BY LINDA A. GOLDSTEIN

FTC and FDA Target Products Claiming Cortisol Control

While there has been a change of administration at the Federal Trade Commission (FTC) with the departure of Chairman Timothy Muris and Bureau Director Howard Beales, the FTC's battle against marketers of dietary supplements, and weight-loss products in particular, does not appear to be waning.

On Oct. 5, 2004, the FTC filed a complaint against the marketers of CortiSlim and CortiStress, their principals and other related individuals for allegedly making false and unsubstantiated claims that their products can cause weight loss and reduce the risk of, or prevent, serious health conditions by reducing and regulating the levels of the stress hormone "cortisol." More specifically, according to the FTC's complaint, the marketers of CortiSlim promoted their product as "the answer" to weight loss. They allegedly claimed that persistently elevated levels of the stress hormone cortisol are the underlying cause of weight gain and weight retention and that by reducing and controlling cortisol levels, CortiSlim can cause substantial weight loss in all users. The product was heavily advertised on television, on radio and in print. The complaint also alleged that the defendants claimed that the effectiveness of the product was supported by over 15 years of scientific evidence on the ingredients and the product. According to the FTC, these claims were false and unsubstantiated.

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In the case of CortiStress, the FTC's complaint alleged that the defendants made false and unsubstantiated health claims. According to the complaint, the defendants claimed that persistent elevated levels of cortisol are the underlying cause of many diseases and health conditions, and that by reducing and regulating the levels of cortisol, the product can reduce the risk of, or prevent, diseases such as osteoporosis, diabetes, Alzheimer's disease, cancer and cardiovascular disease. Again, according to the FTC, none of these claims were properly substantiated.

FDA AND FTC ACTIONS

The parties have entered into an Interim Order, which prohibits them from making false and unsubstantiated product claims in the future. As is common in cases of this type, the FTC will also seek monetary redress for consumers.

While at first blush this case might appear to be simply more of the same from the FTC, there are two interesting aspects to this case that may be indicative of some new regulatory and enforcement trends.

First, this case highlights the increased involvement and scrutiny by the Food and Drug Administration (FDA) over the claims being made in the marketing of dietary supplements. The marketing of dietary supplements is subject to the concurrent jurisdiction of the FTC and the Food and Drug Administration (FDA). The marketing of dietary supplements is principally regulated by the FDA under DSHEA—the Dietary Supplement Health and Education Act of 1994 (Pub. L. No. 103-417, 108 Stat. 4325 (1994)). Under Section 6 of DSHEA (codified at 21 U.S.C. § 343(r)(6)), marketers can make structure/function claims for dietary supplements; however, the law prohibits any labeling claims that a dietary supplement is

intended to prevent, mitigate, treat or cure cancer or any other disease. Many marketers are under the erroneous assumption that as long as their claims for the product are limited to permissible structure/function claims, the FDA will not get involved in the claims being made. Similarly, many marketers are also under the erroneous assumption that as long as the nature of the claims being made for the product do not violate DSHEA, the FTC will not take any action against the claims.

Both assumptions are incorrect, as highlighted by this case. Even if a claim is a permissible structure/function claim under DSHEA, the advertiser still has an independent obligation to substantiate any claims made about the efficacy or benefits of the product with competent and reliable scientific evidence. Failure to properly substantiate the product efficacy claims can expose the marketer to challenge by the FTC for making false and unsubstantiated product claims in violation of Section 5 of the Federal Trade Commission Act, and to challenge by the FDA on the grounds that the product is "misbranded."

PRODUCT MISBRANDING OR LABELING

While historically the FTC, rather than the FDA, has exerted primary jurisdiction over false and unsubstantiated claims made for dietary supplements, in instances where those claims also appear on the labeling and in sales promotional material, the FDA can and has asserted jurisdiction as well. In this case, the FDA apparently sent a warning letter to the marketers of CortiSlim about claims appearing on the label stating that the product eliminates cravings, controls appetite and burns calories more effectively and naturally through thermo genesis. The FDA letter warned that because these and other claims appearing on the label were unsubstantiated, the product was misbranded in violation of the Food, Drug and Cosmetic Act.

If a product is deemed to be misbranded by the FDA, the FDA has the authority to seize the product and to obtain injunctive relief. The increased involvement of the FDA in this area is thus a reminder to marketers of dietary supplements that both FTC and FDA requirements must be considered when developing advertising and marketing claims for the product. Failure to properly substantiate claims can potentially lead not only to FTC action and monetary penalties, but also to the added threat of product seizure and FDA action. Marketers should be aware that the FTC has sent warning letters to approximately 25 other marketers of cortisol products. The FTC letter warns marketers that "any claim that a product affects cortisol and thereby causes weight loss or produces other health benefits must be supported by competent and reliable scientific evidence." The letter goes on to state that the FTC is "aware of no competent and reliable scientific evidence substantiating such claims." The FTC letter also warns marketers that dietary supplement products promoted with unsubstantiated claims about product benefits are misbranded.

Interestingly, it does not appear that an FDA warning letter had been previously sent to the marketers of CortiStress, which was making disease prevention and cure claims for the product. The FTC's warning letter sent to other marketers of cortisol products, however, does remind these marketers that federal law prohibits any labeling claims that a dietary supplement is intended to prevent, mitigate, treat or cure cancer or any other disease and that such claims, if made on the labeling of the product, would cause the product to be a drug and require that it be submitted to the FDA for approval.

In addition to challenging the allegedly false and unsubstantiated product efficacy claims, the FTC complaint also alleged that the format of the show was misleading and deceptive, because it looked like a talk-show episode rather than a paid commercial advertisement. This is actually the second time in just a few months that the FTC has raised this issue.

Back in July, the FTC alleged similar concerns in its complaint against the marketers of Supreme Greens with MSM (*FTC v. Direct Marketing Concepts, Inc., et al.*, 2004 WL 1399185 (D.Mass. 2004)). Among the elements of the show that the FTC found objectionable were the stage set, which had a talk show appearance, reference to the infomercial as "the Breakthroughs Program," introduction of the on-air talent as a "guest," reference to the "audience" and the failure to include a paid advertisement disclosure when the 800 number was presented. The paid advertisement disclosure was only included at the very beginning and at the end of the show.

The FTC staff has indicated to ERA that it would be taking a closer look at infomercial show formats and increasing its scrutiny of programs, which do not clearly communicate that they are paid advertisements. The FTC has also suggested that paid advertisement supers alone may not be sufficient to cure the problem if the overwhelming net impression of the program is that it is a talk or news show rather than a paid advertisement.

Marketers employing such formats would be advised to use extra caution in their choice of language and placement of disclosures to help ensure that the advertising nature of the programming is clearly communicated to consumers.

Linda A. Goldstein *is a partner of the advertising, marketing and media practice group of Manatt Phelps & Phillips LLP in New York. She can be reached at lgoldstein@manatt.com.*