



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

MAY 10 2005 10 14 5 MAY 13 P2:33

Mr. William J. Neumann
Vice President, Quality and Regulatory Affairs
Inverness Medical Nutritional Group
500 Halls Mill Road
Freehold, New Jersey 07728

Dear Mr. Neumann:

This is in response to your letters of April 27, 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)).

The product **Daily For Women** containing folic acid is using the claim "[M]ay reduce their risk of having a child with neural tube birth defects." This statement is not a statement of nutritional support subject to 21 U.S.C. 343(r)(6), but a health claim subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized a health claim on the relationship between folate and neural tube defects (see 21 CFR 101.79). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between the folate and the risk of neural tube defects. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in the regulation above would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, making a claim that is not in accordance with the requirements in the respective regulation subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease.

Please contact us if we may be of further assistance.

Sincerely yours,

for Robert J. Mervin

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

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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, New Jersey District Office, Office of Compliance, HFR-CE340

MAY - 3 2005

April 27, 2005

Dr. Robert Moore
Division of Compliance and Enforcement/ONPLDS
Center for Food and Safety and Applied Nutrition
U.S. Food and Drug Administration
HFS - 810

5100 Paint Branch Parkway
College Park, MD 20740

Dear Dr. Moore:

Inverness Medical Nutritionals Group has launched a new dietary supplement and wishes to notify the Food and Drug Administration, pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section 101.93.

The supplement, *Daily For Women* consists of the following active ingredients (per 1 tablet): Vitamin A (20% Beta-Carotene) 2,500 IU, Vitamin C 60 mg, Vitamin D 400 IU, Vitamin E (as dl-alpha tocopheryl acetate) 30 IU, Thiamin (as thiamin mononitrate) 1.5 mg, Riboflavin 1.7 mg, Niacin (as niacinamide) 10 mg, Vitamin B-6 (as pyridoxine hydrochloride) 2 mg, Folate (as folic acid) 400 mcg, Vitamin B-12 (as cyanocobalamin) 6 mcg, Pantothenic Acid 5 mg, Calcium (as calcium carbonate) 450 mg, Iron (as ferrous fumarate) 18 mg, Magnesium (as magnesium oxide) 50 mg, Zinc (as zinc oxide) 15 mg, and will bear the following structure/function statements on the label and folding carton.

Display Panel (Folding Carton and Bottle Label)

- Promotes Strong Healthy Bones
- Maintains a Healthy Reproductive System*

Complete Multivitamin/Multimineral supplement contains important vitamins and minerals designed for women to help maintain:*

- Bone Health with Calcium, Magnesium, Vitamin D, and Vitamin A
- Reproductive Health with Folic Acid, Vitamins B6, B12, Magnesium, Zinc, and Calcium
- Antioxidants such as Beta-Carotene, Vitamins C and E
- 100% Daily Value of Folic Acid with a healthy diet may reduce the risk of having a child with neural tube birth defects.

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Key Benefits for Women:*

- Bone Health – Calcium, Magnesium, Zinc, Vitamins A and D
- Healthy Skin, Hair and Nails – Vitamins C, B12, Iron and Zinc
- Healthy Reproductive System – Folic Acid, Vitamins B6, B12, Calcium, Magnesium, & Zinc
- Energy – Vitamins B6, B12, Thiamin, Riboflavin, Niacin, Pantothenic Acid, Folic Acid & Iron
- Enhances Immunity – Vitamins A, C, E, & Zinc

*** These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.**

We certify that the information contained in this notice is complete and accurate, and we have substantiation that the above structure/function statements are truthful and not misleading.

Sincerely,

A handwritten signature in black ink, appearing to read "W. Neumann", with a long horizontal flourish extending to the right.

William J. Neumann
Vice President
Quality and Regulatory Affairs