



U.S. Department  
of Transportation

**Pipeline and Hazardous  
Materials Safety  
Administration**

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

MAY 20 2008

Mr. Bret Alan Skinner  
Technical Specialist  
Triumvirate Environmental  
61 Inner Belt Road  
Somerville, MA 02143

Ref. No.: 08-0073

Dear Mr. Skinner:

This is in response to your March 6, 2008 letter requesting clarification regarding the applicability of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) to the transportation of "Consumer commodity, ORM-D" materials. Specifically, you request information concerning the applicability of consumer commodity exceptions to pharmaceutical products shipped as hazardous waste to a disposal facility. Your questions have been paraphrased and answered as follows:

Q1. Assuming the pharmaceutical products met the definition of consumer commodity when originally purchased, would a container of pharmaceuticals that has been removed from the original outer packaging, placed into a drum and shipped as a hazardous waste to a disposal facility still meet the definition of a consumer commodity?

A1. The answer is yes. Exceptions for shipment of a material described as "Waste Consumer Commodity, ORM-D" are provided in § 173.156. Strong outer packagings, the marking requirements specified in Part 172 of the HMR, and the 30 kg (66 pounds) gross weight limitations are not required for materials classed as ORM-D when: (1) unitized in cages, carts, boxes or similar overpacks; (2) transported by rail, private or contract motor carrier, or common carrier in a vehicle under exclusive use for such service; and (3) transported to or from a manufacturer, a distribution center, or a retail outlet, or transported to a disposal facility from one offeror.

Q2. Assuming the pharmaceuticals met the definition of consumer commodity when originally purchased, would a container of pharmaceuticals that has been removed from the original outer packaging, opened and partially or fully used before being reclosed and placed into a drum still meet the definition of consumer commodity?

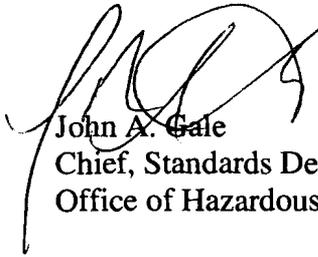
A2. Yes. See A1.

Q3. Pharmaceutical solutions are mixed from original containers that met the definition of consumer commodity and put into Intravenous (IV) bags for patient care. These IV bags are partially used before being placed into drums. Would these partially used IV bags still meet the definition of consumer commodity?

A3. Based on the information you provided, the pharmaceutical solutions in the IV bags are not in the same form or package as originally distributed. You did not provide sufficient information on the characteristics of the solution to enable us to make a determination regarding classification. Further, it remains uncertain that a partially used IV bag is packaged in a form suitable for sale through retail sales agencies for consumption by individuals for the purposes of personal care or household use.

I hope this information is helpful. Please contact us if you require additional assistance.

Sincerely,

A handwritten signature in black ink, appearing to read 'John A. Gale', is written over the typed name and title.

John A. Gale  
Chief, Standards Development  
Office of Hazardous Materials Standards

Leary  
§171.8  
Definitions  
08-0073

March 6, 2008

Mr. Edward Mazzullo, Director  
Office of Hazardous Materials Standards  
USDOT/PHMSA (DHM-10)  
400 7<sup>th</sup> Street, SW  
Washington D.C., 20590-0001

Dear Mr. Mazzullo,

Please accept this letter as a request for formal interpretation from your office. Triumvirate Environmental, Inc. wishes to receive clarification regarding the applicability of "Consumer Commodity" as defined in 171.8 to pharmaceuticals shipped off-site as hazardous waste for destruction.

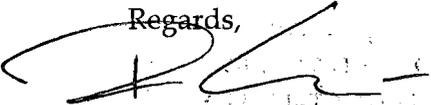
**Q1: Assuming that it originally met the definition of a consumer commodity as purchased, would a container of a pharmaceutical that has been removed from the original outer packaging and placed into a drum for shipment off-site as hazardous waste meet the definition of a consumer commodity?**

**Q2: Assuming that it originally met the definition of a consumer commodity as purchased, would a container of a pharmaceutical that has been removed from the original outer packaging, opened and partially or fully used before being tightly closed and placed into a drum for shipment off-site as hazardous wastes meet the definition of a consumer commodity?**

**Q3: Preparations of pharmaceutical solutions are mixed, from original containers that were received consumer commodities and put into "IV Bags" for patient care. These "IV bags" are partially used before being placed into drums for shipment off-site as hazardous wastes. Do these "IV bags" meet the definition of a consumer commodity?**

Thank you in advance for your time and your input on these questions. Please contact me at (617)628-8098, [bskinner@triumvirate.com](mailto:bskinner@triumvirate.com) or by mail if there are any needed clarifications to properly address these questions.

Regards,

  
Bret Alan Skinner  
Technical Specialist  
Triumvirate Environmental, Inc.