U.S. Department
of Transportation

**Pipeline and Hazardous
Materials Safety
Administration**

1200 New Jersey Avenue SE
Washington, DC 20590

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Ms. Darcy Britt
Global Logistics Compliance Supervisor
BioStorage Technologies
2910 Fortune Circle West Drive, Suite E
Indianapolis, IN 46241

Reference No. 11-0314

Dear Ms. Britt:

This is in response to your December 19, 2011 letter requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) applicable to human specimens collected from multiple patients at their residences as part of a clinical trial to develop diagnostic tests for detecting colon cancer or pre-cancerous cells.

Specifically, you state when a sufficient number of the samples have been collected, the parent company conducting the study ships them in bulk packages on dry ice to a third-party warehouse where they are held for long-term storage at -80 °C. You also state at a future date these samples will be shipped from the third-party warehouse to a clinical laboratory for routine testing, but at no point will they be tested to determine their hazard class – so it is unknown. In addition, you state the parent company employees are hazmat trained in accordance with 49 CFR Part 172, Subparts H (training) and I (security), and have determined the proper classification of the specimens is "Exempt Human Specimen," a designation authorized under Section 6.3.2.3.6 of the International Civil Aviation Organization (ICAO) Technical Instructions for the Safe Transportation of Dangerous Goods by Air (Technical Instructions). We have paraphrased your questions and answered them in the order you provided.

Q1. Do batched shipments of numerous, different patient specimens classed by trained personnel as "Exempt Human Specimen," and shipped in bulk packages from a parent company to a third-party warehouse for long-term, ultra-cold storage qualify as excepted from regulation under the HMR in conformance with § 173.134(b)(11)?

A1. The answer is yes. Under § 173.134(b)(11), a human or animal sample being transported for routine testing not related to the diagnosis of an infectious disease and for which there is a low probability that the sample is infectious is not subject to regulation under the HMR. For your information, please note that "Exempt Human Specimen" is not a hazard class or wording that appears in the HMR. It is a

marking required under Part 2, Chapter 6, § 6.3.2.3.6 of the ICAO Technical Instructions for patient specimens for which professional judgment has been used to determine that there is minimal likelihood pathogens are present, and the specimens are packaged in conformance with that section and offered or intended for transportation by aircraft. 49 CFR Part 171, Subpart C, and, specifically, §§ 171.22, 171.23 and 171.24 authorize the use of the ICAO Technical Instructions for the transportation of hazardous materials by aircraft. However, since the specimens you describe are excepted from regulation under the HMR, use of the "Exempt Human Specimen" marking is neither required nor prohibited.

Q2. Is it a violation of the HMR to label these shipments "Exempt Human Specimen" and claim the exception under § 173.134(b)(11) when ordered by the parent company to ship these specimens to a clinical laboratory for routine testing?

A2. The answer is no. See Answer A1.

Sincerely,

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

Edmonson
§173.134
§173.197
Regulated Medical Waste
11-0314

BioStorage.
TECHNOLOGIES

19 December 2011

Office of Hazardous Materials Standards

Pipeline and Hazardous Materials Safety Administration

Attn: PHH-10

U.S. Department of Transportation, East Building

1200 New Jersey Avenue, SE.

Washington, DC 20590-0001

To Whom It May Concern:

I am writing to request written clarification regarding the following shipping situation:

In a clinical trial for the development of diagnostic testing for the detection of Colon Cancer or pre-cancerous cells from a stool sample, fecal material is collected from human subjects in their residence and shipped to the warehouse of the parent company conducting the clinical study.

Specimens collected from multiple patients are held until a sufficient amount of specimens are present and are then shipped via bulk packaging on dry ice to a third party warehouse for long term storage at ultra-cold temperatures of -80° Celsius. Prior to shipping to the third party warehouse, the specimens are not routinely tested for the presence of an infectious substance. These samples are considered liquid, but in a frozen state.

At a future date, the parent company will request that these specimens be shipped from the third party warehouse to a clinical laboratory for routing testing. At the time of shipping to the clinical laboratory, it is not known to the third party warehouse if that routine testing is related to the diagnosis of an infectious disease.

Employees at the company conducting the clinical study, in charge of determining the hazard class of these specimens are considered hazmat employees, as defined in §171.8, who have been trained and tested by their hazmat employers in accordance with Subpart H of Part 172.

These employees have determined that the proper classification of "Exempt Human Specimen" applies for all transportation throughout the clinical study.

Q 1: Do batched shipments containing numerous different patient's specimens, having been classified by trained personnel as "Exempt Human Specimen" and being shipped in bulk packaging from the parent company to a third party warehouse for long-term ultra-cold storage qualify for exemption from the HMR under 173.134(b) (11)?

Q 2: When ordered by the parent company to ship these specimens to a clinical laboratory for routine testing as part of the clinical study, is it in violation of the HMR to label these shipments as "Exempt Human Specimen" and claim exemption from the HMR under 173.134 (b) (11)?

Thank you for the opportunity to submit this request for interpretation and I look forward to your response. I may be reached at 317-452-4820 for further clarification, if needed.

Regards,

Darcy Britt

Global Logistics Compliance Supervisor

BioStorage Technologies

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