



OCT - 8 1997

Mr. Faisal Shah
General Counsel
Richardson Labs
P.O. Box 570
Meridian, Idaho 83680

0764 '97 DEC 16 P1:37

Dear Mr. Shah:

This is in response to your letter of September 23, 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 submission states that Richardson Labs™ is making claims for a product, Pyruvate-C.

Chromium picolinate enhances the actions of the hormone insulin in stabilizing blood sugar and supporting metabolism

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 statement that you are making for this product suggest that it is intended to treat or mitigate diseases, in that, it claims to stabilize blood sugar. This claims does not meet the requirements of section 403(r)(6) of the act. This claims suggest that this product is intended for use as a drug within the meaning of section 201(g)(1)(B) of the act, and that it is subject to regulation under the drug provisions of the act. If you intend to make a claim 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 yours,

James T. Tanner, Ph.D.
Acting 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, Seattle District Office, Office of Compliance, HFR-PA300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

975-0163

LET 71

Innovation



Marketing

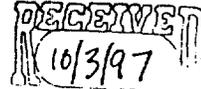
Quality

Science

writer's direct dial
(208) 893-6754

0765 '97 SEP 16 11:37
September 23, 1997

**CERTIFIED MAIL, RETURN
RECEIPT REQUESTED**



Dr. Elizabeth Yetley
Office of Special Nutritionals
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

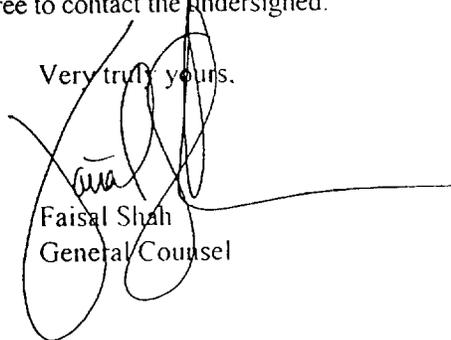
RE: Notification of Product Claims

Dear Dr. Yetley:

This letter serves as notification of the nutritional support label statements being made by Richardson Labs, LLC, located at 3475 Commercial Court, Meridian, Idaho 83642 in connection with products being marketed by Richardson Labs, LLC. A list of the products and their respective nutritional support statements are listed in the attached Exhibit "A".

If you have any questions, please feel free to contact the undersigned.

Very truly yours,

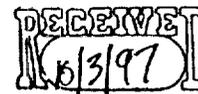


Faisal Shah
General Counsel

Enc.
cc: Edward D. Priddy

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ATTACHMENT "A"



1. St. John's Wort: A dietary supplement containing standardized extract of 0.3% hypericin.

Nutritional Support Statements:

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- St. John's Wort Extract Is Nutritional Support For Healthy Mental And Nervous System Function.
- St. John's Wort Extract Provides Healthy Mental And Nervous System Support.

2. Chitosan CP400: A dietary supplement containing chitosan and chromium picolinate.

Nutritional Support Statements:

- Chitosan Combines Two Of Today's Most Talked About Weight Management Ingredients, All-Natural Chitosan And Chromium Picolinate.
- Recent Research Shows That 400 Mcg Of Chromium Picolinate Enhances The Loss Of Body Fat While Maintaining Lean Muscle Mass.

3. Energia® 250: A dietary supplement containing an herbal complex, including Ginseng Extracts, Gotu Kola and Vitamin B-6.

Nutritional Support Statements:

- High Potency Ginseng For Maximum Energy.
- Energia Provides You With The Energy You Need, When You Need It.
- Energia 250 Provides An Energy Boost With Sustained Effects.
- Energia 250 Increases Energy.

4. Pyruvate-C: A dietary supplement containing calcium pyruvate and chromium picolinate.

Nutritional Support Statements:

- Pyruvate-C Stimulates Metabolism.
- Pyruvate-C Reduces Body Fat.
- Pyruvate-C Increases Lean Muscle.
- Pyruvate Is A Naturally Occurring Substance Which Is Essential To Energy Metabolism.
- Pyruvate Is A Key Component In The Chemical Process By Which The Body Creates Energy From Carbohydrates (Sugar) And Fat.
- Recent Research Shows That 400 Mcg Of Chromium Picolinate Enhances The Loss Of Body Fat While Maintaining Lean Muscle Mass. Chromium Picolinate Enhances The Actions Of The Hormone Insulin In Stabilizing Blood Sugar And Supporting Metabolism.

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