



JUN 26 2006  
Catalysis, S.L.  
Ma Carena Street – Number 14  
Madrid, Madrid 28016  
Spain

Ref. No. CL-06-HFS-810-217

To Whom It May Concern:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address <http://www.catalysisusa.net> and has determined that the product "DIAMEL®" is promoted for conditions that cause the product to be a drug under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)]. You are identified on the website's registration as the contact for this website. The therapeutic claims on your web site establish that the product is a drug because it is intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of this product with these claims violates the Act.

Examples of some of the claims observed on your web site include:

- **DIAMEL®**  
"Open Clinical Research of Food Supplement DIAMEL® in the Treatment of the Second Type of Diabetes Mellitus"  
*"Food supplement made of lettuce and oligoelements for diabetic patients"*
- [Next to the heading "**DIAMEL**"]  
"[D]esigned for  
Diabetes mellitus (types 1 and 2)  
benefits  
\* Natural therapy  
\* Regulates your blood sugar levels  
\* Reduces your level of HbA1c and triglycerids [sic]  
\* Controls your cholesterol levels ...  
\* Reduces insulin intake for diabetic patients  
\* Improves male sexual function"
- Links on your website titled "Clinical studies" and "Last Clinical Study" lead to claims concerning clinical studies in Latvia and Romania. Examples of claims made concerning these studies include:  
  
[under the heading "Conclusions" in connection with the purported Latvian study]  
"The administration of the food supplement DIAMEL ... indicates the reduction of resistance to insulin."

[under the heading "Conclusions" in connection with the purported Romanian study]  
"The administration of **DIAMEL®** ... as a treatment associated with antidiabetic therapy presents the following advantages:

...

\* **DIAMEL®** can be used as a hypo-glycaemic preparation for diabetes mellitus type II, ..."

Furthermore, your product is not generally recognized as safe and effective for the above referenced conditions and therefore, the product is also a "new drug" under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

FDA is aware that Internet distributors may not know that the products they offer are regulated as drugs or that these drugs are not in compliance with the law. Many of these products may be legally marketed as dietary supplements if claims about diagnosis, cure, mitigation, treatment, or prevention are removed from the promotional materials and the products otherwise comply with all applicable provisions of the Act and FDA regulations.

Under the Act, as amended by the Dietary Supplement Health and Education Act, dietary supplements may be legally marketed with truthful and non-misleading claims to affect the structure or function of the body (structure/function claims), if certain requirements are met. However, claims that dietary supplements are intended to prevent, diagnose, mitigate, treat, or cure disease (disease claims), excepting health claims authorized for use by FDA, cause the products to be drugs. The intended use of a product may be established through product labels and labeling, catalogs, brochures, audio and videotapes, Internet sites, or other circumstances surrounding the distribution of the product. FDA has published a final rule intended to clarify the distinction between structure/function claims and disease claims. This document is available on the Internet at <http://vm.cfsan.fda.gov/~lrd/fr000106.html> (codified at 21 C.F.R. § 101.93(g)).

In addition, only products that are intended for ingestion may be lawfully marketed as dietary supplements. Topical products and products intended to enter the body directly through the skin or mucosal tissues, such as transdermal or sublingual products, are not dietary supplements. For these products, both disease and structure/function claims may cause them to be new drugs.

Certain over-the-counter drugs are not new drugs and may be legally marketed without prior approval from FDA. Additional information is available in Title 21 of the Code of Federal Regulations (21 C.F.R.) Parts 310 and 330-358, which contain FDA's regulations on over-the-counter drugs.

The agency is taking steps to warn our citizens that drugs from foreign sources that are promoted and sold via the Internet may not be approved for marketing in this country, and that unapproved new drugs cannot be legally imported. Unapproved new drugs offered for importation into the United States are subject to detention and refusal of admission. With copies of this letter, we are advising the drug regulatory officials in the countries from which

you operate that FDA considers your product to be an unapproved new drug that cannot be legally marketed to consumers in the U.S.

This letter is not intended to be an all-inclusive review of your web site and products your firm markets. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

If you need additional information or have questions concerning any products distributed through your web site, please contact FDA. You may respond in writing to Linda J. Webb, Compliance Officer, Food and Drug Administration, Division of Dietary Supplement Programs, 5100 Paint Branch Parkway, College Park, Maryland 20740-3835. If you have any questions concerning this letter, please contact Ms. Webb at (301) 436-2375.

Sincerely yours,

/s/

Susan J. Walker, M.D.  
Director  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition