



1535 6 FEB 18 P2:43

DEC 13 2006

Mr. Thomas Miano
Vice President
World Nutrition, Inc.
7001 N. Scottsdale Road, Suite 2000
Scottsdale, Arizona 85253

Dear Mr. Miano:

This is in response to your December 11, 2006 letter 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 submission does not meet the requirements for that submission under 21 CFR 101.93(a).

21 CFR 101.93(a)(3)¹ requires that the notice submitted pursuant to 21 U.S.C. 343(r)(6) of 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 signature of the responsible individual as required by the regulation; 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(r)(6) and must submit a notification 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 product that is the subject of the notification to regulation under the drug provisions of the Act.

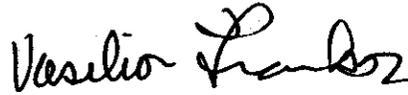
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¹You can access the Code of Federal Regulations at
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm>.

Page 2 - Mr. Thomas Miano

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink that reads "Vasilios Frankos". The signature is written in a cursive style with a large, prominent initial "V".

Vasilios H. Frankos, Ph.D.
Acting Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

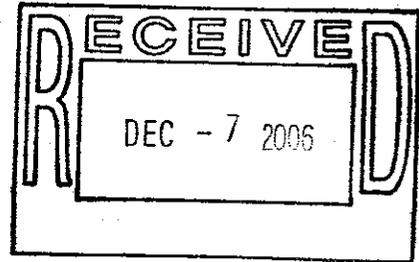
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Los Angeles District Office, Office of Compliance, HFR-PA240



World Nutrition
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Dr Taylor,

The following is a structure function claim. If you would send this structure function claim to the appropriate personnel, as per our phone conversation I would greatly appreciate it. Let me know if this is all that is needed. Also Thank You for the direction regarding Food Registration, worked out perfect. As always it is a pleasure working with you.

Best Regards,

Thomas Miano

World Nutrition

Vice President

800-548-2710 EXT 171

2006-9035

#1819



AMERICAN INSTITUTE OF EASTERN MEDICINE
INCORPORATED

November 28, 2006

Kenneth Taylor, PHD Chemist
Food and Drug Administration
Division Of Dietary Supplement Programs,
5100 Paint Branch Parkway, College Park, Maryland 20740-3835

Dear Sir or Madam:

World Nutrition hereby notifies the Food and Drug Administration (FDA) that it will be using the following statements on the labeling of **Wang's Juemingjing Extract**.

<u>Product Name</u>	<u>Dietary Ingredients</u>	<u>Structure/Function Claim</u>
Wang's Juemingjing Herb Extract	Flatstem Milkvetch Seed Chinese Wild yam Safflower, Milkvetch root Cape jasmine fruit, Kudzu vine Root, Licorice Root, Korean ginseng	Wang's Juemingjing extract is a unique blend of herbs formulated to help to maintain normalized blood sugar levels and keep a healthy circulatory system.

Sincerely,

Tom Miano
VP Sales and Marketing
World Nutrition, Inc.