

AUG - 6 1997

Ms. Sonia Rodriguez  
VP of Marketing and Regulatory Affairs  
Mason Vitamins, Inc.  
5105 N.W. 159th Street  
Miami Lakes, Florida 33014-6370

Dear Ms. Rodriguez:

This is in response to your letter of July 30, 1997 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that you are making the following statements for your products, L-Lysine 500MG and 1000MG.

Promotes growth and tissue repair.

Vital to building and repair of muscle tissue.

Promotes cold sore relief when taken at doses of up [to] 1500mg a day for the first few months of supplementation. For best results, use in combination with 100mg of Bioflavonoids and 1000mg of Vitamin C.

Section 403(r)(6) of the act 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 statements that you are making for these products suggest that they are intended to treat or mitigate a disease, cold sores. This claim does not meet the requirements of section 403(r)(6) of the act. This claim suggests that these products are intended for use as drugs within the meaning of section 201(g)(1)(B) of the act, and that they are subject to regulation under the drug provisions of the act. If you intend to make a claim 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 yours,

James Tanner, Ph.D.  
Acting Director  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals  
Center for Food Safety and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Florida District Office, Office of Compliance, HFR-SE240

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

975-0163

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The Vitamin Marketing Experts

July 30, 1997

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 supplements L-LYSINE 500MG & 1000MG.

L-LYSINE 500MG & 1000MG will be first marketed with these statements of nutritional support on August 15, 1997. The statements of nutritional support are as follows:

Promotes growth and tissue repair.  
Vital to building and repair of muscle tissue.  
Promotes cold sore relief when taken at doses of up 1500mg a day for the first few months of supplementation. For best results, use in combination with 100mg of Bioflavonoids and 1000mg of Vitamin C.

Very truly yours,

Mason Vitamins, Inc.

Sonia Rodriguez  
VP of Marketing & Regulatory Affairs

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