
41	Respiratory Agents	15	27	180	222
46	Gastrointestinal Agents	1		236	237
53	Genitourinary Products	1	12	29	42
57	Central Nervous System Drugs	10		239	249
64	Analgesics and Anesthetics	2	23	396	421
72	Neuromuscular Drugs		32	86	118
77	Nutritional Products	3	6	148	157
82	Hematological Agents	9	5	100	114
86	Topical Products	39	18	306	363
92	Miscellaneous Products	10	16	147	173
Total		163	314	2659	3136

How are Chemotherapy Drugs Disposed Today?

- Chemotherapy items usually segregated into yellow Regulated Medical Waste containers
  - Disposed through incineration at an RMW facility
- What's wrong with this picture?
  - Nine chemotherapy drugs are RCRA hazardous wastes and are being disposed in violation of RCRA regulations
  - Over 100 chemotherapy drugs are not regulated as hazardous waste federally

How are Unused IVs Disposed Today?

- Unused IVs other than chemotherapy are being disposed down the drain
- What's wrong with this picture?
  - P, U, and D listed hazardous wastes are being drain disposed without permission from the POTW, state regulatory authority, and Regional EPA
  - Additional potent drugs such as endocrine disruptors and antibiotics can be legally disposed through sewering

How are Vials, Ampules, and Other Injectables Disposed Today?

- Vials and ampules containing drugs are being disposed in red sharps containers.
- What's wrong with this picture?
  - Red sharps containers are regulated medical waste and are for the most part being autoclaved or microwaved, shredded, and landfilled in a municipal non-hazardous landfill. Contents will likely leach and at some time enter water resources.

How are other Solid and Liquid Dosage Forms Being Disposed Today?

- Ointments, oral liquids, and other multi-dose containers are often discarded in the trash
- What's wrong with this picture?
  - RCRA hazardous wastes and other potent drugs are being landfilled which will eventually result in leachate which will enter water resources

Which Discarded Drugs Become Hazardous Waste?

- P-listed chemicals
  - Sole active ingredient
- U-listed chemicals
  - Sole active ingredient
- Characteristic of hazardous waste
  - Ignitability
  - Toxicity
  - Corrosivity
  - Reactivity

Examples of P-Listed Pharmaceutical Waste

Arsenic trioxide	P012
Epinephrine	P042
Nicotine	P075
Nitroglycerin*	P081
Phentermine (CIV)	P046
Physostigmine	P204
Physostigmine Salicylate	P188
Warfarin >0.3%	P001

*Excluded from the P list federally and in many states

A Success Story

- Nitroglycerin is P-listed under RCRA for reactivity
- In 2001, under the Hazardous Waste Identification Rule, if waste containing a P and U listed chemical that was listed for either ignitability, corrosivity, or reactivity, no longer exhibits that characteristic, the waste is excluded from regulation.
- This action removed waste nitroglycerin in finished dosage forms from regulation as a P-listed waste federally. States have been adopting this exclusion and a majority no longer regulate medicinal nitroglycerin as hazardous waste unless it exhibits another characteristic of hazardous waste, such as ignitability.
- This action has provided important regulatory relief by reconciling the actual environmental risk with generator responsibility

Examples of U-listed Pharmaceutical Waste*

- Chloral Hydrate(CIV) U034
- *Chlorambucil* U035
- *Cyclophosphamide* U058
- *Daunomycin* U059
- *Diethylstilbestrol* U089
- *Melphalan* U150
- *Mitomycin C* U010
- *Streptozotocin* U206
- Lindane U129
- Saccharin U202
- Selenium Sulfide U205
- *Uracil Mustard* U237
- Warfarin<0.3% U248

*Drugs in italics are chemotherapy agents.

How Should RCRA Hazardous Drugs Be Disposed?

- Pharmaceuticals which meet the definitions of hazardous waste under RCRA should be segregated and managed as hazardous waste
- Disposal should be through incineration at a federally permitted RCRA treatment, storage, and disposal facility (TSDF)

How Should Non-RCRA Hazardous Drugs Be Disposed?

- Strongly recommend these be discarded as RCRA hazardous waste
- Consider adding to the P and U list or find an alternative method of regulation
  - Includes hazardous drugs as defined in the NIOSH Hazardous Drug Alert, Appendix A, released October, 2004
  - Includes other endocrine disruptors, over 100 chemotherapy agents, known carcinogens, etc.

How Should Other Potent Drugs Be Disposed?

