

UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION BUREAU OF CONSUMER PROTECTION WASHINGTON, D.C. 20580

VIA ELECTRONIC MAIL

TO:	Internet Advertisers of Products Claiming to Affect Cortisol

FROM: Mary K. Engle M. K. Engle Associate Director Division of Advertising Practices

RE: Notice of Potential Illegal Marketing of Products that Claim to Cause Weight Loss, Reduce the Risk of Disease, or Produce Other Health Benefits by Affecting the Stress-Related Hormone Cortisol: IMMEDIATE ACTION REQUIRED

DATE: **October 1, 2004**

Federal Trade Commission staff has reviewed marketing claims on your website regarding a product that claims to produce health benefits by affecting the stress hormone cortisol. This letter places you on notice that any claim that a product affects cortisol and thereby causes weight loss (including rapid and significant weight loss; a specified amount of weight loss; weight loss specifically from the abdomen, stomach and thighs; or weight loss without the need for diet or exercise) or produces other health benefits (including reduced risk of serious health conditions such as cancer, diabetes, Alzheimers' disease, and cardiovascular disease) **must be supported by competent and reliable scientific evidence**. We are aware of no competent and reliable scientific evidence supporting such claims. Without such evidence, the claims are illegal under the Federal Trade Commission Act and **should be discontinued immediately**. Violations of the FTC Act may result in legal action, which may in turn require you to pay money back to consumers.

The FTC recently sued a group of companies and individuals in connection with the advertising and sale of two purported cortisol-affecting products. In that case, *FTC v. Window Rock Enterprises, Inc., Infinity Advertising, Inc., Stephen F. Cheng, Shawn M. Talbott, and Gregory S. Cynaumon,* No. 04-8190-DSF (C.D. Cal. filed Sept. 30, 2004), the FTC alleges that the defendants violated the FTC Act by claiming, falsely or without substantiation, that a product called CortiSlim causes weight loss of 10 to 50 pounds or more for virtually all users; that it causes users to lose as much as 4 to 10 pounds per week over multiple weeks; that it causes users to lose weight specifically from the abdomen, stomach, and thighs; that it causes rapid and substantial weight loss; that it causes long-term or permanent weight loss; and that the efficacy of CortiSlim and all its ingredients is demonstrated by over 15 years of scientific research. In addition, the FTC's complaint alleges that the defendants claim, falsely or without substantiation, that a second product – CortiStress – reduces the risk of or prevents conditions such as osteoporosis, obesity, diabetes, Alzheimers' disease, cancer, and cardiovascular disease. The FTC is seeking refunds for all consumers who purchased these products. The Commission and the Window Rock defendants also submitted a stipulated interim agreement that, with the court's approval, will become an order. Under that agreement, advertising for CortiSlim and CortiStress cannot make any of the claims alleged in the FTC's complaint. In addition, the Window Rock defendants agree to limit their future advertising

to claims that are supported by competent and reliable scientific evidence and agree not to misrepresent that their products are supported by scientific studies. Additional information, including copies of the complaint and the stipulated interim order, is available on the FTC's website, <u>www.ftc.gov</u>.

You are responsible for all claims, whether express or implied, that are made on your website and in other advertising. Please note that consumer testimonials constitute claims that your product will provide the advertised benefit; therefore, all testimonials must be supported by competent and reliable scientific evidence. We strongly urge you to review immediately all claims on your website and all other advertising and to delete or revise those claims as necessary to comply with the law.

You should also be aware that the FDA recently issued a warning letter advising Window Rock Enterprises that CortiSlim's labeling violates the Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Dietary Supplement Health and Education Act of 1994, by promoting unsubstantiated structure and function claims related to weight loss and that CortiSlim's cortisol-affecting claims are also unsubstantiated. Under the Act, dietary supplement products promoted with unsubstantiated claims about benefits are misbranded and illegal to sell. Consequently, misbranded products are subject to seizure and firms and/or individuals selling these products are subject to possible injunction as authorized by the Act. A copy of the FDA's warning letter is available on the FDA's website, <u>http://www.fda.gov/foi/warning_letters/g4945d.pdf</u>. You should also be aware that FDA law prohibits any labeling claims that a dietary supplement is intended to prevent, mitigate, treat, or cure cancer or any other disease. Such claims would cause the product to be a drug and would require that the product comply with the applicable drug requirements, including that the product be submitted for FDA approval as a new drug before it can be marketed.

The FTC staff strongly urges you to review all claims that you are making for your product. If your website or other advertising includes any express or implied claims about weight loss, disease prevention, or other health benefits that are not substantiated by competent and reliable scientific evidence or that are otherwise false or deceptive, you should discontinue these claims immediately.

FTC investigators have copied and preserved your website and other advertising materials and will revisit your website and re-review your online and other advertising materials soon.

Please notify us within seven (7) days of the specific actions that you have taken to address the FTC's concerns. Please send your notification to the FTC staff by email to <u>cortisol@ftc.gov</u>. Questions can be sent to that same email address.