



DEPARTMENT OF HEALTH & HUMAN SERVICES

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CERTIFIED MAIL
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Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

October 5, 2001

WARNING LETTER
2002-DT-02

Mr. Sangyeol Kwon, President
Vesta Pharmaceuticals, Inc.
8768 E. 33rd Street
Indianapolis, IN 46226

Dear Mr. Kwon:

The U.S. Food and Drug Administration has reviewed product labeling during an inspection of your firm, located at 8768 E 33rd Street, Indianapolis, IN 46226, [March 10, 15, and 17, 2000], and found that you have serious violations of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and the food, drug, and dietary supplement labeling regulations through links in the Food and Drug Administration's world wide web home page at: <http://www.fda.gov>.

The labeling of the Vesta Pharmaceuticals, Inc. products ArthramineTM (500mg) glucosamine sulfate, CynaraTM (200mg), DHEA (Dehydroepiandrosterone) (25 mg and 50 mg), Ginkgo biloba (60 mg), *Agaricus Blazei Murill* (ABM) Mushroom (250 mg), and Melatonin (3 mg) include statements or suggestions that these products may be useful in the treatment of various diseases. ArthramineTM claims that it "is thought to help repair the ravages of osteoarthritis," and can "help to prevent or address excessive susceptibility to bacterial and fungal infection," "breakdown and inflammation of synovial fluid," "damage to muscles and ligaments," and "inflamed joints, discs, and sciatic nerve." CynaraTM claims to "remove cholesterol from the blood," has "traditional use for atherosclerosis" and "been reported to lower cholesterol and triglyceride levels," and possesses "diuretic activities...used for kidney diseases and proteinuria." DHEA claims to have therapeutic application in "the prevention and/or treatment of heart disease, diabetes, obesity, osteoporosis, and arthritis." Ginkgo biloba claims that it can "decrease inflammation," has implications in "a wide variety of diseases including asthma, heart arrhythmias, myocardial infarction, and atherosclerosis," and helps "with cases of Alzheimer's disease, memory loss, concentration problems, vertigo, tinnitus and dizziness," "peripheral vascular diseases such as Raynaud's syndrome, intermittent claudication, numbness and tingling," and "head injuries, macular degeneration, asthma, and impotence." ABM Mushroom claims to be related to "low incidences of cancer and certain bacterial diseases and improvement in resistance to disease." Melatonin claims that it is a supplement for "Seasonal Affective Disorder (Winter Depression)."

Although you may be marketing these products as dietary supplements or foods, your labeling includes statements that represent or suggest that these products are intended for use in the cure, mitigation, treatment, or prevention of disease, and therefore, these products are drugs within the meaning of 201(g) of the Act. We are unaware of any evidence that establishes that these drugs are generally recognized as safe and effective for their intended uses. Therefore, these products are new drugs as described in section 201(p) of the Act that may not be marketed since no new drug application as required by section 505(a) of the Act has been approved.

These drugs are also misbranded because their labeling is false and misleading in that it suggests that there is evidence that these drugs are safe and effective for their intended uses when such evidence has not been established [section 502(a) of the Act]. These drugs are additionally misbranded because their labeling does not have adequate directions for use for the conditions indicated [section 502(f)(1) of the Act].

Even if the products above were not drug products and were marketed as dietary supplements, they would violate other provisions of the Act.

The product Vesta Pharmaceuticals, Inc. *Agaricus Blazei Murill* (ABM) Mushroom (250 mg) is misbranded because the label does not include the mandatory statement of identity required for dietary supplements, namely that the term "dietary supplement" appear as part of the statement of identity [21 CFR §101.3(d) and (g) and sections 403(i)(1) and 403(s)(2)(B) of the Act].

The products Vesta Pharmaceuticals, Inc. Arthramine™ (500mg) glucosamine sulfate, Vesta Pharmaceuticals, Inc. Chitosan (250 mg), Vesta Pharmaceuticals, Inc. Cynara™ (200 mg) standardized artichoke extract, Vesta Pharmaceuticals, Inc. DHEA (25 mg and 50 mg), Vesta Pharmaceuticals, Inc. Gingko biloba, (60 mg), Vesta Pharmaceuticals, Inc. Melatonin (3 mg), and Vesta Pharmaceuticals, Inc. St. John's Wort quality extract standardized to 0.3% hypericin (300 mg) are misbranded because they do not bear appropriate "Supplement Facts" labeling as prescribed by regulation [21 CFR §101.36(e)(10) and section 403 (q)(5)(F) of the Act].

