



U.S. Department
of Transportation

Pipeline and Hazardous Materials
Safety Administration

1200 New Jersey Ave., SE
Washington, DC 20590

Mr. Junius Johnson
Regulatory Compliance Manager
Inmark, Inc.
675 Hartman Road, Suite 100
Austell, GA 30168

MAY 5 2009

Reference No. 09-0102

Dear Mr. Johnson:

This is in response to your April 29, and April 30, 2009 e-mails asking for clarification of the classification and packaging requirements for the swine flu virus under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). Specifically, you ask if the swine flu virus must be classed as a Category A infectious substance during a pandemic. You also ask if a specimen, regardless of whether or not it is infectious, must be classed as a Category A infectious substance if it is collected from a region where a pandemic is occurring.

Based on information we received from the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO), it is our understanding that human and animal specimen samples known or suspected of containing the swine flu virus or a Category B infectious substance must be transported under the proper shipping description "UN 3373, Biological substance, Category B, 6.2." Such samples must be transported in conformance with the requirements prescribed in § 173.199 of the HMR. Cultures of the swine flu virus, cultures of certain other Category B infectious substances, and Category A infectious substances must be transported under the shipping description "UN 2814, Infectious substances, affecting humans, 6.2," or "UN 2900, Infectious substances, affecting animals, 6.2," as appropriate. Swine flu cultures must be transported in conformance with the requirements prescribed in § 173.196.

Note that for purposes of the HMR a culture is defined as an infectious substance containing a pathogen that has been intentionally propagated. The term **does not include** patient specimens collected directly from humans or animals and transported for diagnosis, research, or investigational purposes. Please see the definitions in § 173.134.

I hope this satisfies your request. Please feel free to contact me if you have questions or need additional information.

Sincerely,

Susan Gorsky
Regulations Officer
Office of Hazardous Materials Standards

Edmonson

3173.199

3173.196

Drakeford, Carolyn <PHMSA>

From: Edmonson, Eileen <PHMSA>
Sent: Thursday, April 30, 2009 6:37 PM
To: Drakeford, Carolyn <PHMSA>
Subject: Please give this letter a reference no. & assign it to me

Infectious Substances
09-0102

From: Jay Johnson [mailto:jayj@inmarkinc.com]
Sent: Wednesday, April 29, 2009 5:15 PM
To: Gorsky, Susan <PHMSA>
Cc: Willke, Ted <PHMSA>; Frank Orvino
Subject: Classification of human biologic samples during a pandemic

Susan,

Thanks for your help in addressing this immediate concern to the transport of clinical samples during a pandemic.

We are getting calls from pharmaceutical companies and laboratories concerned about human samples coming out of Central America (Mexico to be specific) as the Swine Flu worsens there. Sources are now saying that if a pandemic is declared, then all biologics coming out of the area would be classified as Infectious Substance, Category A (UN2814). I need something in writing to provide guidance to clinics and carriers on what is the current classification for human body fluids with Swine Flu (currently they are classified as Biological Substance, Category B (UN3373)) and if this classification changes when a pandemic is declared. More importantly, would all biologic samples from a region (known infected or not known to be infected) change if a pandemic is declared in a region?

Thanks for your help during this global outbreak,
Jay

Junius Johnson,
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jayj@inmarkinc.com www.inmarkinc.com

Drakeford, Carolyn <PHMSA>

From: Edmonson, Eileen <PHMSA>
Sent: Thursday, April 30, 2009 6:37 PM
To: Drakeford, Carolyn <PHMSA>
Subject: Please give this letter a reference no. & assign it to me

From: Jay Johnson [mailto:jayj@inmarkinc.com]
Sent: Thursday, April 30, 2009 10:29 AM
To: Gorsky, Susan <PHMSA>
Cc: Willke, Ted <PHMSA>; Frank Orvino
Subject: RE: Classification of human biologic samples during a pandemic

Good Morning Susan,
Thanks for getting back to me so quickly with this. Having something in writing from you will go a long way in securing that clinical trial samples continue to move in a timely manner during this crisis.

There are numerous clinical and safety samples that move from hospitals to labs every day which have nothing to do with swine flu. However, the concern is that since they are coming from a region where the flu is present then they may now be stopped or reclassified as a Category A and the patient's lives could be put in jeopardy from the delay.

Thanks for your help,
Jay

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From: susan.gorsky@dot.gov [mailto:susan.gorsky@dot.gov]
Sent: Thursday, April 30, 2009 7:50 AM
To: Jay Johnson
Cc: Ted.Willke@dot.gov; Frank Orvino
Subject: RE: Classification of human biologic samples during a pandemic

Jay,

It is our understanding, based on information forwarded from IATA, that the World Health Organization is advising health authorities to ship specimens taken from humans or animals that are suspected to contain the swine flu virus under the shipping description "UN 3373, Biological Substance, Category B, 6.2." Such samples must be transported in accordance with the requirements in § 173.199 of the HMR. WHO advises health authorities to ship cultures of the swine flu virus under the shipping description "UN 2814, Infectious substances affecting humans, 6.2." Swine flu cultures must be transported in accordance with the requirements in § 173.196. We plan to confirm this information with CDC this morning and to ask if CDC expects this transportation advice to change if a pandemic is declared. I will let you know what CDC tells us. Once we hear from CDC, I can put this information in a formal letter if that would be helpful.

Susan