

Food and Drug Administration College Park, MD 20740

0515 JAN 2FEB 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 January 19, 2005. These letters appear to be submissions 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)). Your letters state that Beulah Land Corporation intends to make the following statements, among others, for the following products:

Female Age Well Menstrual Support

"[M]ay help with...chronic fatigue."

EnhanceMENt Plus

"Natural alternative to Viagra...."

Paracid-B-Gone

"[A]ssist in conditions such as parasite infections, intestinal dysbiosis...."

De-Yeast Plus

"[H]elpful for conditions such as Candida Albicans, intestinal dysbiosis, stomach flu, and irritable bowel syndrome."

Pro-Cartilage

"[H]elp with joint injuries...."

"[H]elp to relieve pain and arthritis symptoms...."

"[R]educe pain and accelerate the inflammatory healing response for painful joint conditions, sports injury...."

"[M]ay help rebuild cartilage and alleviate pain in joint injury and other painful joint conditions."

Page 2 - President, Beulah Land Corporation

You also submitted a letter for the product Lipid Balance that uses the claim [M]ay be used to help normalize 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. Therefore, because the claim you are making for this product represents that the product is intended to normalize an abnormal blood cholesterol level 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.

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 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.

We would also like to note one other issue with your notices. 21 CFR 101.93(a)(3) requires that the notice submitted pursuant to 21 U.S.C. 343®)(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 submission does not meet this requirement in that the notice does not contain the name and signature of a responsible individual; 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®)(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.

Page 3 - President, Beulah Land Corporation

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

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:

May be beneficial for Menopausal women! Natural Medicine Use: Female Age Well may help with menopause symptoms and menstrual pain.

Why these ingredients? Black Cohosh may help alleviate menopausal symptoms, PMS and Dysmenorrhea (painful menstruation). Licorice Root may help with skin conditions and also in <u>chronic fatigue</u>. Gamma Oryzanal may help in menopausal symptoms and anxiety. Dong Quai Dong Quai Root is a Chinese herb which may be used for menstrual disorders and menstrual pain.

Dietary Ingredients:

2 Capsules Contain: Black Cohosh Root Extract 160mg, Protykin 8mg, Licorice Root Extract 75mg, Gamma Oryzanal 300mg, Dong Quai Root Extract 75mg.

Dietary Supplement Name:

Female Age Well

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



#1555

Dear Sir/Madam:

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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: Menstrual Support is a blend of herbs that may help with menstrual pain, PMS, menstrual irregularities, heavy menstrual bleeding, and chronic fatique.

Why these Ingredients? Chaste Berry is a fruit used since the ancient times. It is in here because it may help alleviate PMS symptoms and cyclic breast discomfort. Dong Quai Root is a chinese herb which may be used for menstrual disorders and menstrual pain. Yarrow Leaf may be used to help ease heavy bleeding. Ladies Mantle may be used to help alleviate menstrual pain and cramping. Mother Wort has been used for centuries to help ease uterine pain.

Dietary Ingredients:

1 Capsule Contains: Vitamin C 80mg, Chaste Berry Fruit Extract 320mg, Dong Quai Root Extract 80mg, Yarrow Powder 60mg, Ladies Mantle Powder 60mg, Motherwory 40mg.

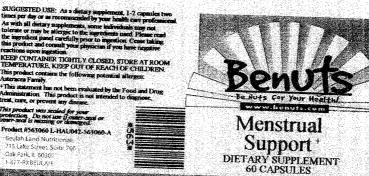
Dietary Supplement Name:

Menstrual Support

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.

www.benuts.com

Sincerely, Beulah Land Corporation



BEULAH LAND NUTRENOWALS

Supplement Facts

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of to be free of allergers derived from: Gh

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

JAN 19 2006

Name of Manufacturer:

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

Statement Text:

Natural alternative to Viagra. Natural Medicine Use: EnhanceMENt Plus may be used to help stimulate male organs.

Dietary Ingredients:

1 capsule contains: Muira Puama Extract 400mg, Ginkgo Biloba 60mg, Panax Ginseng Root Extract 100mg.

Dietary Supplement Name:

EnhanceMENt Plus

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Sincerely, Beulah Land Corporation



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

JAN 19 2006

Name of Manufacturer:

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

Statement Text:

Natural Medicine Use: Paracid B-Gone may assist in conditions such as parasite infections, intestinal dysbiosis, and other gastrointestinal disorders.

Dietary Ingredients:

1 Capsule Contains: Atremesia Annua Herb Powder 150mg, Olive Leaf Extract 90mg, Oregano Leaf Extract 70mg, Grapefruit Seed Extract 65mg, Goldenseal Root Extract 50mg, Berberine Sulfate 50mg.

