



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

MAY 1 2003

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

Mr. Joseph Orlando
Health Care Waste Services
1370 Viele Avenue
Bronx, NY 10474

Reference No.: 02-0303

Dear Mr. Orlando:

This is in response to your letter asking if your company's 1.5 gallon reusable sharps container designed to transport "Regulated medical waste (RMW), 6.2, UN 3291, PG II" must comply with the requirements in 49 CFR 173.197(e)(3) for a sharps inner packaging in a non-specification bulk packaging under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). We apologize for the delay in responding and any inconvenience this may have caused.

The answer is no. The requirements in § 173.197(e)(3) apply only to a sharps packaging intended for transportation in a large packaging, wheeled cart (Cart), or bulk outer packaging (BOP). However, other requirements in the HMR do apply to non-bulk sharps containers. Section 173.197(b) authorizes the use of a non-bulk single or combination packaging that is puncture-resistant and meets the requirements in Part 178 at the Packing Group II performance level. Section 173.134(c) authorizes the use of a non-bulk, non-specification packaging that meets the general packaging requirements in 49 CFR 173.24 and 173.24a, and those of the U.S. Department of Labor, Occupational Safety and Health Administration, in 29 CFR 1910.1030, provided the sharps are transported by a private or contract carrier. Also, note that § 173.28(f) requires reusable Division 6.2 packagings to be disinfected prior to reuse.

I hope this satisfies your request.

Sincerely,

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



020303

173.197



Edmonson
§ 173.197
Regulated Medical Waste
02-0303

1370 Viele Ave. Bronx, NY 10474 TEL (718) 842-9486 FAX (718) 842-9722

November 16, 2002

Department of Transportation
Office of Hazardous Materials Standards,
Research and Special Program Administration
400 Seventh Street SW
Washington DC 20590

Attn: Susan Gorsky

Re: **Federal Register Part III 49 CFR Part 171 et. al.**

Dear Ms. Gorsky,

I have read Part III Department of Transportation 49 CFR Part 171 et. al. and have a question concerning section 173.197 Regulated medical waste (3) *Sharps*. My company Health Care Waste Services provides a reusable container exchange service to many medical providers and one of our products is a 1.5 Gallon reusable sharps container. I would like to verify that this section (173.197 Regulated medical waste (3) *Sharps*) applies only if the 1.5 Gallon reusable container is transported in Large Packaging, Cart, or BOP. If the 1.5 gallon reusable container is not transported in Large Packaging, Cart, or BOP then 173.197 Regulated medical waste (3) *Sharps* does not apply.

173.197 Regulated medical waste (3) *Sharps*

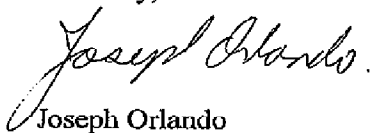
Sharps transported in a Large Packaging, Cart, BOP must be packaged in a puncture-resistant inner packaging (sharps container). Each sharps container exceeding 76 L (20 gallons) in volume must be capable of passing the performance the performance tests in 178.601 of this subchapter at the Packing Group II performance level. A sharps container may be reused only if it conforms to the following criteria:

- (i) The sharps container is specifically approved and certified by the U.S. Food and Drug Administration as a medical device for reuse.
- (ii) The sharps container must be permanently marked for reuse.
- (iii) The sharps container must be disinfected prior to reuse by any means effective for the infectious substance the container previously contaminated.
- (iv) The sharps container must have a capacity greater than 7.57 L (2 Gallons) and not greater than 151.42 L (40 gallons) in volume.

I would appreciate a written response to my request as soon as possible.

If you have any questions please call (718) 842-9627.

Sincerely,

A handwritten signature in cursive script that reads "Joseph Orlando".

Joseph Orlando
Health Care Waste Services

dotletter.doc