- Strongly recommend incineration at either a Regulated Medical Waste incinerator or a municipal solid waste incinerator permitted to handle non-hazardous drugs
- STOP deliberate sewering of antibiotics, antihypertensives, etc
- NO state regulatory requirements other than in California, Washington, Minnesota
- Potential for regulation exists at the local POTWs (Publicly Owned Treatment Works) or federally within the Clean Water Act
  - Little Rock, Arkansas – prohibits sewering of drugs

Increasing USEPA Regulatory Activity

- EPA Region 2 (NY, NJ, Puerto Rico, VI) contacted 480 hospitals in 2003; Rx waste included.
- Region 2 Website: http://www.epa.gov/region02/healthcare/
  - North Shore University Hospital, Manhasset, NY fined $40,000 (July 2003)
    - http://www.epa.gov/Region2/news/2003/03066.htm
  - Nassau University Medical Center, East Meadow, NY fined $279,900 (Oct. 2003)
    - http://www.epa.gov/region2/news/2003/03127.htm
  - Mountainside Hospital, Montclair, NJ fined $64,349 (Nov. 2003)
    - http://www.epa.gov/Region2/news/2003/03139.htm
  - Memorial Sloan Kettering Cancer Center, New York , NY, fined $214,420
    - http://www.epa.gov/region02/news/2004/04008.htm
- EPA Region 1 New England contacted 250 hospitals in April, 2004
- Website: http://www.epa.gov/NE/pr/2004/apr/040407.html
  - Enforcement initiative in New England

Region II Statement

“Hospitals and healthcare facilities must consider the proper handling of hazardous waste an integral part of their mandates to protect people's health,” said Jane M. Kenny, EPA Regional Administrator.

“Chemotherapy waste is an especially toxic waste produced by many medical facilities. Hazardous waste regulations are in place to help to ensure that facilities like Sloan-Kettering do not release these or other toxic chemicals into the environment.”

Increasing State Regulatory Activity

- **Florida**
  - A Guide on Hazardous Waste Management for Florida's Pharmacies, www. floridacenter.org
- **Washington State**
  - Managing Pharmaceutical Waste website: http://www.ecy.wa.gov/programs/hwtr/pharmaceuticals/index.html
  - Offered pharmaceutical waste training program October, 2003
- **California**
  - Management of Pharmaceutical Medical Waste, October, 2002
  - Memo on sewer disposal of pharmaceutical waste, September 5, 2003 DHS
- **Minnesota**
  - Training over the past two years
  - Enforcement began July 1, 2005

Why Is Compliance Resisted?

- No perceived threat to a crisis driven industry
- The regulations are not rational from a healthcare perspective
- Specific guidance has been confusing or not forthcoming
- Drug disposal categorization has not been integrated into pharmacy software systems

How Can EPA Assist in Compliance Efforts?

- Enforce the current regulations uniformly across the country so that compliant hospitals are not penalized by an uneven playing field
- Create a special regulatory/classification system for pharmaceutical finished dosage forms in healthcare settings
- Deal with drugs outside the definition of RCRA which are of great concern environmentally
  - Antibiotics
  - Antidepressants
  - Endocrine disruptors, etc.

EPA Assistance

- Expand the current Hotline exemption for epinephrine in a used syringe to other P, U, and toxic D listed wastes to avoid mixed infectious/hazardous wastes

- Re-evaluate the environmental impact of dilute drugs like 1:1000 epinephrine
  - Currently, a vial containing any epinephrine as a sole active ingredient must be disposed of as hazardous waste even if empty
  - This makes no sense environmentally

Regulatory Consensus

- Develop a consensus document nationally that all EPA RCRA and state hazardous waste agencies can use as a reference
  - Minnesota Pollution Control Agency recently completed this process
  - http://www.pca.state.mn.us/publications/w-hw3-35.pdf

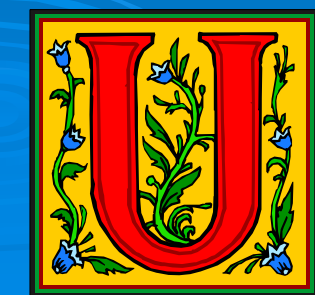
Consensus Issue Examples

- What is the definition of “sole active ingredient”?
  - More than one ingredient exhibiting any activity or more than one ingredient having the same activity?

- What drugs that become RCRA hazardous are allowed to be returned through reverse distribution?
  - Drugs that are potentially creditable?
  - Demonstrated to be creditable?
  - Regardless of creditability?

