



U.S. Department  
of Transportation

**Research and  
Special Programs  
Administration**

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

AUG 27 1999

Mr. Jim D. Smith  
Manager, Environmental Engineering  
GensiaSicor Pharmaceuticals, Inc.  
17 Hughes  
Irvine, CA 92618-1902

Ref. No. 99-0080

Dear Mr. Smith:

This is in response to your letter postmarked March 26, 1999, regarding the relevance of the distribution method in determining whether a drug or medicine is eligible for a consumer commodity exception under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). I apologize for the delay in responding and hope it has not caused any inconvenience.

Drugs and medicines are eligible for consumer commodity exceptions regardless of whether they are suitable or intended for retail sale. Federal, state or local regulations (or industry guidelines) that address controls on the administration of a drug or medicine by a licensed physician, nurse or any other individual are not relevant to a decision to reclassify and rename these materials under applicable provisions of the HMR.

I hope this satisfies your request.

Sincerely,

Thomas G. Allan  
Acting Director  
Office of Hazardous Materials Standards



990080

171.8

**GensiaSicor™**  
PHARMACEUTICALS  
A GensiaSicor Company

Harim  
§ 171.8  
Consumer  
Commodity  
99-0080

~~Ref: 99-044~~

Mr. Ed Mazzullo  
Director Office of Hazardous Materials Standards  
USDOT/RSPA  
400 7<sup>th</sup> Street S.W.  
Washington D.C. 20590-0001

Dear Mr. Mazzullo:

I am writing this letter to request your assistance in interpreting the definition of Consumer commodity as defined in 49 CFR 171.8. In this section Consumer commodity is defined as follows:

*"Consumer commodity means a material that is packaged and distributed in a form intended or suitable for sale through retail sales agencies or instrumentalities for consumption by individuals for purposes of personal care or household use. This term also includes drugs and medicines."*

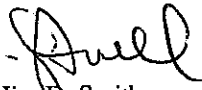
GensiaSicor Pharmaceuticals is a manufacture of injectable drugs. These "drugs or medicines" are not sold directly to the general public but must be administered by a health care professional in a hospital or clinic setting.

Under this definition, "drugs or medicines" that meet one or more of the hazard class definitions and are sold directly to the general public through a retail outlet such as Sav-On Drug or Rite-Aid could be classified and shipped as a consumer commodity. However, injectable drugs that must be administered to a patient by a health care professional in a hospital or clinic setting does not meet this definition and cannot be shipped as a consumer commodity.

Is my interpretation of this definition correct?

Your prompt response and guidance will be appreciated. If you have any questions, please call me at 949-455-4712.

Sincerely,



Jim D. Smith  
Manager, Environmental Engineering