



DEC 19 1997

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Mr. Tod Kimbell
Senior Research Director
Amrion, Inc.
6565 Odell Place
Boulder, CO 80301-3330

Dear Mr. Kimbell:

This is in response to your letters of November 14, 1997 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submissions state that Amrion, Inc. is making the following statements, among others, for the products:

BioEnergy Nutrients Quercetin with Bromelain

“Maximize your body’s allergy fighting ability . ..helps your body block the allergic response...”

BioEnergy Nutrients Niacin NSE

“...proven to help control healthy cholesterol levels...helps decrease your body’s production of LDL cholesterol. ..”

BioEnergy Nutrients Healthy Joints

“...promote the regeneration of damaged cartilage...”

BioEnergy Nutrients Chondroitin Sulfate

“...keeps movement flexible and painless”

BioEnergy Nutrients Select E

“...plays a role in keeping your heart healthy. Two recent Harvard medical School studies prove the protective effects of vitamin E supplementation on the heart.* *New England Journal of Medicine, 1993: 328; 1444-9, 1450-6.

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BioEnergy Nutrients St. John's Wort GPH

“The prestigious British Medical Journal* found that this herbal extract had a promising impact on promoting a positive mood when taken on a daily basis.
•British Medical Journal 1996; 313:253-8”

Section 403(r)(6) of the act 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 these products suggest that they are intended to treat, prevent, mitigate, or prevent diseases, namely allergies, hypercholesterolemia, joint disorders characterized by cartilage damage, and to relieve pain. Additionally, the claims made for the products BioEnergy Nutrients St. John's Wort GPH and BioEnergy Nutrients Select E each contain, as a part of the claims, citations to one or two articles published in research journals. These citations do not appear to be eligible for the exemption from being considered as labeling provided for in section 403B of the act because they do not meet the requirements of that section. For example, the citation of one or two publications used in connection with the sale of a dietary supplement does not appear to be presented, such as with other such items on the same subject matter, so as to present a balanced view of the available scientific information on the dietary supplement.

The claims being made for these products do not meet the requirements of section 403(r)(6) of the act. These claims suggest that these products are intended for use as drugs within the meaning of section 201 (g)(1)(B) of the act, and that they are 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-3 10, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritional
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, Compliance Branch, HFR-SW240



Bioenergy Nutrients
6565 Odell Place
Boulder, CO 80301-3330
(303) 530-2508
Fax: (303) 530-2592

November 1-t. 1997

A Division of AMRION, Inc

Office of Special Nutritional (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 c street. Sw
Washington. DC 2020-i

10/15/97

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). 21U.S.C §343(r)(6).

Name of dietary supplement: BioEnergy Nutrients Healthy Joints

Statement(s) of
nutritional support:

for joint health
nutrients your body uses to rebuild healthy joint structures. And one study shows that *glucosamine sulfate* helps promote the regeneration of damaged cartilage . glucosamine sulfate, an important building block of cartilage. ligaments and tendons helps form lubricating fluid surrounding joints

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

Tod Kimbell
Senior Research Director
AMRION, INC.

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November 14, 1997

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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: BioEnergy Nutrients Chondroitin Sulfate

Statement(s) of nutritional support: Keep joints flexible
synovial fluid which cushions joints and keeps movement flexible and painless.

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

Tod Kimbell
Senior Research Director
AMRION, INC.

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November 14, 1997

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11/14/97

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
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Washington, DC 20204

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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: BioEnergy Nutrients Select E

Statement(s) of
nutritional support:

plays a role in keeping your heart healthy Two recent Harvard Medical School studies prove the protective effects of vitamin E supplementation on the heart. * New England Journal of Medicine. 1993; 328: 1444-9. 1450-6

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

Tod Kimbell
Senior Research Director
AMRION, INC.

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Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 c street Sw
Washington DC 20204

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NOTIFICATION OF STATEMENTS
OF NUTRITIONAL SUPPORT

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

Name of dietary supplement: BioEnergy Nutrients St John-s Won GPH

Statement(s) of nutritional support: The prestigious British Medical Journal” found that this herbal extract had a promising impact on promoting a positive mood when taken on a daily basis
*British Medical Journal 1996:313253-8

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.

Tod Kimbell
Senior Research Director
AMRION, INC.

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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: BioEnergy Nutrients Quercetin with Bromelain

Statements] of
nutritional support: Maximize your body's allergy fighting ability
helps your body block the allergic response .

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.

Tod Kimbell
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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: BioEnergy Nutrients Niacin NSE®

Statement(s) of nutritional support: proven to help control healthy cholesterol levels helps decrease your body's production of LDL cholesterol

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.

Tod Kimbell
Senior Research Director
AMRION, INC.

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