



OCT 10 1997

0775 '97 DEC 16 P1:38

John Herzog, D.O.
President
Coastal Nutrition Laboratory, Inc.
P. O. Box 10722
Portland, Maine 04104-6122

Dear Dr. Herzog:

This is in response to your letter of April 18, 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 Coastal Nutrition Laboratory, Inc. is making the following claims, among others, for the product BioSlim:

- can lower LDL cholesterol levels (bad cholesterol)
- can increase HDL cholesterol (good cholesterol)
- can lower blood pressure
- helps to prevent constipation
- ...decreased risk of gastro-intestinal cancers

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 this product suggests that it is intended to treat, mitigate, or prevent disease, namely hypercholesterolemia, hypertension, constipation, and gastrointestinal cancers. These claims do not meet the requirements of section 403(r)(6) of the act. These 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.

Your label bears the statement "BioSlim absorbs the fat in your food and keeps your body from digesting the fat." Section 403(r)(6) of the act requires that a statement made under section 403(r)(6) of the act contain, prominently displayed and in boldface type, the following: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." The claim you are making on the label of BioSlim does not contain this statement. This claim represents the product as an article (other than food) intended to affect the structure or any function of the body of man and, therefore, evidences that the product is intended for use as a drug within the meaning of section 201(g)(1)(C) of the act.

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Page 2 - Dr. John Herzog

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,

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, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, New England District, Compliance Office, HFR-NE240

John Herzog, D.O.
Coastal Nutrition Laboratory, Inc
P.O. Box 10722
Portland, ME 04104-6122
April 18, 1997
0776 97 DEC 16 P1:39

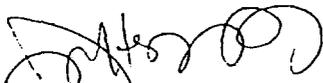
Jeanne E. Latham, R.D., M.S., L.D.
Consumer Safety Officer
Office of Special Nutritionals, HFS-456
200 C Street, S.W.
Washington, D.C. 20204

Dear Ms. Latham

Accompanying this letter are copies of our web page and product labeling. Coastal Nutrition Laboratory is marketing BioSlim, a dietary fiber containing cellulose and chitosan. We are providing copies of our marketing and product label to comply with Public Law 103-417, sections 6 and 7.

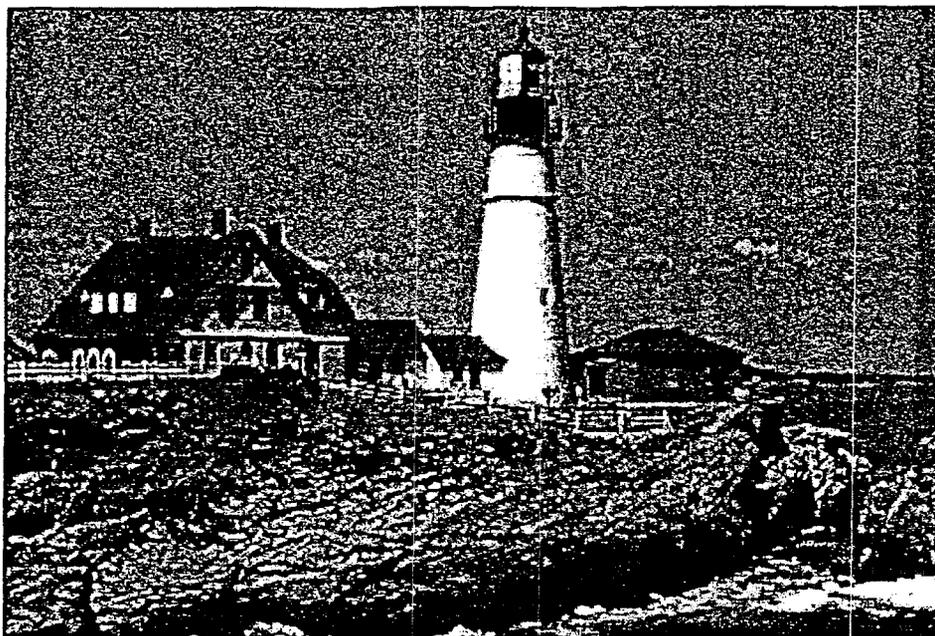
If there are any questions or concerns, please contact myself, Andrew Snyder or Titan Fan at the above address.

