



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

OCT 23 1997

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

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Dear Mr. Callaghan:

This is in response to your letter of September 25, 1997 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that The Daily Wellness Company, Inc. is making a claim that the product "ELIX COLD/FLU" is "to help soothe cold and flu."

Section 403(r)(6) of the act 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 this product and the inclusion of the term "COLD/FLU" in the product name suggest that it is intended to treat, mitigate, or prevent a disease, namely the common cold and flu. This claim does not meet the requirements of section 403(r)(6) of the act. This claim suggests that this product is intended for use as a drug within the meaning of section 201(g)(1)(B) of the act, 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 we may be of further assistance.

Sincerely yours,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
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, San Francisco District, Compliance Office, HFR-PA140

975-0163

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The Daily Wellness Company

OCT 21 1997

September 25, 1997

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:

ELIX COLD/FLU

Echinacea/Zinc

Powerful combination of Echinacea plus Zinc (200% daily value) and Vitamin C (350% daily value) to help soothe cold and flu.

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

Sincerely,

Kevin Callaghan
Chief Operating Officer

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