



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

ComCore 21 Corporation  
2169 NW 140 Ave.  
Pembroke Pines, FL 33028

Re: HealthCore21

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.healthcore21.com> and has determined that the product Soy Isoflavone Extract 40% (250mg) 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:

- “Soy Isoflavones may reduce ...cancer ... risk.”

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 Isoflavone Extract 40% (250mg) 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. 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