



JAN 24 2000 7 9 8 3 '00 FEB -8 P1 :59

Thomas D. Rosenberg, M.D.
Medical Consultant
Nutriex
P.O. Box 57820
Salt Lake City, Utah 84157

Dear Dr. Rosenberg:

This is in response to your letter of January 11, 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 Nutriex is making the following statement for the product "Nutriex Glucosamine and Chondroitin:

"For Arthritis.

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 statement that you are making for this product suggests that it is intended to prevent, treat, cure, or mitigate disease, namely arthritis. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests 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.

Please contact us if we may be of further assistance.

Sincerely,

John B. Foret, Jr.
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

975-0163

LET 331

Page 2 - Dr. Thomas D. Rosenberg

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, Denver District Office, Office of Compliance, HFR-SW240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (file, r/f)

HFS-450 (file, r/f)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-605

HFV-228 (Benz)

GCF-1 (Dorsey, Barnett)

f/t:HFS-456:rjm:1/21/00:docname:68832.adv:disc44



Jeff Allred
Technical Consultant

Bonnie Beardsley, MPH, LDN, RD
Nutritional Consultant

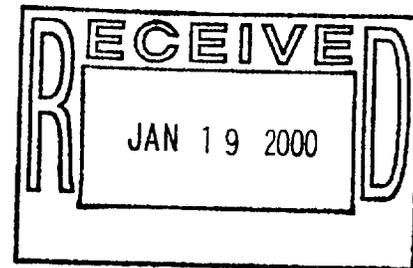
Kathleen Deffner, M.S.
Bioengineer

Cary Nichols
Operational Consultant

Thomas Rosenberg, M.D.
Medical Consultant

January 11, 2000

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C. St. SW.
Washington, D.C. 20204



Dear Sir or Madam:

This letter is intended to notify you that we are using a structure/function claim on the label of our product. The following information is provided for you in compliance with 21 CFR 101.93:

- 1) Distributor name and address:

Nutriex, L.C.
P.O. Box 57820
Salt Lake City, UT 84157

- 2) Text of statement being made:

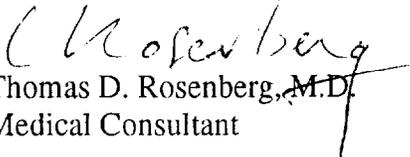
For Arthritis

- 3) Name of the supplement that is the subject of the statement:

Nutriex Glucosamine and Chondroitin

Please do not hesitate to contact me if you have any questions about this notification.

Sincerely,


Thomas D. Rosenberg, M.D.
Medical Consultant

68832