



OCT - 2 2000

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Mr. James Komorowski
Director, Product Development
AMBI, Inc.
4 Manhattanville Road
Purchase, New York 10577-2197

Dear Mr. Komorowski:

This is in response to your letter of September 26, 2000 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 AMBI, Inc. is making the following claims, among others, for the following products:

CardiaNutrition™ Lipid Metabolism

“...maintain healthy cholesterol metabolism”

CardiaNutrition™ Heart Health

“...maintain their normal blood pressure levels.”

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 statements that you are making for these products suggest that they are intended to treat, prevent, cure or mitigate diseases, namely hypercholesterolemia and coronary heart disease and hypertension. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), 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-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

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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, New York District Office, Office of Compliance, HFR-NE140

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-810

HFS-811 (file)

HFD-310

HFD-314 (Aronson)

HFS-605

HFV-228 (Benz)

GCF-1 (Dorsey, Nickerson)

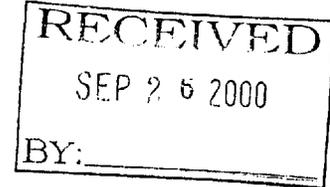
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AMBI

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AMBI Inc.
4 Manhattanville Road
Purchase, New York 10577-2197
Telephone 914 701-4500
Facsimile 914 696-0860
www.AMBInc.com

September 26, 2000



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

**NOTIFICATION OF STATEMENTS
OF NUTRITIONAL SUPPORT**

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

Name of dietary supplement: CardiaNutrition™ Heart Health

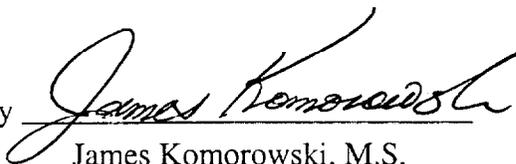
Dietary ingredients: Vitamin D, Calcium, Magnesium, Potassium

Statements of nutritional support:

- Magnesium helps promote overall cardiovascular health.
- Most commonly found in bananas, potassium is essential for maintaining cardiovascular health.
- In addition to supporting bone health, calcium plays a role in maintaining cardiovascular health.
- Vitamin D is essential for proper calcium absorption.
- Potassium, magnesium and calcium are essential minerals and important dietary nutrients.
- CardiaNutrition™ Heart Health is designed for healthy women and men interested in helping to maintain their normal blood pressure levels.
- They are an affordable way to help maintain everyday cardiovascular health - safely and confidently.
- Promotes cardiovascular health.

- CardiaNutrition™ CoQ10 & Carnitine is a powerful combination of nutrients that support essential cardiovascular functions.
- CoQ10 is essential in the body's natural production of energy.
- To help the body metabolize fat, we've formulated our CoQ10 with carnitine.
- Carnitine is fundamental in transporting fatty acids into cells where they're converted into a major source of energy for all muscles --especially the heart.
- CardiaNutrition™ Lipid Metabolism contains ingredients designed for women and men interested in helping to maintain healthy cholesterol and fat metabolism.
- This specially-designed combination of advanced nutritional supplements can help you maintain healthy blood lipid metabolism.
- They are an affordable way to help maintain everyday cardiovascular health - safely and confidently.
- Supports healthy blood lipid metabolism.

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.

By 
James Komorowski, M.S.
Director, Product Development

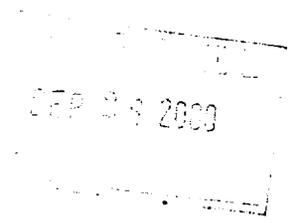


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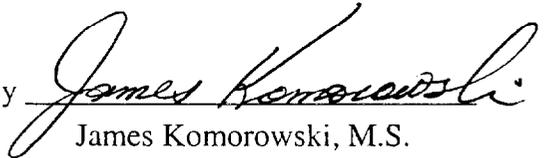
Name of dietary supplement: CardiaNutrition™ Lipid Metabolism

Dietary ingredients: Vitamin E, Niacin, Chromium, Omega-3 Fatty Acids, L-Carnitine, Garlic extract, Coenzyme Q10, Soybean isoflavones.

Statements of nutritional support:

- Omega -3 fatty acids, primarily found in fish, help to maintain healthy cholesterol metabolism.
- These fatty acids play an important role in supporting overall cardiovascular health.
- This unique formula combines our patented Chromax® chromium picolinate (USP-NF) and niacin to help maintain healthy cholesterol metabolism.
- Chromax® also plays a role in fat metabolism.
- Chromax® chromium picolinate (USP-NF) is a good source of chromium, a trace mineral essential for carbohydrate, protein and fat metabolism.
- Chromax® is a patented form of chromium picolinate that can help you maintain healthy blood lipid metabolism and a healthier, leaner body, when combined with a healthy diet and regular exercise.
- By helping to promote healthy metabolism, it is an ideal nutritional component for any diet or weight management program.

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.

By 
James Komorowski, M.S.
Director, Product Development