DIETARY SUPPLEMENT
HEALTH AND EDUCATION ACT OF 1994

For decades, the Food and Drug Administration regulated dietary supplements as foods, in most circumstances, to ensure that they were safe and wholesome, and that their labeling was truthful and not misleading. An important facet of ensuring safety was FDA's evaluation of the safety of all new ingredients, including those used in dietary supplements, under the 1958 Food Additive Amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act). However, with passage of the Dietary Supplements Health and Education Act of 1994 (DSHEA), Congress amended the FD&C Act to include several provisions that apply only to dietary supplements and dietary ingredients of dietary supplements. As a result of these provisions, dietary ingredients used in dietary supplements are no longer subject to the premarket safety evaluations required of other new food ingredients or for new uses of old food ingredients. They must, however, meet the requirements of other safety provisions.

Signed by President Clinton on October 25, 1994, the DSHEA acknowledges that millions of consumers believe dietary supplements may help to augment daily diets and provide health benefits. Congress's intent in enacting the DSHEA was to meet the concerns of consumers and manufacturers to help ensure that safe and appropriately labeled products remain available to those who want to use them. In the findings associated with the DSHEA, Congress stated that there may be a positive relationship between sound dietary practice and good health, and that, although further scientific research is needed, there may be a connection between dietary supplement use, reduced health-care expenses, and disease prevention.

The provisions of DSHEA define dietary supplements and dietary ingredients; establish a new framework for assuring safety; outline guidelines for literature displayed where supplements are sold; provide for use of claims and nutritional support statements; require ingredient and nutrition labeling; and grant FDA the authority to establish good manufacturing practice (GMP) regulations. The law also requires formation of an executive level Commission on Dietary Supplement Labels and an Office of Dietary Supplements within the National Institutes of Health. These specific provisions of the DSHEA are synopsized below.

DEFINITION OF DIETARY SUPPLEMENT

FDA traditionally considered dietary supplements to be composed only of essential nutrients, such as vitamins, minerals, and proteins. The Nutrition Labeling and Education Act of 1990 added "herbs, or similar nutritional substances," to the term "dietary supplement." Through the DSHEA, Congress expanded the meaning of the term "dietary supplements" beyond essential nutrients to include such substances as ginseng, garlic, fish oils, psyllium, enzymes, glandulars, and mixtures of these.

The DSHEA established a formal definition of "dietary supplement" using several criteria.

A dietary supplement:

- is a product (other than tobacco) that is intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients.
  is intended for ingestion in pill, capsule, tablet, or liquid form.
  is not represented for use as a conventional food or as the sole item of a meal or diet.
- is labeled as a "dietary supplement."
- includes products such as an approved new drug, certified antibiotic, or licensed biologic that was marketed as a dietary supplement or food before approval, certification, or license (unless the Secretary of Health and Human Services waives this provision).

SAFETY

The DSHEA amends the adulteration provisions of the FD&C Act. Under DSHEA a dietary supplement is adulterated if it or one of its ingredients presents "a significant or unreasonable risk of illness or injury" when used as directed on the label, or under normal conditions of use (if there are no directions). A dietary supplement that contains a new dietary ingredient (i.e., an ingredient not marketed for dietary supplement use in the U.S. prior to October 15, 1994) may be adulterated when there is inadequate information to provide reasonable assurance that the ingredient will not present a significant or unreasonable risk of illness or injury. The Secretary of HHS may also declare that a dietary supplement or dietary ingredient poses an imminent hazard to public health or safety. However, like any other foods, it is a manufacturer's responsibility to ensure that its products are safe and properly labeled prior to marketing.

LITERATURE

The DSHEA provides that retail outlets may make available "third-party" material s to help inform consumers about any health-related benefits of dietary supplements. These materials include articles, book chapters, scientific abstracts, or other third-party publications. These provisions stipulate that the information must not be false or misleading; cannot promote a specific supplement brand; must be displayed with other similar materials to present a balanced view; must be displayed separate from supplements; and may not have other information attached (product promotional literature, for example).

