



OCT 28 1997

0809 '97 DEC 16 P1:42

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

Dear Mr. Shah:

This is in response to your letter of October 22, 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 the following claims, among others, for the following products:

Chroma Slim Daily Fiber

“...relieve constipation and reduce cholesterol”

Femilax for Women

“...gentle, all-natural laxative”
“...provides gentle relief from occasional irregularity”
“...relief from occasional irregularity”

Mother's Market and Kitchen Psyllium Husk (capsules)

“...provides gentle effective relief from constipation”

Mother's Market and Kitchen Psyllium Husk (powder)

“...provides gentle effective relief from constipation”

Proleve 40

“...relieves difficult urination”
“...improve urinary flow in cases of enlargement”
“Prostate enlargement is associated with increased urinary frequency”
“Prostate enlargement is associated with decreased urinary flow”
“Prostate enlargement frequently results in a weak urinary system”

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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 statements that you are making for these products suggest that they are intended to treat, prevent, cure, or mitigate diseases, in that they claim to be laxatives and to treat irregularity and constipation, claim to treat, prevent, or mitigate benign prostatic hypertrophy, or claim to and treat or prevent hypercholesterolemia by lower blood cholesterol. These claims do not meet the requirements of section 403(r)(6) of the act. These claims suggest that these products are intended for use as drugs within the meaning of section 201(g)(1)(B) of the act, 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 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

Innovation



Marketing

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writer's direct dial
(208) 893-6754

DEC 23 1997

DEC 16 P1:43
October 22, 1997

Via Facsimile and Federal Express

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

5536

Exhibit A

CLAIM SUBMISSION OF: 10/22/97

CHROMA SLIM - CHITOSAN WITH CHROMIUM PICOLINATEDescription

Chroma Slim Chitosan is a dietary supplement which contains the ingredients: Chitosan and Chromium Picolinate.

Claims

[Chroma Slim Chitosan helps] reduce body fat.

Recent research shows that chromium picolinate enhances the loss of body fat while maintaining lean muscle mass when used in conjunction with the enclosed plan.

[Chroma Slim Chitosan supports] a trimmer, firmer, leaner body.

CHROMA SLIM BIOZAN-C WITH CHITOSANDescription

A dietary supplement containing BioZan, a proprietary blend of soluble and insoluble fibers, including Chitosan and Chromium Picolinate.

Claims

Chromium picolinate supports natural blood sugar function when used in conjunction with the enclosed Chroma Slim Plan.

[Chromium picolinate] supports metabolic processes when used in conjunction with the enclosed Chroma Slim Plan.

CHROMA SLIM COMPLETEDescription

Chroma Slim Complete System is a dietary supplement which contains Chromium Picolinate, L-Carnitine, HCA, Ginseng, Choline and other ingredients.

Claims

[Chroma Slim Complete System is] an all-natural, easy to follow system that will help you lose weight.

Chroma Slim Complete System will help you lose weight naturally.

[Chroma Slim Complete System will help you] feel healthy, fit and energetic.

Chroma Slim Complete is an intelligently engineered system that will help you reduce body fat; stimulate metabolism.

[Chroma Slim Complete System] controls appetite.

[Chroma Slim Complete System will help you] establish a pattern for long term weight loss.

[Chroma Slim Complete System] increases energy.

[Chroma Slim Complete System will help you] trim inches off your thighs, buttocks and hips.

[Chroma Slim Complete System will help you] suppress food intake.

CHROMA SLIM DAILY FIBERDescription

Chroma Slim Daily Fiber is a dietary supplement which combines Psyllium Husk with a blend of natural fibers and other ingredients.

Claims

Chroma Slim Daily Fiber uses only all-natural fibers to support digestive function.

Research shows that fiber helps support weight loss, promote regularity, gently encourage elimination, relieve constipation, and reduce cholesterol.

[Chroma Slim Daily Fiber includes ingredients] for the support and balancing of intestinal bacteria.

Exhibit A
CLAIM SUBMISSION OF: 10/22/97

ENERGIA PYRUVATE

Description

A dietary supplement containing pyruvate and chromium picolinate.

Claims

Energia Pyruvate helps to provide direct energy for active muscles in conjunction with diet and exercise.

