U.S. Department of Transportation
Pipeline and Hazardous Materials Safety Administration

1200 New Jersey Ave, S.E.
Washington, D.C. 20590

FEB 2 4 2009

Mr. Dan Fadgen
Stericycle, Inc.
103 Brannon Drive
Canton, GA 30115

Reference No. 08-0249

Dear Mr. Fadgen:

This is in response to your recent e-mail to two of our enforcement officers concerning requirements in the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) that apply to the transportation of hazardous wastes. Your letter was directed to the Office of Hazardous Materials Standards for reply. You ask if incompatible Resource Conservation and Recovery Act (RCRA) pharmaceutical waste, such as oxidizers and corrosives, may be placed in the same package either in separate inner packagings or commingled without inner packagings. Your questions are paraphrased and answered in the order provided.

Q1. A typical hospital pharmacy inventory includes pharmaceuticals that meet the definition of Class 3 (flammable liquid), Class 2.1 (flammable gas), Class 2.2 (non-toxic, non-flammable gas), Division 5.1 (oxidizer), Division 6.1 (poisonous), and Class 8 (corrosive) materials. When transported as wastes, the materials must conform to RCRA regulations. If the hazard class of each pharmaceutical is not identified and segregated prior to packaging for transport, how can the generator or transporter (carrier) ensure that these materials are not capable of reacting dangerously with each other, causing combustion, or any of the other reactions prohibited under § 173.21(e) or § 173.24(e)(4) of the HMR?

A1. In accordance with § 173.22 of the HMR, it is the shipper's responsibility to properly class a hazardous material and assign it a proper shipping name from the Hazardous Materials Table (HMT; § 172.101). It is also the shipper's responsibility to segregate incompatible hazardous materials before offering them for transportation in commerce and to determine if any dangerous reactions can occur. See § 173.21(e). Thus, the shipper of pharmaceutical waste must ascertain whether the waste materials will react dangerously with each other or cause combustion; a dangerous evolution of heat; evolution of flammable, poisonous, or asphyxiant gases or vapors; or form an unstable or corrosive material. If so, the materials may not be transported in a single packaging.

Although the HMR place primary responsibility on the shipper, or "person who offers," to properly class and communicate the hazard of a hazardous material, a carrier may be held responsible for non-compliance with applicable requirements to the extent that the carrier knows, or should have known, that a material offered for transportation is hazardous. A carrier may rely on information provided by the shipper, unless the carrier knows, or a

reasonable person, acting in the circumstances and exercising reasonable care, would have knowledge that the information provided is incorrect.

Q2. Pharmaceutical waste typically takes the form of partial vials (without safety seal), ampoules, partial syringes, partial IV bags, loose tablets, and capsules. How can the shipper ensure that there will be no dangerous reaction if these materials are shipped in a single container or packaging?

A2. Under the HMR, shippers may combine hazardous materials with other hazardous or non-hazardous materials in the same package provided these materials are not capable of reacting dangerously with each other or causing combustion; a dangerous evolution of heat; evolution of flammable, poisonous, or asphyxiant gases or vapors; or forming an unstable or corrosive material. See §§ 173.21(e) and 173.24(e)(4). Shippers may use a variety of methods to determine whether or not a hazardous material will react dangerously with other materials in a packaging, including testing or similar analysis, experience, information from a Material Safety Data Sheet, or information from publications or reference material pertaining to chemicals and their interactions.

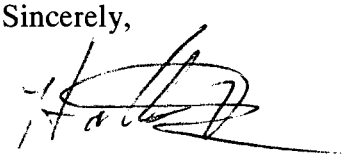
If the materials and method your company wants to use, such as randomly combining hazardous waste pharmaceuticals in one package, do not conform with the existing HMR requirements, your company may wish to seek authorization to transport these materials under the terms of a special permit. The procedures for submitting an application for a special permit are prescribed in 49 CFR 107.105. Please note the application must contain sufficient information to demonstrate that, if a special permit is issued, a level of safety will be achieved that is equal to or greater than that required under the HMR.

Q3. Would combining RCRA hazardous and non-hazardous pharmaceuticals consisting of partial vials, partial syringes, partial IV bags, loose tablets and capsules, etc., meet the requirement stated in PHMSA's letter of March 21, 2008 (Reference No. 08-0035): "provided these materials are not capable of reacting dangerously with each other or causing combustion...."? If not, must RCRA hazardous pharmaceutical waste be segregated and packaged?

A3. The materials you describe would be subject to the compatibility requirements discussed in our March 21, 2008 letter and prescribed in several sections of the HMR, including §§ 173.21(e) and 173.24(e)(4), and 173.24a(c). See Answer A2.

I hope this satisfies your request.

