



JUN 20 2001 101 JUL -2 P1 58

Mr. Kenn Israel
New Product Development Coordinator
Country Life
101 Corporate Drive
Hauppauge, New York 11788

Dear Mr. Israel:

This is in response to your letters of April 24, 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, among others, for the product **Maxi Pre-Natal Vegicaps**:

“Supports healthy glucose 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 disorders of blood glucose levels. 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.

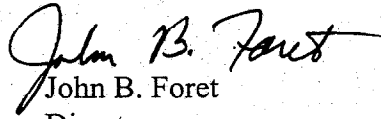
978-0163

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Page 2 - Mr. Kenn Israel

Please contact us if we may be of further assistance.

Sincerely,

Handwritten signature of John B. Foret in cursive script.

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

Page 3 - Mr. Kenn Israel

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-810

HFS-811 (file)

HFD-310

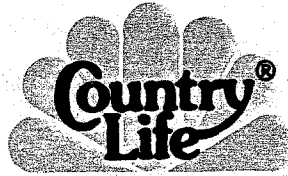
HFD-314 (Aronson)

HFS-605

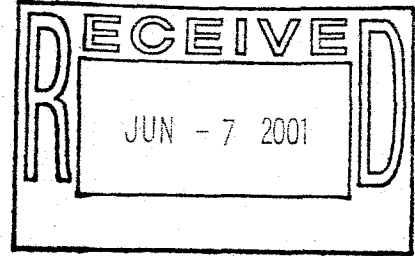
HFV-228 (Benz)

GCF-1 (Nickerson)

f/t:HFS-811:rjm:6/7/01:docname:76250.adv:disc58



Partners in Health and Beauty



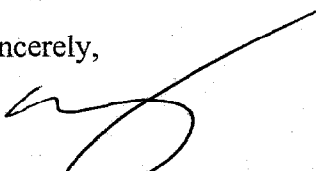
Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, D.C. 20204

April 24, 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 Maxi Pre-Natal Vegicaps (dietary ingredients: vitamin A, vitamin C, vitamin D, vitamin E, vitamin K, thiamin, riboflavin, niacin, vitamin B-6, folic acid, vitamin B-12, pantothenic acid, calcium, iron, phosphorus, iodine, magnesium, zinc, selenium, copper, manganese, chromium, potassium, taurine, Neuromins® (docosahexaenoic acid), ginger, red raspberry, betaine hydrochloride, PABA (para-aminobenzoic acid), inositol, rutin, citrus bioflavonoids, choline bitartrate & BGOV (bis glycinato oxovanadium)). This statement is accompanied by the required disclaimer. To the best of my knowledge, the information contained in this notice is complete and accurate.

Specifically formulated for optimal neuro development with DHA & 1000 mcg of folic acid. Supports healthy glucose levels with chromium & vanadium.

Sincerely,


Kenn Israel
New Product Development Coordinator

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