DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

JUL 31 2001

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

Dear Mr. Walker:

This is in response to your letter of July 5, 2001 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 Nature's Way Products, Inc. is making the following claim for the product **ProstoL™ Dual Action Prostate Formula**:

> "ProstoL™ dual Action Prostate formula...inhibit 5-alpha-reductase and aromatase activity. Increases urine flow. Decreases residual urine in the bladder. Reduces frequency of urination. Reduces post-urination dribbling."

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 this product suggest that it is intended to treat, prevent, cure, or mitigate diseases, namely, benign prostatic hypertrophy. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest 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, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

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Please contact us if we may be of further assistance.

Sincerely,

John B. Foret
Director
Division of Compliance and Enforcement
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, Denver District Office, Office of Compliance, HFR-SW240

Nature's Way®
Trust The Leaf™

July 5, 2001

Office of Nutritional Products Labeling and Dietary Supplements
Division of Compliance and Enforcement
Dietary Supplements Branch (HFS-810)
Food and Drug Administration
200 "C" St. S.W.
Washington, D.C. 20204

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To Whom It May Concern:

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 under Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act.

The dietary supplement for which the statement is made is Prostol™. The dietary ingredients that are the subject of the statement are Sabal Extract (saw palmetto) and Urtica Extract (nettle). The statement reads as follows:

> "ProstoL™ Dual Action Prostate Formula combines the synergistic benefits of SaBal (saw palmetto) and Urtica (nettle) in a preparation proven to inhibit 5-alpha-reductase and aromatase activity. Increases urine flow. Decreases residual urine in the bladder. Reduces frequency of urination. Reduces post-urination dribbling. "

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

The information contained in this notice is complete and accurate and the above statement is based on data which renders these statements substantiated, truthful and non-misleading.

Sincerely,

NATURE'S WAY PRODUCTS, INC.

Gordon M. Walker
General Counsel

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Regulatory\STRUCTURE-FUNCTION/NW-NoticesSent/Prostol

10 Mountain Springs Parkway • Springville, Utah 84663 • Phone 801/489-1500 • Fax: 801/489-1700