



MAR 19 2003 1389 '03 MAR 24 P1:52

Mr. Karl Riedel  
M.K. Health Food Distributor's  
(dba as Nature's Life)  
7180 Lampson Avenue  
Garden Grove, California 92841-3914

Dear Mr. Riedel:

This is in response to your letter of January 6, 2003 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 M.K. Health Food Distributor's, dba as Nature's Life, is making the following claims for the product **Policosanol 23mg**.

This product uses the claims "Supports Cholesterol Health" and "Supports healthy levels of LDL (low density lipoprotein)...cholesterol." In the preamble to the January 6, 2000 final rule on structure/function claims for dietary supplements (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The cholesterol claims for your product contains no such clarification, however. Therefore, FDA considers them to be implied claims to prevent coronary heart disease by preventing the development of elevated cholesterol levels or reducing elevated cholesterol.

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, or mitigate a disease. 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

LET 679

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Please contact us if we may be of further assistance.

Sincerely,

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

Susan J. Walker, M.D.  
Acting 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-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200

FDA, Los Angeles District Office, Office of 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

January 6, 2003

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:

Supports Cholesterol Health

Supports healthy levels of LDL (low density lipoprotein) and HDL (high density lipoprotein) cholesterol.

Policosanol has also been shown to reduce free radical damage to cholesterol caused by oxidation.

Policosanol from sugar cane (*Saccharum officinarum* L) is the dietary ingredient that is the subject of these statements and *Policosanol 23 mg* 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.

**Quality You Can Trust**

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