DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

MAY - 2 2003

2756 '03 MAY 28 P2:34

Mr. Tom Cleland
President
Indiana Botanic Gardens, Inc.
3401 West 37th Avenue
Hobart, Indiana 46342

Dear Mr. Cleland:

This is in response to your letter of April 8, 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 **Folic Acid Tablets** is using the claim "Folic acid is needed to keep homocysteine levels in balance. Excess homocysteine has been linked to an increased risk of 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 implies that the product will prevent a disease (i.e., heart 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.

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

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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 eligible to use the claim (for example, it does not contain the B vitamins which the qualified claim is the subject of) or 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).

The product **Folic Acid Tablets** is using the claim "Folic acid early in pregnancy is important to prevent most neural tube birth defects and protect against some birth defects of the arms, legs, and heart." This statement is not a statement of nutritional support subject to 21 U.S.C. 343(r)(6), but a health claim subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized a health claim on the relationship between folate and neural tube defects (see 21 CFR 101.79). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between folate and neural tube defects. A health claim for folate and neural tube defects on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.79 would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, making a claim that is not in accordance with the requirements in 21 CFR 101.79 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, neural tube defects.

Please contact us if we may be of further assistance.

Sincerely yours,

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
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NOTIFICATION PURSUANT TO SECTION 6 OF DSHEA AND 21 CFR § 101.93

This notification is being filed on behalf of Indiana Botanic Gardens, Inc., which is the distributor of the product which bears the statements in this notification. Its business address is: 3401 West 37th Avenue, Hobart, IN 46342. This notification is being made pursuant to Section 6 of the DSHEA and Rule 21 CFR § 101.93. The dietary supplement product on whose labeling the statements appear is Folic Acid Tablets.

The text of each structure-function statement for Folic Acid Tablets for which notification is now being given is:

Did you know?

(statement 1): Folic acid is needed to keep homocysteine levels in balance. Excess homocysteine has been linked to an increased risk of heart disease.

(statement 2): Folic acid early in pregnancy is important to prevent most neural tube birth defects and protect against some birth defects of the arms, legs, and heart?

The following identifies the brand name of each supplement for which a statement is made:

Statement Number	Brand Name	Label or Labeling?
1	Botanic Choice (Folic Acid Tablets)	labeling
2	Botanic Choice (Folic Acid Tablets)	labeling

I, Tim Cleland, am authorized to certify this notification on behalf of Indiana Botanic Gardens, Inc. I certify that the information presented and contained in this notification is complete and accurate, and that Indiana Botanic Gardens, Inc., has substantiation that each structure- function claim is truthful and not misleading.

Tim Cleland, President

04/08/03
Date signed

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