Energia Pyruvate helps to: increase lean muscle, provide direct energy for active muscles, stimulate and support metabolism, and reduce body fat in conjunction with diet and exercise.

FAT BURNER +L-CARNITINE

Description

Fat Burner + L-Carnitine is a dietary supplement that combines L-Carnitine, Lipotropics, Choline and Chromium picolinate, among other ingredients.

Claims

The Advanced Research Fat Burner, a balanced diet, and regular exercise, work together to help you reduce body fat and stimulate metabolism.

Fat Burner +L-Carnitine includes a special blend of lipotropics (fat emulsifiers).

FEMLAX FOR WOMEN

Description

Femlax for Women contains a combination of Psyllium husk powder, Senna, Papaya, Fennel, Peppermint, Cascara sagrada, Rose hips, Buckhorn, Celery seed, Oregon grape seed, and Acidophilus.

Claims

[Femlax for Women is a] gentle, all-natural laxative.

[Femlax for Women] provides gentle relief from occasional irregularity, plus a unique blend of herbs and acidophilus for soothing action.

[Femlax for Women provides] relief from occasional irregularity.

[Femlax for Women] includes psyllium, an effective source of fiber to support elimination.

[Femlax for Women] combines a unique blend of herbs and acidophilus for soothing action.

FRESHE'

Description

A dietary supplement breath freshener which contains a combination of Sunflower Seed Oil, Parsley Seed Oil, Chlorophyll, Kosher Gelatin (softgel),

Claims

Freshe' liquid gels work internally through the digestive system which is often the primary source of bad breath.

Freshe' helps neutralize and eliminate tough breath odors such as onions, garlic and morning breath.

Exhibit A
CLAIM SUBMISSION OF: 10/22/97

GINKOMAX

Description

Ginkomax is a dietary supplement which contains the active ingredient Ginkgo Biloba, Phosphatidyl Complex (Phosphatidyl choline and Phosphatidyl serine) and Vitamin B-6.

Claims

- [Ginkgo biloba extract] increases circulation, enhances oxygen use and improves the uptake of blood sugar in the brain.
- [Ginkomax] improves concentration.
- [Ginkomax] enhances memory.
- [Ginkomax] enhances mental alertness and mental function.
- Ginkgo biloba extract is a natural antioxidant which helps protect the brain from free radical damage.

MENOPRO FOR WOMEN

Description

Menopro for Women is a combination of Black cohosh extract, Dong quai extract, and other select vitamins and minerals.

Claims

- [Menopro is an] all-natural support for a woman's changing needs throughout menopause.
- Menopause represents a natural and healthy progression of a woman's biochemistry.

MOTHER'S MARKET AND KITCHEN COLON THERAPY

Description

Mother's Market and Kitchen Colon Therapy is a dietary supplement that combines Purified Psyllium Husk Seed and Herbs.

Claims

- [The blend of Purified Psyllium Husk Seed and Herbs] helps purify and cleanse the colon and provides friendly bacteria for the inner lining of the colon.
- Colon Therapy may be used to satisfy hunger when dieting or fasting.

MOTHER'S MARKET AND KITCHEN COLON THERAPY POWDER

Description

Mother's Market and Kitchen Colon Therapy is a dietary supplement powder that combines Purified Psyllium Husk Seed and Herbs.

Claims

- [The blend of Purified Psyllium Husk seed and herbs] helps purify and cleanse the colon and provides friendly bacteria for the inner lining of the colon.

MOTHER'S MARKET AND KITCHEN PSYLLIUM HUSK (CAPSULES)

Description

Mother's Market and Kitchen Psyllium Husk contains whole Psyllium Husk.

Claims

- Research shows that psyllium husk is 8-10 times better than oat bran in providing important health benefits.
- Psyllium Husk helps maintain regularity and provides gentle effective relief from constipation.
- [Mother's Market and Kitchen Psyllium Husk] may be used to satisfy hunger when fasting or dieting.

Exhibit A
CLAIM SUBMISSION OF: 10/22/97

MOTHER'S MARKET AND KITCHEN PSYLLIUM HUSK

Description

Mother's Market and Kitchen Psyllium Husk is a dietary supplement powder that contains whole Psyllium Husk.

