



MAR 18 2005

Ms. Bobbie Martin
Consultant
Nutronix International
7518 Mechanicsville Turnpike
Mechanicsville, Virginia 23111

Dear Ms. Martin:

This is in response to your letter of January 28, 2005 to the Food and Drug Administration (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 letter states that the following statement will be made for the product Bio Mins Multi-Vitamin/Minerals: “[H]elps maintain healthy blood sugar...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. The same principle applies to a claim about the control of blood sugar level; that is, a claim that does not establish that the claim is about blood sugar level that is already within normal limits implies that the product is intended to treat elevated blood sugar levels (diabetes), which is a disease. Therefore, because the claim you are making for this product represents that the product is intended to affect blood sugar levels but does not also include a statement about it being intended to affect blood sugar levels that are already in the normal ranges, 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 statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate a disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for

Page 2 - Ms. Bobbie Martin

use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is 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,

A handwritten signature in black ink, appearing to read 'SJW', written over a horizontal line.

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, Baltimore District Office, Office of Compliance, HFR-CE240

Bobbie Martin (Compliance Dept)
Nutronix International
7518 Mechanicsville Turnpike
Mechanicsville, VA 23111

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Nutronix International

January 28, 2005

Dr. Robert Moore, Branch Chief
Dietary Supplement Branch (HFS-811)
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling, Dietary Supplements
5100 Paint Branch Parkway
College Park, MD 20740-3835

FEB - 8 2005

Dear Dr. Moore:

Re: Label Claims/Structure Function Claims/Notification of Statements on Dietary Supplements

This letter is to notify you that Nutronix International located at 7518 Mechanicsville Turnpike, Mechanicsville, VA 23111 is a distributor and has included statements provided for by section 403 (r)(6) of the Food and Cosmetic Act on labels of the following product.

BioMins Multi-Vitamin/Minerals

Structure Function Claim: The benefit of 35 All natural vitamins, Minerals, Amino Acids, and Herbs to energize and balance your body.

| Supplement Facts: | Amount per Serving | % Daily Value |
|----------------------------|--------------------|---------------|
| Calcium Caronate/Ascorbate | 400 mg | 40 |
| Magnesium (Citrate) | 28 mg | 7 |
| Chromium Polynicotinate | 200 mcg | * |
| Iron (Ferrous Sulfate) | 20 mg | 115 |
| Manganese (Gluconate) | 1 mg | 45 |
| Selenium | 20 mcg | 28 |
| Vanadium | 40 mcg | * |
| Potassium | 20 mg | 2 |
| Zinc (Gluconate) | 2 mg | 12 |
| Vitamin A | 10,000 IU | 200 |
| Vitamin C | 420 mg | 420 |
| Vitamin E | 60 IU | 186 |

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|------------------------|---------|-----|
| Vitamin B-1 | 8 mg | 533 |
| Vitamin B-2 | 6 mg | 355 |
| Vitamin B-6 | 8 mg | 392 |
| Vitamin B-12 | 24 mcg | 400 |
| Niacinamide (B-3) | 20 mg | 100 |
| Pantothenic Acid (B-5) | 28 mg | 348 |
| Folic Acid | 400 mcg | 100 |
| Biotin | 400 mcg | 125 |
| Vitamin D-3 | 400 IU | 100 |

Photonutrients (20 mg of each of the following): Alfalfa leaf, Garlic, Cayenne, Rose Hips, Ginkgo Biloba, White Willow Bark, Horsetail and Panax Ginseng. Amino Acids (20 mg of each of the following): L-Lysine, L-Proline, L-Glutamine, L-Arginine, L-Histidine.

I certify that the information contained in this notice is complete and accurate.

If you have any questions and or concerns, please feel free to contact me at 702-367-1994

Enclosed are 3 labels

Sincerely,



Bobbie Martin
Consultant
Nutronix International

BIOMINS™ is a powerful antioxidant multi-vitamin and pytonutrient supplement to help support and protect good health. BIOMINS™ contains L-OptiZinc, a patented [H]21]-methylmethionine-bound zinc complex shown to be significantly more bioavailable and a far more potent antioxidant than other zinc supplements tested. Zinc is an essential trace element important to cell growth and development, maintaining healthy skin, hair and nails, and supporting the reproductive, digestive, respiratory, nerve, brain, vision, and immune functions of the body. BIOMINS™ contains ChromeMate, a patented [H]818 niacin-bound chromium complex shown to be significantly more bioavailable and biologically active than other chromium supplements tested, including chromium picolinate. Chromium is an essential trace element which promotes proper insulin function and helps maintain healthy blood sugar and blood lipid levels. RECOMMENDED: As a dietary supplement, take 2 capsules with morning and 2 capsules with afternoon meals. These statements have not been evaluated by the FDA. This product is not intended to prevent, treat or cure any disease.

For Bioactive Products Of
CHROME MATE™ **Nutronix** **L-OptiZinc**
INTERNATIONAL

Supplement Facts
Serving Size: 4 capsules

| Amount Per Serving | % Daily Value | Amount Per Serving | % Daily Value |
|---|---------------|---|---------------|
| Vit. A (Retinol) | 1000 IU | Calcium (from Acid Citrate) | 20 mg |
| Vit. C (Ascorbic Acid & Calcium Ascorbate) | 400 mg | Vanillin (from Acid Citrate) | 40 mg |
| Vit. D3 | 400 IU | Inositol (Choline) | 20 mg |
| Vit. E (d-Alpha Tocopherol Acetate) | 40 IU | Zinc (from Methylmethionine, L-OptiZinc®) | 2 mg |
| Vit. B1 (Thiamine Mononitrate) | 8 mg | Alfalfa | 20 mg |
| Vit. B2 (Riboflavin) | 6 mg | Garlic | 20 mg |
| Niacinamide (Vit. B3) | 20 mg | Cayenne | 20 mg |
| Vit. B6 (Pyridoxine HCl) | 8 mg | Rose Hips | 20 mg |
| Folic Acid | 400 mcg | Ginkgo Biloba leaves | 20 mg |
| Vit. B12 | 24 mcg | Green Tea | 20 mg |
| Biotin (Vit. H) | 400 mcg | Lysine HCl | 20 mg |
| Pantothenic Acid (Calcium Pantothenate) | 28 mg | Proline | 20 mg |
| Calcium (Calcium Ascorbate) | 400 mg | L-Glutamine | 20 mg |
| Arginine (L-Alanine) | 20 mg | L-Arginine | 20 mg |
| Chromium (Chromium Picolinate, ChromeMate®) | 200 mcg | Histidine | 20 mg |
| Glutamine (L-Glutamic Acid) | 20 mg | | |

**RDI not established.
Other Ingredients: Cellulose, Gelatin, Glycerin, Magnesium Stearate, Silicon Dioxide
L-OptiZinc® and ChromeMate® are trademarks of Interhealth N.I.
L-OptiZinc® (Patents 5,278,329 and 4,764,833)
ChromeMate® (Patents 4,823,855, 4,954,492 and 5,184,815)