



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

DEC - 6 2000 0206 '00 DEC - 7 P3:08

Mr. 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 letter to the Food and Drug Administration (FDA) dated November 9, 2000. Thank you for responding to our letter dated October 10, 2000. In your letter, you stated that M.K. Health Food Distributors, Inc. intended to revise the claim for its Cardio-Tonic Heart Support Formula product in response to our letter dated October 10, 2000 in which we expressed FDA's view that the claim "...maintain healthy cholesterol levels" suggests that your product is intended to treat, prevent, cure, or mitigate disease. You stated that you intend to revise the claim to state that the product is to "...maintain normal cholesterol levels" and that you believed that this claim would be compliant with the requirements of section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act).

In the preamble to the January 6, 2000 final rule on claims for dietary supplements, FDA concluded that not all claims related to cholesterol are disease claims under the the Act. In the preamble to the final rule, FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims (see 65 FR 1000 at 1018). 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 making a cholesterol maintenance claim into an implied claim, a cholesterol maintenance claim would have to explicitly disclaim the implied ability of the product to prevent the development of elevated cholesterol levels or to reduce an elevated cholesterol. Therefore, an appropriate structure/function claim about maintaining cholesterol should explicitly state that the cholesterol levels that are the subject of the claim are "already within the normal range." The claim that you propose to use (i.e., "...maintain normal cholesterol levels") does not explicitly limit the claim to cholesterol levels "already within the normal range." Therefore, we believe that the proposed new claim is a disease claim that subjects your product to regulation under the drug provisions of the Act.

995-0163

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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

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-800 (file, r/f)
HFS-811 (r/f, file)
HFD-40 (Behrman)
HFD-310
HFD-314 (Aronson)
HFS-605
HFV-228 (Betz)
GCF-1 (Nickerson, Dorsey)
f/t:rjm:HFS-811:11/28/00:docname:riedel.adv:disc52



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11/9/2000

John B. Foret, Director
Division of Compliance and Enforcement
Food and Drug Administration
Washington, DC 20204

RE: 403(r)(6) Courtesy Letter

Dear Mr. Foret,

Thank you for your courtesy letter of Oct. 10, 2000 with your response to our 403(r)(6) submission of August 18, 2000 regarding our new products and their label statements. We agree with your assessment and have made what we hope to be the appropriate changes.

For our Tri-Sulfate Joint Ease Formula, the banner statement will change, and will now read "*Eases movement and maintains cartilage*" On the side panel, we will revise the text to read as follows: "*Known to help ease joint movement*". All uses of the word "pain" have been eliminated from the product label. We believe that these changes will make this label compliant with the provision of section 403(r)(6) of the Act.

For our Cardio-Tonic Heart Support Formula, we will change the text on the side panel to read as follows: "...maintain normal cholesterol levels." We believe that this change will make this label compliant with the provision of section 403(r)(6) of the Act.

We anticipate that you will find this response satisfactory. Included in our company's Code of Ethics is the pledge to "...fully comply with both the spirit and the letter of the law", and we deem this response, and our pursuant actions, to be fully compliant with all applicable laws and regulations. Please contact me directly with any further comments and questions, and again, thank you for your reply to our original submissions.

Regards & Health,

Karl Riedel

cc Office of Compliance, #HFD-300, Center for Drug Evaluation and Research, Food and Drug Administration
Office of Compliance, #HFD-310, Center for Drug Evaluation and Research, Food and Drug Administration
Office of Enforcement, #HFC-200, Office of the Associate Commissioner for Regulatory Affairs, USFDA
Office of Compliance, #HFR-PA240, Los Angeles District Office, Food and Drug Administration

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