Claims

Research shows that Psyllium Husk is 8-10 times better than oat bran in providing important health benefit. [Mother's Market and Kitchen Psyllium Husk] may be used to satisfy hunger when fasting or dieting. Psyllium Husk helps maintain regularity and provides gentle effective relief from constipation.

MULTIVITE FOR WOMEN

Description

Multivite is a multivitamin supplement for women that contains antioxidant nutrients, B-complex vitamins and hair, skin and nail factors.

Claims

High potency nutrition for women.

NATURAL PERFORMANCE CHITOSAN-C WITH CHROMIUM PICOLINATE

Description

Natural Performance Chitosan-C with Chitosan-C is a dietary supplement that combines Chitosan and Chromium Picolinate.

Claims

Chitosan-C when used in conjunction with the enclosed diet plan helps to reduce body fat and lose weight. Recent research shows that 400mcg of chromium picolinate enhances the loss of body fat while maintaining lean muscle mass.

NATURAL PERFORMANCE MAXIMUM STRENGTH CHROMIUM PICOLINATE

Description

Natural Performance Maximum Strength Chromium Picolinate is a dietary supplement containing chromium picolinate.

Claims

[Natural Performance Maximum Strength Chromium Picolinate] helps reduce body fat and stay lean and healthy with regular exercise and nutritious foods.

Exhibit A
CLAIM SUBMISSION OF: 10/22/97

PREMEREX FOR WOMEN

Description

A dietary supplement containing Vitamin B-6, Vitamin E, Magnesium, and a blend of herbs.

Claims

[Premerex for Women] provides gentle relief from pre-menstrual irritability and tension.

[Premerex for Women] provides gentle relief from pre-menstrual discomfort.

Premex [for Women] supports your body's systems with balancing herbal and nutritional factors, which help alleviate the discomforts of the monthly cycle.

[Premerex for Women provides] all-natural support for menstrual discomfort.

PROLEVE 40

Description

Proleve 40 is a dietary supplement containing Saw palmetto extract, Pumpkin seed oil, B-sitosterol, Zinc, and Vitamin B6.

Claims

[Proleve 40] helps maintain a healthy prostate. [Proleve 40] relieves difficult urination. [Proleve 40] promotes free urinary flow.

[Proleve 40] inhibits formation of harmful chemicals and blocks them from binding to cells of the prostate.

Proleve 40 [provides] natural support for the prostate.

Proleve 40 also combines zinc and vitamin B-6 to support a healthy prostate.

Proleve 40 offers men a safe and effective approach to maintaining optimal prostate health.

[The ingredients in Proleve 40] have also been shown to support healthy prostate function and improve urinary flow in cases of enlargement.

Nutritional and dietary habits, elevated cholesterol levels, and age-related hormone changes are believed to impact prostate health.

Prostate enlargement is associated with increased urinary frequency.

Prostate enlargement is associated with decreased urinary flow.

Prostate enlargement frequently results in a weak urinary system.

ULTRA CHROMA SLIM PLUS

Description

Ultra Chroma Slim Plus is a dietary supplement that combines Garcinia Cambogia, Lipotropics, Chromiutn Picolinate and thermogenic herbs.

Claims

Ultra Chroma Slim should be taken in conjunction with the enclosed diet and exercise plan.

Ultra Chroma Slim combines all-natural ingredients to help you overcome the greatest obstacles of weight loss: reduction in body fat, inefficient metabolism, hunger control and blood sugar regulation.

[The ingredients in Ultra Chroma Slim assists in] the transport of fats.

[The ingredients in Ultra Chroma Slim assist in the] utilization of fats.

[The ingredients in Ultra Chroma Slim] assists in the conversion of amino acids into lean muscle tissue.

[The ingredients in Ultra Chroma Slim] helps support the body's heat mechanism to stimulate metabolism.

[The ingredients in Ultra Chroma Slim] helps support the body's heat mechanism to activate energy.

Garcinia cambogia, an all-natural, fruit derived ingredient provides hunger control effects.

[Garcinia cambogia] works to directly inhibit the conversion of carbohydrate to fat.

[Ultra Chroma Slim] reduces body fat.

[Ultra Chroma Slim] increases lean muscle.

[Ultra Chroma Slim] stimulates metabolism.
