



CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

**WARNING LETTER**

October 12, 2006

Enhansulin.com Corporation  
1005 Terminal Way  
Suite 110  
Reno, Nevada 89502

Dear Sir or Madam:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address <http://www.enhansulin.com> and has determined that the product Enhansulin® is promoted for conditions that cause this product to be a drug under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)]. The therapeutic claims on your web site establish that this 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:

Enhansulin®

- “Lower blood sugar and cholesterol levels naturally—with no side effects.”
- “For centuries the leaves of the Caucasian blueberry plant have been effectively used to manage the effects of diabetes. Now, thorough modern science, the benefits of this special plant have been made available in Enhansulin® brand Caucasian blueberry leaves extract.”
- “[H]elps lower their blood sugar, LDL cholesterol and triglyceride levels naturally, without side effects...”
- “In double-blind, placebo-controlled studies...Caucasian blueberry leaves extract was repeatedly shown to significantly reduce blood glucose levels.”
- “Borderline-diabetics can also get help managing their blood sugar naturally through the consumption of Caucasian blueberry leaves extract.”

Furthermore, these claims are supplemented by the metatags you use to bring consumers to your website. These metatags include “Lower your blood sugar, cholesterol, and triglyceride levels with Enhansulin, the natural diabetes remedy,” “Clinical Research Summary for Enhansulin-The Natural Diabetes Remedy,” and “Pre-Diabetes is a serious matter that deserves immediate attention. Enhansulin, a natural diabetes remedy, can help put you back in control of your life.”

Furthermore, your product is not generally recognized as safe and effective for the above referenced conditions and therefore, it is also 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.

This product is also misbranded within the meaning of Section 502(f)(1) of the Act, in that the 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. We noticed that you promoted other products for disease treatment and/or prevention. It is your responsibility to ensure that products marketed by your firm comply with the Act and its implementing regulations. We urge you to review your web site, product labels, and other labeling and promotional materials for your products to ensure that the claims you make for your products do not cause them to violate the Act.

Failure to promptly correct the violations specified above may result in enforcement action without further notice. Enforcement action may include seizure of violative products and/or injunction against the manufacturers and distributors of violative products.

Please advise this office in writing, within 15 working days of receipt of this letter, as to the specific steps you have taken or will be taking to correct these violations, including the steps taken to assure that similar violations do not recur. Include any documentation necessary to show that correction has been achieved. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Your reply should be sent to Quyen Tien, Compliance Officer, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Division of Enforcement (HFS-607), 5100 Paint Branch Parkway, College Park, Maryland 20740-3835.

Sincerely,

Joseph R. Baca  
Director  
Office of Compliance  
Center for Food Safety  
and Applied Nutrition