



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

Rec'd 3-26-98

MAR 13 1998

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

Dear Ms. Rodriguez:

This is in response to your letter of May 1, 1997 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 is making the following claim for the product Zinc Lozenges 23 mg Lemon Flavored:

“Promotes general well-being during the cold & flu season. Supports the body’s natural defense system.”

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 prevent, treat or mitigate disease, namely the common cold and influenza. 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.

Please contact us if we may be of further assistance.

Sincerely,

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

975-0162

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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, KCarson)

HFS-456 (File)

HFS-450 (file, r/f)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-600 (Reynolds)

HFS-605 (Bowers)

GCF-1 (Nickerson, Dorsey)

r/d:HFS-456:RMoore:3/12/98

Init:GCF-1:LNickerson:3/12/98

f/t:HFS-456:rjm:3/13/98:docname:mason.adv:disc26



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Mason Distributors, Inc
Since 1967

The Vitamin Experts

May 1, 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

5/9/97

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 ZINC LOZENGES 23 MG LEMON FLAVORED. ZINC LOZENGES 23 MG LEMON FLAVORED was first marketed with these statements of nutritional support on Friday, May 2, 1997. The statements of nutritional support are as follows:

Promotes general well-being during the cold & flu season.
Supports the body's natural defense system.

Very truly yours,

Mason Distributors, Inc.

Sonia C. Rodriguez
VP of Marketing & Regulatory Affairs

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