



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

0196 '00 DEC -7 P3:07
NOV 17 2000

Mr. Morag Thorsen
Regulatory Affairs Manager
Country Life
180 Vanderbilt Motor Parkway
Hauppauge, New York 11788

Dear Dr. Thorsen:

This is in response to your letter of October 13, 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 Country Life is making the following claim, among others, for the product Arthro-Joint and Muscle Relief Factors Softgels:

“Athro-Pain [sic] Relief Factors is a synergistic complex which provides the building blocks used in the production of bone, cartilage, tendons, joints and membranes.”

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 treat, prevent, cure, or mitigate disease, namely, the pain associated with joint or muscle disorders. 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.

Q7S-0163

LET422

Page 2 - Mr. Morag Thorsen

Please contact us if we may be of further assistance.

Sincerely,

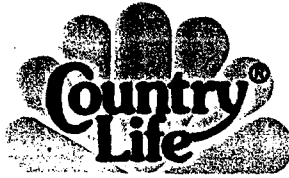
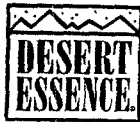
John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

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, New York District Office, Office of Compliance, HFR-NE140

cc:

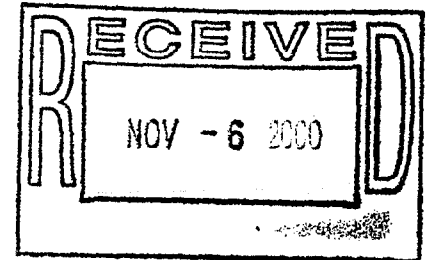
HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-800 (r/f, file)
HFS-811 (file)
HFD-40 (Behrman)
HFD-310
HFD-314 (Aronson)
HFS-605
HFV-228 (Benz)
GCF-1 (Dorsey, Nickerson)
f/t:HFS-811:rjm:11/9/00:docname:73243.adv:disc52



Partners in Health and Beauty

73243

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



October 13, 2000

This letter serves as a 30 day notification pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 (DSHEA), that Country Life® is using the following statement on the label of product Arthro-Joint and Muscle Relief Factors Softgels (dietary ingredients: vitamin C, vitamin E, manganese, boswellia serrata extract, omega-3 fish oil concentrate, glucosamine HCL, glucosamine sulfate, chondroitin sulfate, poly NAG, green-lipped mussel extract, CMO, gamma-linolenic acid & boron. This statement is accompanied by the required disclaimer. To the best of my knowledge, the information contained in this notice is complete and accurate.

Athro-Pain Relief Factors is a synergistic complex which provides the building blocks used in the production of bone, cartilage, tendons, joints and membranes. Herbal extracts and nutrients are included which help reduce free radical production.

Sincerely,

Morag Thorsen
Regulatory Affairs Manager B.A., M.A.L.S.