



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

1010 5 MAY 13 P2:32

MAR 28 2005

Mr. Ben Lewis
Marketing Manager
World Nutrition, Inc.
7001 N. Scottsdale Road
Suite 2000
Scottsdale, Arizona 85253

Dear Mr. Lewis:

This is in response to your letter dated March 1, 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 product **Wang's Hakusotsu Blend**:

“[M]ay help the immune system's sensitivity to pollens.”

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 diseases, namely allergies. The claim you are making for this product 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, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

97S 0153 LET 823

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Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to be 'S. Walker', written in a cursive style.

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

CTS 91198
DDSP

MAR 24 2005



World Nutrition
INCORPORATED

March 1, 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 will be using the following statements on the labeling of **Wang's Hakusotsu Blend**.

Product Name	Dietary Ingredients	Structure/Function Claim
Wang's Hakusotsu Blend	Chrysanthemum extract, Chameleon plant, Perilla, Chinese yam, Sansho, Licorice root, Lily bulb, Cordyceps	Wang's Hakusotsu Blend contains a unique formulation that may help the immune system's sensitivity to pollens.

Sincerely,

Ben Lewis
Marketing Manager
World Nutrition, Inc.

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