



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 10 2000

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Food and Drug Administration  
Washington, DC 20204

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

Dear Mr. Riedel:

This is in response to your letters of August 18, 2000 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 submissions state that M. K. Health Food Distributors, Inc., dba Nature's Life Company is making the following claims, among others, for the following products below:

**MSM Tri-Sulfate Joint Ease™**

"Reduces Pain & Maintain Cartilage;"  
"known to help relieve joint pain;"  
"..relieve joint pain..."

**Cardio Tonic™ Heart Support**

"...maintain healthy cholesterol levels."

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 these products suggest that they are intended to treat, prevent, or mitigate diseases, namely joint disorders and hypercholesterolemia. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are 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

LET402

Page 2 - Mr. Karl Riedel

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, Office of Compliance, HFR-PA250

Page 3 - Mr. Karl Riedel

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (r/f, file)

HFS-450 (r/f, file)

HFD-310

HFD-314 (Aronson)

HFS-605 (Bowers)

HFV-228 (Benz)

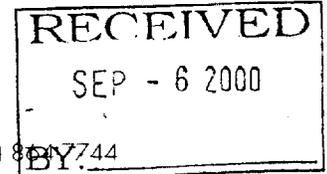
GCF-1 (Nickerson, Barnett, Dorsey)

f/t:HFS-811:afp:9/27/00:72277:discl

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7180 Lampson Avenue, Garden Grove, CA 92841-3914 USA  
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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

August 18, 2000

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

Helps to Maintain Cardiovascular Health.

Vitamins C & E and Selenium are proven free-radical scavengers.

The combination of B-6, B-12 and Folic Acid helps maintain healthy homocysteine levels, having a direct effect on cardiovascular health.

Magnesium is necessary for proper heart muscle function.

Standardized Garlic clove with *allicin* is known to support circulation and maintain healthy cholesterol levels.

Vitamin C, vitamin E, selenium, vitamin B-6, vitamin B-12, folic acid, magnesium, and standardized garlic clove extract providing 1% *allicin* are the dietary ingredients that are the subject of these statements and Cardio Tonic™ Heart Support is the name of the dietary supplement that is the subject of these statements.

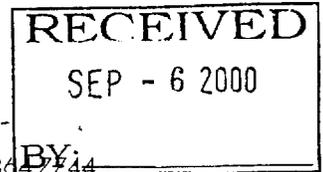
Regards & Health,

Karl Riedel

encl: Two Copies of this Notice

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

**Quality You Can Trust**



7180 Lampson Avenue, Garden Grove, CA 92841-3914 USA  
(714) 379-6500 • (800) 854-6837 • Fax (714) 379-6501 • Fax (800) 844-7744  
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Dr. Christine Lewis, Ph.D., Director  
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Reduces Pain & Maintains Cartilage.

Methylsulfonyl Methane (MSM) is a source of dietary sulfur, known to help relieve joint pain and contribute to the formation of connective tissue, including joint cartilage.

Chondroitin and Glucosamine Sulfates are well-researched to not only relieve joint pain, but also help to maintain cartilage and slow the natural cycle of enzyme destruction.

Vitamin C acts as an antioxidant, and is critical to the production of collagen and cartilage.

Methylsulfonyl Methane (MSM), chondroitin sulfate, glucosamine sulfate and vitamin C are the dietary ingredients that are the subject of these statements and MSM Tri-Sulfate Joint Ease™ 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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