

VITAL NUTRIENTS

October 8, 2004

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

Re: Notification for Statement on Dietary Supplement Labels

Dear Sir/Madam:

This notification is being submitted on behalf of Vital Nutrients, Middletown, Connecticut, a distributor of dietary supplement products.

Pursuant to the requirements of Section 6 of the Dietary Supplement Health and Education Act of 1994, 21 U.S.C. § 343(r)(6), and in accordance with the authorized provisions of 21 CFR § 101.93(a), your Agency is hereby notified that Vital Nutrients has made statements of "nutritional support", as described in 21 U.S.C. § 343(r)(6)(A), for its dietary supplement(s) as follows:

[SEE ATTACHED LIST OF EACH SUPPLEMENT NAME AND
TEXT OF EACH STATEMENT BEING MADE]

As required, enclosed are two photocopies of this notification.

The undersigned certifies on behalf of Vital Nutrients that the information presented and contained in this correspondence is complete and accurate.

Sincerely yours,



Mitch Kennedy, ND
Consultant to Vital Nutrients
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VITAL NUTRIENTS STATEMENTS OF NUTRITIONAL SUPPORT

October 8, 2004

PRODUCT NAME: CONJUGATED LINOLEIC ACID (CLA)

PRODUCT STATEMENT:

Support for healthy metabolism of dietary fats and weight maintenance.

Conjugated linoleic acid (CLA) is a slightly altered form of the essential fatty acid linoleic acid. CLA is found in highest concentrations in dairy products and also in beef and poultry, eggs, and corn oil. CLA helps maintain optimal weight in physically active people. CLA maintains cholesterol levels that are already within the normal range in healthy people.

PRODUCT NAME: BLOOD SUGAR SUPPORT

PRODUCT STATEMENT:

Support for maintaining blood sugar levels already in the normal range in healthy individuals.

This product contains a synergistic blend of seven ingredients to provide support for optimal pancreatic function. American Ginseng, a well known adaptogenic herb provides support in extending cortisol levels in healthy individuals. Holy Basil and Gymnema sylvestre has been used for centuries in Ayurvedic medicine for similar purposes. Chromium assists with the maintenance of lean muscle mass in healthy individuals. Used in Asia for a variety of purposes, Cinnamon may have a beneficial effect in the maintenance of blood sugar levels that are already in the normal range in healthy people.

PRODUCT NAME: POLICOSANOL

PRODUCT STATEMENT:

Supports healthy lipid metabolism

Policosanols are mixtures of long chain alcohols extracted from sugar cane wax. Through an as yet unknown mechanism, policosanols support cardiovascular health, platelet function and the metabolism and use of fatty acids in healthy people.