



Date: August 29, 2016

To: Any customer requesting Safety Data Sheets (SDS) for GAVIS products

From: GAVIS Pharmaceuticals, LLC

Subject: OSHA Requirements

This correspondence has been drafted in response to numerous inquiries and requests that GAVIS Pharmaceuticals receives for Safety Data Sheets (SDS). The Code of Federal Regulations, Title 29-Labor, §1910.1200, section (b), addresses the scope and application of an employee hazardous communication program. Subsection (6) indicates that the hazardous communication program specified previous **does not apply to:** ... §1910.1200(b)(6)(vii) "Any drug, as that term is defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), when it is in solid, final form for direct administration to the patient (e.g., tablets or pills); drugs which are packaged by the chemical manufacturer for sale to consumers in a retail establishment (e.g., over-the-counter drugs); and drugs intended for personal consumption by employees while in the workplace (e.g., first aid supplies)" – **29 CFR 1910.1200 Revision 3, issued in the Federal Register, March 26, 2012. This rule became effective May 25, 2012.**

Therefore, for all GAVIS solid dosage pharmaceutical products, SDS will not be created. If absolutely necessary, GAVIS may provide the SDS for the constituent compounds. A customer request is to be submitted in writing, specify the product, along with the primary use of the product. SDS information will only be provided to **direct customers**. All requests should be submitted to GAVIS Customer Service. These requests will be addressed on a limited basis.

Sincerely,

A handwritten signature in blue ink, appearing to read "Jeffrey C. Palmer".

Jeffrey C. Palmer
Director of Quality Assurance
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