Dietary supplement manufacturers and marketers are subject to numerous laws that regulate their marketing activities. The industry has been faced with many recent regulatory actions, as well as private litigation and review through the self-regulatory process. This article provides an overview of applicable regulators and suggests some important principles for increasing your odds of avoiding regulatory scrutiny.

It’s a Jungle Out There

Dietary supplement advertising claims are regulated in numerous ways. Increasingly, enforcement actions lead not only to orders regulating claims but also to steep monetary sanctions. However, before discussing who regulates dietary supplement advertising, it is worth taking a moment to talk about who does not. Under the Dietary Supplement Health and Education Act (DSHEA), dietary supplement makers do not need express Food and Drug Administration (FDA) approval to make claims related to the role of the supplement to affect or maintain a structure or function in humans.¹ Making sure your claim is a “structure or function” claim as opposed to a disease claim, which does require FDA review and approval, is of critical importance. The Federal Trade Commission (FTC) and FDA share responsibility for oversight of dietary supplements, with the FTC regulating advertising and FDA regulating labeling (including point-of-sale materials).² As a general matter, while FDA has jurisdiction over dietary supplement labeling and requires that structure-function claims be substantiated, the agency recently tends to focus its enforcement efforts on cases where clear disease claims are at issue and/or where there is a suspicion of product being adulterated. Bear in mind, though, FDA may not see eye to eye with its sister regulators as to what constitutes a disease claim, particularly when it comes to disclaimers. For example, if you want to claim that your supplement helps combat fatigue and you include a testimonial from a hepatitis patient that she feels less tired after using your...
supplement, the FTC may agree that a disclaimer stating that the product is not intended to treat hepatitis eliminates the possibility of an implied disease claim. FDA, however, may not be so forgiving, viewing the disclaimer as insufficient or possibly even reinforcing a disease treatment claim.

Assuming that you navigate past FDA, what other dangers lurk? At the federal level, the FTC has primary enforcement authority under §5 of the FTC Act, which prohibits deceptive advertising.³ The FTC has issued guidelines to assist the dietary supplement industry in understanding what substantiation the FTC believes is needed for claims.³ Remedies available to the FTC include injunctive relief (both preliminary and permanent), consumer redress or disgorgement and corrective advertising.³ Corrective advertising is still a rarely used remedy, but may become more of a focus of the FTC Staff in the future.⁶

One trend that has been seen in recent years is that the FTC has become increasingly aggressive in seeking consumer redress. Because redress is often calculated in terms of sales (the measure of harm allegedly suffered by consumers), companies are sometimes unable to pay the full amount sought by the FTC. In such cases, after a detailed examination of sworn financial statements, the FTC will calculate redress based upon an ability to pay but will include a “waterfall” provision giving it the right to collect the full amount due should it conclude that the defendant misled the Commission about its financial condition.⁷

Also at the federal level, competitors can bring a claim under the Lanham Act. Typically thought of as an avenue for injunctive relief, courts have increasingly awarded damages for lost profits as well as attorneys’ fees.⁸

At the state level, most states have consumer protection statutes that mirror §5 and can be enforced either by state attorneys general or, in some cases, by private parties. Consumer class actions are also another real threat. In both cases, damages are available as a remedy, and state attorneys general will often also seek the costs of their investigation as part of any settlement. Substantively, the legal standard typically follows that determined by the FTC.

Finally, the National Advertising Division (NAD) of the Counsel of Better Business Bureaus is a self-regulatory body that provides a forum for competitors to challenge advertising through a process designed to be faster and less expensive than the Lanham Act litigation route.⁹ The Council for Responsible Nutrition (CRN), an industry trade association, partnered with the NAD beginning in January 2007 to increase its oversight of dietary supplement advertising.¹⁰

The CRN has committed grant dollars to the NAD; in turn, the NAD has added a staff attorney whose focus will be on dietary supplement cases and has committed to increasing its annual caseload of dietary supplement cases. Since January 2007, the NAD has heard 35 dietary supplement cases, up from an average of eight per year prior to the CRN partnership—five based on competitor challenges, eight based on referrals from the CRN and the balance initiated by the NAD based on its monitoring of industry advertising.¹¹

The CRN has engaged in an aggressive advertising campaign to encourage industry members to take advantage of the NAD self-regulatory process.¹² While the NAD can only recommend rather than force changes to advertising, the NAD refers non-participating and non-compliant companies to the FTC, and the FTC takes such referrals quite seriously.

Traps for the Unwary

One of the key issues is to understand that the advertising claims you think you are making may not be the same as the claims that consumers or regulators think you are making. You are responsible for supporting all the claims that consumers reasonably take away from your advertising. If you do not have a complete understanding of what claims your advertising is making, it may be hard to substantiate claims you were not aware of in the first place.

Your advertising can make not only express claims (what the words literally say) but also implied claims. Implied claims can be drawn from words, pictures or from interpretations of the advertisement as a whole.¹³ For example, if you advertise a supplement for weight loss and show someone gorging themselves on pizza or ice cream, you may be implying that consumers can lose weight without dieting even if you do not say those precise words.

It is important to remember that a claim can be literally true but yet misleading, or literally false but not misleading. For example, the FTC alleged that stating that a cheese slice provides calcium and was made from five ounces of milk, while literally true, falsely implied that the cheese slice had the same amount of calcium as five ounces of milk when some was lost in processing.¹⁴ Conversely, when Hertz stated that it had more cars than Avis, while literally true, falsely implied that the cheese slice had the same amount of calcium as five ounces of milk when some was lost in processing.¹⁴
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So, how to avoid this trap? Courts have said that the FTC has the necessary expertise to decide what claims consumers will take away from your advertising. Unfortunately, courts have not extended that same presumption to advertisers, though experienced counsel or marketers can help in that regard. The safest route is to survey consumers using techniques accepted by the FTC and the courts. Though this option can be costly and sometimes time consuming depending upon the nature and importance of the claim at issue, a consumer survey may be a worthwhile insurance policy against regulatory action.

Finally, once you have gotten a handle on what claims you are making, take a look at those claims. If they are extreme or sound too good to be true, they are likely to invite close regulatory scrutiny or sound too good to be true, they are likely to invite close regulatory scrutiny of your support for those claims.

It is True—Really!

Knowing your claims is an important first step but just as important is the ability to prove them, or in FTC speak, substantiate them. Most dietary supplement claims relate to health. As a result, while you are unlikely to be required to have the large, sophisticated clinical trials a drug manufacturer might possess, the FTC is likely to require scientific substantiation and most likely one or more clinical trials. (And if you call out in your marketing “clinically proven” you probably need two such studies.) Important principles to bear in mind include the following:

1. Make sure your studies have a placebo—the FTC firmly believes in the placebo effect. So should you.
2. Make sure the result is statistically significant.
3. Make sure the product in the study is the same as your product. If the ingredients or proportion of the ingredients are different in the product tested than in the product you are actually marketing, the FTC will likely require evidence that the study results are not dependent on that particular combination of ingredients. In other words, if your product is missing one of the ingredients present in the tested product, will it still work the same way?
4. Be a people watcher—while animal studies can be used to substantiate a claim, studies with people are clearly preferable and do not require explaining why an outcome in three-toed sloths is transferable to humans.
5. Quality not quantity—clients often say to us, “I have fifteen studies supporting my claim.” The problem is that the FTC cares more about the quality of the study than the quantity. One well-conducted study is worth more than fifteen poorly conducted ones.
6. Testimonials are not studies—you may have hundreds of letters or emails from satisfied users of your products. However, these are not substitutes for a clinical study that produces same results under controlled conditions.
7. No mixing and matching—make sure that your survey supports the claim you want to make. No matter how well-designed the survey and how statistically significant the results, there needs to be a clear fit between the survey results and the benefit you are advertising.
8. “Up to” claims must be attainable—if you want to claim your product provides benefits “up to” a certain amount or percentage, your studies should have an appreciable number of participants and a significant percentage, at least 10 percent, of study participants who have achieved that level.

The Bottom Line

There are numerous regulators out there with jurisdiction over misleading dietary supplement claims. The risks associated with misleading claims are increasing, particularly the risk of some type of consumer redress or monetary sanction. In light of these growing risks, dietary supplement manufacturers would be prudent to give claims and substantiation close scrutiny before the products come to market.

2 See Working Agreement Between FTC and FDA, 3 Trade Reg. Rep. (CCH) ¶ 9,859,01 (1971); see also Updated FTC-FDA Liaison Agreement—Advertising of Over-the-Counter Drugs, 4 Trade Reg. Rep. (CCH) ¶ 9,851 (1971).
3 15 U.S.C. § 52(a) (2008). In addition, the FTC regulates supplements under Sections 12 and 15, prohibiting false advertisements for food, drugs, devices or cosmetics. 15 U.S.C. §§ 45(a) and 52.
5 15 U.S.C. § 45(b) & (l). 
6 Commissioner Rosch dissented from approving the settlement with Airborne because he believed, in addition to injunctive relief and consumer redress, that corrective advertising should have been ordered. FTC v. Airborne Health, Inc., et al., No. CV-08-01094, slip op. at 5-10 (C.D. Cal. Feb. 25, 2008), available at http://www.ftc.gov/os/caselist/0623234/080227order7.pdf.
7 When assessing “ability to pay” the FTC has looked to the value of personal property, including homes and automobiles. The FTC has successfully gone after defendants to reinstate the full amount when they believe the party has not been truthful about his or her financial picture. See FTC v. Mark Nutritional, Inc. et al., No. SA02CA1151SR, Stipulated Order to Reinstatement Judgment for $155 Million Against Defendant Harry Siskind at 2 (W.D. Tex. Oct. 23, 2004), available at http://www.ftc.gov/os/caselist/0623234/080227order7.pdf. Siskind also pled guilty to criminal charges earlier this year for these misrepresentations to the FTC.
8 Randall Miller, Money Damages Come Easier in Deceptive Advertising Cases, 26 ADVERT. COMPLIANCE SERV. 11 (J.LCom Publ’g, Roxbury, N.J.), (June 2008), available at http://www.ftc.gov/os/caselist/0723383/080814airbornedissentingstmt.pdf. This may signal to the FTC Staff that this remedy should be considered more readily in future enforcement actions.
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11. These statistics were presented by NAD attorney, Mark Levine, at the 2008 NAD Advertising Conference held in New York on Sept. 23, 2008.

12. The "There’s a New Sheriff in Town. You." Campaign ran in industry trade journals last year. See http://

www.crnusa.org/pdfs/CRN_NAD_ad.pdf.


14. Kraft Inc. v. FTC, 970 F.2d 311, 322 (7th Cir. (1992)).

15. Avis Rent A Car Sys. v. Hertz Corp., 782 F.2d 381, 383-386 (2d Cir. (1986)).

16. See, e.g., Clorox Co. P. R. v. Proctor & Gamble Commercial Co., 228 F.3d 24, 36 (1st Cir. (2000)).