U.S. Department
of Transportation

**Pipeline and Hazardous
Materials Safety
Administration**

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

SEP 2 3 2014

Ms. Louise J. Calabretta
Director, Project Management
Discovery Laboratories, Inc.
2600 Kelly Road
Suite 100
Warrington, PA 18976-3622

Ref. No. 14-0080

Dear Ms. Calabretta:

This responds to your April 7, 2014 request for clarification on applicability of the Hazardous Materials Regulations (HMR; 49 CFR parts 171-180) for the transportation of used medical device heating units. Specifically, you ask if shipments of used medical device heating units from a hospital or medical facility back to your laboratory would meet the definition of a "used health care product" under § 173.134(a)(8).

In your letter you indicate your company has developed a medical device heating unit, called a WARMING CRADLE®, to warm glass vials containing a drug used to prevent respiratory distress syndrome (RDS) in premature infants at high risk for developing RDS. You indicate that the WARMING CRADLE® would most likely be stored in the Neonatal Intensive Care Unit of a hospital or medical facility and that, on occasion, the hospital or medical facility may wish to return used WARMING CRADLES®.

You indicate that it is your understanding that the WARMING CRADLE® is classified as a Division 6.2, Category B material, and meets the definition of a "used health care product," as you assume there is the potential, although minimal, that pathogens would be present on the device following the intended use. You also noted in a follow-up communication with a member of my staff that: (1) you are not aware of contamination by any specific pathogen (whether Category A or B); and (2) you assume that hospitals and medical facilities are adhering to occupational Safety and Health Administration (OSHA) standard 29 CFR 1910.1030 to clean and disinfect surfaces after contact with blood or other potentially infectious materials

Section 173.22 states that it is the shipper's responsibility to classify a hazardous material. This office does not perform that function. Based on your incoming letter, we would agree a used WARMING CANDLE® would be considered a used health care product as defined in § 173.134(a)(8) and be subject to the HMR. However, based on your follow-up communication, if there is no pathogen present or if a hospital or medical facility is complying with 29 CFR 1910.1030, then the device is not regulated as an infectious substance

under the HMR. Furthermore, if there is a pathogen present and/or there is no adherence to 29 CFR 1910.1030, then a used health care product may be excepted from the HMR as an infectious substance by complying with one of two options under § 173.134(b)(12): (1) comply with OSHA 29 CFR 1910.1030 (note this option does not apply to transport for disposal purposes); or (2) comply with the packaging requirements of § 173.134(b)(12)(ii) (note this option applies to used health care products returned to the manufacturer and does not apply to transport of a Category A substance).

I hope this answers your inquiry. If you need additional assistance, please contact this office at 202-366-8553.

Sincerely,

Robert Benedict
Chief, Standards Development Branch
Standards and Rulemaking Division

DiscoveryLabs®
Inspired Innovation

April 7, 2014

Boothe
§173.134
Definitions
14-0080

Mr. Charles E. Betts
Director, Standards and Rulemaking Division
U.S. DOT/PHMSA (PHH-10)
1200 New Jersey Avenue, SE East Building, 2nd Floor
Washington, DC 20590-0001

Subject: Interpretation on Infectious Substance Classification

Dear Sir:

Discovery Laboratories, Inc (Discovery Labs) is seeking to understand the applicability of DOT shipping requirements for "used health care products" under 49 CFR 173.134 for Class 6, Division 6.2.

Discovery Labs manufactures SURFAXIN® drug product for the prevention of respiratory distress syndrome (RDS) in premature infants at high risk for developing RDS. In order to properly administer drug product at optimum conditions, it must be warmed to a pre-set temperature prior to administration. Discovery has developed a medical device heating unit, or WARMING CRADLE®, to warm the contents of one or two 25-mm-diameter glass vials at a preset temperature of 44°C ± 1°C for 15 minutes. This warming unit will most likely reside in the Neonatal Intensive Care Unit (NICU) of a hospital/medical facility such that it is accessible to medical care providers at point of use.

If a hospital and/or medical facility encounters a defective warming cradle and wishes to send the unit back to Discovery Labs or no longer has a need for the unit and wishes to return it, there must be an established process by which the unit will be shipped such that it complies with U.S. Department of Transportation (DOT) shipment regulations and other established federal guidelines.

