



MAR 13 1998

Rec'd 3/26/98

Mr. Tod Kimbell
Senior Research Director
NATRIX International, LLC.
AMRION, Inc.
6565 Odell Place
Boulder, Colorado 80301-3330

Dear Mr. Kimbell:

This is in response to your letter of November 14, 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 Natrix International, LLC. is making the following claim for the product Natrix EchinAide:

“It was created to power up your body’s own natural defenses...So this cold season, give your immune system a boost with EchinAide.”

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 a disease, namely the common cold. 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

975-0163

LET 133

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Copies:

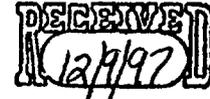
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Denver District Office, Office of Compliance, HFR-SW240

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:natrix.adv:disc26

NATRIX INTERNATIONAL, LLC.
A Joint Venture of Amrion, Inc., Boulder, CO and Indena, Milan, Italy

November 14, 1997



Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20204

NOTIFICATION OF STATEMENTS
OF NUTRITIONAL SUPPORT

This Notification is filed pursuant to §403(r)(6) of the Federal Food Drug and Cosmetic Act (FDC Act), 21 U.S.C. §343(r)(6).

Name of dietary supplement: Natrix EchinAide

Statement(s) of
nutritional support: It was created to power up your body's own natural defenses ... So this cold
season, give your immune system a boost with EchinAide.

I certify that the information contained in this notice is complete and accurate, and that we have substantiation that the statement[s] is [are] truthful and not misleading.

A handwritten signature in black ink, appearing to read "Tod Kimbell".

Tod Kimbell
Senior Research Director
AMRION, INC.