

"ISSUES RELATING TO EPHEDRA-CONTAINING DIETARY SUPPLEMENTS"

The FTC has challenged marketers of dietary supplements containing ephedra when they make claims that the products cause substantial weight loss or are safe or have no side effects. The recently released Department of Health and Human Services report, Ephedra and Ephedrine for Weight Loss and Athletic Performance Enhancement: Clinical Efficacy and Side Effects ("Rand Report"), concluded that the existing scientific evidence on the efficacy for weight loss of ephedra-containing dietary supplements supports only "modest" weight loss of about ½ pound per week for up to four to six months.⁽¹⁷⁾ Furthermore, in contrast to assurances in ads that ephedra is safe or without side effects, the Rand Report concluded that "the use of ephedrine and/or the use of ephedra or ephedrine plus caffeine is associated with two to three times the risk of nausea, vomiting, psychiatric symptoms such as anxiety and change in mood, autonomic hyperactivity, and palpitations."⁽¹⁸⁾ Moreover, the Rand Report noted that adverse event reports for the supplement contain a sufficient number of cases of death, myocardial infarction, cerebrovascular accident, seizure, or serious psychiatric illness in young adults to warrant a case-control study to determine whether ephedra consumption may be causally related to these serious adverse events.⁽¹⁹⁾

Since 1997, the FTC has brought seven enforcement actions challenging efficacy and safety/no side effects claims for supplements containing ephedra.⁽²⁰⁾

These cases have challenged claims for ephedra products marketed for weight loss, body-building and energy supplements, and as alternatives to street drugs such as Ecstasy. In these cases, we have challenged allegedly deceptive efficacy and safety claims as false or unsubstantiated. Our orders have required a strong disclosure warning about safety risks in future advertising and labeling.⁽²¹⁾

For example, the Commission filed two additional settlements with companies that made allegedly deceptive safety and weight loss claims for ephedra supplements. In one case, the Commission's complaint challenged, as false or unsubstantiated, dramatic claims of substantial and safe weight loss for users of a product called Berry Trim Plus.⁽²²⁾ Ads for this product made claims such as "Teacher Loses 70 lbs. In Only 8 Weeks Easily!" and "100% safe!" In the second case, the FTC challenged as false or unsubstantiated claims for an ephedra product called Meta Biological.⁽²³⁾ Ads for this product claimed that "you lose pounds and inches SAFELY. . . without counting calories, without depriving yourself of tasty, delicious foods."

In these two cases, we alleged that there is not sufficient evidence to show that these products work as advertised or are safe for everybody. In both cases, the defendants agreed to an order that bans them from making certain false weight loss claims, requires substantiation for other weight loss claims, prohibits safety claims for ephedra without reliable scientific evidence, and requires the defendants to include a strong warning about safety risks in future advertising and labeling.⁽²⁴⁾ Both orders also require the defendants to pay consumer redress.

In addition, last month, the U.S. Department of Justice, on the Commission's behalf, sued Michael Levey, Gary Ballen, and their companies.⁽²⁵⁾ The complaint alleges that these defendants deceptively claim that their ephedra

products, Zephra and 3MilliMax, "cause fast (or) substantial weight loss with (or) little (or) no exercise" (12/20/2012 10:53:25)

2. Our authority in this area derives from Section 5 of the Federal Trade Commission Act, which prohibits "unfair or deceptive acts and practices in or affecting commerce," and Section 12, which prohibits the false advertisement of "food, drugs, devices, services or cosmetics." 15 U.S.C. §§ 45, 52.
3. Supplement Business Report 2002, Nutrition Bus. J., § 2 (2002)
4. This represents the total sales for products the Commission challenged in seventeen actions since December 2002.
5. See, e.g., FTC v. A. Glenn Braswell, et al., Civ. Action No. CV 03-3700 DT (PJWx) (C.D. Cal. filed May 27, 2003)(complaint for permanent injunction and other equitable relief); FTC v. Enforma Natural Prod., Inc., No. 00-4376JSL (Cwx) (C.D. Cal. Apr. 25, 2000) (stipulated final judgment with \$10 million in consumer redress); FTC v. Slim Down Solution, LLC, No. 03-80051-CIV-PAINE (S.D. Fla. filed Jan. 24, 2003) (complaint for permanent injunction and other equitable relief); FTC v. KCD Inc., 123 F.T.C. 1535 (1997) (consent order). A complete list of the Commission's dietary supplement cases is available at <http://www.ftc.gov/bcp/online/pubs/buspubs/dietadvertisingcases.pdf>.
6. FTC v. Health Laboratories of North America, Civ. No. 03 1457 (D.D.C. July 1, 2003) (stipulated final order involving safety and weight loss claims for a supplement containing ephedra); FTC v. USA Pharmacal Sales, Inc., Civ. No. 8:03-CV-1366-T-23EAJ (M.D. Fla. July 1, 2003) (stipulated final order involving safety and weight loss claims for a supplement containing ephedra); U.S. v. Michael S. Levey, Civ. No. CV-02-4670 GAF (AJWx) (C.D. Cal. June 30, 2002) (complaint challenging no side effects and weight loss claims for a supplement containing ephedra).
7. See, e.g., FTC v. Enforma Natural Prods., Inc., 04376JSL (CWx) (C.D.Cal. Apr. 25, 2000) (stipulated final order including \$10 million in consumer redress); FTC v. Slim America, Inc., 97-6072-CIV-Ferguson (S.D. Fla. June 30, 1999) (final judgment for permanent injunction and damages, including \$8.3 million in consumer redress).
8. See, e.g., FTC v. Health Laboratories of North America, Civ. No. 03 1457 (D.D.C. July 1, 2003).
9. Marketdata Enterprises, Inc., The U.S. Weight Loss & Diet Control Market 6 (2002). Marketdata estimated that the total U.S. weight-loss market for 2001 was \$37.1 billion and growing at a rate of 6 to 7 % a year.
10. Copies of the Weight Loss Advertising Report can be found at <http://www3.ftc.gov/bcp/reports/weightloss.pdf>.
11. Weight Loss Advertising Report at 21.
12. Advertising of Weight Loss Products, 67 Fed. Reg. 59,289 (2002).

26. The Commission also charged the defendants with making similar deceptive weight loss claims for a non-ephedra supplement called "Serotril."