



U.S. Department of Transportation
**Pipeline and Hazardous Materials
Safety Administration**

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

SEP 22 2010

Mr. John Edgcomb
Edgcomb Law Group
115 Sansome Street, Suite 700
San Francisco, CA 94104

Ref. No.: 10-0093R

Dear Mr. Edgcomb:

This responds to your letter dated April 22, 2010 and follow-up letter on July 22, 2010 regarding the requirements for shipping a "Consumer commodity, ORM-D" material in accordance with the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). This is a revision to our original response from June 14, 2010.

According to your letter, your client is a pharmaceutical distributor, and proposes to unitize products classified as "Consumer commodity, ORM-D" into securely fastened, plastic boxes ("totes") for delivery from its distribution centers to its customers in their healthcare settings, including retail pharmacies, hospitals, physician practices, extended-care facilities, home-care agencies and government medical facilities. The individual totes are loaded into a contract carrier's motor vehicle, which is used exclusively for the delivery of the totes. Also, your client's customers sometimes return the totes containing similar materials using the same methods. You ask, would the exception in § 173.156(b)(1) apply to these ORM-D materials and whether the ORM-D marking is required on the "totes".

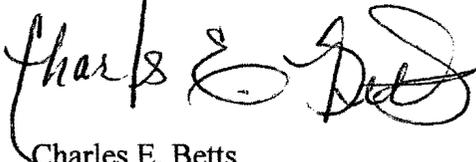
In general, the HMR permit materials that meet the definition of a consumer commodity in § 171.8 and that are packaged as provided in the appropriate limited quantity packaging section to be renamed "Consumer commodity" and reclassified as ORM-D. An ORM-D material is excepted from labeling, placarding and specification packaging, and except for shipments by aircraft, the shipping paper requirements, unless the materials meet the definition of a hazardous substance, hazardous waste, or marine pollutant.

Consumer commodity, ORM-D materials may be transported utilizing the exceptions in § 173.156(b)(1), including the exception from the marking requirements of Subpart D of Part 172 (i.e., "ORM-D" marking), provided the material is (1) unitized in cages, carts, boxes, or similar overpacks; (2) offered for transportation or 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, a distribution center, and a retail outlet, or transported to a disposal facility from one offeror. According to your incoming letter, your clients shipping methods satisfy all three of these conditions. Thus, your client may take advantage of the

exceptions provided in § 173.156(b)(1), including the exception from marking the box or tote "ORM-D".

I hope this information is helpful. If we can be of further assistance, please contact us.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles E. Betts". The signature is written in a cursive style with a large, stylized initial "C".

Charles E. Betts
Chief, Standards Development
Office of Hazardous Materials Standards

EDGCOMB LAW GROUP

115 Sansome Street, Suite 700
San Francisco, California 94104
415.399.1555 direct
415.399.1885 fax
jedgcomb@edgcomb-law.com

Eichenlaub
§ 173.156(b)
Exceptions for ORM-D
Materials
10-0158

BY OVERNIGHT MAIL

July 22, 2010

Mr. Edward T. Mazzullo
Director, Office of Hazardous Materials Standards
U.S. DOT/PHMSA (PHH-10)
1200 New Jersey Avenue, SE
Washington, D.C. 20590-0001

Re: Request for Additional Interpretation of 49 C.F.R. § 173.156(b)

Dear Mr. Mazzullo:

I write to request additional clarification regarding the applicability of the exception to the marking requirements for ORM-D materials provided in 49 C.F.R. § 173.156(b).

My April 22, 2010 letter sought clarification on whether the exception in § 173.156(b)(1) applied to “consumer commodity” ORM-D materials distributed by my client. More specifically, we asked whether the ORM-D marking was required when such materials were unitized in boxes/plastic totes and offered for transport by private, contract, or common carrier dedicated for such service and transported from the distributor directly to a retail outlet, pharmacy, hospitals, physician offices, or other healthcare facilities (the dedicated transporters may make multiple stops/deliveries to said healthcare facilities along their routes).

The June 14, 2010 response I received from Charles E. Betts, Chief of Standards Development, contains what could be construed to be an interpretation of § 173.156(b)(1) and (2) that is inconsistent with a prior interpretation issued by the Pipeline and Hazardous Materials Safety Administration (“PHMSA”). Specifically, the last paragraph of Mr. Betts’ June 14, 2010 response restates the requirements of both § 173.156(b)(1) and (2), and thus *could* be construed to suggest that the conditions described in *both* (b)(1) and (2) must be met under the factual circumstances we describe above and still require the package to be marked with the ORM-D marking in accordance with § 172.316. We do not believe this to be correct and therefore seek a further clarification.

Mr. Edward T. Mazzullo
Director, Office of Hazardous Materials Standards
July 22, 2010

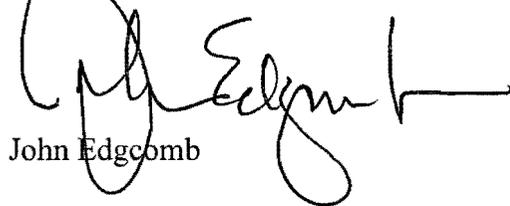
The terms of § 173.156(b)(2) simply provide another, separate exception to 30 kg weight limitation in addition to the one provided in § 173.156(b)(1). The terms of § 173.156(b)(2) apply only to the shipping of consumer commodities with inner packagings packed in a specified manner (i.e.: those set forth in sub-section (b)(2)(i)-(iv)). Thus, it is our understanding that the requirement of § 173.156(b)(2) to place the ORM-D mark on such packages is inapplicable to our factual circumstances, to which § 173.156(b)(1) applies, meaning that compliance with the ORM-D marking requirements is specifically excluded.

Our understanding in this regard is consistent with the PHMSA's prior interpretation of the ORM-D marking exception provided by § 173.156(b)(1). In Interpretation 99-0036, issued on May 24, 1999, the PHMSA stated that if the requirements of § 173.156(b)(1) [alone] are met, then the ORM-D marking requirements in § 172.316 need not be met. See also Interpretation 10-0030, issued on March 10, 2010.

Thus, we write to seek further clarification that a shipper whose shipment meets the requirements of § 173.156(b)(1) qualifies for the exception from the ORM-D marking requirements of § 172.316, without any regard to the terms of § 173.156(b)(2) whatsoever.

Thank you for your attention to this request. I look forward to your response.

Very truly yours,

A handwritten signature in black ink, appearing to read "John Edgcomb", with a long horizontal flourish extending to the right.

John Edgcomb