U.S. Department
of Transportation

**Pipeline and Hazardous
Materials Safety
Administration**

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

MAY 17 2016

Mr. Thomas Brugato
Covington & Burling LLP
One CityCenter
850 Tenth Street NW
Washington, DC 20001-495

Ref. No. 15-0142

Dear Mr. Brugato:

This letter is in response to your July 7, 2015 e-mail requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) applicable to medicines containing limited quantities of ethyl alcohol or ethanol. You ask whether Federal Drug Administration (FDA) regulated drugs which are transported for clinical trials or which must be dispensed to patients directly by doctors or similar healthcare professionals are considered "medicines" for the purposes of the exception provided in § 173.150(g). You also ask whether "medicines" must be "sold as retail products" to be transported under the exception provided in § 173.150(g).

As you are aware, final rule HM-233C, published March 18, 2014 [79 FR 15033] adopted DOT Special Permit 9275 (DOT-SP 9275) with modifications into the HMR in § 173.150(g). The intent of the rule was to limit the exception to consumer products containing ethyl alcohol. As adopted, the exception in § 173.150(g) applies to the following specific consumer products containing ethyl alcohol, "beverages, food, cosmetics, and medicines, medical screening solutions." The final rule also provides an exception for ethyl alcohol contained in "concentrates sold as retail products." The HMR does not define the terms beverages, food, cosmetics, or medicines. The word "medicine" is defined by the Merriam Webster's dictionary as a "substance that is used in treating disease or relieving pain." In accordance with § 173.22, it is the shipper's responsibility to properly classify a hazardous material. This Office does not generally perform that function.

However, it is the opinion of this Office that any medicines containing ethyl alcohol, including those intended for use in a clinical trial or administered to patients by healthcare professionals are eligible for the exception in § 173.150(g), provided all other requirements are met.

I trust this information is helpful. If you have further questions, please do not hesitate to contact this office.

Sincerely,

T. Glenn Foster

T. Glenn Foster
Chief, Regulatory Review and Reinvention Branch
Standards and Rulemaking Division

Orchak
173.150(g)
Exceptions for Class 3
15-0142

Goodall, Shante CTR (PHMSA)

From: Geller, Shelby CTR (PHMSA)
Sent: Wednesday, July 08, 2015 12:47 PM
To: Hazmat Interps
Subject: FW: Scope of 49 C.F.R. § 173.150(g)
Attachments: 2015-07-07 Letter.pdf

Dear Shante and Alice,

Attached is a request for a formal letter of interpretation.

Thanks,
Shelby

From: Brugato, Thomas [mailto:tbrugato@cov.com]
Sent: Tuesday, July 07, 2015 5:48 PM
To: PHMSA HM InfoCenter
Subject: Scope of 49 C.F.R. § 173.150(g)

Good afternoon,

Please see the attached letter, which requests information regarding the interpretation of 49 C.F.R. § 173.150(g).

Best,

Thomas R. Brugato
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street, NW
Washington, DC 20001-495
tel: 202.662.5515
tbrugato@cov.com

COVINGTON

BEIJING BRUSSELS LONDON LOS ANGELES
NEW YORK SAN FRANCISCO SEOUL
SHANGHAI SILICON VALLEY WASHINGTON

Thomas R. Brugato

Covington & Burling LLP
One CityCenter
850 Tenth Street, NW
Washington, DC 20001-4956
T +1 202 662 5515
tbrugato@cov.com

BY ELECTRONIC MAIL

July 7, 2015

U.S. DOT
PHMSA Office of Hazardous Materials Standards
Attn: PHH-10
East Building
1200 New Jersey Avenue, SE.
Washington, DC 20590-0001
phmsa.hm-infocenter@dot.gov

Re: Scope of 49 C.F.R. § 173.150(g)

Dear Sir or Madam:

PHMSA recently released a final rule which codified an exception at 49 C.F.R. § 173.150(g) for certain products containing ethyl alcohol. The question I have is whether an Investigational New Drug (regulated by the FDA) being shipped to clinical trial sites qualifies for the exception as a medicine.

By way of background, our client produces an investigational new drug, which it plans to send to clinical trial sites for use in clinical trials. The drug is contained in 100 mL bottles and contains ethanol.

The investigational drug at issue would seem to clearly fall within the common meaning of the term "medicine," as a "substance or preparation used in treating disease." *Webster's Third International Dictionary*. However, the term "medicine" in the regulation is not defined, and so it would be useful to clarify for the regulated community that "medicine" is not limited to FDA-approved drugs, but also extends to Investigational New Drugs.

There is a second question of whether the exception might not apply because the investigational new drug is shipped to clinical trial sites for administration by doctors in clinical trials, as opposed to retail sale. The regulation does contain the phrase "sold as retail products," but it is not clear whether that phrase applies only to concentrates or instead to all of the listed products. Notably, DOT-SP 9275, which the regulation codified, did not contain any "retail product" limitation, but rather simply applied to "[b]verages, foods, cosmetics and medicines, medical screening solutions, and concentrates used therein containing ethyl alcohol classed as a flammable liquid or as solids containing a flammable liquid." Nothing in the NPRM or final rule codifying DOT-SP 9275 evinces an intent to narrow the scope of the exception. *See* 77 Fed. Reg. 64,450 (Oct. 22, 2012); 79 Fed. Reg. 15,033 (Mar. 18, 2014).

Moreover, other exceptions use the phrase "consumer commodity," which is limited to "material [including medicines] that is packaged and distributed in a form intended or suitable for sale through retail sales agencies or instrumentalities for consumption by individuals for purposes of personal care or household use." 49 C.F.R. § 171.8. Presumably PHMSA would simply have used the defined term "consumer commodity" had it intended 49 C.F.R. § 173.150(g) to be limited to medicines packaged and distributed for end-use consumption by individuals, but instead it chose not to do so and drafted a more expansive exception.

The vast majority of FDA-approved drugs are dispensed by pharmacists pursuant to a prescription from a physician. Such pharmacies are generally considered "retail pharmacies" and we therefore it should follow that these drugs are "retail products" that fall within the scope of the exception. Could you confirm this assessment is correct? However, some FDA-approved drugs are only administered to patients by doctors or other healthcare providers. It seems unlikely that PHMSA intended to exclude such FDA-approved drugs from the scope of this exception, simply because the drugs are administered to patients by doctors. Could you confirm that these FDA-approved drugs are also "retail products" within the scope of 49 C.F.R. § 173.150(g)?

For the foregoing reasons, in our view the exception should apply to medicines that meet all requirements of the regulation, even if they are not "retail products." In the alternative, "retail products" should be viewed as a broad enough term to encompass the type of clinical trial use and administration by doctors at issue here. Please advise whether PHMSA agrees with this understanding of the regulation.

Thank you for your assistance in this matter.

Regards,

Thomas Brugato