



## WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

October 12, 2006

HEE Corporation  
6209 N. K61 Highway  
Hutchinson, KS 67502

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.hpb84.net> and has determined that the product HPB-84 is promoted for conditions that cause the 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 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:

- “Now is the time for HPB-84! Are you suffering from diabetes? Do you have Metabolic syndrome? Have you been told you are pre-diabetic? Do you have insulin resistance? Do you suffer from sexual dysfunction? People using HPB-84 have ... had feeling restored to legs and feet, and reduced blood sugars.”
- “Q: How does HPB-84 work? A: Each of the ingredients works in different ways to lower blood glucose levels.”
- “Are the blood glucose lowering properties of HPB-84 proven? A: The product has shown positive results in the majority of test patients. There are also any number of articles and scientific reports explaining the blood glucose lowering properties of many of the ingredients.”
- “It is recommended that prior to using the HPB-84 you consult your physician. This is particularly important if you are currently taking any diabetic medications as experience has shown people may need to lower the amount of other diabetic medications as the blood glucose lowering effect of HPB-84 is manifested.”

Your web site also contains claims in the form of testimonials, including:

- “HPB-84 is a natural way of controlling my diabetes. I believe it enhances my pancreatic function and helps to reduce my blood sugar. “
- “After the first week I could already see huge improvement in my blood sugar levels. Two weeks into the treatment, I threw all my medications that I had been prescribed away, and decided to rely only on the product, HPB-84.”

Furthermore, your product is not generally recognized as safe and effective for the above referenced conditions and therefore, the product 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. Your product “HPB-84” 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)].

This letter is not intended to be an all-inclusive review of your web site and products your firm markets. While reviewing your web site, we noticed that you promote other products for disease treatment and/or prevention. It is your responsibility to ensure that all 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 addressed to Kristen Moe, Compliance Officer, Food and Drug Administration, Division of Compliance and Enforcement, 5100 Paint Branch Parkway, College Park, Maryland 20740-3835.

If you prefer to respond electronically, send your e-mail to [kristen.moe1@FDA.HHS.GOV](mailto:kristen.moe1@FDA.HHS.GOV).  
If you have any questions concerning this letter, please contact Ms. Moe at 301-436-2064.

Sincerely,

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