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San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

Our Reference: 2910775

May 30, 2000

Robert E. Brassfield, Chairman of the Board
Golden Neo-Life Diamite International, Inc.
3500 Gateway Blvd.
Fremont, CA 94538

WARNING LETTER

Dear Mr. Brassfield:

The U.S. Food and Drug Administration (FDA) has reviewed the labels of two dietary supplements: (1) Omega III Salmon Oil Dietary Supplement and (2) Liver Plus C Dietary Supplement, which were collected by Investigator Helen J. Hamaoka during her inspection of your firm on March 28, 2000. Our review reveals that the labels cause the above two products to be in violation of section 403 of the Federal Food, Drug, and Cosmetic Act (the Act), and Title 21, Code of Federal Regulations (21 CFR), Part 101- Food Labeling, as follows:

OMEGA III SALMON OIL DIETARY SUPPLEMENT:

1. The product is misbranded within the meaning of sections 403(i)(1) and 403(s)(2)(B) of the Act in that "DIETARY SUPPLEMENT" in the product identity is not as prominent and conspicuous as "OMEGA III SALMON OIL," and its placement is so far removed from "OMEGA III SALMON OIL" that it can easily be misinterpreted as not part of the product identity (21 CFR 101.3(d) and 21 CFR 101.3(g)).
2. The product is misbranded within the meaning of section 403(r)(1)(A) of the Act in that the label bears the nutrient content claim, "Naturally High in EPA and DHA," which has not been authorized by FDA regulation or on the basis of an authoritative statement under section 403(r)(2)(G) of the Act (21 CFR 101.54(a)(1), 21 CFR 101.54(a)(2), 21 CFR 101.54(a)(3), and 21 CFR 101.54(b)(1)).
3. The product is misbranded within the meaning of section 403(i)(2) of the Act in that the ingredients, d-alpha tocopherol and soybean oil (declared in the bulk label of the softgels from Banner Pharmacaps) are not declared in the ingredient statement (21 CFR 101.4).
4. The product is misbranded within the meaning of section 403(a)(1) of the Act in that the statement, "Pure Concentrated Salmon Oil," is false and misleading because the product also contains gelatin, glycerin, water, d-alpha tocopherol and soybean oil.

LIVER PLUS C DIETARY SUPPLEMENT:

1. The product is misbranded within the meaning of sections 403(i)(1) and 403(s)(2)(B) of the Act in that "DIETARY SUPPLEMENT" in the product identity is not as prominent and conspicuous as "LIVER PLUS C," and its placement is so far removed from "LIVER PLUS C" that it can easily be misinterpreted as not part of the product identity (21 CFR 101.3(d) and 21 CFR 101.3(g)).
2. The product is misbranded within the meaning of 403(r)(1)(A) of the Act in that the Supplement Facts panel does not list the mandatory (b)(2) nutrients to which the label refers describing liver as a rich source of protein, B-Complex vitamins (especially B-12), iron, chromium, magnesium, copper, selenium, and potassium (21 CFR 101.36(b)(2)). Also, it cannot be ascertained from the label if the nutrients are present at 20% or more of the established Reference Daily Intake (RDI) or the Daily Reference Value (DRV) to qualify for the nutrient content claim, "rich in" (21 CFR 101.54(a)(1), 21 CFR 101.54(a)(2), 21 CFR 101.54(a)(3), and 21 CFR 101.54(b)(1)).

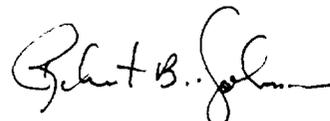
Most of the above violations concern certain new labeling requirements. The above violations are not meant to be an all-inclusive list of deficiencies on your labels. Other label violations can subject the dietary supplements to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes and regulations enforced by FDA.

You should take prompt measures to correct the violations. Failure to promptly correct these violations may result in regulatory action without further notice. Such action includes seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 days, state the reasons for the delay and the time at which the corrections will be completed.

Your reply should be directed to Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda 94502-7070. If you have any questions concerning the violations noted, then please contact Ms. Kishida at (510) 337-6824.

Sincerely,



Robert B. Johnson
Acting District Director

cc: John E. Seibert, Vice President of Legal Services & Chief Financial Officer
Golden Neo-Life Diamite International, Inc.
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