



JUL 28 1999

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Mr. Kevin Callaghan
Chief Operating Officer
The Daily Wellness Company
350 East Middlefield Road
Mountain View, California 94043

Dear Mr. Callaghan:

This is in response to your letter of April 25, 1999 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 submission states that The Daily Wellness Company is making the following claim for the product **ArginMax - Dietary supplement for female sexual fitness**:

“Calcium...has been shown to relieve PMS symptoms.”

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 disease, namely premenstrual syndrome. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for 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, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if you require further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

975-0163

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, San Francisco District Office, Office of Compliance, HFR-PA140

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-456 (file)
HFS-450 (r/f, file)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-605 (Bowers)
HFV-228 (Benz)
GCF-1 (Dorsey, Barnett)
f/t:HFS-456:rjm:7/27/99:docname:64928.adv:disc39

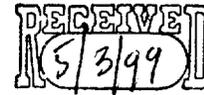


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The Daily Wellness Company

April 25, 1999

Office of Special Nutritionals
HFS 450
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street SW
Washington, DC 20204



As per section 6 of the Dietary Supplement Health and Education Act of 1994, I respectfully submit the following information:

The Daily Wellness Company
350 East Middlefield Road
Mountain View, CA 94043

Product and claims to be filed:

ArginMax – dietary supplement for female sexual fitness

A premium formula of L-Arginine, Ginseng, Ginkgo, Damiana, vitamins, calcium & other minerals for the improved enjoyment of sex.

L-ARGININE is an amino acid that plays a key role in the body's sexual responsiveness.

GINSENG, used for thousands of years, promotes energy, stamina, and endurance.

GINKGO supports blood circulation and mental focus, which is essential for sexual enjoyment, and is known as the "elixir" of youth.

DAMIANA is an aromatic herb which helps calm anxiety and induce a relaxed state of mind.

VITAMINS, antioxidants A, C and E and the B-vitamins, contribute to general good health and an improved complexion.

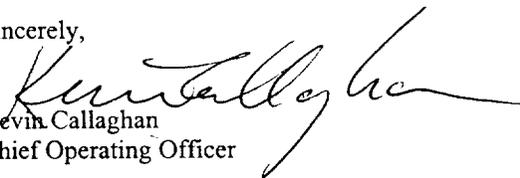
CALCIUM is essential for strong bones, muscle contractions, and nerve transmissions, and has been shown to relieve PMS symptoms.

IRON supports energy metabolism and helps to combat fatigue in women.

ZINC is important for cell growth and the maintenance of healthy, glowing skin.

I hereby certify that the information contained in the above notice is complete and accurate, and that The Daily Wellness Company has substantiation that these statements are truthful and not misleading.

Sincerely,


Kevin Callaghan
Chief Operating Officer