



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)(2) 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 VITAMIN A 5,000 i.u. FAMILY ESSENTIALS™ WITH REFERENCE TO ANY CLAIM CONCERNING VITAMIN A 5,000 i.u. were first marketed with these statements of nutritional support on Friday, March 6, 1998. The statements of nutritional support are as follows:

- "Promotes good vision and healthy skin"
- "Supports strong immune system"
- "Vitamin A is needed to maintain a healthy immune system"
- "Vitamin A to enhance vision and immune system function"
- "Contributes to healthy skin and hair"

Very truly yours,

MASON VITAMINS, INC.

Sonia C. Rodriguez  
VP Marketing & Regulatory Affairs

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March 9, 1998

Page 2

### **STUDIES FOR VITAMIN A CLAIMS**

**“Pathogenese von Hyperoxalurien und Kalziumoxalatsteinen bei Darmerkrankungen” Muller, V.G., Schutte, W., Moller T. Dtsch. Z. Verdau.-Stoffwechs.krankh. 47 (1987) 105-112**

**“The Effects of 13-cis-Retinoic Acid and Beta Carotene on Cellular Immunity in Humans” Prabhala, R.H., Garewal, H.S., Hicks, M.J. Cancer Vol. 67 March 15, 1991 1556-1560**

**“Vitamin A, Carotenoids, and Retinoids” Hennekens, C.H., Mayrent, S.L., Willett, W. Cancer Vol. 58, 1986 1837-1841**

**“Night Vision in a case of vitamin A deficiency due to malabsorption” Perlman, I., Barzilai, D. Haim, T. British Journal of Ophthalmology, 1983 37-42**

**“Visual function and vitamin A/zinc nutriture in patients with complaints of night blindness” Hinck, M., Hirons, R.R., Yolton, D.P. Journal of the American Optometric Association Vol. 55 No. 8, 8/84 567-571**