

## *Legal Matters*

# **The Dietary Supplement and Health Education Act** *Far-Reaching Consequences for Consumers and Manufacturers*

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**T**he past several decades have seen a growing awareness of the key role nutrition plays in the quality of our health; it is now widely recognized, for example, that low-fat diets can help prevent certain cancers and heart diseases. As manufacturers of health foods and nutritional supplements sought to bring this information to the attention of the public including, in some cases, hyperbole about "brain food" and other questionable claims—Congress began to question whether health claims should be allowed for foods and supplements. Congress passed the Nutritional Labeling and Education Act (NLEA) in 1990 in an effort to provide the Food and Drug Administration (FDA) with the tools and direction it needed to determine which health claims could properly be made. The FDA took a position in response to the NLEA, which many, including some in Congress, took to reflect an overeagerness to place undue restrictions upon claims made for dietary supplements. In response to this concern, and buoyed by an unusually strong public response, Congress passed the Dietary Supplement Health and Education Act of 1994 (DSHEA).

The DSHEA sought to moderate the approach to the regulation of dietary supplements embodied in the FDA's pro-posed regulations under the NLEA. One of the key issues is the standard of proof a manufacturer needs to meet in order to make a health claim. The NLEA required a manufacturer to show "significant scientific agreement" supporting the proposed health claim. This standard was an effort to create an intermediate threshold for the approval of health claims on foods. Congress was concerned about radical and unregulated claims being made for some health foods, but it did not wish to place the expensive and technical requirements upon supplements that it had placed on drugs. The standard requiring "significant scientific agreement" was unsatisfactory to the health food industry and many consumers. One problem with the standard was that it was not one with a history developed at law, so that the meaning of the standard was unclear; it could be interpreted as a requirement as simple as a dozen published articles in agreement with the claim, or as difficult as agreement by a National Institutes of Health (NIH) consensus panel. The standard also raised concerns, given the hesitation and conservatism of the scientific community toward recognizing the positive health benefits of nutritional interventions, that this would create an unduly high threshold. The lobbying, which ultimately resulted in the passage of the DSHEA, arose in large measure because of dissatisfaction with this requirement.

Unfortunately, the supporters of the DSHEA were not able to revise this standard. The DSHEA thus took other approaches to moderate the severity of this standard. One approach taken was to allow a manufacturer of a supplement to make truthful structure and function claims—claims that do not describe an indication or make a specific "health" claim—without requiring that those claims be subjected to regulatory approval by the FDA. A manufacturer can claim, for example, that antioxidants help remove oxidized material in the body, but could not, without approval of a health claim, state that antioxidants have a beneficial effect in preventing cancer.

The DSHEA also allows manufacturers and distributors of supplements greater latitude in informing the public about the health benefits of their products. The law regulating claims made for food and drugs prescribes what can be placed on the label - the packaging affixed to the product - the separate materials that are distributed with the product such as package inserts or sales brochures. As

*The Dietary Supplement Health and Education Act of 1994 (DSHEA) could revolutionize the regulation of the use of dietary supplements. Consumers, health care professionals, and manufacturers and distributors of such products are not sure about the content and implications of this legislation. While the Act provides new marketing opportunities for dietary supplements and perhaps more informed use of such supplements by consumers—it is the first step in regulatory control of the rapidly expanding dietary supplement industry.*

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discussed below, the OSHEA removed many types of literature from the definition of labeling, allowing consumers greater access to materials describing the health benefits of supplements, and allowing other members of the industry to make claims for products which the manufacturers of the products could not.

### **The Findings Section**

The findings section of the Act deserves special consideration because it reflects the underlying issues that Congress was addressing when the legislation was under consideration. Several important issues emerged in the findings section of the DSHEA. There was a general recognition that dietary supplements have been shown to be of use in the prevention of chronic disease and an inference emerged that their use, in an appropriate manner, may reduce the prevalence of several common chronic disorders. The notion that this approach could lead to a reduction in long-term health care costs was entertained but nutriceconomic studies - investigations of the cost effectiveness of nutraceuticals - were not included in the Act.

The rights of consumers to make informed decisions about preventive health care strategies was revisited in the Act, with an emphasis on the importance of the quest for scientific knowledge about the benefits or hazards of dietary supplements. It was noted that approximately one half of all Americans may use dietary supplements to improve their nutrition and that much greater relevance is being placed on alternative health care providers because of the high cost of conventional medical interventions. This reinforced the need to protect a consumer's right to safe dietary supplements. These and other factors underscored the need for a framework to be established that supersedes what many perceived as "ad hoc" regulatory policies.