Update the P and U List to Reflect Drug Development

- Only 9 chemotherapy drugs listed – none added since 1976
- Consider harmonizing the EPA list of hazardous drugs with the NIOSH Hazardous Drug Alert, Appendix A
- Develop a system for annual updates based on drug development – NIOSH model

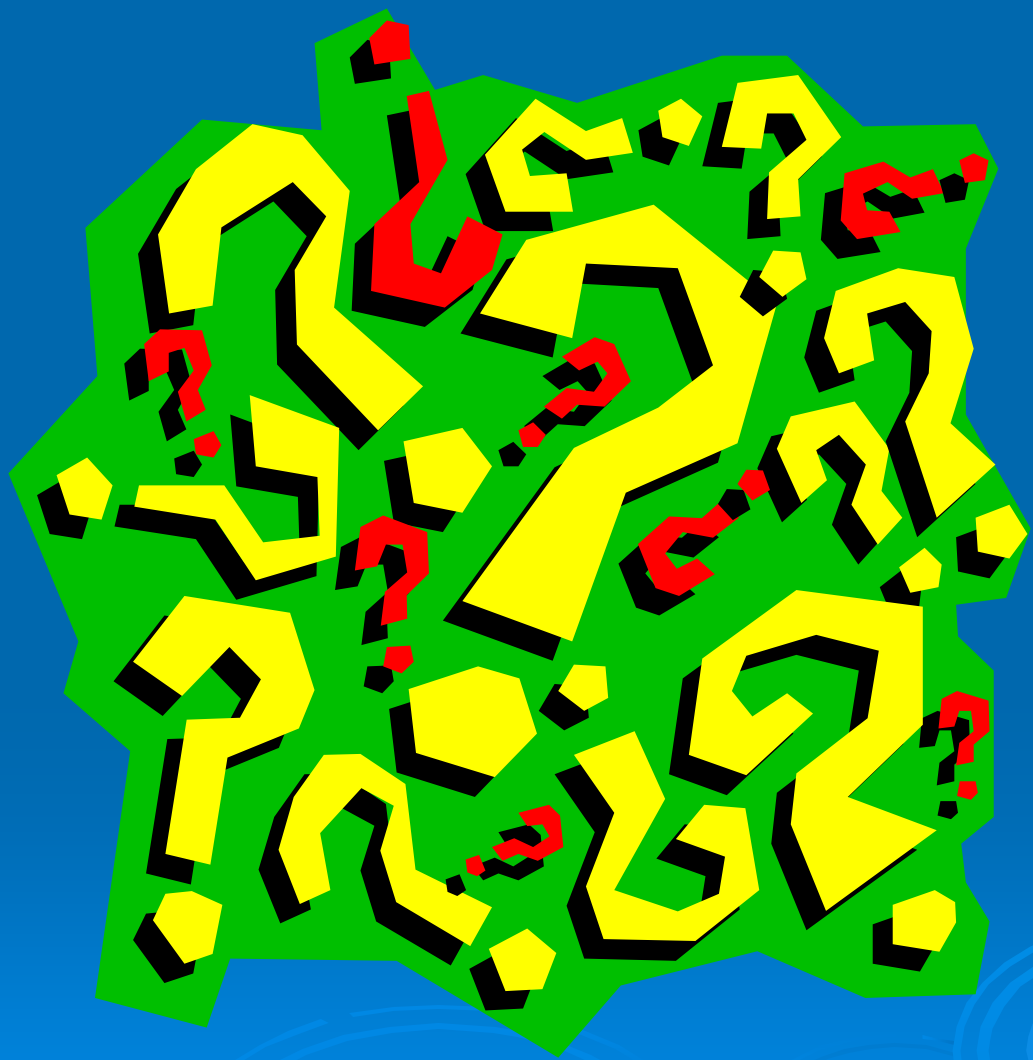


NIOSH Hazardous Drug Alert

- National Institutes of Occupational Safety & Health
- Non-enforcement arm of OSHA, administered under Centers for Disease Control (CDC)
- Hazardous Drug Work Group met for 4 years
- Recently released comprehensive new guidelines for total life cycle management of OSHA “Hazardous Drug”
- Identifies “hazardous waste” and need for appropriate disposal
- http://www.cdc.gov/niosh/topics/hazdrug/

