



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

JUL 17 2000

Rec'd 8/11/00
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Mr. Mark Gaeta
Chief Operating Officer
Country Life
180 Vanderbilt Motor Parkway
Hauppauge, New York 11788

Dear Mr. Gaeta:

This is in response to your letters of June 15, 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 Rice Bran Oil Softgels:

“Rice bran oil helps maintain healthy cholesterol levels”

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, hypercholesterolemia. 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.

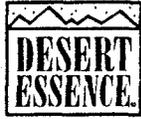
Please contact us if we may be of further assistance.

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

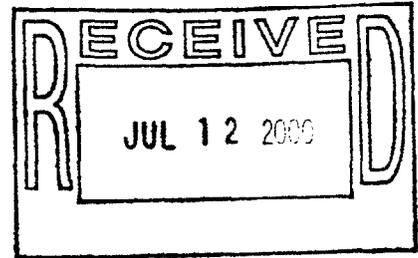
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Partners in Health and Beauty

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



June 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 Rice Bran Oil Softgels. This statement is accompanied by the required disclaimer. To the best of my knowledge, the information contained in this notice is complete and accurate.

Antioxidant Vitamin E. Rice Bran Oil helps maintain healthy cholesterol levels.

Sincerely,

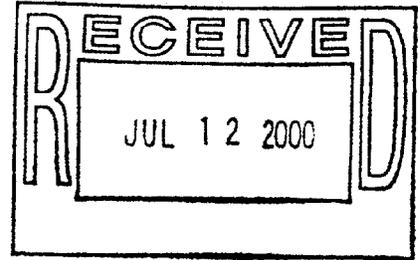
Mark Gaeta
Chief Operating Officer

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