The Vesta Pharmaceuticals, Inc. products Arthramine™ (500 mg), Chitosan™ (250 mg), Cynara™ (200 mg), DHEA (50 mg), Gingko biloba (60 mg), Melatonin (3 mg), and St. John's Wort (300 mg) are misbranded under section 403 (r)(1)(A) of the Act because the labels make the unauthorized nutrient content claim "A High Potency Dietary Supplement," or "A Maximum Potency Dietary Supplement" when these products do not contain any ingredients that have established Reference Daily Intake (RDI) [21 CFR § 101.9 (c)(8)(iv)] or Daily Reference Value (DRV) [21 CFR § 101.9(c)(9)]. FDA considers "maximum" to be synonymous with "high" in the context used on these labels. "High potency" claims may be used to describe individual vitamins or minerals that are

present at 100 percent or greater of the RDI per reference amount customarily consumed [21 CFR § 101.54(f)]. Because these products do not contain vitamins or minerals of at least 100 percent of the RDI, the use of "high potency" claims misbrands these products.

The Vesta Pharmaceuticals, Inc. products Antiox™ and Roma Trim™ are misbranded under section 403 (r)(1)(A) of the Act because the labels bear the nutrient content claim "A High Potency Nutraceutical" but do not indicate which vitamins or minerals are described by the term "high potency" [21 CFR §101.54(f) (ii)].

The product Doctors' Research Originals FAT WHACKER!™ is misbranded under section 403 (r)(1)(A) of the Act because its label bears an unauthorized nutrient content claim, "Super CHITOSAN Formula Plus Super Citrimax™, L-Carnitine, St. John's Wort." The term "plus" is authorized for nutrients that have a Reference Daily Intake (RDI) [21 CFR § 101.9 (c)(8)(iv)] or Daily Reference Value (DRV) [21 CFR § 101.9(c)(9)]. The term "plus" is a "more claim" in which the food must contain at least 10 percent of the RDI for vitamins or minerals or of the DRV for protein, dietary fiber, or potassium per reference amount customarily consumed than an appropriate reference food [21 CFR § 101.54 (e)] and bear a reference to a similar food [21 CFR § 101.13 (j)(1)(i)]. This claim is not authorized for substances without a RDI or DRV. Since there is no RDI or DRV for Super Citrimax™, L- Carnitine, and St. John's Wort, and there is no reference to a similar food, the claims "Super CHITOSAN Formula Plus Super Citrimax™, L-Carnitine, St. John's Wort" is an unauthorized nutrient content claims that misbrands this product.

The products Vesta Pharmaceuticals, Inc. Antiox™, Vesta Pharmaceuticals, Inc. Roma Trim™, Doctors' Research Originals FAT WHACKER!™, and Herrschner Formula 70 Geriatric Tablets are misbranded because they deviate from the prescribed labeling regulation by not separating dietary information for dietary ingredients that have a Reference Daily Intake (RDI) or a Daily Reference Value (DRV) [see 21 C.F.R. § 101.36 (b)(2)] established by regulation in section 21 C.F.R. § 101.9 (c)(8)(iv) from declared dietary ingredients for which RDI's and DRV's have not been established [21 C.F.R. § 101.36 (b)(3)] [section 403(q)(5)(F) of the Act and 21 C.F.R. § 101.36(e)].

The product Continental Quest Research Corporation Herrschner Formula 70 Geriatric Tablets is misbranded because it declares magnesium, zinc, and potassium in the nutrition label. These ingredients are present in amounts corresponding to less than 2% and cannot be declared. Also the ingredients are not listed in the order required by regulation [21 C.F.R. § 101.36(b) and section 403 (q)(5)(F) of the Act].

This letter is not intended to be an all-inclusive list of deficiencies in your labeling. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

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You should review all of the labels of your products to assure that they comply with the Act and regulations.

You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizure and/or obtaining a court injunction against further marketing of your dietary products.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date that you receive this letter what steps you have or plan to take to correct the problems and your timeframe for correction. We also request that you provide documentation to FDA to show the corrections that have been made and that you explain how you intend to prevent these violations from happening again. If you need more time, then let us know why and when you expect to complete your corrections.

Your written response should be directed to the attention of Greta L. Budweg, Compliance Officer, Food and Drug Administration, 1560 E. Jefferson, Detroit, MI 48207.

Sincerely,

A handwritten signature in cursive script, appearing to read "Joann M. Givens".

Joann M. Givens
District Director
Detroit District