DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-09-05

January 9, 2009

Alan Cohen
South Beach Supplements
18205 Biscayne Blvd Suite 2213
Aventura, FL 33180

Dear Mr. Cohen:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your website at the Internet address www.glycogone.com and has determined that the product "Glycogone Diabetic Formula" is promoted for conditions that cause the product to be a drug under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B)]. The therapeutic claims on your website establish that the product is a drug because it is intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of this product with these claims violates the Act.

Examples of some of the claims observed on your web site include:

- "Controlling diabetes naturally with GLYCOGONE™,,
- "GLYCOGONE™ is a non-prescription all natural supplement designed to control your blood sugar levels!"
- "GLYCOGONE™ is one of the most popular natural solutions for men and women of all ages worldwide who are battling Type 2 Diabetes! GLYCOGONE ™,s ingredients have also produced outstanding results in helping to: Reduce Obesity, Reduce High Cholesterol, Reduce Arteriosclerosis . . . ."
- "What Makes Glycogone UNIQUE . . . Reduce hypoglycemia"
- "GLYCOGONE™ is a natural treatment for diabetes"
- "GLYCOGONE™, along with a healthy diet and lifestyle, helps to lower blood sugar . . . ."
- "GLYCOGONE™ . . . works naturally affecting the body at a cellular level to reduce insulin resistance and assist with glucose regulation."
- " Aid to the conversion of bad LDL, reduce cardiac disease."
- "18 Amino acids . . . reduces anxiety and depression"
- "Vitamin E and C [antioxidants] E helps prevent blood clots and formation of fatty plaques on artery walls, helps counteract nerve damage associated with diabetes"
- "Vitamin B1, 2, 3 [lowers cholesterol, reduces dangerous effects of high blood sugar]"
- "Vitamin B12 works with folic acid to reduce risk of stroke and cancer"

- "Potassium to prevent impaired glucose tolerance and insulin secretion"

Your website also contains disease claims in the form of personal testimonials, including:

- "I have been a diabetic for over 20 years. I started using GLYCOGONE, four weeks ago . . . I have found my blood sugar numbers to be steadily improving from 171 to 158 to 137 to 131 and now they range between 91 to 97."
- "I have had amazing results in just 10 days with Glycogone. I have been on all kinds of medicines for my Diabetes for the last 23 years and have never seen such wonderful numbers on my meter. I have reduced the number of units of insulin I take as well as other meds since I am on this product."
- "In just 7 days of taking Glycogone my cholesteral [sic] numbers dropped by 30%."

Furthermore, the name of your product, "Glycogone Diabetic Formula," is a disease claim because it implies that the product is for use in the cure, mitigation, treatment, or prevention of diabetes.

These claims are supplemented by the metatags used to bring consumers to your website through Internet searches. Examples of these metatags include "diabetes," "Diabetes Control Program," "high blood sugar," "teens and high blood sugar," "type 1 diabetes," "type 2 diabetes," "controlling blood sugar levels," "diabetes medicines," "diabetic ketoacidosis," "treating high blood sugar," "diabetes emergencies," "hyperglycemic," and "preventing hyperglylcemia and dka."

Your product is not generally recognized as safe and effective for the above referenced uses and, therefore, the product is a "new drug" under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective. Your product "Glycogone Diabetic Formula" is also misbranded within the meaning of section 502(f)(1) of the Act in that labeling for this drug fails to bear adequate directions for use [21 U.S.C. § 352(f)(1)].

The above violations are not meant to be an all-inclusive list of deficiencies in your products and their labeling. It is your responsibility to ensure that products marketed by your firm comply with the Act and its implementing regulations. We advise you to review your website, product labels, and other labeling and promotional materials for your product to ensure that the claims you make for your products do not cause them to violate the Act.

You should take prompt action to correct these deviations and prevent their future recurrence. Failure to do so may result in enforcement action without further notice. The Act authorizes the seizure of illegal products and injunctions against manufacturers and distributors of those products [21 §§ U.S.C. 332 and 334].

Please notify this office, in writing, within fifteen (15) working days of the receipt of this letter, as to the specific steps you have taken to correct the violations noted above and to assure that similar violations do not occur. Include any documentation necessary to show that correction has been achieved. If corrective actions cannot be completed within fifteen

working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be directed to Shari H. Shambaugh, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have any questions regarding any issues in this letter, please contact Ms. Shambaugh at 407-475-4730.

Sincerely,

Emma R. Singleton
Director, Florida District