



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

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

SEP 24 1997

3/24/98

Dear Mr. Shah:

This is in response to your letter of June 12, 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, Chitosan-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

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cc:

HFA-224 (w/incoming)

HFS-22 (CCO, KCarson)

HFS-456 (r/f, Miles, Moore)

HFS-450 (r/f)

HFD-304 (Aronson)

HFS-600 (Reynolds)

r/d: C:\miles:6/30/97:C:\Miles\suppl\53165

Initial: RMoore: 7/1/97

f/t: RMoore: 8/27/97: docname: 53165.adv: Disc22

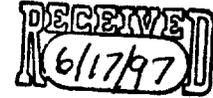
Submission



Marketing

Quality

Science



June 12, 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: Chitosan-C™ Label Claims

Dear Dr. Yetley:

As required by Title 21, Section 343(r)(6) of the U.S.C.A., this letter serves as notification of the claims being made by Richardson Labs™ LLC, located at Post Office Box 570, Meridian, Idaho 83680, in regards to its new Chitosan-C™ product.

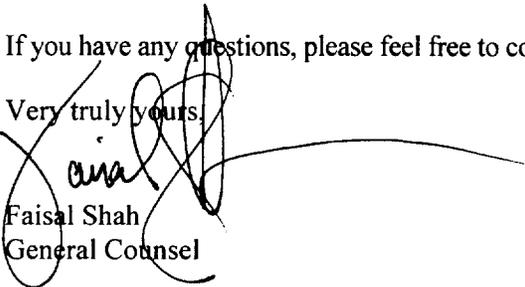
Chitosan-C™ is an all-natural combination of two weight management ingredients, Chitosan and Chromium Picolinate.

The label claims being made by Richardson Labs™ LLC for Chitosan-C™ are as follows:

- 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; and
- Chitosan-C™, in combination with a diet and exercise plan, will help you lose weight and reduce body fat safely and effectively.

If you have any questions, please feel free to contact the undersigned at (208) 893-6754.

Very truly yours,

  
Faisal Shah  
General Counsel

cc: Edward D. Priddy

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