



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

5172 '02 MAY 29 P2:38

MAY 24 2002

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 letters of May 1, 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)). Your submission states that M.K. Health Food Distributor's, dba as Nature's Life, is making the following claims for the following products.

The product **Yucca 500 mg** uses the claims "...helps to maintain normal cholesterol and blood pressure levels." 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 claim for your product contains no such clarification, however. Therefore, FDA considers it to be an implied claim to prevent coronary heart disease by preventing the development of elevated cholesterol levels or reducing elevated cholesterol. The same principle applies to your claim about support and maintenance of blood pressure level; that is, a claim that does not make clear that the product is only for people with blood pressure that is already within normal limits implies that the product is intended to treat hypertension, which is a disease.

The product **Yucca 500 mg** also uses the claim "...help to reduce joint discomfort..." This claim is a disease claim because it suggests that the product is intended to treat, prevent, or mitigate diseases, namely joint disorders such as arthritis. Although the claim does not expressly state that the product is intended for joint pain, the use of the term "reduce joint discomfort" infers that the product is intended for joint pain. In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at

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1016-17), FDA stated that "joint pain" is characteristic of arthritis and that it is the most sensitive physical sign of rheumatoid arthritis. For that reason, the agency concluded that claims about relieving joint pain are implied disease claims because they represent that the product will have an affect on a characteristic sign or symptom of a disease (see 21 CFR 101.93(g)(2)(ii)). Moreover, elsewhere in the preamble to the final rule (see 65 FR 1000 at 1030) FDA discussed the circumstances under which claims about pain would imply disease treatment. We stated that since pain is not a normal state, nor are there "normal pain levels," a claim about pain treatment or prevention is ordinarily a disease claim. We addressed the issue of joint pain claims in particular, noting that such claims are disease claims because joint pain is a characteristic symptom of arthritis. We added, however, that a acceptable structure/function claim could be made for pain associated with non-disease states, such as muscle pain following exercise.

You also submitted a notification that the following claim, among others, is being made for various herbs, including standardized milk thistle and artichoke leaf: "...help prevent fatty deposits in the liver."

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 suggests that they are 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 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.

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

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

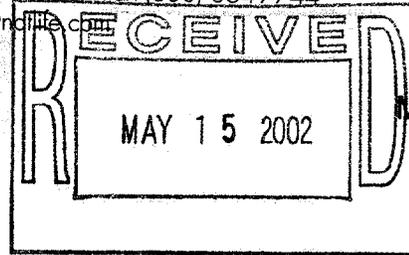
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

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



**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:

Maintains Healthy Joints*
Herbal Supplement

Saponins found in Yucca help to reduce joint discomfort, as well as helps to maintain normal cholesterol and blood pressure levels.*

Yucca schidigera is the dietary ingredient that is the subject of these statements and Yucca 500 mg is the name of the supplement that is the subject of these statements.

Sincerely,

Karl Riedel
encl: Two Copies of this Notice
ref: B-544
cc: M.K., K.R., S.S.

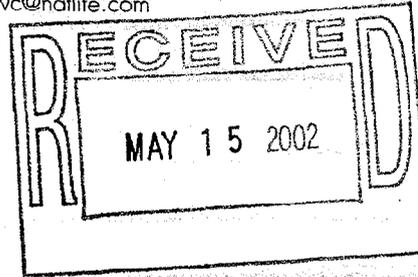
Quality You Can Trust

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May 1, 2002

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**Support Healthy Liver Function*
High Potency Dietary Supplement**

Vitamins, minerals, and amino acids are critical for proper liver function.* Hepato-protective herbs such as Standardized Milk Thistle and Artichoke Leaf help liver detoxification by stimulating liver function and protecting liver cells.* Many of these herbs also possess strong antioxidant and lipid-regulating properties that help prevent fatty deposits in the liver.*

Vitamin A (as Betatene™ mixed Carotenoids), Vitamin C (as Ascorbic Acid), Vitamin E (as d-Alpha Tocopheryl Succinate), Thiamine (Vitamin B-1 as Thiamine HCl), Riboflavin (Vitamin B-2), Niacin, Vitamin B-6 (as Pyridoxine HCl), Vitamin B-12 (as Cyanocobalamin), Folic Acid, Pantothenic Acid (as Calcium Pantothenate) Magnesium (as Magnesium Oxide/Citrate), Zinc (as Zinc Citrate/Picolinate), Selenium (high selenium yeast) Copper (as Copper Citrate), Molybdenum (as Sodium Molybdate), Betaine (as Anhydrous Betaine), NAC (N-Acetyl L-Cysteine), Milk Thistle Seed Extract (*Silybum marianum*), Silymarin, Choline Bitartrate, Methionine, Inositol, Hepato-Protective Herbal Blend, Artichoke Leaf Powder (*Cynara scolymus*), Green Cabbage Leaf Powder (*Brassica oleracea italica*), Lemon Peel Powder (*Citrus limon*), Dandelion Root Powder (*Taraxacum officinale*) are the subject of these statements and Liver Vitality is the name of the dietary supplement that is the subject of these statements.

Sincerely,

Karl Riedel
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cc: M.K., K.R., S.S.

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