



0031 6 SEP -5 P2:22

AUG 31 2006

Marion A. Hauser, MS, RD  
C.E.O.  
Beulah Land Corporation  
715 Lake Street  
Suite 706  
Oak Park, Illinois 60301

Dear Ms. Hauser:

This is in response to your letter received by the Food and Drug Administration (FDA) on August 9, 2006 pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

In your letter, you state that the following statement will be made for the product Lipid Balance:

“[H]elp maintain normal cholesterol levels. It is not meant to prevent or treat heart disease.”

In a letter to you dated May 23, 2006, FDA informed you that the claim “[H]elp support normal cholesterol levels” was an implied disease claim. We explained that in the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because “many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease,” in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. Because the claim you are making for this product represents that the product is intended to affect blood cholesterol but does not also include a statement about it being intended to affect blood cholesterol that is already in the normal range, it is an implied disease claim.

The modified claim that is the subject of your present notification is not substantively different from the previous claim you submitted and it too is an implied disease claim.

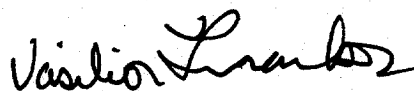
You proposed to include in your claim a disclaimer that states “It [your product] is not meant to prevent or treat heart disease.” However, the use of this disclaimer does not correct the implicit disease claim you are making by claiming that the product will “maintain normal cholesterol,” a claim that implies your product will prevent or lower elevated cholesterol (hypercholesterolemia), a disease, thereby implicitly representing

that the product will prevent heart disease. A manufacturer cannot disclaim drug status by representing his products to be effective in the prevention or treatment of disease while at the same time stating that the product is not intended for any such use. See, e.g., Kasz Enters., Inc., 855 F. Supp. 534, 542 (D.R.I. 1994) ("It is the *objective* intent of the vendor, not the vendor's subjective explanations and disclaimers, which determines the intended use of a product....") (first emphasis in original; second emphasis added), amended on other grounds, 862 F. Supp. 717 (D.R.I. 1994); United States v. 3 Cartons... "No. 26 Formula GM," 132 F. Supp. 569, 574 (S.D. Cal. 1952) ("Where a person has set in motion forces that result in creating an impression that an article has value in the treatment of disease, he cannot avoid the legal consequences of such action by a disclaimer in the labeling asserting there is no scientific evidence that the article has therapeutic value.")

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,



Vasilios H. Frankos, Ph.D.  
Acting Director  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, Chicago District Office, Office of Compliance, HFR-CE640

Office of Special Nutritional (HFS-450)  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

AUG - 9 2006

Dear Sir/Madam:

This letter will serve as notification, pursuant to 21 USC 343(r)(6) (section 403(r)(6)) of the Federal, Food, Drug, and Cosmetic Act and 21 CFR 101.93, that I am using the following claim on my label (see attached label).

**Name of Distributor:**  
Beulah Land Corporation  
715 Lake Street, Suite 706  
Oak Park, IL 60301

**Name of Manufacturer:**  
Ortho Molecular Products, Inc.  
3017 Business Park Drive  
P.O. Box 1060  
Stevens Point, WI 54481

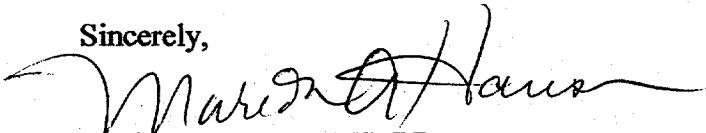
**Statement Text:**  
Natural Medicine Use: Lipid Balance may help maintain normal cholesterol levels. It is not meant to prevent or treat heart disease.

**Dietary Ingredients:**  
3 Capsules Contain: Chromium 200mcg, Inositol Hexaniacinate 1,350mg, Gugal Resin 500mg, Guar Gum 225mg, Artichoke Leaf Extract 150mg.

**Dietary Supplement Name:**  
Lipid Balance

As required, enclosed are two photocopies of this notification. I certify that the information presented and contained in this notice is complete and accurate, and that I have substantiation that the statement is truthful and not misleading.

Sincerely,



Marion A. Hauser, MS. RD  
C.E.O.  
Beulah Land Corporation

*AMS*  
*2006-6611*

#1756

Supplement Facts	
3 capsules contain	% Daily Value
Chromium (ChromoMate®) 200 mcg	167%
Inositol Hexaniacinate 1,350 mg	*
Gugal Resin 500 mg	*
Guar Gum 225 mg	*
Artichoke Leaf Extract 150 mg (Standardized to contain 5% Cynarin)	*
* % Daily Value not established	

Other Ingredients: Natural Vegetable Capsules. This product may contain one or more of the following: Gelatin, Soybean Lecithin, Soybean Starch, Microcrystalline Cellulose and Silicon Dioxide.

Formulated to be free of allergens derived from: Gluten, corn, egg, dairy, peanuts, yeast, artificial colors and flavors.

ChromoMate® is a registered trademark of Nutrilite Nutritionals, Inc.

Product #530090 L-HAU042-530090-C

1-877-792-3852