Sincerely,



Hattie L. Mitchell
Chief, Regulatory Review and Reinvention
Office of Hazardous Materials Safety

Edmonson
§173.197
§173.24
Regulated Medical Waste
08-0249

Drakeford, Carolyn <PHMSA>

From: Mitchell, Hattie <PHMSA>
Sent: Tuesday, October 07, 2008 12:57 PM
To: Edmonson, Eileen <PHMSA>
Cc: Drakeford, Carolyn <PHMSA>
Subject: FW: FL DEP - Oct 16 Meeting: Clarification Requested
Attachments: DOT Letter - FL DEP.pdf

From: Fadgen, Dan [mailto:DFadgen@STERICYCLE.com]
Sent: Thursday, October 02, 2008 2:28 PM
To: Razny, Mark <PHMSA>; Stevens, William <PHMSA>
Subject: FL DEP - Oct 16 Meeting: Clarification Requested

Gentlemen,

Please excuse this lengthy email but as you both are aware, FL DEP has formed a Biomedical-Pharma Technical Advisory Committee to assist in developing curriculum on hazardous pharmaceutical waste management for FL DEP's distribution to FL health care providers including hospitals, cancer treatment centers and, nursing homes. The next committee meeting is scheduled for Oct. 16th, at Gaylord Palms Resort Hotel in Kissimmee, FL.

This email requests clarification on U.S. DOT regulations concerning segregation of hazardous materials (including pharmaceuticals) due to confusion arising out of the Aug. 27th committee meeting. Unfortunately the FL DOT representative at the August 27th committee meeting was seemingly unknowledgeable on this matter and failed to provide clarification on this issue.

Mr. Barry Fernandez of Clean Fuels and, a second committee member representing HWS (Hazardous Waste Services), presented the attached letter from Hattie Mitchell, U.S. DOT, as documentation of their understanding that all RCRA hazardous pharmaceutical waste generated by a hospital can be commingled in a common container for transport. Clean Fuels and HWS are reportedly directing FL hospitals to commingle RCRA hazardous and RCRA non-hazardous pharmaceutical waste into common containers (without identification or segregation of RCRA hazardous or incompatible RCRA hazardous pharmaceuticals - oxidizers & corrosives) and are transporting the commingled containers over public highways.

Mr. Fernandez's understanding of Ms. Mitchell's letter is directly counter to my understanding of consistent interpretations of U.S. DOT regulations on segregation of hazardous materials (including pharmaceutical waste) including: a 7/16/08 response to an email inquiry submitted to the U.S. DOT Hazardous Materials Information Center, plus verbal interpretations received from David Clark, U.S. DOT NE Region Office, Laura Kwilinski, U.S. DOT Western Regional Office and, phone conversations with both of you. All cited interpretations consistently specify that hazardous materials (including RCRA hazardous pharmaceuticals), must be segregated and packaged per U.S. DOT's Segregation Table for Hazardous Materials (174.81).

Ms. Mitchell's statement that "Under the HMR, shippers may combine hazardous materials with other hazardous or non-hazardous materials in the same package provided **these materials are not capable of reacting dangerously with each other or causing combustion**...." Seemingly assumes (1) that all of the hazardous pharmaceutical materials are chemically compatible and, (2) that the individual item containers will not break or leak.

(1) A typical hospital's pharmacy inventory includes pharmaceuticals that when declared waste are RCRA hazardous include: Class 3 – Flammable liquids, Class 2.1 – Flammable gas, Class 2.2 – Non-toxic, non-flammable gas, Class 5.1 – Oxidizers, Class 6.1 – Poisonous Liquids and, Class 8 – Corrosive liquids. **QUESTION: Unless the hazardous Rx waste is identified and segregated prior to packaging for**

transport, how can the generator or transporter assure "these materials are not capable of reacting dangerously with each other or causing combustion..." ?

(2) Pharmaceutical waste typically takes the form of partial vials (without safety seal), ampoules, partial syringes, partial IV bags and loose tablets and capsules.
QUESTION: How can such items be randomly thrown into a common container without packaging safe guards and there be assurance of no leaking or breaking - thus resulting in a potential dangerous reaction?

OBSERVATION: During a recent 4 month study at a 208 bed hospital, Stericycle inspected the contents of 269 8gal and 17gal containers used for satellite accumulation of compatible pharmaceutical waste and found free liquids in 14% of the containers.

CLARIFICATION REQUESTED:

(1) Would the combining of RCRA hazardous and RCRA non-hazardous pharmaceuticals consisting of partial vials, partial syringes, partial IV's, loose tablets & capsules etc., meet the requirement stated in Ms. Mitchell's letter re: "provided these materials are not capable of reacting dangerously with each other or causing combustion...."?

(2) If not, must RCRA hazardous pharmaceutical waste be segregated and packaged?

U.S. DOT PARTICIPATION:

Will someone from U.S. DOT will be at the Oct. 16th FL DEP Biomedical-Pharma Technical Advisory Committee meeting to clarify this issue? If so, who will be present?

I respectfully await your response.

Dan Fadgen
Stericycle, Inc.
103 Brannon Drive
Canton, GA 30115
Office: (770) 751-7589
Mobile: (404) 372-7485
dfadgen@stericycle.com