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FEB 10 2006

Mr. Neal D. Fortin, Esq.
Law Office of Neal D. Fortin
P.O. Box 230
Okemos, Michigan 48805

Dear Mr. Fortin:

This is in response to your letter of January 24, 2006, on behalf of your clients Brownwood Acres Foods, Inc./Flavonoid Sciences, 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 submission states that Brownwood Acres Foods, Inc./Flavonoid Sciences¹ is making the following claims, among others, for the product **Concord Grape Juice Concentrate**:

“Helps maintain healthy blood pressure levels.”
“Resveratrol...to lower cholesterol.”

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. The same principle applies to claims about the control of blood pressure; that is, a claim that does not establish that the claims are about blood pressures that are already within normal limits implies that the product is intended to treat elevated blood pressure (hypertension), which is a disease. The agency further stated in the preamble to the final rule that claims about lowering blood cholesterol would be treated as disease claims. Therefore, because the claims you are making for this product represent that the product is intended to affect blood pressure and blood cholesterol but do not also include a statement about them being intended to affect blood pressure and blood cholesterol that are already in the normal ranges, they are disease claims.

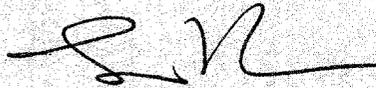
¹P.O. Box 486, 4819 U.S. 31, Eastport, Michigan 49627.

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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 statements that you are making for this product suggest that it is intended to treat, prevent, or mitigate diseases, such as hypertension and hypercholesterolemia. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest 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 20852.

Please contact us if we may be of further assistance.

Sincerely yours,



Susan J. Walker, M.D.
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, Detroit District Office, Office of Compliance, HFR-CE740

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January 24, 2006

2006-723

Office of Nutritional Products,
Labeling, and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

To the Food and Drug Administration:

Subject: Notification of Nutritional Support Statements

Pursuant to section 403(r)(6) for the Federal Food, Drug, and Cosmetic Act (FD&C Act), we hereby notify the U.S. Food and Drug Administration (FDA) that and Brownwood Acres Foods, Inc / Flavonoid Sciences have included the following statements in labeling for its Concord Grape Juice Concentrate that it manufactures and markets.

Name and address of the manufacturer

Brownwood Acres Foods, Inc., and Flavonoid Sciences, P.O. Box 486, 4819 U.S. 31, Eastport, MI 49627.

Product

Concord Grape Juice Concentrate

Statements

- May improve short term memory.
- Improves Short Term Memory and supports healthy brain function.
- The brain benefits of grape juice come from its flavonoids, natural plant chemicals that act as antioxidants.
- Supports healthy cardiovascular function.
- Helps maintain healthy blood pressure levels.
- Contributes to good health by helping to maintain cardiovascular function.
- Contains resveratrol, proanthocyanidins and polyphenols.
- Contains proanthocyanidins to maintain healthy heart function.
- Contains flavonoids, resveratrol, proanthocyanidins and polyphenols.

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- Concord Grapes are particularly rich in proanthocyanidins, one of the heart-healthiest of flavonoids.
- Resveratrol—the heart healthy compound found in wine and thought to lower cholesterol—is also found in Concord Grape Juice.

Disclaimer

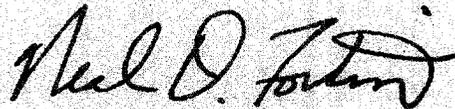
These statements prominently bear the disclaimer: “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.”

Certification

Please be advised that Flavonoid Sciences and Brownwood Acres Foods, Inc., possess substantiation that the statements are truthful and not misleading and certify that the information contained in this notice is complete and accurate.

If you have any questions, please do not hesitate to contact me.

Sincerely,



Neal D. Fortin
Representing Brownwood Acres Foods, Inc.
and Flavonoid Sciences

cc: Bob Underwood, Flavonoid Sciences
Stephen de Tar, President, Brownwood Acres Foods, Inc.