



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

FEB 10 2006  
0517 6 FEB 16 P2:33

President  
Beulah Land Corporation  
715 Lake Street, Suite 706  
Oak Park, IL 60301

Dear Sir:

This is in response to your letters received by the Food and Drug Administration (FDA) on February 1, 2006. These letters were submitted to FDA pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

21 CFR 101.93(a)(3) requires that the notice submitted pursuant to 21 U.S.C. 343(r)(6) and this section be signed by a responsible individual who can certify the accuracy of the information presented and contained in the notice, and that the individual certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading. Your submissions do not meet this requirement in that the notices do not contain the name and signature of a responsible individual; as such, each notice does not certify that the firm is in compliance with the requirements of the Act and the regulation. Therefore, your firm has not complied with the notification requirement in 21 U.S.C. 343(r)(6) and must submit notifications in accordance with the requirements in 21 CFR 101.93(a). The failure to submit a valid notice as required by the Act and the agency's regulation may subject the products that are the subject of the notification to regulation under the drug provisions of the Act.

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

975 0162 LET 861

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**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

2006-726  
undated/unrevised

SEP 1 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: Beulah's Bone Plus Pack may help promote bone health.

**Dietary Ingredients:**

2 packets contain: Vitamin D3 1000IU, Vitamin K 1mg, Folic Acid 800mcg, Calcium 1000mg, Phosphorus 400mg, Magnesium 400mg, Selenium 200mcg, Copper 1mg, Manganese 10mg, Molybdenum 150mcg, Ipraflavone 600mg, Strontium Citrate 1000mg, Montmorillonite 150mg, Boron 5mg

**Dietary Supplement Name:**

Beulah's Bone Plus Pack

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,  
Beulah Land Corporation

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



**SUGGESTED USE:** As a diet taking one Clear/White packet in the PM. Maintenance: 1 packet on odd days and 1 Clear recommended by your health ca  
As with all dietary supplements may be allergic to the ingredient panel carefully prior to ingestion consult your physician if you ha  
*If you are pregnant or nursing before taking this product.*  
**KEEP CONTAINER TIGHTLY TEMPERATURE, KEEP OUT**  
+ This statement has not been ex Administration. This product i cure, or prevent any disease.  
*This product was sealed to if outer-seal or inner-seal.*  
Product #350060 L-H

#1575

plement, 2 packets per day  
AM and one Clear/Clear packet  
or day alternating 1 Clear/White  
packet on even days or as  
professional.

Individuals may not tolerate or  
d. Please read the ingredient  
list before taking this product and  
be aware of any adverse  
reactions upon ingestion.  
*consult your physician*

KEEP IN A COOL, DRY PLACE.  
STORE AT ROOM TEMPERATURE.  
KEEP OUT OF REACH OF CHILDREN.  
Approved by the Food and Drug  
Administration for use in the  
treatment of osteoporosis.

For protection. Do not use  
if packaging is torn, missing or damaged.  
42-350060-B



# Beulah's Bone Plus Pack<sup>+</sup>

DIETARY SUPPLEMENT  
60 PACKETS

Supplement Facts	
Serving Size: 2 Packets Servings Per Container: 30	
2 packets contain	% Daily Value
Vitamin D3 (as Cholecalciferol)	1000 IU 250%
Vitamin K (as Phytonadione)	1 mg 1250%
Folic Acid	800 mcg 200%
Calcium (as Hydroxyapatite, Citrimal <sup>®</sup> )	1000 mg** 100%
Phosphorus (as Calcium Hydroxyapatite, Chelate)	400 mg 40%
Magnesium (as Buffered Amino Acid Chelate, Citrate, Aspartate)	400 mg 40%
Selenium (as Amino Acid Complex)	200 mcg 296%
Copper (as Lysinate)	1 mg 50%
Manganese (as Chelazome <sup>®</sup> )	10 mg 500%
Molybdenum (as Amino Acid Chelate)	150 mcg 200%
Iperflavone	600 mg *
Strontium Citrate	1000 mg***
Monmonillonite	150 mg *
Boron (as Probenite)	5 mg *

Other Ingredients: Natural vegetable capsules, Cranberry Juice Concentrate and Turmeric Root Extract. This product may contain one or more of the following: Ascorbyl palmitate, magnesium stearate, microcrystalline cellulose, and silicon dioxide.

Formulated to be free of allergens derived from: Gluten, corn, egg, dairy, peanuts, artificial colors and flavors.  
Chelazome<sup>®</sup> and Citrimal<sup>®</sup> are registered trademarks of Albion, Inc.

www.benuts.com

BEULAH LAND NUTRITIONALS

1-877-792-3852