



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

AUG 20 1999

0713 '99 SEP -3 10:39

Ms. Sonia C. Rodriguez  
VP Marketing & 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 August 11, 1999 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 Mason Vitamins, Inc. is making the following claim, among others, for the products "MSM 1000 mg" and "MSM/Glucosamine complex:"

"Doctor recommended anti-inflammatory for back, head, knees and persons sensitive to the pollen season."

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 these products suggest that they are intended to treat, prevent, cure, or mitigate disease, namely certain inflammatory disorders and allergies. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that these products are intended for use as drugs within the meaning of 21 U.S.C 321(g)(1)(B), and that they are 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,

Lynn A. Larsen, Ph.D.  
Director  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals  
Center for Food Safety  
and Applied Nutrition

975-0163

LET 295

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

cc:

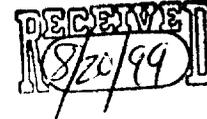
HFA-224 (w/incoming)  
HFA-305 (docket 97S-0163)  
HFS-22 (CCO)  
HFS-456 (r/f, File)  
HFS-450 (r/f, File)  
HFD-310 (BWilliams)  
HFD-314 (Aronson)  
HFS-605 (Bowers)  
GCF-1 (Dorsey, Nickerson, Dorsey)  
HFV-228 (SBenz)  
f/t:HFS-456:rjm:8/20/99:docname:66744.adv:disc40



The Vitamin Marketing Experts

16744

August 11, 1999



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

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 MSM 1000mg and MSM/GLUCOSAMINE COMPLEX. MSM 1000mg and MSM/GLUCOSAMINE COMPLEX will be first marketed with these statements of nutritional support on Monday, August 16, 1999. The statements of nutritional support are as follows:

“Supports healthy, comfortable joint and muscle movement”

“Doctor recommended anti-inflammatory for back, head, knees and persons sensitive to the pollen season”

Very truly yours,

MASON VITAMINS, INC.

Sonia C. Rodriguez  
VP Marketing & Regulatory Affairs