Conclusions

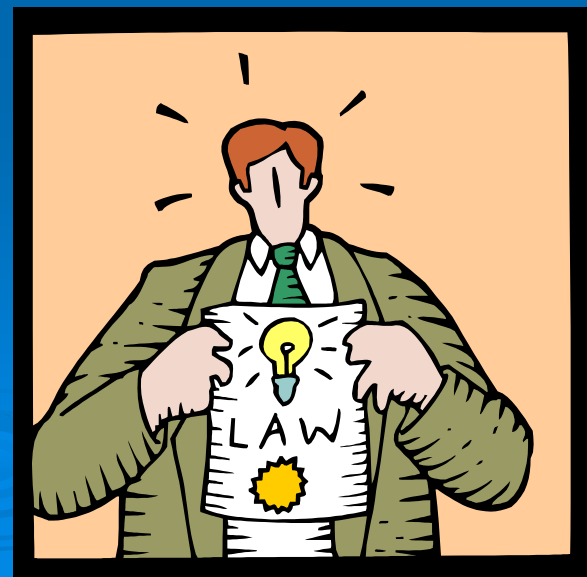
- A comprehensive dialog needs to be undertaken to determine the most effective methods of preventing drugs from entering the environment
- Representatives from healthcare facilities, including hospitals, long term care, assisted living, and other alternate care sites, need to be intimately involved along with all supply chain members (manufacturers, wholesalers, pharmacies, reverse distributors)
- New regulations may be needed to provide the most rational and effective method of insuring environmentally sound management practices for waste pharmaceuticals



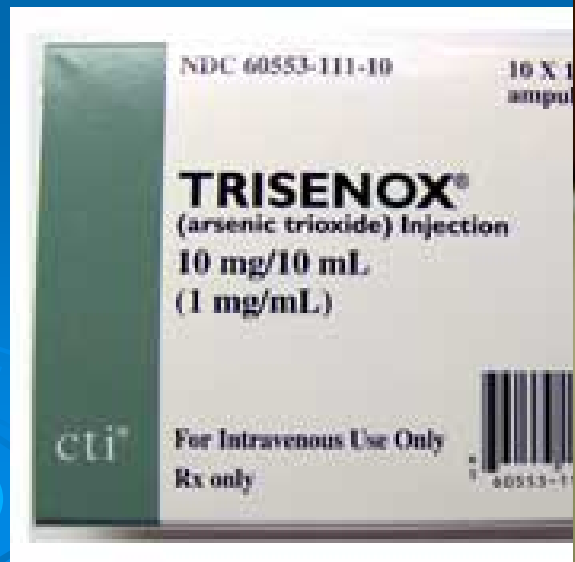
Appendix and Resources

RCRA: The Defining Regulation

- Resource Conservation & Recovery Act
  - Enacted in 1976, enforced by the EPA
  - Federal regulation of the disposal of solid wastes
  - Encourages the minimization of waste generation
- Defines “hazardous waste”
- “Cradle to Grave” tracking of hazardous waste
- Households are exempt



Examples of P-Listed Pharmaceuticals



Impact of P-listed Waste

- Only 1 kg or 2.2 pounds/month cause facility to become a large quantity generator
- Weights of P-listed drug waste must be combined with any other P-listed waste generated at the facility in a given month
- Technically, containers that have held P-listed wastes are not “RCRA empty” unless they are triple rinsed and the rinsate discarded as hazardous
  - Exception: EPA Hotline guidance and MPCA guidance exempts epinephrine syringe that has been injected into a patient and is therefore infectious waste; recently expanded to all P and U listed drugs in used syringes

Chemotherapy Waste

- Eight chemotherapy agents are U-listed; one is P-listed
- Medical waste hauler protocols for “Chemo Waste”
  - Empty vials, syringes, IV’s
  - Treated as infectious medical waste preferably through regulated medical waste incineration
- If not empty, should be placed into Hazardous Waste container

Definition of “Empty”

- “P” List

  Containers of “P” listed chemicals are considered hazardous waste, unless they have been rinsed three times and the rinsate discarded as hazardous waste.

