U.S. Department of Transportation

Pipeline and Hazardous Materials Safety Administration

1200 New Jersey Ave, SE
Washington, D.C. 20590

DEC 0 8 2010

Mr. William Perry
Health and Environmental Investigator II
Public Health, Seattle and King County
401 Fifth Avenue, Suite 1100
Seattle, WA 98104

Reference No. 10-0153

Dear Mr. Perry:

This is in response to your telephone conversation with a member of my staff, and your subsequent e-mail and attachments requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) applicable to waste pharmaceuticals. Specifically, you present two transportation plans pertaining to a pilot program the City of Seattle and King County, Washington, would like to begin in these communities to collect waste pharmaceuticals from consumers and transport them for disposal by common carriers using motor vehicles. You described the plans for collecting these materials and conditions common to both, and ask if a special permit or competent authority approval is needed to transport these materials on a one-time or long-term operational basis. You also ask how long it would take to obtain this type of permission. We have paraphrased your questions and answered them in the order you provided.

You state conditions common to the pharmaceuticals in both scenarios are these materials are: 1) Drug Enforcement Administration Schedule 2-5 controlled substances; 2) household hazardous waste exempt under the Environmental Protection Agency's Resource Conservation and Recovery Act and Washington State Dangerous Waste Regulations; and 3) unwanted medications delivered by residents to approved drop-off locations or collected by law enforcement offices in Snohomish County, WA.

Before packing, you state: 1) all the materials collected will be reviewed by a pharmacist experienced at screening returned medicines and sorted by this pharmacist into controlled and non-controlled categories; 2) unacceptable items under the program's criteria will be removed (e.g., sharps, liquid mercury, aerosol cans, etc.); 3) non-controlled medicines will be packaged by a permitted hazardous waste disposal vendor; and 4) controlled medicines will be packaged in a 4 milliliter thick plastic drum liner that is closed with a zip-tie and placed in a 10 or 15 gallon, UN 1G standard fiber drum. You also state full packages will be sealed with tamper-evident tape, tracked and shipped by a common carrier from the Bothell, WA, Police Department to the Sauget, IL, Police Department, and disposed of using an approved method, such as incineration.

You provided one photograph of typical medicines collected, one photograph of a completed package, and two website links that contain examples of the fiber drum packaging.

Scenario A

Medicines will be left in their original consumer packagings. As items containing liquids are packed, the integrity and tightness of their lids will be checked and corrected as needed. Liquid containers will be packed upright and pill vial packagings will be used to separate the liquid containers from each other and the sides of the fiber drum. By weight, an estimate of the contents, based on inventories of materials collected from another pilot program (PH:ARM), is 66 percent will be medications and 34 percent will be packaging materials and containers, and 70 percent of the medicines will be solids and 30 percent will be liquids. The materials packed according to Scenario A will be marked and labeled as "Consumer commodity, ORM-D." This completed package will weigh 66 pounds or less.

Scenario B

Solid medicines will be removed from their original packagings and transferred into an approved outer packaging. Liquids and ointments will remain in their original consumer packagings. As items containing liquids are packed, the integrity and tightness of their lids will be checked and corrected as needed. Liquid containers will be packed upright and loose pills will be used to separate the liquid containers from each other and the sides of the fiber drum. Additional commercial absorbent (e.g., kitty litter) will be used as needed to provide protective cushioning and absorb any leaked liquid contents. By weight, an estimate of the contents, based on inventories of materials collected from another pilot program (PH:ARM), is 90 percent of the contents will be solids, and 10 percent will be liquids or ointments and their containers. The materials packed according to this scenario will be marked, labeled, and described as "UN 3249, Medicine, solid, toxic, n.o.s., 6.1 (poisonous), Packing Group (PG) II" or "UN 1851, Medicine, liquid, toxic, n.o.s., 6.1, Packing Group (PG) II." This completed package will weigh approximately 60 pounds.

Based on the information you submitted, the materials packaged as described in both scenarios are permitted in transportation under the HMR provided these materials are compatible with the packaging materials and do not react dangerously with each other (see §§ 173.21, 173.24, 173.24a, and 173.153). Completed packages that contain liquids must be marked with directional arrows to indicate the correct (upright) orientation of these inner packagings and their closures within the outer packaging (see § 172.312(a)(2)). Also, please note materials prepared in conformance with Scenario B must have the technical name entered in parentheses as a part of the proper shipping description on a shipping paper either after the proper shipping name or at the end of the basic description (see § 172.203(k)). As defined in § 171.8 of the HMR, "technical name" means a recognized chemical name or microbiological name currently used in scientific and technical handbooks, journals, and texts. A generic description may be used as a technical name for a Division 6.1 material provided it readily identifies the general chemical group.

