



SEP 29 2004

Ms. Amy M. Abedi
Technical Nutrition Specialist
Anabolic Laboratories, Inc.
26021 Commercecentre Drive
Lake Forest, California 92630

Dear Ms. Abedi:

This is in response to your letter of June 30, 2004 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 **Alpha-Lipoic Acid 300 mg Capsules**:

“Supports healthy blood sugar.”

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 glucose levels; that is, a claim that does not establish that the claim is about blood glucose levels that are already within normal limits implies that the product is intended to treat elevated blood glucose (diabetes), which is a disease. Therefore, because the claim you are making for this product represents that the product is intended to affect blood glucose but does not also include a statement about it being intended to affect blood glucose levels that are already in the normal range, 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 disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this

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LGT 782

Page 2 - Ms. Amy M. Abedi

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.

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'SJK', with a long horizontal flourish extending to the right.

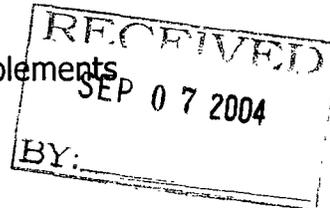
Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

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, Los Angeles District Office, Office of Compliance, HFR-PA240

June 30, 2004

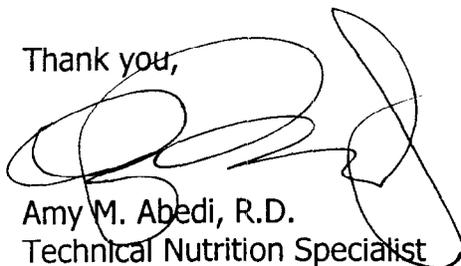
Christine L. Taylor, Ph.D.
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food & Drug Administration
200 C Street SW
(HFS-450)
Washington, D.C. 20204



Dear Dr. Taylor:

This letter is to notify you, as per section 6 of the Dietary Supplement Health and Education Act of 1994 (DSHEA), that Anabolic Laboratories, Inc. is offering for sale Alpha-Lipoic Acid 300 mg Capsules, as a dietary supplement. It contains the following structure/function statement: "Supports Healthy Blood Sugar." This will be sold as a private label product and the label contains the proper disclaimer as well.

Thank you,



Amy M. Abedi, R.D.
Technical Nutrition Specialist

8/9/88