U.S. Department
of Transportation
**Research and
Special Programs
Administration**

400 Seventh St., S.W.
Washington, D.C. 20590

MAR 9 2004

Mr. Chris Younghans-Haug
University of California, Irvine
4600 Bison Avenue
Irvine, CA 92697-2725

Ref. No. 04-0034

Dear Mr. Younghans-Haug:

This is in response to your letter asking whether human cells and human cell lines are regulated under the Hazardous Materials Regulations (HMR; 49 CFR, Parts 171-180), the International Civil Aviation Association (ICAO) Technical Instructions for the Safe Transport of Dangerous Goods by Air, and the International Air Transport Association (IATA) Dangerous Goods Regulations. You state that the materials are being transported for research purposes and do not contain pathogens. You also ask for clarification regarding the marking of packages and use of a shipper's declaration if these materials are not subject to the regulations.

The HMR authorizes the use of the ICAO Technical Instructions with certain exceptions as an alternative to the HMR, but does not authorize the use of the IATA Dangerous Goods Regulations. For questions regarding the use of the IATA Dangerous Goods Regulations, we suggest you contact the organization at 514/390-6770.

Human cells and human cell lines that do not meet the definition of Division 6.2 materials are not regulated under the HMR or the ICAO Technical Instructions unless the materials meet the definition of another hazard class or are contained in packages with other materials that are subject to the regulations, such as formalin (Class 3) or carbon dioxide (Class 9).

You also ask whether these materials, if non-regulated, require a proper shipping name, UN number and hazard class to be marked on packages and whether such materials require a shipper's declaration stating that the materials are hazardous. Packages

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171.2

containing materials that are not subject to the regulations may not be marked, certified, or otherwise represented as a hazardous material when a hazardous material is not present (see § 171.2(f)(2)).

I hope this information is helpful. Please contact this office if you have additional questions.

Sincerely,

Hattie L Mitchell

Hattie L. Mitchell, Chief
Regulatory Review and Reinvention
Office of Hazardous Materials Standards

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MC Intake
§171.2
§173.134
Applicability/
Definition
04-0034

February 9, 2004

Director Ed Mazzullo
Department of Transportation
Office of Hazardous Materials Safety
Routing Attn: DHM-10
400 Seventh Street, SW
Washington DC, 20590

Subject: Request for formal Letter of Interpretation

Dear Director Mazzullo:

I would like to know whether human cells and human cell lines commonly used in medical research—not Diagnostic Specimens—are regulated under the Hazardous Materials Regulations including those of ICAO and IATA.

While we handle human cells and human cell lines in our research labs according to the safety principles and practices of Universal Precautions, Standard Precautions, and those described in Appendix H (http://www.cdc.gov/od/ohs/biosfty/bmbl4/b4ah.htm) of Center for Disease Control's Biosafety for Medical and Biomedical Laboratories, 4th Edition, the cells are not known to contain pathogens or cause harm to the environment.

The amount of sample per primary container that I would anticipate that a researcher might ship to colleagues at other research institutions ranges from less one (1) milliliter up to one hundred (100) milliliters. Generally, sample size would be less than ten (10) milliliters.

Our packaging consists of watertight primary container, absorbent padding, watertight secondary container, and then fiberboard outer packaging.

If human cells and human cell lines for research purposes—not Diagnostic Specimens—and not known to contain pathogens or harm the environment are not regulated by the Hazardous Materials Regulations including those of ICAO and IATA, then proper markings of the outer package would not require an UN number, proper shipping name, or class. Nor would the shipper need to complete the Shipper's Declaration to declare the goods as dangerous.

Your office's formal Letter of Interpretation will allow us to provide accurate shipping guidance to our medical researchers.

Cordially,

Chris Younghans-Haug
Chemical Safety Programs Specialist