



MAY 22 2000

4285 '00 MAY 25 P2:01

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

Dear Ms. Cadman:

This is in response to your letters of May 15, 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 Bioenergy Nutrients is making the following claims, among others, for the products:

**Bioenergy Nutrients Bromelain GPH™**

“Promote normal inflammation”

“...promote a normal inflammatory response”

**Bioenergy Nutrients Breathe Freely™**

“Promotes relaxed, open bronchial passages and a healthy allergic response”

**Bioenergy Nutrients Breathe Freely™ Plus**

“Total sinus and respiratory aid”

“Breathe more easily”

“...Maintain a healthy inflammatory response”

“Keep breathing comfortable and easy”

“...aids healthy breathing by maintaining relaxed, open bronchial passages”

**Bioenergy Nutrients Breath of Life®**

“Immediate support for clear breathing, naturally”

“Immediate support for respiratory health”

“...supports the natural relaxation of bronchial tubes...which in turn makes breathing easy.”

“Provides fast-acting support for clear, deep breathing”

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, or mitigate a diseases, namely,

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inflammatory disorders, including respiratory disorders. 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.

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:

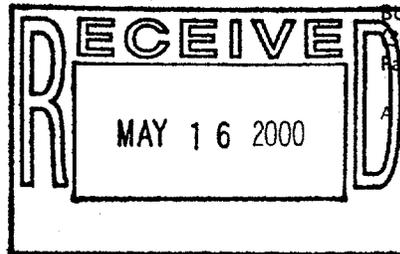
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, Denver District Office, Office of Compliance, HFR-SW240

cc:

HFA-224 (w/incoming)  
HFA-305 (docket 97S-0163)  
HFS-22 (CCO)  
HFS-800 (r/f, file)  
HFS-811 (file)  
HFD-40 (Behrman)  
HFD-310  
HFD-314 (Aronson)  
HFS-605  
HFV-228 (Benz)  
GCF-1 (Dorsey, Barnett, Nickerson)  
f/t:HFS-811:rjm:5/18/00:docname:70764.adv:disc47



**Bioenergy Nutrients**  
6565 Odell Place  
Boulder, CO 80301-3330  
(303) 530-2508  
Fax: (303) 530-2592  
A Division of AMRION, Inc.



May 15, 2000

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 Breath of Life®

Statement[s] of  
nutritional support:

For easier breathing.

Immediate support for clear breathing, naturally.

Immediate support for respiratory health.

Ma huang supports the natural relaxation of bronchial tubes... which in turn makes breathing easy.

Provides fast-acting support for clear, deep breathing.

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

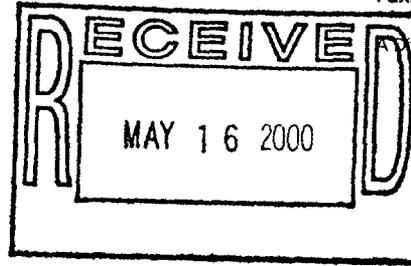
Senior Research Scientist



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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 Breathe Freely™ Plus

Statement[s] of  
nutritional support:

Total sinus and respiratory aid.

Breathe more easily.

Helps maintain relaxed air passages for easy, deep breathing.

For extra sinus support.

Helps your body maintain a healthy inflammatory response.

Keep breathing comfortable and easy.

Quercetin aids healthy breathing by maintaining relaxed, open bronchial passages.

Ginkgo biloba promotes bronchial tissue health.

Increase respiratory health.

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AMRION, INC.

  
Evelyn D. Cadman, CN  
Senior Research Scientist

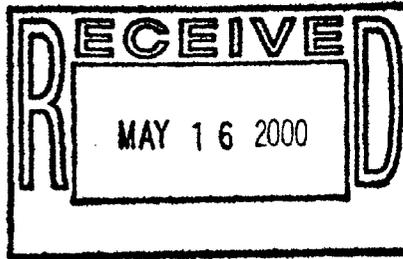


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Name of dietary supplement: **Bioenergy Nutrients Bromelain GPH™**

Statement[s] of  
nutritional support: **Promote normal inflammation.**

**Bromelain can help promote a normal inflammatory response.**

**Perfect for people looking for increased joint comfort.**

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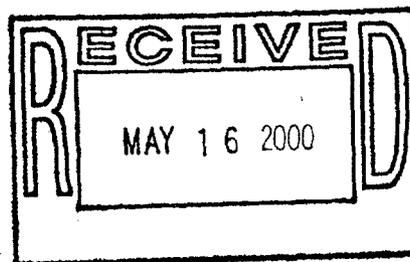
  
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Name of dietary supplement: **Bioenergy Nutrients Breathe Freely™**

Statement[s] of  
nutritional support: **Powerful respiratory support.**

**For respiratory health.**

**Promotes relaxed, open bronchial passages and a healthy allergic response.**

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AMRION, INC.

  
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