Dietary Supplement Name:

Paracid-B-Gone

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

SUGGESTED USE: As a dietary supplement, 2-3 capsules three times per day 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. Do not consume this product of your one pregnant or nursing. Consult your physician for further information.

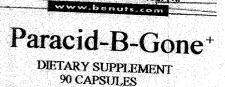
This product was sealed for your protection. Do not use if outer-seal or inner-seal is missing or damaged.

+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.

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19 Fish's Street, Suite 206
Gak Park, If 60,901
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Puts for Your Health

BEULAH LAND MUTRITIONALS

Dear Sir/Madam:

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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 for conditions such as Candida Albicans, intestinal dysbiosis, stomach flu, and irritable bowel syndrome.

Dietary Ingredients:

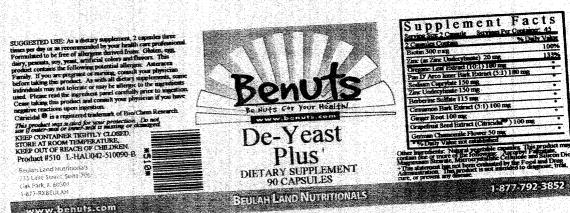
2 Capsules Contain: Biotin 300mcg, Zinc (as Zinc Undecylinate) 20mg, Sodium Caprylate 150mg, Oregano Leaf Extract 180mg, Pau D' Arco inner bark extract 180mg, Zinc Undecylinate 150mg, Berberine Sulfate 115mg, Cinnamon bark extract 100mg, Ginger root powder 100mg, Grapefruit seed extract 100mg, Chamomile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

Dietary Supplement Name:

De Yeast

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**



AN A SOLD

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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

JAN 19 2006

Statement Text:

Natural Medicine Use: Pro-Cartilage may help with joint injuries, loss of mobility, and after Prolotherapy to aid soft-tissue healing. Why these ingredients?

Vitamin C is a wonderful antioxidant and is well known for its healing abilities.

Glucosamine may help to relieve pain and arthritis symptoms by helping re-build cartilage.

Bromelain may help reduce pain and accelerate the inflammatory healing response for painful joint conditions, sports injury and after Prolotherapy.

Chondroitin may help rebuild cartilage and alleviate pain in joint injury and other painful joint conditions.

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, Beulah Land Corporation

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SUGGESTED USE: As a dietary aspplement, I	Water Committee
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as recommended by your health care professional	
As with all dietary supplements, some and victuals may not tolerate or may be allergic to the ingredients used. Please	
read the sugrethers passed currefully prior to impention. Cease	
taking this product and commit your physician if you have	
negative reactions upon ingration	
If you are pregnant or mirsing, consult your	
physician before taking this product.	~ DOMING ~!
Formulated to be free of allergers derived from: Gluten, corn.	
egg, charry, peanuts, soy, years, artificial colors and flavors.	
This statement has not been evaluated by the Food and Drug	Be Nots For Your Health!
Administration. This product is not intended to disguose, treat.	Andrew Work Brauts com
cure, or prevent any disease	
KEEP CONTAINER TIGHTLY CLOSED.	
STORE AT ROOM TEMPERATURE.	■ Pro-Cartilage' 🚆
CEVE OUT OF REACH OF CORE DREAD	

DIETARY SUPPLEMENT 90 CAPSULES

BEULAH LAND NUTRITIONALS 1-877-792-3852

Supplement Facts

Vitamin C 60 mg (as Ascorbic Acid USP [™])

Glucosamine Sulfate 1,500 mg

Chondroitin Sulfate 900 mg

Bronnelain (2,400 GDU/g) 45 n

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

JAN 1 9 2006

Name of Manufacturer:

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

Statement Text:

Trim the fat! Natural Medicine Use: Lipid Balance may be used to help normalize cholesterol levels.

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, Beulah Land Corporation

SUGGESTED USE: As a dictary supplement, I capsule three times per day on an empty stomach or as recommended by your health care professional. As with all dictary supplements, some individuals may not tolerate or may be allergie to the ingredient local. Please read the ingredient panel cardially prior to ingression. Cease lating this product and corosally surplyseisan if you have negative reactions upon ingestion.

This product contains the following potential allergen: Asteracca Farmly.

Do not constant this product if you are pregnant or marsing. Consult your physician for partner information. This product was usually for your protection. Do not use if outer-seed or inner-seed is mixing or damaged.

This stratement has not been evaluated by the Food and Drug Administration. This product is not intended to dispose, brest, early CONTAINER TIGHTLY (CLOSED.

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

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Lipid Balance⁺
DIETARY SUPPLEMENT
90 CAPSULES

BEULAH LAND NUTRITIONALS