



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

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AUG 20 2001

Mr. Karl Riedel
M.K. Health Food Distributors, Inc.
Nature's Life
7180 Lampson Avenue
Garden Grove, California 92841-3914

Dear Mr. Riedel:

This is in response to your letter to the Food and Drug Administration (FDA), dated May 30, 2001, 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 Distributors, Inc., dba Nature's Life, is making the following claims, among others, for the product **Enteric Coated Garlic Gels™**:

“...maintaining normal cholesterol...levels and inhibiting platelet aggregation.”

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 diseases. 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.

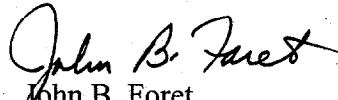
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Please contact us if we may be of further assistance.

Sincerely,



John B. Foret

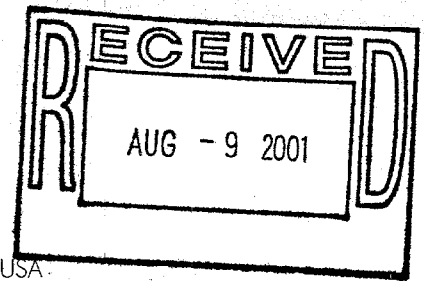
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

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, Los Angeles District Office, Compliance Branch, HFR-PA240



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

May 30, 2001

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

Dr. Lewis,

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 Cardiovascular Health.

Garlic supports healthy cardiovascular function by maintaining normal cholesterol and triglyceride levels and Inhibiting platelet aggregation.

The pyhtonutrients found in Garlic, particularly Allicin and Allin, are believed to be responsible for its Cardio-supportive properties.

Garlic Clove Extract is the dietary ingredient that is subject of these statements and Enteric Coated Garlic Gels™ is the name of the dietary supplement that is the subject of these statements.

Regards & Health,

Karl Riedel

encl: Two Copies of this Notice

cc: M.K., C.M., K.C.

Quality You Can Trust

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