



CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

October 12, 2006

Sweet Sunnah Black Seed
17 Oberfest St.
P.O. Box 109
Liberty, NY 12754

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.sweetsunnah.com> and has determined that the product NyGymnema Herbal Blood Sugar Balance 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 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:

NyGymnema Herbal Blood Sugar Balance

- “[A] safe, effective and natural herbal formula to aid against diabetes. Our formula ... lowers cholesterol levels”
- “It has been used in India for treatment of diabetes for about 2000 years. Today in India it is being used to treat primarily type II diabetes and type I as well.”
- “The herb has shown to reduce blood sugar”

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. While reviewing your web site, 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 website, 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 ensure 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