- “U” List

  Containers of “U” listed chemicals are empty only when

  - All contents removed that can be removed through normal means
  - And no more than 3% by weight remains

Examples of U-Listed Pharmaceuticals

Characteristic of Ignitability

- Aqueous Solution containing 24% alcohol or more by volume & flash point<140° F.
- Hazardous Waste Number: D001
- Rubbing Alcohol
- Topical Preparation
- Injections

Characteristic of Corrosivity

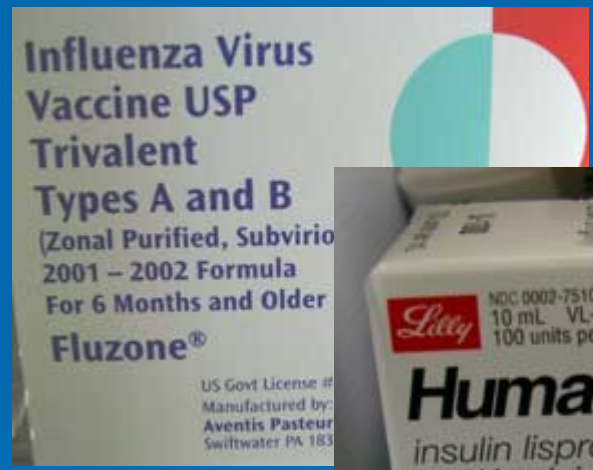
- An aqueous solution having a pH < or = 2 or > or = to 12.5
- Examples: Primarily compounding chemicals
  - Glacial Acetic Acid
  - Sodium Hydroxide
- Hazardous waste number: D002

Characteristic of Toxicity

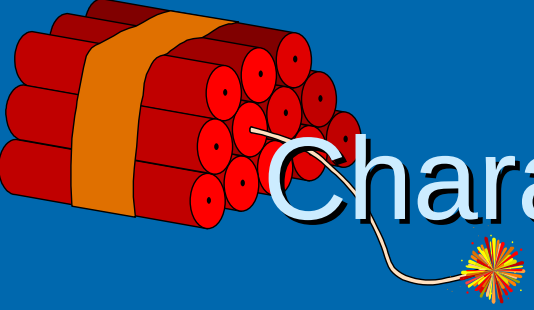
- Approximately 40 chemicals which meet specific leaching concentrations
- Examples of potential toxic pharmaceuticals:
- Arsenic
- Barium
- Cadmium
- Chloroform
- Chromium
- Lindane
- m-Cresol
- Mercury (thimerosal)
- phenylmercuric acetate)
- Selenium
- Silver

Examples of Pharmaceuticals Exhibiting the Characteristic of Toxicity

Heavy Metals: Selenium, Chromium and Silver



Preservatives: thimerosal & m-cresol



Characteristic of Reactivity

- Meet eight separate criteria identifying certain explosive and water reactive wastes
- Nitroglycerin formulations may be considered excluded from the P081 listing as non-reactive as of August 14, 2001 under FR: May 16, 2001, unless they exhibit another characteristics, such as ignitability.
- Many states have adopted the HWIR exclusion. Still must be evaluated for ignitability.
- Hazardous Waste Number for reactives: D003

How Can Hazardous RX Waste Generation Be Minimized?

- Inherent limitations on substitution of a less hazardous drug since the hazardous nature of the chemical often provides the therapeutic effect
- Tighter inventory control to reduce outdate generation, both original manufacturers' containers and repacks
- Single dose vials vs. multiple dose vials
- Patient specific oral syringes vs. 10 cc. repacks (e.g. choral hydrate for pediatric use)

Solutions to Help Identify & Manage Pharmaceutical Hazardous Waste

- PharmE™ Formulary Analysis
  - A detailed analysis report of the hospital's formulary with complete pharmaceutical waste stream recommendations identifying all federally hazardous and PharmE Hazardous™ waste.

- PharmE™ Waste Wizard
  - On-line subscription to over 135,000 items, updated with an average of 300 new items weekly; over 1,000 new hazardous items added in the past six months.

Identifying Hazardous Pharmaceutical Waste Using the PharmE™ Waste Wizard

- **Federal Hazardous Waste**
- **PharmE Hazardous Waste**
- **“Non-hazardous” Waste**

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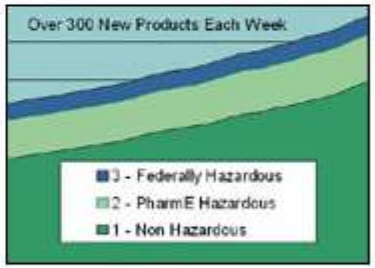

Pharm@™ On-Site Risk Assessment
Find out how your current pharmaceutical waste management practices can be improved

Pharm@™ Policies and Procedures
Use our EPA Resource Conservation and Recovery Act (RCRA) compliant templates to upgrade your policies and procedures

News Alert: PharmEcology® Announces a New Brand, a New Wizard, and New Waste Categories!