If the packaging and accompanying materials do not meet the criteria prescribed in the HMR, the packaging will have to be approved under the terms of a special permit. The application process is described in 49 CFR Part 107, Subpart B. Processing times for the issuance of a special permit vary based on the complexity and completeness of the application, but this agency requests that the application be submitted at least 120 days before the requested date the applicant want the special permit becomes effective. For a special permit to be issued, the Pipeline and Hazardous Materials Safety Administration must find that the procedure the applicant has requested maintains a level of safety at least equal to the level required under the HMR.

I hope this satisfies your request.

Sincerely,

T. Glenn Foster
Chief, Regulatory Review and Reinvention
Standards and Rulemaking Division

Edmonson
§ 172.101

Edmonson, Eileen (PHMSA)

Applicability
10-0153

From: Perry, William [William.Perry@kingcounty.gov]
Sent: Monday, June 14, 2010 6:04 PM
To: Edmonson, Eileen (PHMSA)
Cc: Grasso, Cheri
Subject: Details of Shipment of Waste Medicines - WA State Pilot
Attachments: Packaging Description_WP_06142010.doc

Greetings, Eileen -

I'm following up on our conversation of a couple of weeks ago regarding the shipment of pharmaceutical materials via common carrier. I've attached a description of the pilot project that we've cooked up here, now with two scenarios.
<<Packaging Description_WP_06142010.doc>>

From our conversation, it sounds like our procedures and packaging generally meet DOT's criteria for safe shipment of this material. My questions to you now would be -

For this one time demonstration, are their any special approvals from DOT that would be required ?
If this were being done on an operational basis, would it require a special permit? If so, how long would that take.?

Thanks for your help with this issue - the complexity of the DOT regulations and website make it especially nice to communicate with a real person -

Tata - Will

Will Perry
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OUTLINE FOR THE SHIPMENT OF CONTROLLED SUBSTANCES TO HAZARDOUS WASTE INCINERATION Will Perry 6-14-2010

POINTS COMMON TO SCENARIO A OR B

Material used in this pilot will be unwanted medications from residents, collected by the law enforcement offices in Snohomish County, Washington.

All materials will be HHW exempt by RCRA and WA State Dangerous Waste Regulations criteria.

Contents will be Controlled Substances listed as Schedule 2 – 5 drugs by the Drug Enforcement Administration.

Before packing, all materials will be screened by a pharmacist that is experienced at screening returned medicines. This screening will remove sharps, liquid mercury, aerosol cans or any other materials that are not acceptable under the program criteria. The pharmacist will sort the collected medicines into controlled and non-controlled categories. Non-controlled medicines will be packed for pickup by a permitted hazardous waste disposal vendor.

The controlled substance medications identified by the pharmacist will be packaged for shipment *via* common carrier. Outer packaging will be a 10 or 15 gallon 1G fiber drums. Examples – http://www.uline.com/Product/Detail/S-10756/Drums-And-Pails/10-Gallon-Fiber-Drum http://www.grainger.com/Grainger/items/2PYK7?Pid=search

A 4-mil plastic drum liner will be used, and closed with a zip-tie before the fiber drum is closed.

Full packages will be sealed using tamper-evident tape, and then shipped by common carrier (UPS or FedEx) from the Bothell, WA Police Department to the Sauget, IL Police Department. Throughout the shipment, the custody and location of the package will be tracked and documented using the carrier's procedures.

SCENARIO A

Medicines will be left in their original consumer packaging. As liquid containers are packed, the integrity & tightness of the lids will be checked and corrected as needed. Liquid containers will be packed upright, with pill vials providing separation from other liquid containers and the sides of the fiber drum.

By weight, an estimated 66% of the contents will be medications – and estimated 34 % will be packaging and containers.
By weight, an estimated 70% of the medicines will be solids (*e. g.*, pills, patches)
By weight, an estimated 30% of the medicines will be liquids (*e. g.*, narcotic cough syrups)
Estimates are based on inventories of collected material from the PH:ARM pilot.

The drum will be shipped and labeled as ORM-D.

SCENARIO B

Solid medicines will be removed from their original packaging and poured into an approved outer package. Liquids & ointments will be left in their original consumer packaging. As liquid containers are packed, the integrity & tightness of the lids will be checked and corrected as needed. Liquid containers will be packed upright, with the loose pills providing separation from other containers and the sides of the fiber drum. Additional commercial absorbent ("kitty litter") will be used as needed to provide protective cushioning.

By weight, an estimated 90% of the contents will be solids (*e. g.,* pills, patches)
By weight, an estimated 10% of the contents will be liquids or ointments (*e. g.,* narcotic cough syrups) and their containers

Estimates are based on inventories of collected material from the PH:ARM pilot.

The drum will be shipped and labeled as Medicine, solid, toxic, n.o.s.; Packing Group II. and Medicine, liquid, toxic, n.o.s., Packing Group II.

In the interest of convenient handling, the sealed package will weigh around 60 pounds.

If there are questions or items for discussion, please contact -

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