



FEB -2 2000 7 9 8 7 '00 FEB -8 P1 :59

Ms. Sonia C. Rodriguez
President
Mason Vitamins, Inc.
5105 N.W. 159th Street
Miami Lakes, Florida 33014-6370

Dear Ms. Rodriguez:

This is in response to your letter of January 19, 2000 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 submissions state that Mason Vitamins, Inc. is making the following claims, among others, for the product **Liver/Kidney Cleanser**:

“Prevents bacteria from sticking to the urinary tract walls for more comfortable urinary flow.”

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 statements that you are making for this product suggests that it is intended to treat, cure, prevent, or mitigate disease, namely urinary tract diseases caused by pathogenic microorganisms. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest 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 yours,

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

975-0163

LET 335

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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, Compliance Branch, 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-600 (Reynolds)

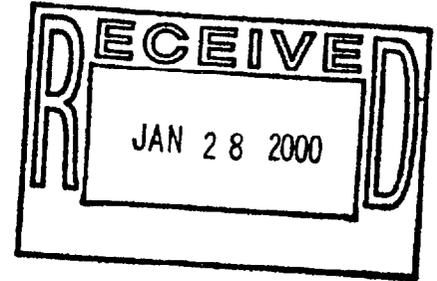
HFS-605

HFV-228 (Benz)

GCF-1 (Nickerson, Dorsey, Barnett)

f/t:rjm:HFS-456:1/31/00:68966.adv:disc44

January 19, 2000



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 supplement LIVER/KIDNEY CLEANSER. LIVER/KIDNEY CLEANSER was first marketed with these statements of nutritional support on Monday, January 3, 2000. The statements of nutritional support are as follows:

"Protects liver from toxic substances such as alcohol, paint, and smoke"

"Prevents bacteria from sticking to the urinary tract walls for more comfortable urinary flow"

Very truly yours,

MASON VITAMINS, INC.

A handwritten signature in cursive script that reads "Sonia C. Rodriguez".

Sonia C. Rodriguez
President

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