



OCT 23 2002

2003 OCT 23 10 41 AM '02

Yousry Naguib, Ph.D.
Soft Gel Technologies, Inc.
6982 Bandini Boulevard
Los Angeles, California 90040-3326

Dear Dr. Naguib:

This is in response to your letter of October 15, 2002 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)).

The product **Algium™** uses the claim "...as part of a diet low in saturated fat and cholesterol, promotes heart health by maintaining a healthy cholesterol level" In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The claim for your product, that is, the claim about maintaining a healthy cholesterol level, does not establish that the claim is about blood cholesterol levels that are already within normal limits and, therefore, implies that the product is intended to treat elevated blood cholesterol levels and reduce the risk of a disease, namely, coronary heart disease.

The same principle applies to your claim about the ability of Algium to "maintain healthy blood glucose level;" that is, a claim that does not establish that the claim is about blood sugar that is already within normal limits implies that the product is intended to treat elevated blood sugar or diabetes, which is a disease.

The statements that you are making for this product suggest that it is intended to treat, prevent, or mitigate a disease. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is 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.

975-0163

LET 649

Page 2 - Dr. Yousry Naguib

Please contact us if we may be of further assistance.

Sincerely yours,


for

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:

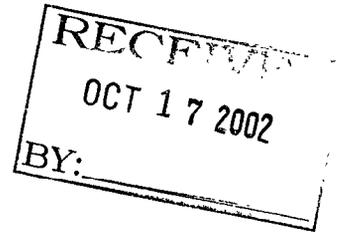
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Los Angeles District Office, Office of Compliance, HFR-PA240

SOFT GEL

TECHNOLOGIES, INC.™



October 15, 2002

Office of Special Nutritional (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug administration
200 C St. SW
Washington, DC 20204

Dear Sir or Madam:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 343(r)(6)) and Section 101.93 of FDA's regulations (21 C.F.R.), we hereby notify you that we are using the following statement(s):

- (1) A low molecular weight soluble fiber from the seaweed kombu (Kelp) (Algium™) helps healthy regularity
- (2) A low molecular weight soluble fiber from the seaweed kombu (Kelp) (Algium™), as part of a diet low in saturated fat and cholesterol, promotes heart health by maintaining a healthy cholesterol level
- (3) A low molecular weight soluble fiber from the seaweed kombu (Kelp) (Algium™) helps maintain healthy blood glucose level

Soft Gel Technologies at 6982 Bandini Boulevard, Los Angeles, CA 90040, is the distributor of the dietary fiber Algium™ (a low molecular weight soluble fiber from the seaweed kombu (Kelp))

The undersigned certifies that the information contained in this notice is complete and accurate, and that Soft Gel Technologies Inc. has substantiation that each statement is truthful and not misleading.

Sincerely yours,

Yousry Naguib, Ph.D.
Soft Gel Technologies Inc.