



FEB - 4 2005

President
B2 Marketing Group, LLC
1259 E. Hickenlooper Way
Draper, Utah 84020

Dear Sir:

This is in response to your letters of January 12, 2005 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 letter states that the following statement will be made for the product Cortisol Control FX™: "Supports healthy blood sugar 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 a claim about the control of blood sugar level; that is, a claim that does not establish that the claim is about blood sugar level that is already within normal limits implies that the product is intended to treat elevated blood sugar levels (diabetes), which is a disease. Therefore, because the claim you are making for this product represents that the product is intended to affect blood sugar levels but does not also include a statement about it being intended to affect blood sugar levels that are already in the normal ranges, it is an implied disease claim.

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 statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate a disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests 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 20855.

975-0163

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Please contact us if we may be of further assistance.

Sincerely yours,



FOR

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, Denver District Office, Office of Compliance, HFR-SW240

- NOTIFICATION -

DIETARY SUPPLEMENT NUTRITIONAL SUPPORT STATEMENT

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutritionals
Food and Drug Administration
200 C Street, S.W.
Washington D.C. 20204

JAN 27 2005

Manufacturer/Packer/Distributor Name and Address:

B2 Marketing Group, LLC.
1259 E. Hickenlooper Way
Draper, Utah. 84020

Dietary Supplement Name:

Cortisol Control FX™

Dietary Ingredient:

L-Theanine
Ginseng Extract
Green Tea Extract
Cinnamon
Alpha Lipoic Acid
Vanadium

Support Statement Text:

"Reduces your body's response to stress"
"May enhance mental and physical performance"
"Promotes fat metabolism and thermogenesis, may help you manage appetite and food cravings"
"Supports healthy blood sugar levels"

I hereby certify that the information presented and contained in this notice is complete and accurate. I also certify that B2 Marketing Group, LLC has substantiation to verify that the statements listed above are truthful and not misleading.



1-12-05

Signature, Date.

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