



FEB - 4 2005

Mr. David Harrington
Chief Operating Officer
World Nutrition, Inc.
7001 N. Scottsdale Road
Suite 2000
Scottsdale, Arizona 85253

Dear Mr. Harrington:

This is in response to your letter dated January 12, 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 submission states that World Nutrition, Inc. is making the following claims, among others, for the following products:

Wang's Ketusmeishi Diabetic Tea:

"Helps diminish the complications associated with diabetes...."

Wang's Hakusotsu Allergy Blend

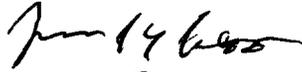
"Helps diminish the complications associated with diabetes...."

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 statements that you are making for these products, as well as the names of the products (i.e., Diabetic Tea and Allergy Blend) which incorporate the name of a disease, suggest that they are intended to treat, prevent, or mitigate diseases, namely allergies and diabetes. The claims you are making for these products do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are 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 20852.

Page 2 - Mr. David Harrington

Please contact us if we may be of further assistance.

Sincerely yours,



Susan J. Walker
FOR

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-300

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
INCORPORATED

Rec'd

January 12, 2005

JAN 27 2005

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

Dear Sir or Madam:

World Nutrition hereby notifies the Food and Drug Administration (FDA) that it is using the following statements on the labeling of Wang's Ketusmeishi Diabetic Tea.

Product Name	Dietary Ingredients	Structure/Function Claim
Wang's Ketusmeishi Diabetic Tea	Flat stem Milkvetch Seed, Chinese Wild Yam, Safflower, Milkvetch Root, Gardenia Fruit, Kudzuvine Root, Liquorice Root, Korean Ginseng	Helps diminish the complications associated with diabetes and may improve the functions of the circulatory system.

Sincerely,

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David Harrington
Chief Operating Officer
World Nutrition, Inc.



World Nutrition
INCORPORATED

rec'd
JAN 24 2005

January 12, 2005

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

Dear Sir or Madam:

World Nutrition hereby notifies the Food and Drug Administration (FDA) that it is using the following statements on the labeling of Wang's Hakusotsu Allergy Blend.

Product Name	Dietary Ingredients	Structure/Function Claim
Wang's Hakusotsu Allergy Blend	Flat stem Milkvetch Seed, Chinese Wild Yam, Safflower, Milkvetch Root, Gardenia Fruit, Kudzuvine Root, Licorice Root, Korean Ginseng	Helps diminish the complications associated with diabetes and may improve the functions of the circulatory system.

Sincerely,

David Harrington
Chief Operating Officer
World Nutrition, Inc.

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