



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

MAR 12 1999 2 61 '99 MAR 23 P2:13

Terese Maltzman, Ph.D.  
Research Scientist  
Amrion, Inc.  
6565 Odell Place  
Boulder, Colorado 80301-3330

Dear Dr. Maltzman:

This is in response to your letter of February 22, 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 Amrion, Inc. is making a statement, among others, that the product **PharmaLogics Folic Acid** "...may reduce a woman's risk of having a child with a brain or spinal cord defect." This statement is not a claim subject to 21 U.S.C. 343(r)(6), but is a health claim subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized a health claim on the relationship between folate and neural tube defects (see 21 CFR 101.79). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between folate and neural tube defects. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.79 would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, failure to make a claim in accordance with the requirements in 21 CFR 101.79 subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, neural tube defects.

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

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

975-0163

LET 258

# AMRION

February 22, 1999

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).

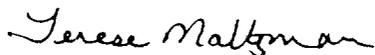
Name of dietary supplement: PharmaLogics Folic Acid

Statements of  
nutritional support:

Balance Homocysteine for Cardiovascular Health; Folic acid is a B vitamin that helps to balance homocysteine. Folic acid limits the production of homocysteine which is important in maintaining arterial health. Adequate folic acid in a healthy diet may reduce a woman's risk of having a child with a brain or spinal cord defect.

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

AMRION, INC.



Terese Maltzman, Ph.D.  
Research Scientist