May 13, 2013

Karl E. Luke, PhD
Diagnostic Hybrids, Inc.
1055 East State Street, Suite 100
Athens, OH 45701

Dear Dr. Luke:

Thank you for your March 18, 2013, letter to the Occupational Safety and Health Administration (OSHA) Regional Office. Your letter was forwarded to OSHA's Directorate of Enforcement Programs to be answered. Your questions concerned the distribution requirements for Safety Data Sheets under the revised Hazard Communication standard (HCS 2012), 29 CFR 1910.1200. This letter constitutes OSHA's interpretation only of the requirements herein, and may not be applicable to any questions not delineated within your original correspondence. Your paraphrased question and our response is below.

Background: Diagnostic Hybrids (DHI) manufactures in vitro diagnostic medical devices for professional use in testing facilities. DHI recently uploaded all of DHI's Safety Data Sheets (SDSs) to the website to make them accessible to all of its customers. DHI also includes an 'e-labeling' product information card with each shipment to inform the customers that the SDSs are available on the DHI website.

Question: Would the 'e-labeling' product information card meet the requirements of 29 CFR 1910.1200(g)(6)(ii) to provide the SDS with the shipped containers or prior to the first shipment?

Response: No. The use of the 'e-labeling' product information card would not be compliant with 29 CFR 1910.1200(g)(6)(ii). While OSHA allows for the use of electronic distribution of SDSs, the system you proposed does not meet all the requirements OSHA has outlined for electronic distribution of SDSs.

As discussed in OSHA's December 30, 1997, letter to the Honorable Charles S. Robb, manufacturers, importers and distributors who would like to use an electronic system for distribution of SDSs must meet the following requirements.

- 1. The manufacturer must ensure that the downstream user has agreed to this type of information access, ("opt-in").
- 2. The manufacturer cannot require the downstream user to purchase new technology in order to obtain the SDS.
- 3. The manufacturer must ensure that some positive and verifiable form of notification (such as a letter or email) is provided with all the information necessary to access the SDS(s).
- 4. The manufacturer must ensure that some positive and verifiable form of notification is provided to ensure that the downstream user is aware when SDSs are updated.

To this end, downstream users must choose whether they would like to receive SDSs electronically through your e-labeling system and be able to "opt-out" at any time. Once a downstream user "opts-out" you must provide them a hard-copy of the SDS as part of their next shipment. If the downstream user elects to receive SDSs electronically, you are required to provide them with information on how to access SDSs and to notify users when SDSs are updated. Also, please note that all SDSs must be provided at no cost to the downstream user, regardless of whether they are shipped as hard-copies or provided electronically. In addition, the use of electronic distribution of SDSs does not eliminate the manufacturer

or importer's requirement under 29 CFR 1910.1200(g)(6)(iv) to provide an SDS (hard-copy) upon request by the distributor or employer.

Thank you for your interest in occupational safety and health. We hope you find this information helpful. OSHA's requirements are set by statute, standards, and regulations. Our letters of interpretation do not create new or additional requirements but rather explain these requirements and how they apply to particular circumstances. This letter constitutes OSHA's interpretation of the requirements discussed. From time to time, letters are affected when the Agency updates a standard, a legal decision impacts a standard, or changes in technology affect the interpretation. To assure that you are using the correct information and guidance, please consult OSHA's website at http://www.osha.gov. If you have further questions, please feel free to contact the Directorate of Enforcement Programs at (202) 693-2100.

Sincerely,

Thomas Galassi, Director
Directorate of Enforcement Programs

¹¹ OSHA's December 30, 1997 letter to the Honorable Charles S. Robb is available at: http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=22512