



U.S. Department
of Transportation

**Research and
Special Programs
Administration**

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

AUG 20 2001

Ms. M. Wendy Bosshardt
Regulatory Affairs Specialist
BD Preamalytical Solutions
1 Becton Drive
Franklin Lakes, NJ 07417

Ref. No. 01-0101

Dear Ms. Bosshardt:

This is in response to your April 24, 2001, letter and subsequent telephone conversation with a member of my staff, requesting clarification on the small quantity exception under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). Specifically, you ask if a vacuum (i.e., negative pressure) in each receptacle and shrink wrap around the tray and stoppered tubes meet the requirement for a positive closure as specified in § 173.4(a)(3) of the HMR. You sent in a sample packaging for our review.

To qualify for the small quantity exception, each inner receptacle with a removable closure must have the closure held securely in place with wire, tape, or other positive means. [§ 173.4(a)(3)] Negative pressure in a receptacle is not a positive means of closure. However, shrink wrap around the tray which securely holds each tube's closure in place may be used to satisfy the requirement of § 173.4(a)(3). Based on the sample which you submitted we note that the shrink wrap is placed loosely over the test tubes and may not ensure that test tubes in the center of the tray have their closures held in place by positive means. This could easily be corrected by placing a piece of fiberboard or other such material over the test tubes before the shrink wrap is affixed or by placing the shrink wrap tightly around the test tubes.

I hope this satisfies your request.

Sincerely,

John A. Gale
Transportation Regulations Specialist
Office of Hazardous Materials Standards

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§ 173.4(a)(10)
Small Quantity Exceptions
01-0101



BD

Indispensable to
human health

April 24, 2001

Mr. Edward T. Mazzullo
Director, Office of Hazardous Materials Standards (DHM-10)
Research and Special Programs Administration ("RSPA")
U.S. Department of Transportation
400 7th Street, SW
Washington, DC 20590-0001
Facsimile (202) 366-3012

Dear Mr. Mazzullo:

Enclosed are plastic blood collection tubes for **Demonstration Purposes Only** with an explanation letter. We have provided plastic, unlabeled empty blood collection tubes for visual purposes only. The plastic tubes are to demonstrate our belief that our product has a positive means of closure that will support BD's certification in accordance with HMR § 173.4(a)(10).

Each blood collection tube is sealed with a rubber stopper, the negative pressure of the evacuated tube provides positive means of closure and the use of plastic shrink wrapping of the seal tubes within the polystyrene tray provide further positive means of closure.

Thank you for your assistance and we look forward to hearing from you. If you need any further information regarding our products please do not hesitate to contact me at (201) 847-6280.

Regards,

Wendy Bosshardt

M. Wendy Bosshardt
Regulatory Affairs Specialist