



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

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DEC 13 2006

Mr. Grant Carlson  
President and CEO  
Calgenex Corporation  
9950 Princess Avenue, Suite 320  
Tampa, Florida 33619

Dear Mr. Carlson:

This is in response to your letter of November 29, 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)). Your notice states that Calgenex Corp. is making the claim "Manage your cholesterol and triglycerides. A natural solution to help maintain blood lipid balance. Helps protect your heart."

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. Because the claim you are making for this product represents that the product is intended to affect blood cholesterol but does not also include a statement about it being intended to affect blood cholesterol that is already in the normal range, it is an implied disease claim.

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, or mitigate 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, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

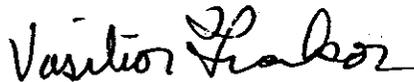
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A claim about omega-3 fatty acids and reduced risk of coronary heart disease is not a claim subject to 21 U.S.C. 343(r)(6), but a claim subject to 21 U.S.C. 343(r)(1)(B) because it represents that the product will reduce the risk of a disease or health 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.

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, Florida District Office, Office of Compliance, HFR-SE240

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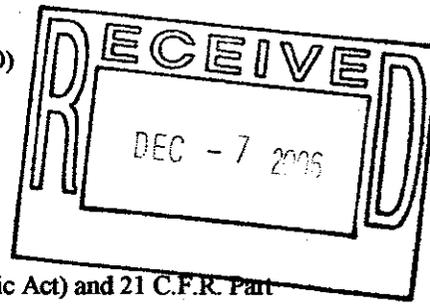
<sup>1</sup>See letters regarding enforcement discretion with respect to use of qualified health claims about reduced risk of coronary heart disease;  
<http://www.cfsan.fda.gov/~dms/lab-qhc.html>.

# CALGENEX

9950 Princess Palm Avenue, Suite 320 Tampa, Florida 33619 Ph:813-823-5268 Fx:813-823-5625 www.calgenex.com

November 29, 2006

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Pkwy  
College Park, MD 20740



In compliance with section 403(r)(6) of the Federal Food, Drug and Cosmetic Act) and 21 C.F.R. Part 101.93, this Notification is filed on behalf of the following distributor:

**CALGENEX CORPORATION**  
9950 Princess Palm Ave., Suite 320  
Tampa, FL 33619

**Product: Omeganol**

**Structure/function claims:** Manage your cholesterol and triglycerides.  
A natural solution to help maintain blood lipid balance.  
Helps protect your heart.

**Subject Ingredients:** Fish oil concentrate, d-alpha tocotrienol, d-beta tocotrienol, d-gamma tocotrienol, d-delta tocotrienol, d-alpha tocopherol.

This notification is submitted along with two copies of the original.

This notice is hereby signed below by a responsible individual by the person who can certify the accuracy of the information presented and contained in the notice. The individual certifies that the information contained in this notice is complete and accurate, and that CALGENEX CORPORATION has substantiation that the statement is truthful and not misleading.

Name (first and last) GRANT CARLSON

Title President & CEO

Signature [Handwritten Signature]

Date 11/28/2006

Enclosures

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