



MAY -3 2006

Ms. Laurie Davis
Director of Analytical Research
and Application Sciences
Davisco Foods International, Inc.
620 North Main Street
Le Sueur, Minnesota 56058

Dear Ms. Davis:

This is in response to your letter of April 18, 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 submission states that Davisco Foods International, Inc. is making the following claims for the product BioZate 1:

“[P]romotes healthy blood pressure”
“[S]upports healthy cholesterol levels.”

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 pressure that is already within normal limits implies that the product is intended to treat elevated blood pressure (hypertension), which is a disease. 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 implied disease claims.

Your submission also states that BioZate 1 “[P]romotes healthy levels of C-Reactive Protein” and that “[H]igh CRP levels may be a better predictor of heart attacks than cholesterol levels.”

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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. 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 you require 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, Minneapolis District Compliance, HFR-CE840



DAVISCO
FOODS INTERNATIONAL, INC.*



AIMS
2006-3663

APR 24 2006

April 18, 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

To Whom It May Concern:

This letter serves as notification of the marketing of a dietary supplement containing structure/function claims. Detailed information is listed below, as required per 21 CFR Part 101.93.

Dietary Supplement:

BioZate 1 – instant hydrolyzed whey protein supplement

Claims:

- BioZate 1 promotes healthy blood pressure.*
- BioZate 1 supports healthy cholesterol levels.*
- BioZate 1 promotes healthy levels of C-Reactive Protein.*
- BioZate 1 contributes protein to the diet, which may increase the body's metabolic rate and nutrient balance. A higher protein diet may contribute to body fat losses.*
- According to recent research, high CRP levels may be a better predictor of heart attacks than cholesterol 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.

Other Disclaimers:

Notice: Use this product as a food supplement only. Do not use as a meal replacement for weight reduction.

Not intended for children under 4 years of age.

It is recommended that before starting any new supplementation, you first consult your health care professional.

Davisco Foods International, Inc.
620 North Main, Le Sueur, MN 56058
PHONE 507-665-8861 FAX 507-665-8869
www.DaviscoFoods.com

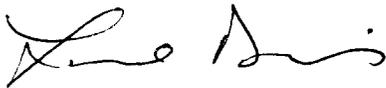
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Distributor:

Davisco Foods International, Inc.
620 North Main St.
Le Sueur, MN 56058

The information contained in this notice is complete and accurate, and Davisco Foods International, Inc. has substantiation that the statements are truthful and not misleading.

Regards,

A handwritten signature in cursive script, appearing to read "Laurie Davis".

Laurie Davis
Director of Analytical Research and Application Sciences