



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

0507 6 JUN 22 P3:18

MAY 23 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 letters received by the Food and Drug Administration (FDA) on May 16, 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 support normal cholesterol levels.”

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.

You also state that the following claims will be made for the products identified below:

De-Yeast Plus

“[N]atural approach to fungus overgrowth.”

Pro-Cartilage

“[H]elp...after Prolotherapy.”

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 statements that you are making for these products

97S 0163 LET 886

Page 2 - Ms. Marion A. Hauser

suggest that they are intended to treat, prevent, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are 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,



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

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

MAY 10 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: Pro-Cartilage may help support joint health and after Prolotherapy.

Dietary Ingredients: 3 Capsules Contain: Vitamin C (ascorbic acid) 60mg, Glucosamine 1500mg, Chondroitin Sulfate 900mg, Bromelain 45mg.

Dietary Supplement Name:
Pro Cartilage

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

06-4372

SUGGESTED USE: As a dietary supplement, 1 capsule three times per day on an empty stomach or as recommended by your health care professional.
As with all dietary supplements, some individuals may not tolerate or may be allergic to the ingredients used. Please read the ingredient panel carefully prior to ingestion. Cease taking this product and consult your physician if you have negative reactions upon ingestion.

If you are pregnant or nursing, consult your physician before taking this product.
Formulated to be free of allergens derived from: Gluten, corn, egg, dairy, peanuts, soy, yeast, artificial colors and flavors.
*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

**KEEP CONTAINER TIGHTLY CLOSED,
STORE AT ROOM TEMPERATURE,
KEEP OUT OF REACH OF CHILDREN.**

Beulah Land Nutritionals
715 Lake Street, Suite 706
Oak Park, IL 60301
1-877-RXBEULAH

Product #537090
L-HAU042-537090-D



Pro-Cartilage⁺
DIETARY SUPPLEMENT
90 CAPSULES

Supplement Facts	
Serving Size: 3 Capsules	Servings Per Container: 30
3 capsules contain	% Daily Value
Vitamin C, 60 mg (as Ascorbic Acid USP™)	100%
Glucosamine Sulfate 1,500 mg	*
Chondroitin Sulfate 900 mg	*
Bromelain (2,400 GDU/g) 45 mg	*
* % Daily Value not established	

Other Ingredients: Natural gelatin capsules. This product may contain one or more of the following: Ascorbyl Palmitate, Magnesium Stearate, Microcrystalline Cellulose, and Silicon Dioxide.
This product was sealed for your protection. Do not use if outer seal or inner seal is missing or damaged.

This product contains the following potential allergens: Pineapple/Bromelain.

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

MAY 18 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

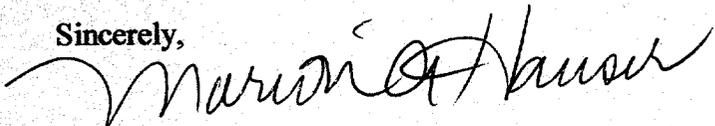
Statement Text:
Natural Medicine Use: De-Yeast Plus may be helpful as a natural approach to fungus overgrowth.

Dietary Ingredients:
2 Capsules Contain: Biotin 300mcg, Zinc (as Zinc Undecylinate) 20mg, Sodium Caprylate 150mg, Oregano Leaf Extract 180mg, Pau D' Arco inner bark extract 180mg, Zinc Undecylinate 150mg, Berberine Sulfate 115mg, Cinnamon bark extract 100mg, Ginger root powder 100mg, Grapefruit seed extract 100mg, Chamomile flowers powder 50mg.

Dietary Supplement Name:
De-Yeast Plus

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

06-4372

SUGGESTED USE: As a dietary supplement, 2 capsules three times per day or as recommended by your health care professional. Formulated to be free of allergens derived from: Gluten, egg, dairy, peanuts, soy, yeast, artificial colors and flavors. This product contains the following potential allergen: Asteraceae Family. If you are pregnant or nursing, consult your physician before taking this product. As with all dietary supplements, some individuals may not tolerate or may be allergic to the ingredients used. Please read the ingredient panel carefully prior to ingestion. Cease taking this product and consult your physician if you have negative reactions upon ingestion.
Citricidal® is a registered trademark of Bio/Chem Research.
*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.
KEEP CONTAINER TIGHTLY CLOSED. STORE AT ROOM TEMPERATURE. KEEP OUT OF REACH OF CHILDREN.
Product #510090
L-HAU042-510090-B
Beulah Land Nutritionals
715 Lake Street, Suite 706
Oak Park, IL 60301
1-877-RXBELAH



Benuts
Be Nuts For Your Health!
www.benuts.com

De-Yeast Plus+
DIETARY SUPPLEMENT
90 CAPSULES

Supplement Facts	
Serving Size: 2 Capsules	Servings Per Container: 45
2 capsules contain:	% Daily Value
Biotin 300 mcg	100%
Zinc (as Zinc Undecylinate) 20 mg	133%
Oregano Leaf Extract (10:1) 180 mg	*
Pau D' Arco Inner Bark Extract (5:1) 180 mg	*
Sodium Caprylate 150 mg	*
Zinc Undecylinate 150 mg	*
Berberine Sulfate 115 mg	*
Cinnamon Bark Extract (5:1) 100 mg	*
Ginger Root 100 mg	*
Grapefruit Seed Extract (Citricidal®) 100 mg	*
German Chamomile Flower 50 mg	*
*% Daily Value not established	

Other Ingredients: Natural Vegetable Capsules. This product may contain one or more of the following: Ascorbyl Palmitate, Magnesium Stearate, Microcrystalline Cellulose and Silicon Dioxide. This product was sealed for your protection. Do not use if outer-seal or inner-seal is missing or damaged.