



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

NOV 22 2000

0199 '00 DEC -7 P3:07

Berrilyn J. Branch
Senior Research Scientist
NatureSmart, Inc.
12777 Claude Court
Thornton, Colorado 80241

Dear Sir/Madam:

This is in response to your letter of October 20, 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 NatureSmart, Inc. is making the following claim, among others, for the product Fish Oil:

“...promote and manage healthy cholesterol levels.”

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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HEALTHSMART

VITAMINS

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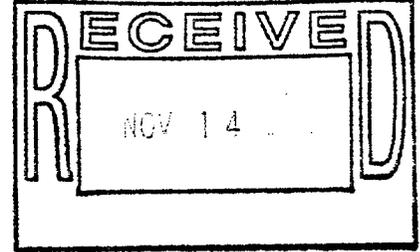
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October 20, 2000

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



NOTIFICATION OF STATEMENTS
OF NUTRITIONAL SUPPORT

This Notification is filed pursuant to § 403(r)(6) of the Federal Food Drug and Cosmetic Act (FDC Act), 21 U.S.C. § 343 (r)(6).

Name of dietary supplement: Fish Oil

Statement(s) of nutritional support:

Fish Oil helps to promote and manage healthy cholesterol levels.

The omega-3 fatty acids in fish oil help to maintain smooth blood flow.

The omega-3 acids in fish oil help to build healthy cell structures, including the protective myelin sheath surrounding nerve endings.

Fish Oil promotes healthy blood pressure by stimulation the production of prostaglandins, which help keep capillaries relaxed and open.

Prostaglandins produced with the aid of fish oil may help the body manage a healthy inflammatory response.

I certify that the information contained in this notice is complete and accurate, and that we have substantiation that the statement(s) is (are) truthful and not misleading. Two copies of this notification are enclosed with this original.

A handwritten signature in cursive script that reads "Berrilyn J. Branch".

Berrilyn J. Branch,
Senior Research Scientist
NatureSmart, Inc.

