



1529 E FEB 18 P2:43

NOV 28 2006

Ms. Nancy Blake  
Labeling & Compliance Officer  
Flora, Inc.  
P.O. Box 73  
Lynden, Washington 98264

Dear Ms. Blake:

This is in response to your letters of November 3, 2006 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 products **Vegetarian DHA Flax Oil** and **Udo's DHA Oil Blend** are using a claim about omega-3 fatty acids and a reduced risk of coronary heart disease. This statement is not a claim subject to 21 U.S.C. 343(r)(6), but a claim subject to 21 U.S.C. 343(r)(1)(B) because it represents that the product will reduce the risk of a disease or health related condition (i.e., coronary heart disease). FDA has issued letters defining the conditions in which it would exercise enforcement discretion with respect to the use of a qualified health claim for dietary supplements containing omega-3 fatty acids.<sup>1</sup> A dietary supplement that meets the eligibility and message requirements set forth in the enforcement discretion letters may bear a claim for the relationship between omega-3 fatty acids and coronary heart disease. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in the relevant enforcement discretion letters would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, failure to make a claim in accordance with the requirements in the applicable enforcement discretion letters subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, coronary heart disease.

<sup>1</sup>See letters regarding enforcement discretion with respect to use of qualified health claims about reduced risk of coronary heart disease;  
<http://www.cfsan.fda.gov/~dms/lab-qhc.html>.

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Please contact us if we may be of further assistance.

Sincerely yours,



Vasilios H. Frankos, Ph.D.  
Acting Director  
Division of Dietary Supplement Programs  
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-310  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, Seattle District Office, Office of Compliance, HFR-PA340



Quality Health From God's Pharmacy

November 3, 2006

RECEIVED  
11/15/06

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
200 C Street, S.W.  
Washington, D.C. 20204

Re: Structure/Function Label Claim

This letter is to notify the Food and Drug Administration that within the past 30 days our company has begun to market **Vegetarian DHA Flax Oil** Dietary Supplement, with the following statement(s) of nutritional support included on the label and in labeling for the product:

- a. Supports cognitive function, heart health, and eye health
- b. DHA is an omega-3 fatty acid that is essential for the proper functioning of our brains as adults, and for the development of our nervous system and visual abilities during the first six months of life.
- c. Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may help reduce the risk of coronary heart disease.

The dietary ingredients of the product that are the subject of the above statements are: Flax seed oil and unrefined DHA algae oil.

It is hereby certified that the information in this notification is complete and accurate, and that our company has substantiation that the above statement(s) is truthful and not misleading.

Very truly yours,

Flora, Inc.

Nancy Blake  
Labeling & Compliance Officer

#1813

06-8642

**Flora, Inc.**

Head Office: P.O. Box 73, Lynden, WA 98264 (360) 354-2110 (800) 446-2110 FAX (360) 354-5355 www.florahealth.com  
Eastern Branch: 62 Seaview Blvd., Port Washington, NY 11050

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Quality Health From God's Pharmacy

RECEIVED  
11/15/06

November 3, 2006

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
200 C Street, S.W.  
Washington, D.C. 20204

Re: Structure/Function Label Claim

This letter is to notify the Food and Drug Administration that within the past 30 days our company has begun to market **Udo's DHA Oil Blend™** Dietary Supplement, with the following statement(s) of nutritional support included on the label and in labeling for the product:

- a. Supports cognitive function, heart health, and eye health
- b. DHA is an omega-3 fatty acid that is essential for the proper functioning of our brains as adults, and for the development of our nervous system and visual abilities during the first six months of life.
- c. Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may help reduce the risk of coronary heart disease.

The dietary ingredients of the product that are the subject of the above statements are: Flax seed oil, sunflower seed oil, sesame seed oil, evening primrose oil, unrefined DHA algae oil, coconut oil, rice germ and bran oil, oat germ and bran oil.

It is hereby certified that the information in this notification is complete and accurate, and that our company has substantiation that the above statement(s) is truthful and not misleading.

Very truly yours,

Flora, Inc.

Nancy Blake  
Labeling & Compliance Officer

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**Flora, Inc.**

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