



CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

**WARNING LETTER**

October 12, 2006

Healing Edge Science  
7451 Warner Avenue  
Suite E169  
Huntington Beach, CA 92647

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.healingedge.net> and has determined that the products Pancreas Tonic 180, Grifon Maitake SX and Diabetan are promoted for conditions that cause these products to be drugs 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 these products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of these products with these claims violates the Act.

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

Pancreas Tonic 180

- “Pancreas Tonic herbs have been used for decades in helping the diabetic patient with their symptoms. . . .”
- As everybody responds to herbs in a unique way, there is no definite therapy timeline. However[,] Pancreas Tonic can be more effective if you take 2 tablets, 3 times/day as suggested continuously for 3-24s. As soon as your sugar level is normalized, then with your doctor’s advice begin reducing your prescription ‘gradually’ as indicated.”
- “There are a number of medical doctors starting to recommend Pancreas tonic to their diabetic patients in addition to their regular prescription after seeing some remarkable lowering of glucose levels with Pancreas Tonic treatment in some of their patients.”
- “Pancreas Tonic has been shown to help or minimize the complications of diabetes in patients with severe neuropathy.”
- “Pancreas Tonic exerts a potent hypoglycemic action to lower Elevated blood glucose levels.”
- “Clinical reports indicate that Pancreas Tonic may function by reducing insulin resistance, a major factor of Type 2 diabetes.”

- “HOW PANCREAS TONIC INGREDIENTS AFFECT DIABETES: \* \* \* Azardirachta Indica: \* \* \* Studies have shown that it decrease the blood sugar level and prevents adrenaline-induced hyperglycemia. . . . Ficus racemosa. . . has long been known . . . as a remedy for diabetes.”

#### Grifon Maitake Sx Fraction

- “[T]he treatment for the patients with Type II diabetes relies mainly on how to overcome insulin resistance. . . . Are there alternative (natural) means to overcome insulin resistance? Yes \* \* \* The good news is Maitake SX Fraction.”
- “The results show that SX Fraction does indeed possess a more potent ability to enhance insulin sensitivity for controlling blood sugar levels. . . .”
- “Short term use of SX-Fraction caused blood sugar to drop from 203 mg/dl to 171 mg/dl. \* \* \* Long-term use of the product caused blood sugar to drop from 196 mg/dl to 137 mg/dl.”
- “This is truly good news for those who suffer from Type II diabetes or for those who would like to prevent it.”
- “Maitake SX Fraction is a safe and very helpful in prevention and for those who suffer from “Syndrome X”, which includes Type II diabetes. . . .”

#### Diabetan

- “Diabetan is formulated to improve glucose metabolism and to normalize blood glucose levels in persons with prediabetes as well as Type-2 diabetes. Persons who have Type-1 diabetes and who are not well controlled may also benefit.”

Furthermore, your products are not generally recognized as safe and effective for the above referenced conditions and therefore, they are also “new drugs” 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.

These products are also misbranded within the meaning of Section 502(f)(1) of the Act, in that the labeling for these drugs fail 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