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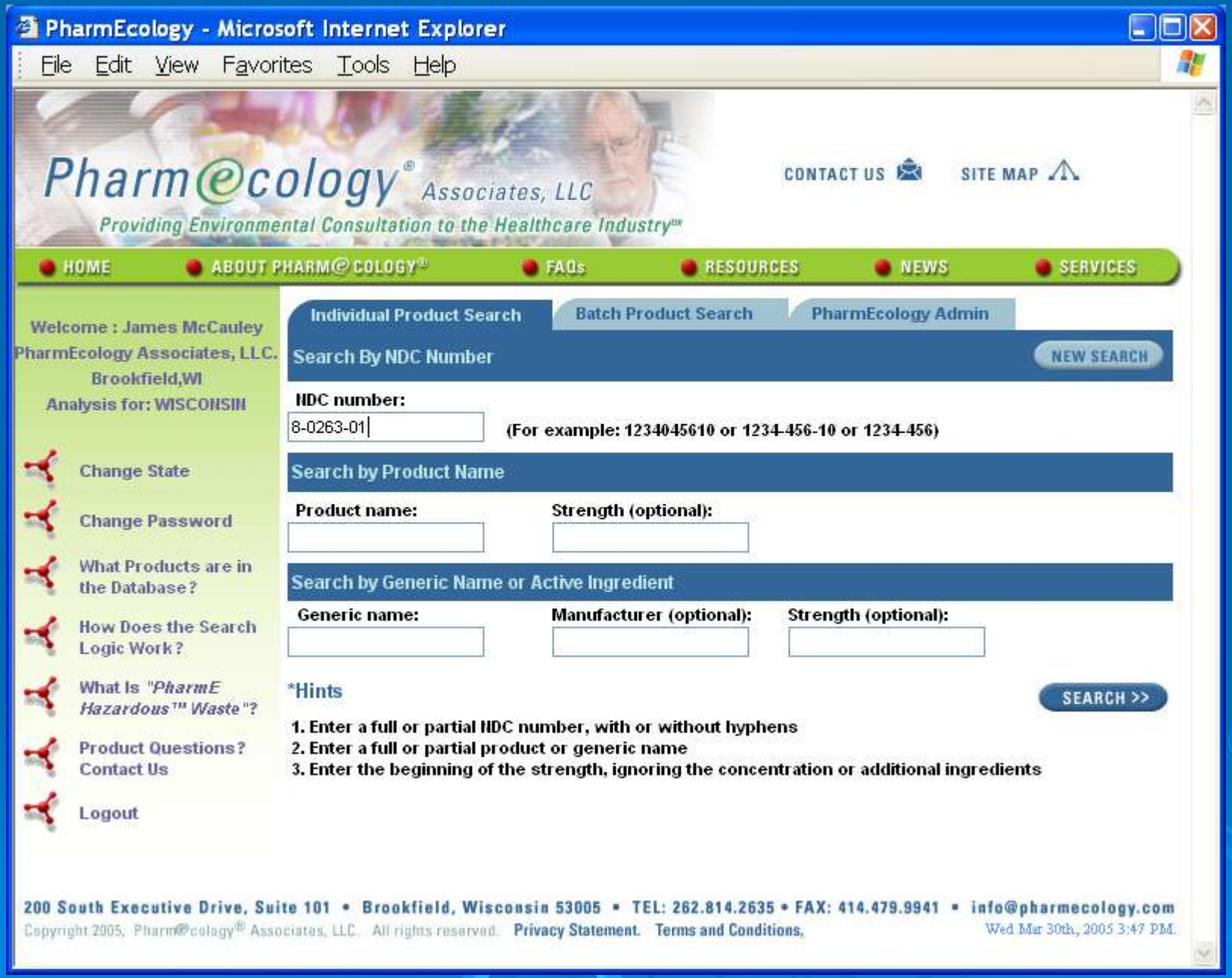
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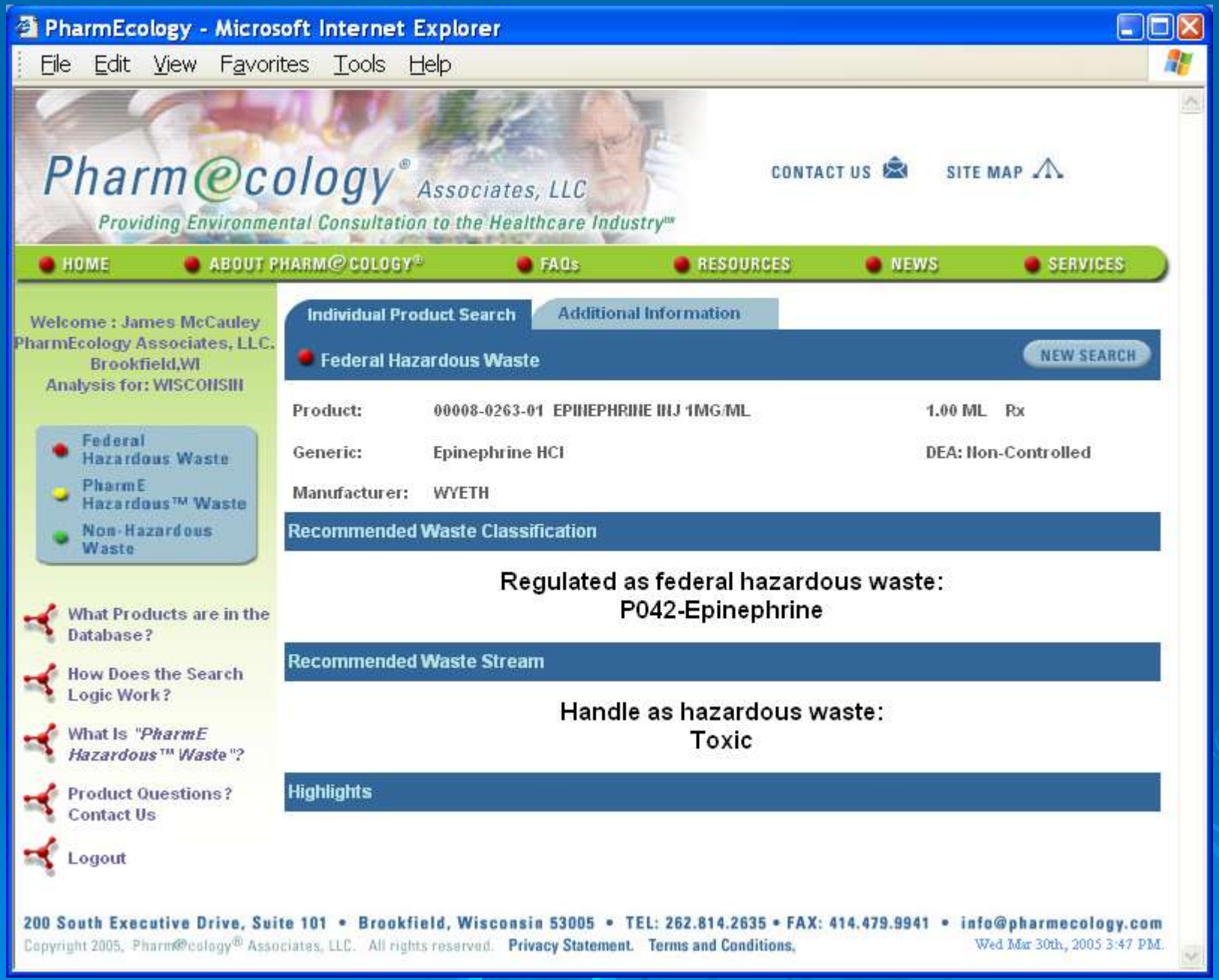
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Recommended Waste Stream
Handle as hazardous waste:
Toxic
Highlights
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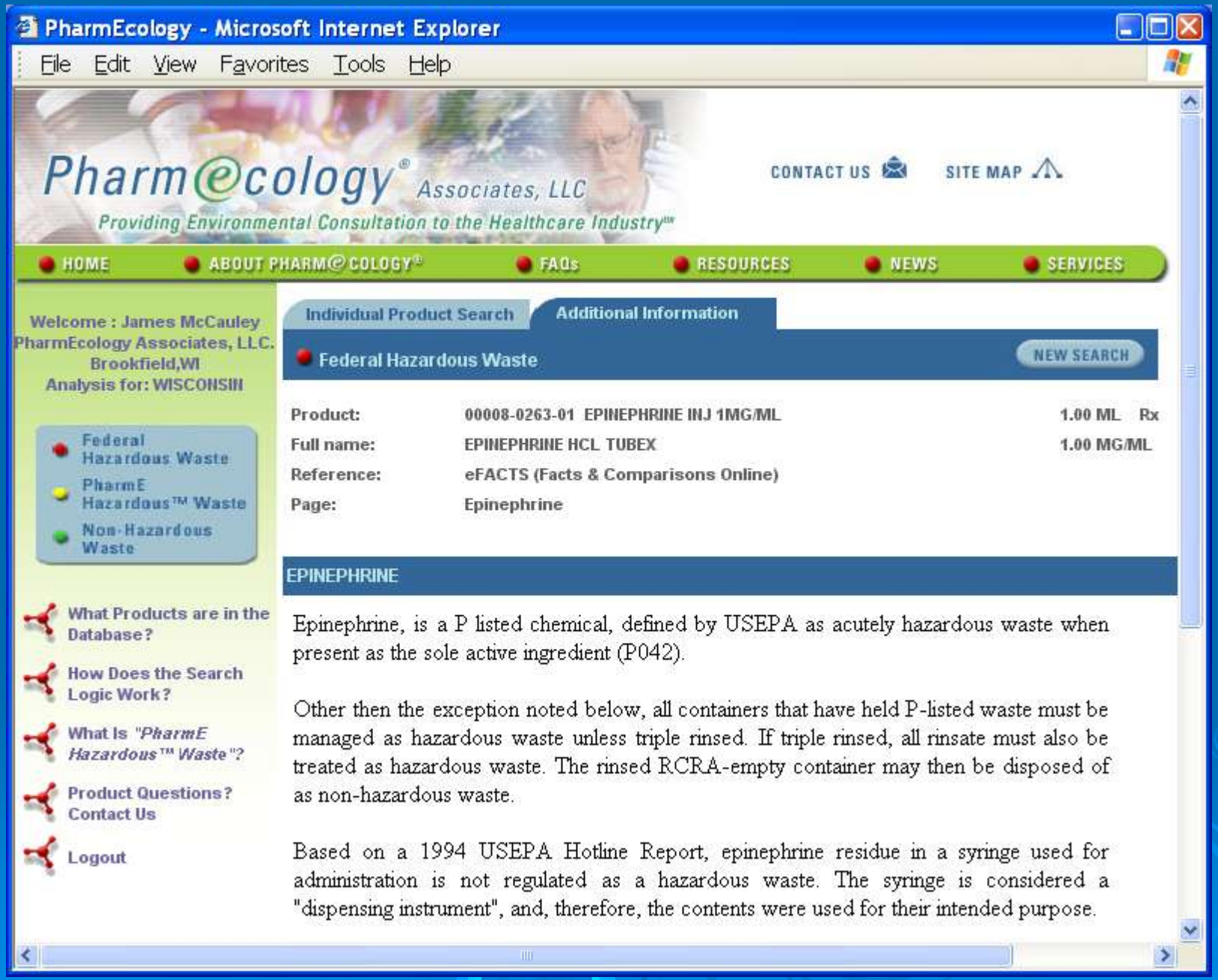
Wed Mar 30th, 2005 3:47 PM.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Providing Environmental Consultation to the Healthcare Industry℠
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Welcome : James McCauley
PharmEcology Associates, LLC.
Brookfield,WI
Analysis for: WISCONSIN
Federal Hazardous Waste