### **Defining a Dietary Supplement**

The most important aspect of the characterization of a "dietary supplement" by the DSHEA is that the dietary supplement is not a new drug or a food additive. Section 3 of the Act refers to a dietary supplement as a substance intended to supplement the diet and that contains one or more of the following components or characteristics: vitamins, minerals, herbs, botanicals, amino acids. It also is a substance for use by humans that supplements the diet by increasing total dietary intake or it is a concentrate, metabolite, constituent, extract, or combination of any of the above mentioned ingredients.

Certain qualifications apply to this definition, including the necessity for labeling of a product as a dietary supplement and not representing the product as a conventional food or as a sole item of a meal or of the diet. Dietary supplements under this definition are to be supplied in dosage forms, such as capsules, tablets, liquids, gels, or powders.

Section 3(b) of the DSHEA clearly distinguishes between a dietary supplement and a food additive. Food additives are subject to strict regulation in a defined process of premarket approval by the PDA. This provision is very important to the health food industry and it prevents the FDA from claiming that certain dietary supplements are food additives that require a process of strict regulatory approval.

### **Safety of Dietary Supplements**

The Secretary of Health and Human Services (HHS) may take action against a supplement which presents a significant or unreasonable risk of injury, or, in the case of a new dietary product, where there is inadequate documentation of safety. The Secretary may also suspend the sale of a dietary supplement if an imminent threat to public safety exists. If the FDA deems a product to be unsafe then the burden of proof rests with the FDA to demonstrate any alleged lack of safety. The Act demands that the FDA both provide 10 days' notice to the manufacturer or distributor of a product that a civil proceeding is imminent and grant an opportunity to discuss such action.

The Act provides useful guidelines as to what constitutes an unsafe product. If a substance is considered to present a significant or unreasonable risk of illness or injury under the conditions of the recommended use on the label or in accompanying labeling, then it is deemed unsafe.

The FDA has to judge the safety of a product, in part, based on the labeling. This should encourage manufacturers to apply warning statements on products. This will lead to safer use of dietary supplements because warnings and cautions are quite permissible and specific dosage instructions should be disclosed by manufacturers or distributors wherever possible.

The Act recognizes that public policy should be that a consumer could make an informed judgment about the use of dietary supplement based on accurate information on the benefits of dietary supplements. This section is very important for those individuals in the industry who are involved in the creation of a platform for the advertising or promotion of dietary supplements and it presents many opportunities for creative marketing of dietary supplements. Such creativity should occur with conformity to the Act.

### **Dietary Supplements and Literature**

Formerly, the use of literature by the distributors of dietary supplements that contained health claims was not allowed. Section 5 of the DSHEA has changed this situation radically. A publication are followed. The Act indicates that the literature can be an article, a publication, a book chapter, or an official abstract of a peer-reviewed scientific publication that was prepared by the author or the editors of the publications. This area of the legislation will be open to interpretation and it will be a likely focus of further contention and definition.

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The literature that can be provided to a consumer in a retail outlet must not be false or misleading. Retailers of dietary supplements have some responsibility to be cognizant of what is being sold in their outlets. This means that if a government agency was to determine that dietary supplement literature was false, there is a potential liability for the retailer. The literature must not promote a particular manufacturer or brand of dietary supplement. The Act indicates that the literature should be displayed or presented with other items on the same subject so as to present a "balanced view" of the available scientific information on the dietary supplement. This is a very difficult problem with "unique" products which may be proprietary formulations or combinations. There may be only one type of a dietary supplement for an author to discuss. If the literature used to sell dietary supplements is displayed in an establishment, such as a retail outlet, then the literature has to be physically separate from the dietary supplement.

It seems likely that the responsible production of an accurate product monograph for consumers would be perceived as appropriate, but no test cases exist under the new legislation where "expanded" literature use as labeling has been used. This portion of the Act does not prevent the sale of books or publications by purveyors of dietary supplements.

Section 5 of the Act is intimately related to dietary supplement claims and labeling. This area of the legislation provides an exemption from the former basic rule that information used to sell a dietary supplement is considered to be "labeling," when it is provided by a manufacturer, distributor, retailer, or even perhaps a health care professional. The Act does not enter into specific detail concerning situations where health care professionals may be selling their own brand of dietary supplements in their own clinic or treatment facilities. The general principles enunciated in the Act will apply in this setting, but this situation involving the health care professional is more complex and it is governed by other authorities such as State Licensing and Registration Departments and federal kickback and anti-referral statutes.

**The Label on the Product**

Labeling—the manufacturer's claims affixed directly to the product is a critical aspect of information transfer from manufacturer to consumer and a primary area of a manufacturer's legal responsibility. The DSHEA allows a labeling statement on a product to be made if the claim is a benefit related to a classical nutrient deficiency disease and the statement discloses the prevalence of the disease state in the United States. The label may also describe the role of a nutrient or dietary ingredient that is intended to affect the structure or function of the body or it may characterize a documented mechanism by which a nutrient or dietary ingredient acts to maintain a bodily structure or function. Finally, the label may describe general well being from consuming a nutrient or dietary ingredient. It would seem reasonable to have a certain degree of uniformity in dietary supplement claims, but this is unlikely to occur and is not specifically mentioned in the Act.

