



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

JUL 19 2000

Rec'd 8/11/00
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Mr. Christian Drapeau
Director of Research and Development
Desert Lake Technologies, LLC.
P.O. Box 489
Klamath Falls, Oregon 97601

Dear Mr. Drapeau:

This is in response to your letters of June 30, 2000 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 Desert Lake Technologies, LLC. is making the following claim, among others, for the product Summa™:

“...may help maintain a healthy cholesterol level.

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 disease, namely, hypercholesterolemia. 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.

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

975-0163

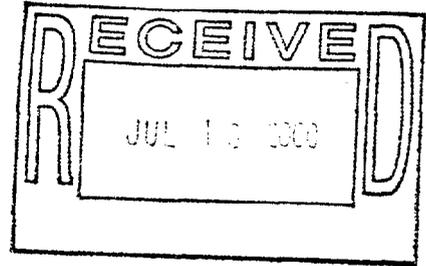
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DESERT LAKE TECHNOLOGIES, LLC.

June 30, 2000

Dr. Elizabeth Yetley, Ph.D.
FDA
Office of Special Nutrition
200 "C" Street, W.W.
Washington, DC 20204



Dear Dr. Yetley,

Please be advised that Desert Lake Technologies, LLC. intends to market a product containing a "Structure and Function" statement on the label. According to the notification requirements set forth by the DSHEA (Dietary Supplement Health and Education Act, 1994) legislation, please be advised of the following:

Name of Product: Summa™

Active Ingredient(s): Blue-green algae (*Aphanizomenon flos-aquae*)

Claim(s): "*Aphanizomenon flos-aquae* contains a bounty of vital nutrients to help nourish and protect the body."
"*Aphanizomenon flos-aquae* stimulates the immune system and may help maintain a healthy cholesterol level."

The following disclaimer appears on the label: These statements have not been evaluated by the Food & Drug Administration. This product is not intended to diagnose, treat, cure or prevent disease.

These claims are limited to, and a result of, what we believe to be a substantial body of scientific evidence supporting the functional role of *Aphanizomenon flos-aquae* or the nutrients it naturally contains. A compendium of relative published research substantiating the above statement(s) is on file at the corporate office.

Respectfully submitted,

Christian Drapeau
Director of Research and Development

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Prototype of intended label.

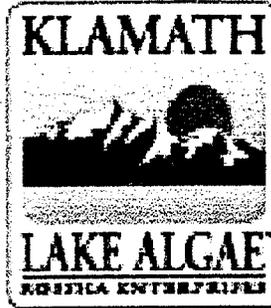
Klamath Lake Algae™ (*Aphanizomenon flos-aquae*) grows naturally in the deep water of Klamath Lake, Oregon. It contains a bounty of vital nutrients to help nourish and protect the body, stimulate the immune system, and it may help maintain a healthy cholesterol level*. Our unique harvesting methods in combination with our proprietary drying process preserve the integrity of the phytonutrients naturally present in the blue-green algae, which includes carotenoids, chlorophyll, omega-3 fatty acids, polysaccharides and phycocyanin.

Contains No Sugar, No Artificial Colors, No Artificial Flavors, No Soy, No Dairy, No Yeast.

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

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A Division of
Desert Lake Technologies, LLC.
P.O. Box 489 Klamath Falls,
OR 97601
800-736-2379
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MADE IN USA

Made in U.S.A



SUMMA™
Blue Green Algae
250 mg 120 Tablets
DIETARY SUPPLEMENT

Supplement Facts

Serving Size 4 capsules
Servings Per Container 30

	Amount Per Serving	% Daily Value
Protein	600mg	<2%
Vitamin A (as carotenoids from algae)	616I.U.	12%
Vitamin K (from algae)	40mcg	50%

Blue-Green Algae Powder	1 g	*
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Percent Daily Values are based on a 2,000calorie diet.
*Daily Value not established.

Other Ingredients: Cellulose (Vegetarian Capsules).

SUGGESTED USE: As a dietary supplement, start by taking 1-2 tablets, 1 to 2 times daily, then slowly increase to 4 tablets, 1 to 2 times daily. Store in a cool, dry place.