



U.S. Department  
of Transportation  
**Research and  
Special Programs  
Administration**

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

JUL 16 2001

Mr. Gary Chilcott  
CEO/President  
Sure-Way Systems, Inc.  
310 East Harry Bridges Boulevard  
Wilmington, CA 90744

Ref. No. 01-0067

Dear Mr. Chilcott:

This is in response to your letter and telephone conversations with members of this office asking if your company's new reusable sharps container satisfies the packaging requirements for the transport of "Regulated medical waste, 6.2, UN 3291, PG II" under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). You stated that this new container is a modification of the container described in your April 16, 2000 letter and our October 18, 2001 response.

The following is your description of the modified packaging. The packaging has sharps container of rigid, oblong, high-density polypropylene, 2 to 4 gallons in size, with a locking lid. Flanges extending from the edge of the container lid are designed to be attached to, and suspended from, a 4-wheeled metal cart rack that is 28 inches wide and 4 feet long at its base. Metal bars placed at the ends of the cart rack where the containers are loaded and unloaded are locked during transportation. The cart is made of a lighter steel frame, has 1/8-inch fiberglass panels attached to the sides and top and a vacuum molded 1/8-inch thick plastic pan with a 12-gallon capacity placed at the bottom. The modified packaging does not have absorbent material in the bottom of each sharps container and does not have 1/8-inch thick polyethylene sheeting surrounding the top, bottom, and sides of the cart.

You state the cart's markings conform to the requirements of the Department of Transportation's HMR for the UN 3291, PG II, material and the Federal Drug Administration (FDA). You also state the sharps container is not to be used for cultures and stocks, and passes FDA's drop, puncture and tip tests. You enclosed photographs that appear to show the cart racks marked with the Occupational Safety and Health Administration (OSHA) "BIOHAZARD" marking. You did not describe the packaging as still meeting OSHA's requirements in 29 CFR 1910.1030, as required by 49 CFR 173.134(b)(3)(ii)(B). Therefore, it is our opinion that the modified polypropylene container would be acceptable only if it meets the requirements in § 173.134(b)(3), including the



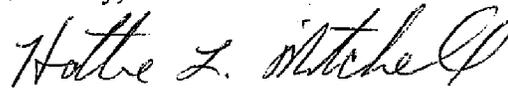
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173.134

general requirements in §§ 173.24 and 173.24a. Section 173.24(f) specifically requires that the closures on the packaging be designed and closed so that there is no identifiable release of hazardous material to the environment from the opening to which the closure is applied and that the closure be secure and leakproof.

I hope this satisfies your request.

Sincerely,

A handwritten signature in cursive script that reads "Hattie L. Mitchell". The signature is written in dark ink and is positioned above the typed name.

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

Edmonson  
§ 193.134  
Packagings

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## SURE-WAY SYSTEMS, INC.

Hattie L. Mitchell  
Chief Regulatory Review and Reinvention  
Office of Hazardous Materials Standards  
Ref No. 00-0128

February 14, 2001

Dear Ms. Mitchell

Thank you for your letter of October 18, 2000 concerning our sharps container DOT approval. Since writing that letter, we have refined our transportation process of containers. We ask that you revise your letter of October 18<sup>th</sup> to reflect the final transportation process. Our containers are the same as in our original request with the exception of the absorbent pad. This has been eliminated since it is not required by OSHA. We are enclosing the testing documentation showing that the containers have been tested and meet the OSHA requirements in 29 CFR 1910.1030 (as well as certain other performance criteria).

The transport cart has been modified by taking away the enclosed sides and side door making it an end loading/unloading cart for improved security, ease of movement through the hospital, and processing at the plant. The stainless steel racks hold 64 -2 gallon containers or 48 -4 gallon containers. The containers are secured in the cart so as not to tip over or fall out of the rack. The rack is on four wheels and is 28" wide and 4" long. The two changes, one to the container and one to the cart, do not seem to be pertinent to your decision that our containers meets the standards laid out in your attached letter of October 18<sup>th</sup>.

I am enclosing your letter of October 18<sup>th</sup> and the test results so your review may be expedited a little. Thank you for your clarification of this modification in your first response letter. We are happy with the system, as are our hospitals.

Respectfully Submitted,

Gary Chilcott Pres/CEO

Sure-Way Systems, Inc.

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