



1530 6 DEC 18 12:43  
NOV 28 2006

President  
Holistic Therapies  
24 S.E. 6 Street  
Boca Raton, Florida 33432

Dear Sir/Madam:

This is in response to your submission to the Food and Drug Administration (FDA) received on November 8, 2006. Although the submission is intended to be the submission required pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)), it does not meet the requirements for that submission under 21 CFR 101.93(a).

21 CFR 101.93(a)(3)<sup>1</sup> requires that the notice submitted pursuant to 21 U.S.C. 343(r)(6) of 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 submission does not meet this requirement in that the notice does not contain the name or signature of the responsible individual as required by the regulation; as such, it 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 a notification 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 product that is the subject of the notification to regulation under the drug provisions of the Act.

<sup>1</sup>You can access the Code of Federal Regulations at  
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm>.

975-0163 LET 9/3

Page 2 - Holistic Therapies

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

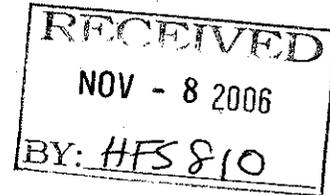
Copies:

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, Florida District Office, Office of Compliance, HFR-SE240

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



Dear Sir/Madam:

This letter will serve as notification, pursuant to section 403 (r)(6) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 101.93, that Ortho Molecular Products, Inc. is using the following claim on its label (see attached labels on page 2).

Name of Distributor: *Holistic Therapies*  
*24 S.E 6 Street*  
*Boca Raton, Florida 33432*

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

Statement Text: *MegaBone*

**Dietary Ingredients:** Vitamin D3 (as Cholecalciferol), Vitamin K (as Phytonadione), Folic Acid, Calcium (as Hydroxyapatite, Citramal), Phosphorus (from Calcium Hydroxyapatite, Chelate), Magnesium (as Buffered Amino Acid Chelate, Citrate, Aspartate), Selenium (as Amino Acid Complex), Copper (as Lysinate), Manganese (as Chelazome), Molybdenum (as Amino Acid Chelate), Ipriflavone, Strontium Citrate, Montmorillonite, Boron (as Proteinate). Natural Vegetable Capsules, Cranberry Juice Concentrate and Tumeric Root Extract. This product may contain Ascorbyl Palmitate, , *Microcrystalline Cellulose, Magnesium Stearate, and Silicone Dioxide.*

**Dietary Supplement Name:** *MegaBone*

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 Ortho Molecular Products, Inc. has substantiation that the statement is truthful and not misleading.

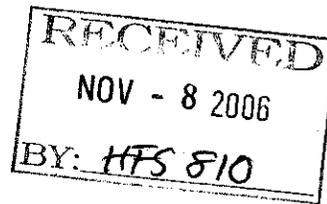
Sincerely,

[Your name here]

2006-  
8639

#1812

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



Dear Sir/Madam:

This letter will serve as notification, pursuant to section 403 (r)(6) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 101.93, that Ortho Molecular Products, Inc. is using the following claim on its label (see attached labels on page 2).

Name of Distributor: *Holistic Therapies*  
24 S.E 6 Street  
Boca Raton, Florida 33432

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

Statement Text: *ThyroMega*

Dietary Ingredients: *Iodine (from Kelp, Potassium), L-Tyrosine USP, Ashwaganda Root Extract (standardized to contain 1.5% Withanolides), Bladderwrack Leaf. Natural Vegetable Capsules- This product may contain Calcium Silicate, Microcrystalline Cellulose, Magnesium Stearate, and Silicone Dioxide.*

Dietary Supplement Name: *ThyroMega*

As required, enclosed are two photocopies of this notification.

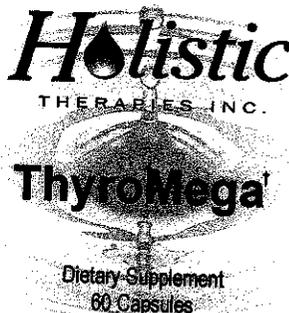
I certify that the information presented and contained in this notice is complete and accurate, and that Ortho Molecular Products, Inc. has substantiation that the statement is truthful and not misleading.

Sincerely,

SUGGESTED USE: As a dietary supplement, take 1-2 capsules 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. Do not consume this product if you are pregnant or nursing. Consult your physician for further information. 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. KEEP CONTAINER TIGHTLY CLOSED. STORE AT ROOM TEMPERATURE. KEEP OUT OF REACH OF CHILDREN. † 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.

Holistic Therapies  
24 S.E. 6th Street • Boca Raton, FL 33432  
561-391-1884 • www.holistic.com

Label ID L-LAZ561-620060-A Product #620060



Supplement Facts		
Serving Size: 1 Capsule		
Servings Per Container: 60		
1 capsule contains	Amount Per Serving	% Daily Value
Iodine (from Kelp, Potassium)	150 mcg	100%
L-Tyrosine USP™	500 mg	*
Ashwaganda Root Extract (Standardized to contain 1.5% Withanolides)	75 mg	*
Bladderwrack Leaf	40 mg	*

\* % Daily Value not established

Other Ingredients: Natural Vegetable Capsules. This product may contain one or more of the following: Calcium Silicate, Microcrystalline Cellulose, Magnesium Stearate and Silicon Dioxide.