



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

APR 28 2000

Ms. Evelyn D. Cadman
Senior Research Scientist
Bioenergy Nutrients
6565 Odell Place
Boulder, Colorado 80301-3330

Dear Ms. Weaver:

This is in response to your letter to the Food and Drug Administration (FDA), dated March 23, 2000, 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 Bioenergy Nutrients is making the following claim, among others, for the product **Bioenergy Nutrients Cardio Q10[®] with Hawthorne and Taurine**:

“Taurine supports smooth blood flow. Helps keep blood from becoming “sticky” so blood flows freely to the heart and other organs.”

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 treat, prevent, or mitigate disease, namely disorders of platelet aggregation. 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.

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Please contact us if we may be of further assistance.

Sincerely,

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, Denver District Office, Compliance Branch, HFR-SW240

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-800 (file, r/f)
HFS-811 (r/f, file)
HFD-40 (Behrman)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-605
HFV-228 (Betz)
GCF-1 (Barnett, Nickerson, Dorsey)
f/t:rjm:HFS-811:4/27/00:70395.adv:disc46

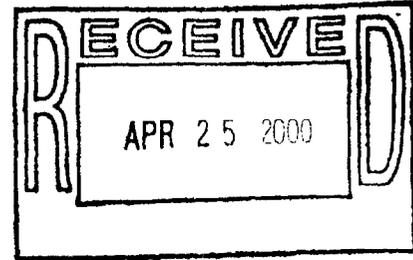


Bioenergy Nutrients
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March 23, 2000

A Division of AMRION, Inc.

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 Cardio Q10[®] with Hawthorne and Taurine

Statement[s] of
nutritional support:

Boost cardiovascular performance.

Works to strengthen and protect your heart.

CoQ10 and selenium are extremely effective at promoting and protecting heart health.

Hawthorne helps increase blood flow to the heart.

Taurine supports smooth blood flow. Helps keep blood from becoming "sticky," so blood flows freely to the heart and other organs.

Coenzyme Q10 assists in the creation of heart muscle energy, provides antioxidant support that helps protect your heart from free radical damage.

Selenium helps the body use its own antioxidants effectively.

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. Two copies of this notification are enclosed with this original.

AMRION, INC.


Evelyn D. Cadman, CN
Senior Research Scientist

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