Problems may emerge in the area of product labeling for many manufacturers. For example, a number of dietary supplements have well-recognized effects *in vitro* but the conclusive demonstration of such effects *in vivo* may often be lacking. In addition, many alleged beneficial effects of certain dietary supplements are recorded from uncontrolled observations or are generated from epidemiologic information. These gray areas may never become distinct or even well demarcated in the near future. It is important to note that certain classes of claims for dietary supplements will likely receive intensive scrutiny by the FDA, especially those involving cancer, acquired immunodeficiency syndrome or claims of immune modulation.

It is of utmost importance to note that labeling statements made under the DSHEA cannot make a claim to diagnose, mitigate, treat, cure, or prevent diseases. Only those specific claims linking a supplement to a disease state that have been preapproved by the FDA under the NLEA, such as soluble fiber and heart disease, may be made. The manufacturer or distributor must have substantiation that the statements used on a label are truthful and not misleading and retailers should be cautious in their presentations to consumers.

Manufacturers must notify the Secretary of Health and Human Services within 30 days after first marketing a dietary supplement. This process of notification is a passive system for the FDA, but failure to notify will be regarded as misbranding. The outcome of such a situation is difficult to anticipate, but it could result in a request by the regulatory agencies to "purge the market" of the product. One important prerequisite of all statements is that they be accompanied by a prominent display on the product or labeling documents of the following disclaimer: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." This disclaimer is an attempt to distinguish dietary supplements from approved drugs that have been through the burdensome but

**What the Act Says About. . .**

**Dietary Supplements:** Includes products added to the total diet that contain at least one of the following: vitamin, mineral, herb, botanical, amino acid, another dietary substance for use to supplement the diet or a concentrate, metabolite, constituent, extract, or combination of any ingredient described above. Products can be ingested as tablets, capsules, powder, softgel, gelcap, or liquid must be labeled as dietary supplement; and cannot be represented for use as conventional food or sole items of a meal or diet.

Dietary supplements, including any ingredient used in them, are generally considered to be foods, but they are excluded from the definition of food additive under FDA regulations. As such supplements cannot be regulated like food additives or drugs, which both require premarket approval regardless of the form or composition of the additive.

**Unsafe Products:** Under Section 4 of the DSHEA, the FDA must prove that a supplement, or an ingredient in it presents a significant or unreasonable risk of illness or injury under conditions of use stated, or under ordinary conditions of use, if none are stated on the label. The agency can also declare the supplement is unsafe if it contains a dietary ingredient for which there is inadequate information to provide a reasonable assurance that it does not represent a significant or unreasonable risk of illness or injury. The burden of proof is with the U.S. government and, in the last case, it must inform the individual or manufacturer 10 days prior to a court investigation.

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necessary process of acceptance for marketing by the FDA. Section 6 of the Act and relevant supporting or complementary sections are often termed the "Structure Function" provisions of the DSHEA. Any purveyor of dietary supplements that ignores these "Structure Function" provisions will not be taking full advantage of the Act as these provisions allow the truthful claims about the dietary properties of the supplement without preapproval. Manufacturers or distributors of the dietary supplement must have adequate substantiation that the labeling statements are truthful. The problem is that the degree of adequacy of the required substantiation is not defined. Manufacturers or distributors of dietary supplements are advised to collect supporting documents and produce a comprehensive database to support any labeling statement. Such a database will be essential in the event that a dispute arises with a regulatory agency.

This "Honest Label" Section of the DSHEA, Section 3, is very important. A persistent fear of the health food industry is the possibility of being issued with a misbranding charge. The ingredient labeling and nutritional information supplied to the consumer has to be accurate. Labels on dietary supplements must include: the name of each ingredient, the total weight of the ingredients, the identity of any part of the plant from which a botanical ingredient is derived, and the term "dietary supplement." Misbranding is present if the supplement claims to conform to an official standard (e.g., U.S.P.) and fails to meet the standard. If a dietary ingredient has no official standard but fails to have a composition or quality, including pharmaceutical formulation characteristics the manufacturer claims it to have, it is deemed misbranded. These regulations are designed to assist consumers in making informed decisions about the use of dietary supplements and protect them from the unscrupulous.

The DSHEA provides an amendment to earlier nutrition labeling regulations. Earlier regulations mandated that dietary supplement labels should use a conventional food nutrition facts panel, but this process has been simplified under the DSHEA. Dietary supplement labels are required to declare an amount of a substance that is required for a Nutrition Facts Panel on conventional foods only if such substances are present in significant amounts. Doubt should be handled by disclosure.

