



Food and Drug Administration
Center for Food Safety and
Applied Nutrition, HFS-607
5100 Paint Branch Parkway
College Park, MD 20740

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

November 9, 2005

Nutriteam, Inc.
404 Wagon Wheel Road
Ripton, VT 05766

Dear Sir/Madam:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address <http://www.nutriteam.com> and has determined that the product Soy Isoflavone Extract 250mg (120 caps) is promoted for conditions that cause the product to be a drug under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B)]. 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:

- “The benefits of soy go beyond reducing long-term cancer risk.”
- “Research suggests that soy isoflavones act...as cancer-enzyme inhibitors....”
- “[I]soflavones also acts as antiestrogens--and many researchers believe this is why they reduce the risk of breast and endometrial cancer.”
- “Isoflavones also reduce cancer risk by inhibiting the activity of tyrosine kinase, an enzyme that promotes cancer cell growth.”
- “[I]soflavones are also powerful antioxidants. Like other antioxidants,they can reduce the long-term risk of cancer by preventing free radical damage to deoxyribonucleic acid (DNA)....”
- “[D]aidzein [one of the soy isoflavones in the product] may reduce the risk of cancer by activating immune cells.”

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 Soy Isoflavones Extract 250mg is also misbranded within the meaning of section 502(f)(1) of the Act, in that the labeling for this drug fail to bear adequate directions for use [21 U.S.C. § 352(f)(1)].

This letter is not an all-inclusive review of your website and the products that your firm markets. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

The Act authorizes injunctions against manufacturers and distributors of illegal products and seizure of such products [21 U.S.C. §§ 332 and 334]. You should take prompt action to correct the violations identified in this letter and any other violations of the Act. Failure to do so may result in enforcement action without further notice.

Furthermore, you should be aware that laws enforced by the Federal Trade Commission (FTC) govern claims made in advertising, including print, broadcast, websites, and other electronic media. The FTC Act, 15 U.S.C. § 41 et seq., prohibits unfair or deceptive acts and practices, including false and unsubstantiated advertising claims. It is against the law to make health claims without substantiation or to overstate the health benefits of the products you promote. Be aware that product claims can be communicated to consumers in a variety of ways, including product name, website name, product testimonials, endorsements, or use of metatags.

Please advise this office, in writing, within fifteen (15) working days of the receipt of this letter, as to the specific steps you have taken to correct the violations noted above and to assure that similar violations do not occur. If corrective actions cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be addressed to Quyen Tien, Compliance Officer, at the above letterhead address.

Sincerely,

/s/

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