DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

MAR 12 2002

6381 '02 MAR 26 P2:20

Nathan Tzodikov, Ph.D.
President
Tsunami Supplements
1195 McDermott Drive
West Chester, Pennsylvania 19380

Dear Dr. Tzodikov:

This is in response to your letter of January 14, 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)). Your submission states that Tsunami Supplements is making the following claims, among others, for the product Wakame Heart Health Formula:

> "...neutralizing "bad" cholesterol (LDL) by minimizing oxidation. Oxidized LDL is known to cause plaque build-up in the blood vessels."

21 U.S.C. 343(r)(6) 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 suggests that it is intended to treat, prevent, cure or mitigate a disease, namely coronary heart disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests 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

LET569

Please contact us if we may be of further assistance.

Sincerely,

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, Philadelphia District Office, Office of Compliance, HFR-MA140

79327

CPG

Tsunami Supplements
A division of CPG

1195 McDermott Drive
Phone 610-696-3730

West Chester PA 19380
FAX 610-696-5530

NTZODIKOV@CPGEN.COM
WWW.VEG-OX.COM

January 14, 2002

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

RECEIVED
FEB 19 2002
BY:

Dear Sir/Madam:

Please accept this notification of certain types of statements for dietary supplements filed pursuant to section 101.93. The following information is submitted in compliance with this section.

i. We manufacture Wakame Heart Health Formula, a dietary supplement and are identified as Tsunami Supplements, a division of Checkpoint Genetics, Inc.. Our address is 1195 McDermott Drive, West Chester, PA 19390.

ii. The label for Wakame Heart Health Formula bears the statement "Proven effective in neutralizing "bad" cholesterol (LDL) by minimizing oxidation. Oxidized LDL is known to cause plaque build-up in the blood vessels. "

iii. The dietary ingredient of Wakame Heart Health Formula is Alaria esculenta, the botanical name for the commonly consumed sea vegetable also known as Alaria.

You will please find our label as appendix A, attached to this notification for your convenience. Please note the information contained in the notice is complete and accurate. It appears exactly as quoted in paragraph ii above. Our company substantiated this statement with laboratory evidence. We believe the statement to be truthful and not misleading.

Please feel free to contact me personally should you have any questions about our label.

Sincerely,

Nathan Tzodikov, Ph. D.
President

encl. appendix A
cc: copies (2) blind

Appendix A

Provides the heart-healthy benefits of the Japanese diet with a patented extract of *Wakame*, a sea vegetable. Proven effective in neutralizing 'bad' cholesterol (LDL) by minimizing oxidation. Oxidized LDL is known to cause plaque build-up in the blood vessels*.

Tsunami
SUPPLEMENTS
A division of CPG
West Chester, PA 19380
www.seavox.com

*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.

Tsunami
SUPPLEMENTS

WAKAME
Heart Health
FORMULA

Neutralizes 'Bad' Cholesterol (LDL)

DIETARY SUPPLEMENT • 60 Vcaps™

SUPPLEMENT FACTS
Serving Size 2 Vcaps™,
Servings per container 30.

2 capsules contain	% Daily Value
Alaria esculenta extract 400 mg	*
Total fat 0 g	0
Cholesterol 0 g	0
Calcium 165 mg	16

*% Daily Value not established

Other ingredients: vegetable cellulose, calcium phosphate, vegetable stearic acid. Contains no preservatives.

Suggested use: 2 capsules per day. May be taken with or without food.

Keep in a cool, dry place.
Keep out of reach of children.

Do not use if imprinted safety seal under cap is broken or missing.