



U.S. Department  
of Transportation

**Pipeline and  
Hazardous Materials Safety  
Administration**

400 Seventh Street, S.W.  
Washington, D.C. 20590

MAY 11 2006

Ms. Carol Brozosky, CET, CHMM  
President  
PTP Consulting, Inc.  
1531 Kings Highway  
Swedesboro, NJ 08085

Ref. No. 06-0098

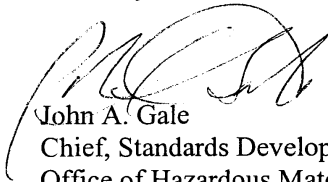
Dear Ms. Brozosky:

This responds to your April 22, 2006 letter concerning the applicability of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) to used health care products. Specifically, you ask whether the HMR apply to used contact lenses returned to the manufacturer by consumers or healthcare professionals.

For purposes of the HMR, a used health care product is a medical, diagnostic, or research device or piece of equipment or a personal care product contaminated with potentially infectious body fluids or materials (see § 173.134(a)(9)). It is the opinion of this Office that although a used contact lens meets the definition for a used health care product, it is not transported in a quantity or form that would pose a risk to transport workers or the general public. Thus, transportation of used contact lenses being returned by consumers or healthcare professionals is not subject to regulation under the HMR.

I hope this answers your inquiry.

Sincerely,



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



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173.134(a)(9)



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Boothe  
§173.134  
Definition & Exceptions  
36-0098

April 22, 2006

Mr. Edward T. Mazzullo  
Director, Office of Hazardous Materials Standards  
US DOT/ RSPA (DHM-10)  
400 7<sup>th</sup> St., S. W.  
Washington, DC 20590-0001  
FAX: 202-366-3012

Dear Mr. Mazzullo:

PTP Consulting has been retained by one of the leading manufacturers of contact lenses to assist with determining the applicability of DOT shipping requirements for "used health care products" under 49CFR §173.134 for Class 6, Division 6.2.

The issue under review involves the shipment of a "used" contact lens from either the consumer or a health care professional back to the manufacturer. Although the manufacturer is not directly responsible as a shipper, they believe they are obligated to advise and ensure compliance with DOT shipping requirements of this type of returned product. Compliance issues under review include training, shipping papers and packaging, which stem from decision making of the Risk Group numbers. It is understood that this decision process would only apply to health care professionals, since consumers are not covered under the standard.

Our questions are two fold:

**Question 1.** It is up to the shipper to determine the RG number, and it is our opinion that the product is RG1. However, we are seeking your opinion and confirmation that our approach in making this determination is consistent with the Department's interpretation of the Standard. The following details our applicability review methodology:

Under §173.134 (a)(6), Risk Group 2 is defined as a "pathogen that can cause human or animal disease but is unlikely to be a serious hazard and, while capable of causing serious infection on exposure, for which there are effective treatments and preventative measures available and the risk of infection is limited." Risk Group 1 is defined as a "micro-organism that is unlikely to cause human or animal disease." It is difficult, if not impossible to screen all used contact lenses for pathogens prior to shipment. The conservative approach using good manufacturing practices related to industrial hygiene would be to select RG2, until the next two concepts are taken into consideration:

- a. The basic definition of a hazardous material under §171.8 means "a substance or material that the Secretary of Transportation has determined is capable of posing unreasonable risk to health, safety, and property when transported in commerce ...]. In our opinion, a used contact lens does not meet this definition as posing an unreasonable risk. During the normal course of transportation, the chance of a used contact lens posing an unreasonable risk to any highway or air transporter is extremely unlikely unless the

package was tampered with, opened and an infected lens was deliberately placed on a mucus membrane (the eyeball). But this is not a normal transportation issue.

b. It is understood that the Department of Transportation regulates hazmat for transportation to ensure safety during loading, transporting and unloading. DOT would not govern the safe handling of a used health care product after it has been received, opened and handled by an employee. The safe handling after a package has been received at a workplace falls under OSHA. It is our opinion that this act of handling a used contact lens is the only point where there is a degree of risk, and procedures are already in place to ensure the product is disinfected before being handled by the manufacturer's employees.

Is this logic is determining that a used contact lens is an RG1 reasonable and within the intention of what the risk group determination was meant to govern?

**Question 2:** Since the manufacturer is not serving as the shipper, and only the receiver, does it have any responsibilities/ liabilities in making this determination in the first place? As indicated above, the company felt obliged to assist the health care professionals, who would be considered the "shipper".

I most sincerely appreciate your prompt attention to this matter, and look forward to your response.

Sincerely,

**PTP Consulting, Inc.**



Carol Brozosky, CET, CHMM  
President