Thank you for your assistance,



John Herzog, D.O.
President
Coastal Nutrition Laboratory, Inc.

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CNL

COASTAL NUTRITION LABORATORIES, INC.

The Most Complete Dietary Fiber!
Use Our Online Order Form

Coastal Nutrition Laboratory, Inc., is proud to introduce the most complete dietary fiber, BioSlim™, containing a combination of remarkable dietary fibers which actually absorbs fat in the foods you eat. BioSlim™ contains a mixture of dietary fibers derived from shellfish and squid. This fiber, poly-D-glucosamine (common name: Chitosan), actually combines with fat in your stomach and intestines and prevents your body from absorbing it. Several animal and human studies have shown that poly-D-glucosamine:

- chemically binds to dietary fat in the stomach and intestines
- can lower LDL cholesterol levels (bad cholesterol)
- can increase HDL cholesterol (good cholesterol)
- can lower blood pressure
- helps to prevent constipation

Poly-D-glucosamine is purified from the crustacean shells (shrimp, crabs, lobsters) and squid pens and is a positively charged polysaccharide chain. The positive charge attracts fats and bile acids in the acid environment of the stomach and combines with them to form an indigestible gel. Bile acids are produced by the liver using the cholesterol from LDL. When poly-D-glucosamine eliminates bile acids, it causes the liver to use more bad cholesterol-LDL, thus lowering the total LDL level. This process speeds up the conversion of cholesterol to bile acid which in turn leads to an increase in good cholesterol-HDL levels.

Poly-D-glucosamine has been shown to lower blood pressure by lower serum chloride levels. ACE, angiotensin converting enzyme is responsible for increasing blood pressure. ACE activity usually increases after a meal in response to an increase in serum chloride levels. Thus the removal of chloride by poly-D-glucosamine lowers ACE activity and consequently lowers blood pressure.

Poly-D-glucosamine has been used by the Japanese for many years as a food additive and for other pharmaceutical purposes. Being a dietary fiber, it keeps the intestines clean, removing excess toxins, bacteria and promoting the fitness of the gastro-intestinal tract. The benefits of a high-fiber diet include improved cardiovascular health as well as a decreased risk of gastro-intestinal cancers. BioSlim™ contains a special poly-D-glucosamine from squid pen. The fine particles of this fiber increase the available surface area for fat binding. The quality of these dietary fibers are approved by the Japanese Health Food and Nutrition Association. BioSlim™ also contains cellulose, a plant fiber, to offer the optimum mix of fat absorption and bulking action.

BioSlim™ is easy to use. Just take 2 - 3 capsules before lunch and dinner, and BioSlim™ takes the fat out of your diet. BioSlim™ itself is not digested, so it has no calories. BioSlim™ absorbs the fat and is naturally excreted from your body.

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

References

BioSlim™ is available as 200 mg capsules in convenient 180 capsule bottles, generally a one month supply. Orders accepted with our order form via a secure server.

BioSlim™
The Most Complete
Dietary Fiber

Coastal Nutrition Laboratory, Inc
P.O. Box 10722
Portland, ME 01404-6122
<http://www.cnl-inc.com>

BioSlim™ dietary supplement, a dietary fiber which helps to eliminate fat from your diet. Taken 20 - 30 minutes before a meal, BioSlim™ absorbs the fat in your food and keeps your body from digesting the fat

Each Capsule Contains:

Poly-D-glucosamine.....	200 mg
Cellulose.....	150 mg
Capsule.....	100% gelatin

Directions:
As a dietary supplement, take 2 - 4 BioSlim™ capsules before a meal. Fat soluble vitamins (A, D, E, and K) and mineral supplements should be taken at least 2 hours before taking BioSlim™.
As when taking any form of fiber, always drink at least 8 cups of water each day.

Warnings: Persons allergic to shellfish should not take this product. Pregnant or lactating women should consult with their physician before taking this product.

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