



Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

May 27, 2010

Telephone: 425-486-8788
FAX: 425-483-4996

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Dr. Leonard G. Horowitz
Healthy World Distributing, LLC
Healing Celebrations, LLC
217 Cedar Street, Suite #326
Sandpoint, Idaho 83864

Dear Dr. Horowitz:

We received your letter on May 19, 2010, written in response to Warning Letter SEA 10-22, dated May 11, 2010. We acknowledge that you have listed yourself as the Overseer and Managing Member for Healthy World Distributing, LLC, and also for Healing Celebrations, LLC.

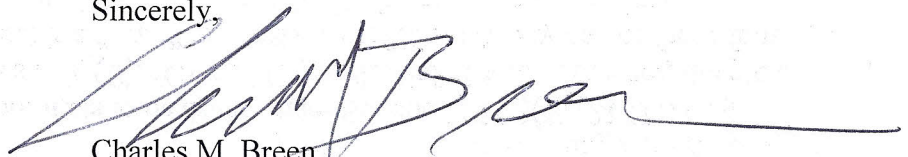
We find that your letter is unresponsive to the serious violations listed in the Warning Letter. You stated in your response that, for your products to be drugs under Section 201(g)(1) [21 U.S.C. § 321(g)(1)], they must satisfy subclauses (A), (B), (C), and (D) of the definition. However, the plain meaning of the statute is that the product is a “drug” under the Act if it meets any one of those four subclauses. Therefore, if your products are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, they meet the statutory definition of a drug under the Act.

The Warning Letter requested you to notify this office, in writing, within fifteen (15) working days of the receipt of the Warning Letter as to the specific steps you have taken to correct the violations listed in the Warning Letter and to include any documentation necessary to show that correction has been achieved. We advised you that if corrective actions could not be completed within fifteen working days, to state the reason for the delay and the time within which the corrections will be completed.

As stated in the Warning Letter, you should take prompt action to correct the violations listed in the Warning Letter and take steps to prevent their future recurrence. Failure to do so may result in enforcement action without further notice.

Your response should be directed to: Lisa Althar, Compliance Officer, U.S. Food and Drug Administration, 22201 23rd Drive SE, Bothell, Washington, 98021-4421.

Sincerely,



Charles M. Breen
District Director