



The Vitamin Marketing Experts

March 9, 1998

Dr. Elizabeth Yetley
Director of the Office of Special Nutritionals
Division of Programs and Enforcement Policy
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street
HFS-455
Washington, D.C. 20204

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Dear Dr. Yetley:

Notice is hereby given pursuant to the requirements of Section 403(r)(6)(21 U.S.C. 343(r)(6) of the Federal Food, Drug and Cosmetic Act of statements of nutritional support which have been made on the label and/or in the labeling in connection with the marketing of the dietary supplement FAMILY ESSENTIALS™ WITH REFERENCE TO ANY CLAIM CONCERNING FOLIC ACID 400 mcg (0.4mg). FAMILY ESSENTIALS™ WITH REFERENCE TO ANY CLAIM CONCERNING FOLIC ACID 400 mcg (0.4mg) were first marketed with these statements of nutritional support on Friday, March 6, 1998. The statements of nutritional support are as follows:

"Needed for red blood cell production, growth and reproduction"

"New studies reveal that Folic acid, at a higher level of 800mcg, along with vitamins B-6 and B-12, can maintain healthy heart function by helping to lower elevated homocysteine blood levels"

"Extra folic acid, as high as 800mcg, is needed as new studies reveal this dose to be important to young women for overall health"

Very truly yours,

MASON VITAMINS, INC.

Sonia C. Rodriguez
VP Marketing & Regulatory Affairs

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STUDIES FOR FOLIC ACID CLAIMS

“Multivitamin/folic Acid Supplementation in Early Pregnancy Reduces the Prevalence of Neural Tube Defects” Milunsky, A., Jick, H., Jick, S.S. JAMA, Vol.262, No. 20 November 24, 1989 2847-2851

“A Quantitative Assessment of Plasma Homocysteine as a Risk Factor for Vascular Disease” Boushey, C.J., Beresford, S.A.A., Omenn, G.S. JAMA, Vol. 274, No. 13 October 4, 1995 1049-1057