DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

APR - 2 2003

Ms. Paula Turner
Label Regulations
Young Living Essential Oils
250 South Main Street
Payson, Utah 84651

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Dear Ms. Turner:

This is in response to your letter of March 12, 2003 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 product **Super B** is using the claim "As part of a well-balanced diet that is low in saturated fat and cholesterol, folic acid, vitamin B6 and vitamin B12 may reduce the risk of vascular disease. FDA evaluated this claim and found that, while it is known that diets low in saturated fat and cholesterol reduce the risk of heart disease and other vascular diseases, the evidence in support this claim is inconclusive." 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 implies that the product will prevent a disease (i.e., vascular disease). In a November 28, 2000 letter, we stated that we had re-evaluated a proposed qualified health claim "As part of a well-balanced diet, rich in fresh fruits and vegetables, daily intake of at least 400 µg folic acid, 3 mg vitamin B_6 and 5 µg vitamin B_{12} may reduce the risk of vascular disease" in response to the court decision directing the FDA to consider qualified health claims for dietary supplement labeling (*Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999)) when the evidence in support of the claim does not meet the significant scientific agreement standard. Our conclusion was that FDA would exercise its enforcement discretion, under certain conditions (November 28 letter, at 25-36), for a qualified claim that contained four elements (*id.* at 33-34). The model claim (*id.* at 33) that we gave as an example of an appropriately qualified claim was:

> It is known that diets low in saturated fat and cholesterol may reduce the risk of heart disease. The scientific evidence about whether folic acid, vitamin B_6 and vitamin B_{12} may also reduce the risk of heart disease and other vascular diseases is suggestive, but not conclusive. Studies in the general population have generally found that these vitamins lower homocysteine, an amino acid found in the blood. It is not known whether elevated levels of homocysteine may cause vascular disease or whether high homocysteine levels are caused by other factors. Studies that will directly evaluate whether reducing homocysteine may also reduce the risk of vascular disease are not yet complete.

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FDA announced on May 15, 2001 that it intended to exercise enforcement discretion to permit dietary supplements labels and labeling to bear a qualified health claim about the relationship between B vitamins and vascular disease; this announcement clarified further the model claim and disclaimer that the agency believed to be appropriate. FDA stated that it would exercise its enforcement discretion for a qualified claim about the relationship between B vitamins and vascular disease for claims and products that complied with the conditions set forth in its letters on the matter dated November 28, 2000 and February 9, 2001. Copies of these letters can be found on FDA's web site at: http://www.cfsan.fda.gov/~dms/ds-labl.html.

A dietary supplement bearing a claim that is not properly qualified or consistent with the weight of the evidence is subject to regulatory action as a misbranded food under section 403(r)(1)(B) of the Act, a misbranded drug under section 502(f)(1), and as an unapproved new drug under section 505(a).

Please contact us if we may be of further assistance.

Sincerely,

for Robert J. Moore

Susan J. Walker, M.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-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, Denver District Office, Office of Compliance, HFR-SW240

March 12, 2003

Young Living ESSENTIAL OILS™

Office of Nutritional Products,
Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
200 C. Street S.W.
Washington, D.C. 20204

Re: Notification for Statements on Dietary Supplement Labeling

Dear Sir/Madam:

This notification is being submitted on behalf of Young Living Essential Oils, Payson, Utah, a distributor of dietary supplement products (hereafter "Young Living").

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 Young Living proposes to make and/or has made statements of "nutritional support", as described in 21 U.S.C. § 343 (r) (6) (A), for its dietary supplements as follows:

Product Name	Statement(s)
Super B	Supports a positive outlook and healthy energy levels. This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease. As part of a well-balanced diet that is low in saturated fat and cholesterol, folic acid, vitamin B6 and vitamin B12 may reduce the risk of vascular disease. FDA evaluated this claim and found that, while it is known that diets low in saturated fat and cholesterol reduce the risk of heart disease and other vascular diseases, the evidence in support of this claim is inconclusive.

The undersigned certifies on behalf of Young Living Essential Oils that the information presented and contained in this correspondence is complete and accurate.

Sincerely yours,

Paula Turner

Paula Turner, Label Regulations

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