It is Discovery Labs' interpretation that the WARMING CRADLE® would fall under the definition of "used health care product", Category B, based on the assumption that there is the potential, although minimal, that pathogens would be present on the device following intended use.

Discovery Labs would like confirmation as to whether you agree with our assessment or have a recommendation that is different than our conclusion.

I most sincerely appreciate your prompt attention to this matter and look forward to your response.

Sincerely,

Louise J. Calabretta
Director, Project Management

Discovery Laboratories, Inc. • 2600 Kelly Road • Suite 100 • Warrington, PA 18976-3622 p 215.488.9300 f 215.488.9301 www.discoverylabs.com

Drakeford, Carolyn (PHMSA)

From: INFOCNTR (PHMSA)
Sent: Monday, April 14, 2014 2:19 PM
To: Drakeford, Carolyn (PHMSA)
Subject: FW: Interpretation inquiry re: 49 CFR 173.134 for Class 6, Division 6.2
Attachments: Interpretation Letter.docx

Importance: High

Hi Carolyn,

This caller requested we submit this e-mail as a formal letter of interpretation. Please note she also mailed a hardcopy of this letter.

Thanks,

Victoria

From: Calabretta, Louise [mailto:LCalabretta@DiscoveryLabs.com]
Sent: Monday, April 14, 2014 1:48 PM
To: PHMSA HM InfoCenter
Subject: Interpretation inquiry re: 49 CFR 173.134 for Class 6, Division 6.2
Importance: High

Dear Mr. Charles E. Betts,

My name is Louise Calabretta and I'm a Project Manager working for Discovery Labs. Discovery Labs is seeking clarification of shipping requirements under 49 CFR 173.134 for Class 6, Division 6.2.
I had sent a letter via Fed Ex to you last week, a copy of which is attached.

Discovery Labs has been wrestling with this issue for the last several months, which is why we finally decided to seek clarification from the source. I am hopeful that you will be able to provide much needed guidance on the subject of Infectious Substance Classification such that Discovery Labs is in full compliance with federal regulations.

Should you have any questions or wish to discuss in greater detail, please don't hesitate to contact me at the number(s) listed below.

I am appreciative of your time and anxiously anticipate your guidance in this matter. Thank you in advance.

Regards,

Louise Calabretta
Director, Project Management
Discovery Laboratories, Inc.
2600 Kelly Road, Suite 100
Warrington, PA 18976-3622

t: 215.488.9507
c: 215.421.0948

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Boothe, Deborah (PHMSA)

From: Calabretta, Louise <LCalabretta@DiscoveryLabs.com>
Sent: Thursday, July 10, 2014 9:57 AM
To: Boothe, Deborah (PHMSA)
Cc: Calabretta, Louise
Subject: Response to bio-hazard dept questions

Hello Deborah,

I received your message and have tried contacting you to discuss your questions but have not been able to reach you by phone. Therefore, please see below information and feel free to contact me with any follow up questions and/or clarifications.

1. Q: What is nature of pathogen?
   A: There is no specific pathogen(s) present to the best of our knowledge. The environment where the unit resides is a hospital neo-intensive care unit.
2. Q: Is pathogen infectious or have potential to be infectious?
   A: As mentioned in 1. above, there is not specific pathogen(s) present of which we're aware. The warming cradle may be exposed to traces of blood or other bodily fluids as other similar devices in a hospital environment are exposed. Any mitigative measures would be precautionary only.
3. Q: Is the warming cradle subject to hazardous mitigation or meet definition of home health care product?
   A: Per OSHA Regulation 29 CFR 1910.1030, all equipment/working surfaces shall be cleaned and decontaminated after contact with blood or other potentially infectious materials. It is our assumption that a hospital/medical facility is adhering to the regulation(s). The warming cradle is not considered a home care product but rather a product intended for use by medical professionals only.

Again, please feel free to reach out to me with any additional questions and/or clarifications.

Thank you,

Louise Calabretta
Director, Project Management
Discovery Laboratories, Inc.
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lcalabretta@discoverylabs.com
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