

MAY -2 2000
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Mr. Karl Riedel
Nature's Life
7180 Lampson Avenue
Garden Grove, California 92841-3914

Dear Mr. Riedel:

This is in response to your letter of April 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 submission states that Nature's Life is making the following statement, among others, for the product "Sugarless C-Chews™."

"Xylitol helps protect teeth from damaging bacteria"

This statement is not a statement of nutritional support subject to 21 U.S.C. 343(r)(6), but is a health claim subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized a health claim on the relationship between dietary sugar alcohols and dental caries (see 21 CFR 101.80). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between dietary sugar alcohols and dental caries. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.81 would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, failure to make a claim in accordance with the requirements in 21 CFR 101.80 subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, dental caries.

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

975-0163

LET 362

Page 2 - Mr. Karl Riedel

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

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (file, r/f)

HFS-810 (r/f)

HFS-811 (file)

HFD-40 (Behrman)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-605

GCF-1 (Nickerson, Dorsey, Barnett)

HFV-228 (Benz)

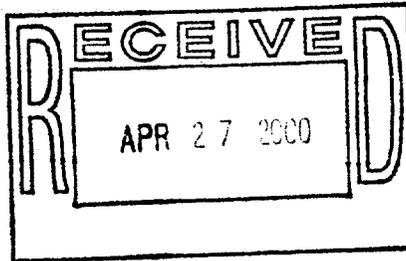
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Dr. Christine Lewis, Ph.D., Director
Office of Nutritional Products Labeling and Dietary Supplements
United States Food and Drug Administration
200 C Street SW, Washington, DC 20204

April 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, USA is marketing a dietary supplement whose label bears 403(r)(6) statements as follows:

Helps Promote Healthy Teeth*

Vitamin C is required for healthy bones and skin and helps protect against harmful cellular changes caused by free radicals.*

Xylitol helps protect teeth from damaging bacteria.*

Vitamin C and Xylitol are the dietary ingredients that are the subject of these statements and Sugarless C-Chews™ 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: MK, CM, KC

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Quality You Can Trust