



**FEDERAL TRADE COMMISSION
BUREAU OF CONSUMER PROTECTION
DIVISION OF ENFORCEMENT
WASHINGTON, DC 20850**

VIA ELECTRONIC MAIL

TO: Internet advertiser of alternative hormone replacement therapy products

**RE: NOTICE OF POTENTIALLY ILLEGAL MARKETING OF
MENOPAUSE/HORMONAL PRODUCTS ON YOUR WEBSITE**

DATE: November 10, 2005

The Federal Trade Commission (FTC) staff has reviewed marketing claims on your website for hormone-related products, including dietary supplements and creams advertised as alternatives to hormone replacement therapy. We believe that some claims made on your website may be false or unsubstantiated and therefore, may violate the law.

The FTC Act¹ prohibits unfair or deceptive acts and practices, including false and unsubstantiated advertising claims. Under FTC law, advertisers must have a reasonable basis of support for all product claims **before disseminating an ad**. Be aware that product claims can be communicated to consumers in a variety of ways, including product name, website name, consumer testimonials, endorsements, or use of metatags. What constitutes a reasonable basis depends on what claims are being made, how they are presented in the context of the entire ad, and how they are qualified. According to FTC case law, health-related claims must be supported by **competent and reliable scientific evidence**. Note that consumer testimonials do **not** constitute adequate support for claiming that a product can prevent, cure, mitigate, or treat health conditions or diseases.

The FTC staff is not aware of any competent and reliable scientific evidence to support the following claims for creams containing plant-based hormones, such as [name of product]:

- **Prevents, treats, or cures cancer, heart disease, or other diseases.**
- **Prevents osteoporosis (bone loss) or increases bone density.**

¹ 15 U.S.C. § 41 *et seq.*

In addition, all other health claims, including claims about the safety of natural hormones, must be supported by reliable scientific evidence. Leading medical experts and organizations have said that research on plant-based hormone products is not sufficient to conclude that they are a “safe” alternative to conventional hormone replacement therapy.

The FTC staff has copied and preserved your online advertising. We strongly advise you to examine your website and other advertising and promotional materials. If they contain false, misleading, or unsubstantiated product claims, please delete or revise them immediately.

Violations of the FTC Act may result in cease and desist orders against you, civil penalties for violations of those orders, or federal court law enforcement actions seeking full refunds for your customers.

We strongly recommend that you review the following FTC business education materials and take steps to ensure that all of your marketing materials, including your website, comply with the FTC Act:

1. *Dietary Supplements: An Advertising Guide for Industry* at:
www.ftc.gov/bcp/online/pubs/buspubs/dietsupp.htm
2. *Frequently Asked Advertising Questions: A Guide for Small Business* at: _____
www.ftc.gov/bcp/online/pubs/buspubs/ad-faqs.htm

Please be advised that you must also comply with laws enforced by the Food and Drug Administration (FDA) that may apply to your product and the labeling claims you make for it. The Federal Food, Drug, and Cosmetic Act (FDCA) defines a drug, in part, as an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of a disease, or to affect the structure or any function of the body.² Drugs that are not generally recognized by qualified, scientific experts as safe and effective for the uses recommended or suggested in their labeling are considered to be new drugs.³ It is illegal to market a new drug in the U.S. without obtaining prior FDA approval.⁴ Violations of the FDCA may result in seizure of illegal products and/or an injunction against the manufacturers and distributors of those products. Remember that you are responsible for ensuring your compliance with both FDA and FTC laws.

If you have any questions, please contact us at hrtalternative@ftc.gov.

² 21 U.S.C. § 321(g).

³ 21 U.S.C. § 321(p).

⁴ 21 U.S.C. §§ 355 and 331(d).