



FEB 22 2001 9618 01 MAR 16 A7:16

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

Dear Mr. Thorsen:

This is in response to your letter of January 2, 2001 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 for the product **Charcoal Caps**:

“...aid intestinal discomfort.

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, or mitigate a disease, namely intestinal 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.

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

97S 0163

LET 446

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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, 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-810 (file)

HFS-811

HFD-40 (Behrman)

HFD-310

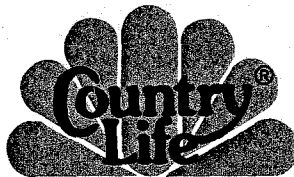
HFD-314 (Aronson)

HFS-607

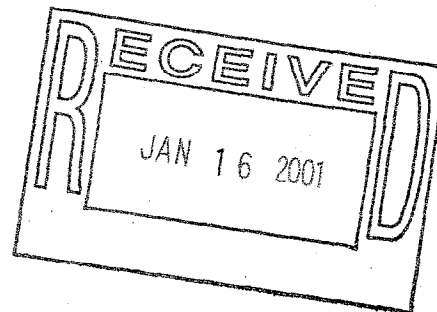
HFV-228 (Benz)

GCF-1 (Nickerson)

f/t:HFS-811:rjm:1/30/01:docname:74087.adv:disc54



Partners in Health and Beauty



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

January 2, 2001

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 Charcoal Caps (dietary ingredient: activated charcoal). This statement is accompanied by the required disclaimer. To the best of my knowledge, the information contained in this notice is complete and accurate.

May be used to aid intestinal discomfort.

Sincerely,

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

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