DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

0576 '03 FEB 12 P1:49

JAN 23 2003

Mr. Scott Eckelbarger
President
Nutriment Innovations, Inc.
P. O. Box 5261
Huntington, Indiana 46750

Dear Mr. Eckelbarger:

This is in response to your submission to the Food and Drug Administration (FDA) received on January 15, 2003. Your submission appears to be intended to be the notification required by 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)) and 21 CFR 101.93(a).

21 CFR 101.93(a) sets forth the procedures for making a submission to FDA for claims made in the labeling of dietary supplements pursuant to 21 U.S.C. 343(r)(6). Among other requirements, 21 CFR 101.93 requires that the notice submitted pursuant to 21 U.S.C. 343(r)(6) and this section be signed by a responsible individual who can certify the accuracy of the information presented and contained in the notice, and that the individual certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading (21 CFR 101.93(a)(3)). Your submission does not meet this requirement in that the notice does not contain the signature of a responsible individual nor do they certify that the firm is in compliance with the requirements of the Act and the regulation. Therefore, your firm has not complied with the notification requirement in 21 U.S.C. 343(r)(6) and must submit a notification to the address in the regulation in accordance with the requirements in 21 CFR 101.93(a)[1].

[1]You can access a copy of Title 21 of the Code of Federal Regulations (21 (CFR) on FDA's web site at: http://www.cfsan.fda.gov/~dms/reg-2.html.

975-0163

LET 666

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

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, Detroit District Office, Office of Compliance, HFR-MW240

Nutriment Innovations Inc.
PO Box 5261
Huntington, IN 46750
260-359-1546
December 17,2002

Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

To whom it may concern:

We are an on-line dietary supplement marketer that is opening for nationwide business beginning next month. We are writing to notify the FDA of the Structure/Function claims we are using in our web page advertisements. Enclosed you will find copies of the product labels and the on-line ad text.

If you have any further questions or need more information, please let us know.

Scott Eckelbarger
President
Nutriment Innovations Inc.
www.nutrimentinnovations.com

Enclosures

03-94