PharmE Hazardous™ Waste
Non-Hazardous Waste
What Products are in the Database?
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NEW SEARCH
Product: 00008-0263-01 EPINEPHRINE INJ 1MG/ML 1.00 ML Rx
Full name: EPINEPHRINE HCL TUBEX 1.00 MG/ML
Reference: eFACTS (Facts & Comparisons Online)
Page: Epinephrine
EPINEPHRINE
Epinephrine, is a P listed chemical, defined by USEPA as acutely hazardous waste when present as the sole active ingredient (P042).
Other then the exception noted below, all containers that have held P-listed waste must be managed as hazardous waste unless triple rinsed. If triple rinsed, all rinsate must also be treated as hazardous waste. The rinsed RCRA-empty container may then be disposed of as non-hazardous waste.
Based on a 1994 USEPA Hotline Report, epinephrine residue in a syringe used for administration is not regulated as a hazardous waste. The syringe is considered a "dispensing instrument", and, therefore, the contents were used for their intended purpose.

Resources

- www.pharmecology.com
- Pharmaceutical Waste: http://www.h2e-online.org/tools/chem-pharm.htm
- Pharmaceuticals and Personal Care Products as Environmental Pollutants: http://www.epa.gov/nerlesd1/chemistry/pharma/index.htm
- Healthcare Environmental Resource Center: http://www.hercenter.org/
- A Guide on Hazardous Waste Management for Florida's Pharmacies, www. floridacenter.org.
- RCRA On-Line http://www.epa.gov/rcraonline/
- RCRA Hot Line 1-800-424-9346