



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

TO WHOM IT MAY CONCERN:

We have reviewed correspondence on behalf of:

Designed Nutritional Products  
PO Box 1242  
Orem, UT 84059-1242

concerning the status of:

Designed Nutritional Products Organic Germanium  
Bis(2-Carboxyethylgermanium Sesquioxide)

These products are regulated by the Food and Drug Administration (FDA) pursuant to the requirements of the Federal Food, Drug and Cosmetic Act (FD&C Act) and the Fair Packaging and Labeling Act (FPLA) and other related laws.

The Food and Drug Administration does not have statutory authority to approve or sanction any food or any food manufacturer or distributor of such products.

The above referenced products are under the jurisdiction of the Food and Drug Administration which has primary responsibility for the administration and enforcement of the Federal Food, Drug and Cosmetic Act (FD&C Act) and related statutes. While we have not examined the specific products being offered for export or reviewed the labels, we can state that such products may be freely marketed in the United States or exported provided that the products conform to all applicable United States laws and regulations. Foods may also be exported if they meet the specifications of section 801(e) of the FD&C Act (21 U.S.C. 318(e)).







The issuance of this certification is for exportation of the products. Under section 801(e) of the Federal Food, Drug, and Cosmetic Act, a food or cosmetic intended for export shall not be deemed to be adulterated or misbranded if it:

- (a) accords to the specifications of the foreign government,
- (b) is not in conflict with the laws of the country to which it is intended for export,
- (c) is labeled on the outside of the shipping package that it is intended for export,
- (d) is not sold or offered for sale in domestic commerce.

Sincerely yours,

G. Vincent Keys  
Program Coordinator  
Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling,  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