### **Overseeing Labeling and Literature of Dietary' Supplements**

Section 12 of the DSHEA calls for the establishment of a Commission on Dietary Supplement Labels. This commission is an independent agency' within the Executive Branch that is charged with the responsibility to evaluate the regulation of dietary supplement label claims, labeling, and related literature. The defined need is to provide consumers with true and scientifically valid information so that they can make good judgments about self-management of their health.

The Commission on Dietary Supplement Labels will be comprised of seven members with appropriate experience and expertise. These individuals will make a final report of their activity to the President and the U.S. Congress. The Commission will have a very broad charge in order to facilitate the collection of information and coordinate hearings on matters relevant to dietary supplements. Any required rulemaking that emanates from the recommendations of the Commission will have to be completed within 2 years of the submission of the report of the Commission or the final regulations on health claims for dietary supplements will be voided.

### **New Dietary and Grandfathered Ingredients**

Section 8 of the DSHEA indicates that a dietary supplement that is first marketed after October 15, 1994 that contains an ingredient not sold prior to this date will be considered a new dietary ingredient. The DSHEA grandfathers all safe dietary supplements or ingredients that were sold prior to October 15, 1994. To be grandfathered, the product in the supplement must be unaltered from the form in which it existed, or there must be historic evidence that the product, when used as recommended, can be reasonably expected to be safe. In the event that a dietary supplement does not qualify as a "nonchemically altered food" but is not a new dietary substance because there is evidence of prior safe use or other relevant safety data, then the dietary supplement may move toward the market, providing that the Secretary of Health and Human Services is notified of these safety data 75 days prior to the sale of the product to a consumer. An individual or group must petition the FDA to obtain an order to permit the sale of a new dietary ingredient, but the process of the assessment of the ingredient by the FDA is likely to be stringent.

### **Other Issues**

Under the DSHEA, it may still not be possible to claim that a dietary supplement is a good, excellent, or rich source of a particular substance unless the Secretary of Health and Human Services has issued an authorizing regulation. This area of percentage level claims covered by the Act means that the Nutrient Contents Claim Regulations are now amended to permit statements on dietary supplement labels that characterize these percentage levels, so long as the FDA has not established a reference daily intake, a daily recommended value, or any other recommendation for daily consumption of a product or nutrient. In addition, under the Act, the Proxmire Amendment (21 U.S.C. 330) is amended to include not only vitamins or minerals but all dietary ingredients, as now defined. Section 9 of the Act covers matters related to good manufacturing practices. The FDA may issue regulations to establish good manufacturing practices for dietary supplements that are modeled after good manufacturing practices that are currently used for foods. However, the FDA may not impose standards if no analytic methods are available, and dietary supplements that are prepared or stored under conditions that do not meet current food good manufacturing practices will be considered adulterated under the Act.

Section II of the Act declares that the advanced notice of proposed rulemaking concerning dietary supplements (58 FR 33690-33700) is declared null and void and of no effect, with a notice to be published in the Federal Register, so stating. The FDA stated its views concerning the general lack of recognition that amino acids are safe and that many herbs are really drugs. In addition, the FDA has reinforced the notion in this report that upper daily intake limits exist for vitamins and minerals, primarily to avoid toxicities. Section 13 of the Act concerns the establishment of an Office of Dietary Supplements Research (ODSR) within the NIH. The

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purpose of the ODSR is to explore the role of dietary supplements to improve health and prevent disease. The Director of the ODSR is to conduct and coordinate research on dietary supplements and diseases and to act as an advisor to the Secretary of HHS, the Director of NIH, the Director of the Centers for Disease Control and Prevention, and the Commissioner of the FDA with regard to dietary supplement regulations, safety, and claims.

**Conclusion**

The DSHEA has far-reaching consequences for the use of dietary supplements by consumers. FDA interpretation of the Act will be a critical element in assessing the success of the DSHEA in reaching its stated goals of providing consumers with safer, properly labeled dietary supplements that are, or may be, supported with information as to their use and benefit.

To position a health food company for the future will require a team approach involving medical, scientific, and legal advice and the utilization of promotional services that are knowledgeable about the new provisions set forth in the DSHEA. On the horizon is increasing regulation, probable industry consolidation, and a rapid disappearance of those health food companies that do not have the foresight to position themselves for important future regulatory issues.

**Resources**

Congressional Research Service  
Report for Congress  
Dietary Supplement Health and  
Education Act of 1994  
P.L 103-417  
December 1, 1994

FDA Backgrounder  
Dietary Supplements  
BG 93-1 (June 15, 1993)

These materials can be obtained through  
the FDA Media office at (202) 205-4144.

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