



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

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NOV 13 2002

Mr. Karl Riedel  
M. K. Health Food Distributors  
Nature's Life  
7180 Lampson Avenue  
Garden Grove, California 92841

Dear Mr. Riedel:

This is in response to your letter of October 9, 2002 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)). In your letter, you stated that intend to use the following claim for your dietary supplement **Full Spectrum Lycopene, 30 mg**:

“Maintains Healthy prostate and mammary cells...helps inhibit abnormal cell growth.”

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 that are characterized by abnormal cell growth in the prostate and mammary cells. This claim 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, 7520 Standish Place, Rockville, Maryland 20855.

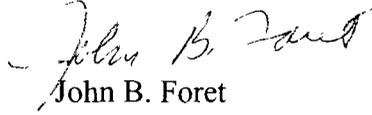
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Please contact us if you require further assistance.

Sincerely yours,

A handwritten signature in cursive script that reads "John B. Foret".

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, Los Angeles District Compliance, HFR-PA240



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Dr. Christine Taylor, Ph.D., Director  
Office of Nutritional Products Labeling and Dietary Supplements  
United States Food and Drug Administration  
200 C Street SW, Washington, DC 20204

NOV 01 2002

October 9, 2002

**Notice of a 403(r)(6) Statement -  
Multiple Statements and Multiple Ingredients**

Dr. Taylor,

This letter serves notice that M.K. Health Food Distributors, Inc., dba Nature's Life, located at 7180 Lampson Avenue, Garden Grove, California, 92841, U.S.A. is marketing a dietary supplement whose label bears 403(r)(6) statements as follows:

Protects Cells from Oxidative Damage  
Maintains Healthy prostate and mammary cells with powerful antioxidant capability and helps inhibit abnormal cell growth

Vitamin A, Vitamin E, Lycopene, Phospholipids, Phytosterol, d-Delta Tocopherol, d-Gamma Tocopherol, Phytoene, Phytofluene, Lutein, Alpha Carotene, Cryptoxanthin, Zeaxanthin, Gamma Caroten, and D-Gamma Tocotrienols are the dietary ingredients that are the subject of these statements and *Full Spectrum Lycopene 30mg* is the name of the dietary supplement that is the subject of these statements.

Regards & Health,

Karl Riedel  
Encl: Two Copies of this Notice  
Ref: B-792  
cc: M.K., S.S.

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