



DEPARTMENT OF HEALTH & HUMAN SERVICES

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New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11430

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

October 30, 2000

Claus Gehringer
President
Abkit, Inc.
207 East 94th Street
New York, New York 10128

Ref: NYK-2001-12

Dear Dr. Gehringer:

This letter is in reference to your firm's product "alpha betic Multi-Vitamin Supplement with Alpha Lipoic Acid", which is being marketed and distributed as "formulated especially for people with diabetes." This claim goes beyond a claim allowed under the Dietary Supplement Health and Education Act and evidences intended use to treat/mitigate diabetes by targeting a specific patient population, in this case diabetics.

The promotional literature (labeling) for the product includes such claims as "...recommends this multi-vitamin to his diabetic patients...demonstrated a unique ability to promote glucose tolerance...formulated especially for people with diabetes...move glucose along its path...this kind of destruction ["free radicals"] may affect your long term health and if you're diabetic, you're even more susceptible to free radical attack...".

Based on the claims made for this product and the targeted patient population, "alpha betic Multi-Vitamin Supplement with Alpha Lipoic Acid" is a drug [Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act)] and a new drug [Section 201(p) of the Act]. Therefore, it may not be marketed in the United States without an approved new drug application [Section 505 of the Act].

This drug is also misbranded [Section 502(f)(1) of the Act] because its labeling fails to bear adequate directions for use. In addition, the labeling is false and misleading because it suggests that the product is safe and effective for its intended uses when, in fact, this has not been established [Section 502(a) of the Act].

This letter is not intended be an all-inclusive review of all of the claims made in your labeling and promotional literature for your product. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and implementing regulations.

Abkit, Inc.
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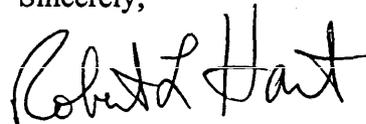
In addition, we are aware that your Internet website, www.alphabetic.com, makes claims similar to those cited above.

We request that you take prompt action to correct these violations. Failure to do so may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please respond to this office in writing within fifteen (15) working days of receipt of this letter. Your response should describe the specific actions you will take, or have taken, to correct the violations. Your response should also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed.

You should send your reply to the Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, NY 11433, Attention: Laurence D. Daurio, Compliance Officer. If you have any questions regarding the content of this letter, Mr. Daurio can be reached at (718) 340-7000, ext. 5585.

Sincerely,



Robert L. Hart
Acting District Director

cc:

