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## ADVERTISING & PROMOTION ISSUE



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# Advertising and Promoting Dietary Supplements: How to Avoid Being Consumed by Government Prosecutors

By Mark E. DuVal and Mark E. Gardner

**T**he government continues to pressure makers of dietary supplements. Regulatory actions are increasing. Many of the issues faced by dietary supplement makers have their origins in unlawful marketing practices that the government deems false or misleading. This article provides an update on the regulatory environment faced today by the dietary supplement industry and focuses on FDA regulations governing dietary supplement claims.

## The Pressure Never Ceases

Last December, Dr. Joshua Sharfstein, then-Principal Deputy Commissioner of FDA, held a meeting announcing that FDA was increasing prosecution of what it has deemed products “masquerading as dietary supplements,” i.e., unapproved new drugs.<sup>1</sup> FDA stated, in reference to spiked products, that “[F]ar too many supplement products continue to be advertised online and elsewhere. And that’s why today to protect the



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public, FDA is stepping up our efforts.”<sup>2</sup> Although the announcement was specific to so-called “spiked” products, which includes drugs, or drug analogues, the announcement reveals the continued concern government has about the advertising of dietary supplements. FDA is also concerned with products that make drug-like claims, which make them unapproved new drugs under the Federal Food, Drug and Cosmetic Act (“FDCA”). Additional attention is on makers whose claims arguably cross the line into drug-like claims, in other words, that products treat, cure, mitigate or prevent disease. The Agency becomes aware of alleged violators through inspections of manufacturers and distributors, the Internet, consumer complaints and adverse event reporting. Now the Agency introduced a new way to catch bad actors.

In December, the Agency introduced a new email address for reporting perceived violators, taintedproducts@fda.hhs.gov, and reiterated the FDA Office of Criminal Investigation’s website, www.fda.gov/oci that can be used for the same purpose.<sup>3</sup> We suspect this new channel will spur reporting for spiking, but also for reporting issues with claims. We foresee its use as a competitive weapon. In other words, why not use this new resource as a competitive weapon if a competitor is suspected of misconduct?

### Warning Letters on the Rise for Regulated Industry

Well before the December announcement, FDA Commissioner Margaret Hamburg, M.D., indicated at a Food and Drug Law Institute meeting in August of 2009 that the Agency was especially concerned with, “violations involving product quality, adulteration, and misbranding; false, misleading, or otherwise unlawful labeling; and misleading advertising,” and that such issues were

on FDA’s radar.<sup>4</sup> True to her word, FDA has been enforcing the FDCA vigorously. In total, across all product classes, FDA’s warning letter database reveals FDA issued 374 warning letters in 2007, 431 warning letters in 2008, 566 warning letters in 2009, 609 warning letters in 2010 and 336 letters through July 14, 2011. Thus, FDA is on pace to send 632 warning letters to dietary supplement, drug and device makers this year.<sup>5</sup> That’s a 47 percent increase in warning letters issued compared to 2008.

The dietary supplement industry is seeing its fair share of these warning letters. This should be of no surprise, Commissioner Hamburg further stated at that 2009 meeting that, “[I]n some cases, serious violations have gone unaddressed for far too long,” and concluded, “I have approved a new policy brought forward by the FDA’s Chief Counsel to limit warning letter review to significant legal issues.”<sup>6</sup> The result is an increase in warning letters, and the trend is not retreating.<sup>7</sup>

### A Disturbing Trend—From FDA Warning Letters to Federal Marshals and Consent Decrees

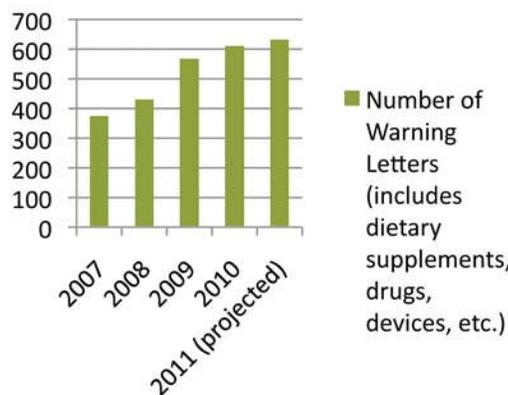
As if to underscore its administrative impatience with violators on the

promotional front, Commissioner Hamburg indicated that “The FDA will no longer issue multiple warning letters to noncompliant firms before taking enforcement action.”<sup>8</sup> The problem we have seen is threefold. First, the amount of time between warning letters can be long--twice we have seen six years. The company can have a clean bill of health in the intervening years and even may have been through a couple of successful FDA inspections. Second, advertising and promotion issues are often subtle and complex and not easily understood. Even the government realizes that when negotiating consent decrees with firms like ours. Third, often these companies have been selling product uneventfully for many, many years.

Yet despite the passage of a significant amount of time and the known complexity of these issues and the longevity of the operation, FDA is moving from a simple Untitled Letter or even Warning Letter (or even a corrective dialogue as part of an FDA inspection), to raids from federal marshals and/or seizure actions followed by consent decrees. When products are seized the company cannot sell its product, it is under federal seal and the company has a federal case, literally a lawsuit, filed against it, which

the company responds to via “claim and answer,” under Rule G of the Federal Rules of Civil Procedure. The government lays claim to the goods under seizure and a company is expected to either litigate to retrieve its own product or sign a consent decree. A consent decree offered in the crisis situation where the company is literally out of business is obviously strong leverage to sign the decree and the government is often fairly

Warning Letters Issued by FDA



unwavering in the terms it attempts to extract. The onerous terms of the consent decrees being proffered today are beyond the scope of this article.

This is a disturbing development. These precipitous seizures are threatening the commercial viability of many companies around the country. It shows the administrative impatience being exhibited by this administration. They are treating companies as recidivists even when the alleged violations are many years apart and the issues are not always straightforward and when resolution could be handled by other means and the companies are otherwise not bad actors. We deserve better from our government, which is treating many well-intended small manufacturers like common criminals. We recognize that the Agency is faced with a big problem and not all manufacturers are innocent, but a once-size-fits-all enforcement strategy is threatening the existence of many firms who want to comply with the law, with their very existence. We have worked with companies whom FDA has almost closed by virtue of its harsh enforcement activities. This means a loss of jobs at a time when the American economy sorely needs them. We have taken these clients to their Congressional delegation with their horror stories.

On the December conference call discussed above, Steve Mister, on behalf of the Council for Responsible Nutrition, stated, "...[w]e appreciate the agency's willingness to distinguish between responsible manufacturers and common criminals."<sup>9</sup> It is not clear that the Agency is always making this distinction. We fear that the salvo announced in December against spiking has turned up the heat on an industry already under serious pressure from regulators. What used to be overlooked, e.g. publishing a scientific, peer-reviewed article on your webpage

that talks about a disease in relation to a supplement, has become the impetus for aggressive government action. Government is shooting first and asking questions later. Consent decrees rather than warning letters have become the enforcement weapon of choice for repeat offenders.

## These Are Not Just Civil Cases

Promotional issues are also being prosecuted using the responsible corporate officer ("RCO") doctrine, also known as the "Park doctrine," under the FDCA. The RCO doctrine is named after a CEO who in 1975 was held criminally responsible for infractions under the FDCA (a filthy and vermin-infested food warehouse) even though he was not personally involved in and lacked knowledge of the wrongdoing.<sup>10</sup> Proof of specific criminal intent is not required to establish a violation and liability can attach vicariously. In other words, the government claims a defendant can be found guilty even without personal knowledge or direct participation in violative promotion. By virtue of the defendant's position within the company, the CEO, executive or manager is personally responsible for regulatory compliance and for stopping and correcting any wrongdoing, such as illegal promotion. Therefore, in the government's eyes, a mere delegation of duties will not absolve an executive or high-ranking manager at a dietary supplement company of this responsibility.

## Do a Few Bad Apples Spoil the Bunch?

Probably the most egregious recent example of illegal dietary supplement promotion and distribution involves the Enzyte case. This case, which featured in an episode of CNBC's "American Greed," has impacted the reputation of the dietary supplement industry.<sup>11</sup>

Berkeley Premium Nutraceuticals ("Berkeley") of Cincinnati, Ohio sold various dietary supplements, including Enzyte, by advertising on the Internet, television and in print famously featuring "Smiling Bob." An FDA inspection of Berkeley's facilities, which may have been prompted by this promotion, revealed significant misbranding of Berkeley's products. The result of the inspection was an FDA Warning Letter.<sup>12</sup> FDA initiated an investigation of Berkeley which revealed concealment of FDA violations during the previous inspection. Other government agencies got involved in the investigation which resulted in arrests of seven Berkeley employees, including its President, Steven Warshak.<sup>13</sup> All of these employees pled guilty to mail and wire fraud involving Berkeley's unauthorized charges to customer credit cards among other crimes revealed by the investigation.<sup>14</sup> On August 27, 2008, Mr. Warshak was sentenced to 25 years in prison, followed by five years of probation, a \$93,000 fine, and criminal forfeiture of over \$503 million.<sup>15</sup> Mr. Warshak's mother, Harriet Warshak, who was officer of the company, was sentenced to prison for two years, followed by three years of probation.<sup>16</sup> Other employees were also jailed and fined.<sup>17</sup> This all started with an inspection, followed by a Warning Letter alleging misbranding under section 403(a)(1) of the FDCA.<sup>18</sup>

Of course, not all cases are this egregious or offensive. In fact, most dietary supplement makers are legitimate corporate citizens that benefit society by providing useful dietary supplements at affordable prices with easy consumer access. It is clear that these companies create great benefits for our society as reflected for a consumer appetite for supplements to the tune of \$25 billion per year in the United States.<sup>19</sup> Even those companies operating

ethically need to take heed of the authority government holds over what they can or cannot say about their products and the attention prosecutors continue to give to their industry.

Manufacturers should not only be concerned about federal enforcement, but also state and municipal enforcement. Failure to do so can have severe consequences as was recently realized by Monrovia, California-based Biotab Neuroceuticals, who was fined \$1.75 million in July of 2011 by Orange County for conduct related to its promotion of a product called ExtenZe.<sup>20</sup> In effect, the product made unsubstantiated drug-like claims that ExtenZe could increase penile size, a claim FDA has pursued from an enforcement perspective for some time now.

### FTC Regulation

FDA and the Federal Trade Commission (“FTC”) share jurisdiction over dietary supplements through a liaison agreement.<sup>21</sup> FTC has jurisdiction over advertising, causing overlap, since the line between labeling and advertising is not clear. Similar to the FDCA, the Federal Trade Commission Act (“FTC Act”) prohibits “unfair and deceptive acts.” In other words, under the FTC Act, advertisements cannot be false, misleading, unsubstantiated or unbalanced.<sup>22</sup> This is similar to the FDCA, the focus of this article.

### FDA Regulation

FDA has authority over claims made on dietary supplement labeling. Labeling includes packaging, product inserts, websites, advertisements and any other promotional materials.<sup>23</sup> This authority emanates from the Dietary Supplement Health and Education Act (DSHEA), which was signed into law by President Clinton in 1994. DSHEA amended the FDCA. Dietary supplements do not have to be approved by the FDA prior to marketing, as opposed to drugs, which require human clinical study. The only time pre-market review is required is in the case of a new dietary ingredient when safety data and other information may be required by law. Save that exception, “a firm does not have to provide FDA with the evidence it relies on to substantiate safety or effectiveness before or after it markets its products.”<sup>24</sup> Claims must be substantiated by evidence and not be false or misleading. Under the FDCA, it is illegal to make claims that a food or dietary supplement can cure, treat, prevent or mitigate disease without approval from the FDA.

If a dietary supplement label or its labeling makes a drug-claim, i.e., that the product can treat, cure, prevent or mitigate disease, then the product is deemed adulterated, misbranded and a new drug under the FDCA and FDA may bring an enforcement action against the maker. As a

“new drug” a company must conduct clinical trials to establish the safety and efficacy of the product and obtain FDA approval and approved labeling. Without approval, the products are subject to seizure and injunction. As revealed by the Enzyte case, the company and individuals involved are subject to criminal proceedings, and in some cases, debarment from the industry.

### Lawful Dietary Supplement Claims under the FDCA

FDA allows dietary supplement makers to make, i) health claims, ii) structure/function claims and iii) nutrient content claims. These are discussed in this order below.

### Three Types of Lawful Dietary Supplement Claims

#### I. Health Claims & Qualified

##### Health Claims

Health claims describe a relationship between dietary supplement and reducing risk of a disease. In order to be a “health claim” a statement must discuss two things, i) a substance, i.e., dietary ingredient; and ii) a disease. FDA has used three laws to determine if *health claims* may be used for a dietary supplement:

- 1) *Nutrition Labeling and Education Act of 1990* (“NLEA”) – allows FDA to issue regulations authorizing health claims for dietary supplements pending FDA’s review of scientific evidence

| Claim Type      | Health Claims (also Qualified)   | Structure/Function Claims  | Nutrient Content Claims  |
|-----------------|--|--|--|
| Common Examples | <ul style="list-style-type: none"> <li>claims about immunity</li> <li>claims about support of the body</li> <li>e.g., “diets high in calcium may reduce the risk of osteoporosis”</li> </ul> | <ul style="list-style-type: none"> <li>Calcium builds strong bones</li> <li>Claims of “well-being” related to consumption</li> <li>antioxidants maintain cell integrity</li> </ul> | <ul style="list-style-type: none"> <li>more, reduced, and lite</li> <li>free, high, and low</li> <li>e.g., “40% omega-3 fatty acids, 10 mg per capsule”</li> </ul> |

## HOT OFF THE PRESS

FDA attention on the dietary supplement industry continues. On June 30, 2011, United States Senator Dick Durbin, D-Ill., introduced S. 1310: Dietary Supplement Labeling Act of 2011. The proposed bill is designed, “[T]o improve the safety of dietary supplements by amending the Federal Food, Drug and Cosmetic Act to require manufacturers of dietary supplements to register dietary supplement products with the Food and Drug Administration and to amend labeling requirements with respect to dietary supplements.”<sup>1</sup> If it becomes law, it will be very onerous on the dietary supplement industry. *The bill is available at* <http://www.govtrack.us/congress/bill-text.xpd?bill=s112-1310>.

In July, FDA published a 53-page document titled, *Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues*. This guidance was recently published and should be the subject of a future article. A quick review of the guidance requires, among other things, that manufacturers submit a New Dietary Ingredient (“NDI”) Notification for dietary ingredients manufactured or sold which were not marketed in the U.S. prior to October 15, 1994, and when manufacturing changes alter an ingredient causing it to become a new ingredient. *The guidance is available at* <http://www.fda.gov/Food/Guidance-ComplianceRegulatoryInformation/GuidanceDocuments/DietarySupplements/ucm257563.htm#iii-scope>.

submitted in a manufacturer’s health claim petition;

2) *Food and Drug Administration Modernization Act of 1997* (“FDAMA”) – allows use of health claims that are based on an “authoritative statement of a scientific body of the U.S. government or the National Academy of Sciences.”<sup>25</sup> Use of such health claims first requires submission as a “health claim notification” to FDA;<sup>26</sup> and

3) *FDA Consumer Health Information for Better Nutrition Initiative of 2003* – allows *qualified* health claims when the “quality and strength of the scientific evidence falls below that required for FDA to issue an authorizing regulation.”<sup>27</sup> These health claims must be “qualified to assure accuracy and non-misleading presentation to consumers.”<sup>28</sup>

NLEA, the Dietary Supplement Act of 1992, and DSHEA, allow health claims on labels and in labeling that describe a link between a dietary supplement and risk of a disease. The claims must meet certain criteria and be authorized by an FDA regulation. FDA has authorized claims like, “diets high in calcium may reduce the risk of osteoporosis.”<sup>29</sup> The Agency has approved these types of health claims, usually based on a health claim submission made by a company, after FDA has reviewed and been convinced by scientific literature on point that the link claimed by the manufacturer indeed exists.

FDAMA went further. It allows for health claims based on an “authoritative statement” from a scientific body of the U.S. Government or the National Academy of Sciences.<sup>30</sup>

The 2003 Consumer Health Information for Better Nutrition Initiative allows the use of *qualified* health claims if new evidence exists showing a connection between a dietary supplement and lowered

risk of disease. “Qualifying language” is used with the claim to reflect the deficiency.<sup>31</sup> FDA uses its enforcement discretion to determine whether to allow qualified health claims. The Agency does this, “after evaluating and ranking the quality and strength of the totality of the scientific evidence.”<sup>32</sup> Qualified letters are then issued to successful petitioners asking to make qualified health claims. These letters are searchable on FDA’s website and helpful for companies in determining lawful qualified health claims.<sup>33</sup> These provisions have not been frequently used by industry.

### II. Structure/Function Claims

DSHEA established regulations for structure/function claims on dietary supplement labels. These claims describe the function of a dietary ingredient that affect human structure or function. An example is, “calcium builds strong bones.”<sup>34</sup> These claims may also discuss how a dietary supplement helps maintain human functions, e.g., “fiber maintains bowel regularity,” or “antioxidants maintain cell integrity.”<sup>35</sup> Structure/function claims can also describe less specific “well-being” resulting from consumption of the product.<sup>36</sup> More specifically, these claims can describe a benefit of a nutrient in the dietary supplement, for example, the benefits of vitamin C on scurvy, a common disease.<sup>37</sup> Such claims about uncommon diseases are not allowed. Manufacturers should be careful to make sure claims are accurate, truthful, not misleading and fairly balanced. Such claims must be accompanied by the following “disclaimer” created by FDA, “*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.*”<sup>38</sup> Only approved drugs can make claims that a product cures, treats, prevents or mitigates disease.

### III. Nutrient Content Claims

NLEA permits describing levels of a nutrient in a dietary supplement in accordance with FDA regulations on point. Such claims describe the level of a substance in a product. Use of words like “free, high, and low,” are acceptable, and use of words like “more, reduced, and lite,” are also acceptable so long as they are not false or misleading.<sup>39</sup> Nutrient content claims usually apply to food products with “established daily values” set by FDA.<sup>40</sup> But dietary supplement makers can make such claims using percentages to describe a dietary ingredient when no daily value is established. For example, a maker may state, “twice the omega-3 fatty acids per capsule (80 mg) as in 100 mg of menhaden oil (40 mg).”<sup>41 42</sup>

### Case Law

Dietary supplements have been the subject of First Amendment litigation which the Agency has lost. The cases, *Pearson vs. Shalala* and *Whitaker vs. Thompson*, stood generally for the proposition that if advertising is truthful, not misleading and fairly balanced, it is subject to First Amendment commercial free speech protection.<sup>43 44</sup> To achieve this, disclaimers clarifying any potential misimpressions can be added. While a disclaimer cannot remedy a totally false or misleading ad, it can provide clarity and context to an otherwise truthful advertisement. These cases also challenged the FDA’s required standard of scientific proof to be unreasonably high. The courts essentially forced FDA to re-fashion its scientific standards from “significant scientific agreement” to “the weight of scientific evidence.” Six days after FDA issued a new guidance entitled “Guidance for Industry: Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements,” which adopted this new, lower scientific stan-

dard, a U.S. District Court judge in the District of Columbia ruled that FDA may not refuse to approve a qualified health claim unless the Agency can show “empirical evidence” that the qualified claim would be misleading.<sup>45</sup>

### What Can Dietary Supplement Makers do to Protect Themselves?

Here are some of the most important things manufacturers can do to protect themselves from enforcement actions. Designing claims for dietary supplements is largely an exercise in avoiding making disease claims that deem a product a drug by FDA. If companies are unclear how to do this, they should hire an expert to review current labeling and institute expert review into the promotional review process going forward, especially for their website.

Options are limited for companies once they are in government’s crosshairs. Legal challenges to government prosecutions are expensive, costing hundreds of thousands of dollars in litigation costs. The government has far greater bargaining power compared to the manufacturer. Unfortunately, might is right. Short of litigation, a company will find itself enjoined from business, relabeling, and/or destroying its product, or worse, subject to criminal penalties.

### Conclusion

Enforcement is not going to let up. FDA resources have increased and policy makers are tired of dealing with violators. The expansion of enforcement means companies should revisit the claims being made on promotional materials, and implement a compliance program which reviews claims. The best defense is a compliance program that remedies issues before they happen. Quoting Benjamin Franklin, “[A]n ounce

of prevention is worth a pound of cure.” Many makers of dietary supplements just do not seem to get it. This paints the rest of the industry with a broad brush. Smart makers of dietary supplements will monitor labeling and claims and stay current with changes in the law and the enforcement climate. ▲

1. See, FDA Media Call, *Tainted Products Marketed as Dietary Supplements*, December 15, 2010, at p. 2. Available at <http://www.fda.gov/downloads/NewsEvents/Newsroom/MediaTranscripts/UCM247280.pdf>. Last visited, July 17, 2011.
2. *Id.* at p. 3.
3. *Id.* at pp. 10-11.
4. FDLI, in remarks entitled “Effective Enforcement and Benefits to Public Health” on August 6, 2009. Available at <http://www.fda.gov/NewsEvents/Speeches/ucm175983.htm>. Last visited, July 22, 2011.
5. See, FDA’s Electronic Reading Room - Warning Letters, at <http://www.accessdata.fda.gov/scripts/warningletters/wlSearchExcel.cfm>. Last visited, July 21, 2011.
6. *Id.*
7. See supra, note 5.
8. See supra, note 4.
9. See supra, note 1, p. 5.
10. *United States v. Park*, 421 U.S. 658 (1975).
11. See CNBC, *American Greed. Case #1: Sexual Performance Pill*. Available at <http://www.cnbc.com/id/35988285>
12. See, e.g. FDA Warning Letter, *Berkeley Premium Nutraceuticals 14-Oct-04*. Available at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2004/ucm146636.htm>. Last visited, July 22, 2011.
13. See, e.g., *Concealment of FDA Violations During an Inspection of Dietary Supplement Manufacturer*, Office of Criminal Investigations, Chapter 6, p. 10. Available at <http://www.fda.gov/downloads/ICECI/EnforcementActions/EnforcementStory/UCM129818.pdf>. Last visited, July 22, 2011.
14. *Id.*
15. *Id.*
16. *Id.*
17. *Id.*
18. *Id.*
19. See Nutrition Business Journal, *NBJ Reviews the \$25 Billion U.S. Supplement Market* (Oct. 20, 2009). Available at <http://newhope360.com/business/nbj-reviews-25-billion-us-supplement-market>. Last visited, July 22, 2011.
20. See Los Angeles Times, *Dietary supplement manufacturer agrees to \$1.75-million fine for false advertising* (July 21, 2011). Available at <http://latimesblogs.latimes.com/lanow/2011/07/dietary-supplement-manufacturer-agrees-to-175-million-fine-for-false-advertising.html>. Last visited, July 22, 2011.
21. FTC-FDA Liaison Agreement, 4 Trade Reg., Rep. (CCH) paragraph 9851 (1971).
22. See FTCA §§ 5(a), 12; 15 U.S.C. §§ 45(a), 52.
23. See Letter from Margaret M. Dotzel, Associate Commissioner for Policy, FDA, to Daniel J. Popeo and Paul D. Kamenar, Washington Legal Foundation (Nov. 1, 2001).
24. See Overview of Dietary Supplements. Available at <http://www.fda.gov/food/dietarysupplements/consumerinformation/ucm110417.htm>. Last visited, July 22, 2011.
25. See Claims That Can Be Made for Conventional Foods and Dietary Supplements, at 1. Health Claims. Sept. 2003. Available at <http://www.fda.gov/food/labelingnutrition/labelclaims/ucm111447.htm>. Last visited July 22, 2011.
26. *Id.*
27. *Id.*
28. *Id.*

29. See *Id.*, at NLEA Authorized Health Claims.
30. See Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body, June 11, 1998. Available at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm056975.htm>. Last visited July 22, 2011.
31. See *supra*, note 25 at Qualified Health Claims.
32. *Id.*
33. See Summary of Qualified Health Claims Subject to Enforcement Discretion. Available at <http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm073992.htm>. Last visited, July 22, 2011.
34. See *supra*, note 25 at III. Structure/Function Claims.
35. *Id.*
36. *Id.*
37. *Id.*
38. See 21 U.S.C. § 343(r)(6) (2000); 21 C.F.R. § 101.93(c-e).
39. See *supra*, note 25 at II. Nutrient Content Claims.
40. See 7. Nutrition Labeling; Questions G1 through P8, October 2009, Guidance for Industry: A Food Labeling Guide. Available at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/ucm064894.htm>. Last visited, July 22, 2011.
41. See 21 C.F.R. 101.13(q)(3)(ii)
42. Additional information at 9. Appendix A: Definitions of Nutrient Content Claims. Available at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/ucm064911.htm>. Last visited July 21, 2011. Also see Appendix B: Additional Requirements for Nutrient Content Claims. Available at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/ucm064916.htm>. Last visited July 21, 2011.
43. See, e.g., *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999).
44. See, e.g., *Whitaker vs. Thompson*, 248 F. Supp. 2d 1, 13 (D.D.C. 2002).
45. See Guidance for Industry: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements. July 2003. <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm053832.htm>. Last visited, July 22, 2011.