



OCT 10 1997

Mr. Gordon M. Walker
Regulatory Counsel
Nature's Way Products, Inc.
10 Mountain Springs parkway
Springville, Utah 84663

0784 '97 DEC 16 P1:39

Dear Mr. Walker:

This is in response to your letter of September 30, 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 Nature's Way Products, Inc. is making the following claim, among others, for a product containing milk thistle:

"...exert a protective effect against alcohol and other substances that may be potentially harmful to the liver"

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 statement that you are making for this product suggests that it is intended to treat, prevent, mitigate a disease, namely, the consequences of excessive alcohol consumption. 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 a claim 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

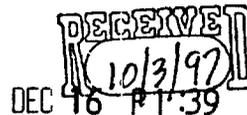
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LET 77



September 30, 1997

0785 '97



Linda S. Kahl, Ph.D.
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" St. S.W. (HFS-450)
Washington, D.C. 20204

Dear Dr. Kahl:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994, Nature's Way Products, Inc. wishes to notify the Food and Drug Administration that it has within the past 30 days, commenced marketing a dietary supplement which bears a statement of nutritional support.

The dietary supplement for which the statement is made is Milk Thistle. The dietary ingredient that is the subject of the statement is Milk Thistle. The statement of nutritional support reads as follows:

"Promotes normal liver function. Nature's Way Milk Thistle (*Silybum marianum*) extract supports normal liver function. The active bioflavonoid complex, silymarin, and its sub-component silibinin, are powerful antioxidants in the liver and exert a protective effect against alcohol and other substances that may be potentially harmful to the liver."

This statement is accompanied by the required disclaimer which is prominently displayed in bold-faced type.

This statement of nutritional support is based on data which renders these statements substantiated, truthful and non-misleading.

Sincerely,

NATURE'S WAY PRODUCTS, INC.

Gordon M. Walker
Regulatory Counsel

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