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Weight-ing for Change

An exploration
of the current
weight
management
sector



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Managing Weight Management Claims

by Justin J. Prochnow

As stories proliferate throughout the media regarding America's "obesity epidemic," the goal of losing weight has become an American obsession. One can't flip through television channels without seeing an infomercial touting the next "hardcore" exercise program or a new pill to "trim the fat." Because of this attention on weight, claims addressing weight loss and weight management are some of the most heavily scrutinized by federal regulators.

INSIDER's Take

- Claims addressing weight loss and weight management are some of the most heavily scrutinized by federal regulators.
- FDA has identified weight-loss products as one of the "high-risk" categories of dietary supplement products.
- Along with express disease claims, implied claims that indicate the diagnosis, treatment, cure or prevention of disease are prohibited.

Federal Regulation

Both FDA and FTC regulate weight management claims made for food, beverage and dietary supplement products. FDA has the primary responsibility of regulating claims made on product labeling, which includes product labels and other written or graphic material accompanying products, such as inserts, brochures, other promotional materials and even websites. FTC, on the other hand, regulates all advertising, including claims in print, television and radio ads, catalogs and direct marketing materials. While FDA, pursuant to a memorandum of understanding between FDA and FTC, has primary responsibility for regulating materials that constitute labeling and advertising, claims that fall under both labeling and advertising, such as claims made on company websites that offer products for sale, may be reviewed by both agencies.

FDA Review of Labeling

FDA has identified weight-loss products as one of the "high-risk" categories of dietary supplement products. FDA dedicated several pages on its website to the regulation of weight-loss products, including a page entitled "Beware of Products Promising Miracle Weight Loss." In addition, FDA has voiced concern over weight-loss products marketed as dietary supplements that were allegedly adulterated due to containing undeclared active drug ingredients, such as sibutramine, known for use in promoting weight loss. Recently, FDA issued 14 public notifications addressing

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dietary supplement products that allegedly contained active drug ingredients; the notifications can be found on another FDA webpage titled “[Tainted Weight Loss Products.](#)”

On the labeling side of weight management, FDA reviews claims with the primary purpose of ensuring that such claims fall into one of the permissible categories of claims (health, nutrient content or structure/function claims) and that such claims are not disease claims. The most frequently used claims pertaining to weight management are structure/function claims, which describe the role of a nutrient or dietary ingredient on the structure or function of the body in humans.

The basic principle that governs all structure/function claims is that non-drug products may not be intended to diagnose, treat, cure or prevent a disease; otherwise, FDA will consider the products to be drugs. Weight management claims directed to overweight people are permissible; however, claims addressing obesity are disease claims because obesity is a disease, while the state of being overweight is not.

Along with express disease claims, implied claims that indicate the diagnosis, treatment, cure or prevention of disease are also prohibited. So, while weight management claims targeting obesity are clearly disease claims, claims pertaining to the lowering of “bad” cholesterol levels or elevating “good” cholesterol levels are also treated as implied disease treatment claims.

Of the two primary federal agencies regulating weight management claims, FTC has been the more aggressive in its enforcement.

FTC Regulation of Advertising

Of the two primary federal agencies regulating weight management claims, FTC has been the more aggressive in its enforcement. Regulation of advertising in the weight management arena falls under FTC’s general enforcement of Section 5 of the FTC Act and the Truth-in-Advertising Law. All advertising must be truthful, not deceptive or misleading, and substantiated.

FTC has disseminated numerous materials to educate consumers on weight-loss claims, such as “[Weighing the Claims in Diet Ads](#)” found on FTC’s website. This FTC fact sheet for consumers identifies claims FTC believes the public should view with skepticism before accepting them as true. Last year, FTC launched several campaigns designed to increase awareness of fraudulent dietary supplement claims. FTC kicked off the year with a big press conference to announce Operation Failed Resolution, an initiative that represented FTC’s ongoing effort to stop misleading claims for products promoting easy weight loss and slim, trim bodies. FTC announced actions against four different marketers and advertisers using allegedly deceptive advertising claims to promote weight-loss products.

In addition to the announcement of the enforcement actions taken against four different weight-loss operations, FTC announced an updated guidance for U.S. publishers, broadcasters and other media, entitled [“Gut Check: A Reference Guide for Media on Spotting False Weight-Loss Claims.”](#) The guidance details seven weight-loss claims FTC asserts can't be true and that should prompt a “gut check” for outlets considering weight-loss advertisements. These include claims that products can cause weight-loss of two pounds or more per week for a month or more without dietary or exercise adjustments, claims that products can cause substantial weight loss no matter what or how much the consumer eats, and claims that a product can cause permanent weight loss even after the consumer stops using product.

Much of FTC's regulation of weight management and weight-loss claims focuses on the use of endorsements and testimonials to promote products. FTC has issued the [“Guides Concerning the Use of Endorsements and Testimonials in Advertising”](#) (Endorsement Guides), which, while not the law, provide a good indication of how FTC is likely to apply Section 5 of the FTC Act to endorsements and testimonials used in advertising.

The Endorsement Guides provide guidance and direction on the use of testimonials to promote weight management. For example, in the section titled “Consumer Endorsements,” found at 16 CFR § 255.2(b), testimonials used in advertising are presumed to be representative of what consumers can expect to achieve when consuming a product; if the experiences described are not representative, the expected results must be clearly disclosed. Claims made in endorsements and testimonials must also be substantiated in the same manner, as if claims are expressly made by a company.



Much of FTC's regulation of weight management and weight-loss claims focuses on the use of endorsements and testimonials to promote products.

Advertisers must have adequate substantiation for all material claims. The standard for substantiation of health claims for food, beverage and supplement products is one of “competent and reliable scientific evidence,” a standard which is often the subject of much debate. While FTC has indicated that the standard may include tests, studies, research, analyses or other evidence based on the expertise of professionals in the relevant area, the specific level of evidence required by FTC often depends on the claims being made.

Furthermore, if a company makes a statement that an ingredient or product is “clinically proven” to cause weight loss or “scientifically proven to increase the body’s metabolism,” the substantiation standard bar is raised and evidence in the form of clinical studies or specific scientific research must be shown. Companies should review prior action taken by FTC or consult with knowledgeable people regarding scientific evidence to ensure that the necessary level of substantiation has been obtained.

The Bottom Line

Products that are targeted for weight loss and weight management come in many different forms. Regardless of the form, claims used to promote such products carry a high probability of close scrutiny from FDA and FTC. Companies must ensure that claims do not indicate the diagnosis, treatment, cure or prevention of disease. Advertisements must also clearly disclose the results consumers can expect to achieve, not just the amazing results of a particular endorser. And, companies must have adequate substantiation for each and every claim. Otherwise, companies may have some weighty problems to address. ■



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