NUTRITIONAL SUPPORT STATEMENTS

The DSHEA provides for the use of various types of statements on the label of dietary supplements, although claims may not be made about the use of a dietary supplement to diagnose, prevent, mitigate, treat, or cure a specific disease (unless approved under the new drug provisions of the FD&C Act). For example, a product may not carry the claim "cures cancer" or “treats arthritis.” Appropriate health claims authorized by FDA--such as the claim linking folic acid and reduce risk of neural tube birth defects and the claim that calcium may reduce the risk of osteoporosis--may be made in supplement labeling if the product qualifies to bear the claim. Under DSHEA, firms can make statements about classical nutrient deficiency diseases--as long as these statements disclose the prevalence of the disease in the United States. In addition, manufacturers may describe the supplement's effects on “structure or function” of the body or the “well-being” achieved by consuming the dietary ingredient. To use these claims, manufacturers must have substantiation that the statements are truthful and not misleading and the product label must bear the statement **“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.”** Unlike health claims, nutritional support statements need not be approved by FDA before manufacturers market products bearing the statements, however, the agency must be notified no later than 30 days after a product that bears the claim is first marketed.

INGREDIENT AND NUTRITION INFORMATION LABELING

Like other foods, dietary supplement products must bear ingredient labeling. This information must include the name and quantity of each dietary ingredient or, for proprietary blends, the total quantity of all dietary ingredients (excluding inert ingredients) in the blend. The label must also identify the product as a "dietary supplement" (e.g., “Vitamin C Dietary Supplement”). Labeling of products containing herbal and botanical ingredients must state the part of the plant from which the ingredient is derived. If a supplement is covered by specifications in an official compendium and is represented as conforming, it is misbranded if it does not conform to those specifications. Official compendia include the U.S. Pharmacopeia, the Homeopathic Pharmacopeia of the United States, or the National Formulary. If not covered by a compendium, a dietary supplement must be the product identified on the label and have the strength it is represented as having.

Labels also must provide nutrition labeling. This labeling must first list dietary ingredients present in "significant amounts" for which FDA has established daily consumption recommendations, followed by dietary ingredients with no daily intake recommendations. Dietary ingredients that are not present in significant amounts need not be listed. The nutrition labeling must include the quantity per serving for each dietary ingredient (or proprietary blend) and may include the source of a dietary ingredient (for example, “calcium from calcium gluconate”). If an ingredient is listed in the nutrition labeling, it need not appear in the statement of ingredients. Nutrition information must precede ingredient statements on the product label.

NEW DIETARY INGREDIENTS

Supplements may contain new dietary ingredients--those not marketed in the United States before October 15, 1994--only if those ingredients have been present in the food supply as an article used for food in a form in which the food has not been chemically altered or there is a history of use, or some other evidence of safety exists that establishes that there is a reasonable expectation of safety when the product is used according to recommended conditions of use. Supplement manufacturers must notify FDA at least 75 days before marketing products containing new dietary ingredients, providing the agency with the information on which the conclusion that a dietary supplement containing the new dietary ingredient "will reasonably be expected to be safe" was based. Any interested party, including a manufacturer of a dietary supplement, may petition FDA to issue an order prescribing the conditions of use under which a new dietary ingredient will reasonably be expected to be safe.

GOOD MANUFACTURING PRACTICES (GMPs)

DSHEA grants FDA the authority to establish GMP regulations governing the preparation, packing, and holding of dietary supplements under conditions that ensure their safety. These regulations are to be modeled after current good manufacturing practice regulations in effect for the rest of the food industry. FDA intends to work with the supplement industry and other interested persons to develop GMPs and, in doing so, will seek public comment as to their scope.

COMMISSION ON DIETARY SUPPLEMENTS

The DSHEA requires the formation of a Commission to conduct a study and make recommendations on the regulation of label claims and statements for dietary supplements and procedures for the evaluation of the claims. The members of the Commission will evaluate how best to provide truthful, scientifically valid, and not misleading information to consumers so that they can make informed and appropriate health care choices. The Commission will be composed of seven members, appointed by the President, with experience in dietary supplements and in the manufacture, regulation, distribution, and use of supplements. Three members must be qualified by scientific training and experience to evaluate supplements’ health benefits, and one of these must be trained in pharmacognosy, medical botany, traditional herbal medicine, or other related sciences. All Commission members and staff should be unbiased about supplement use.
On October 2, 1995, the White House announced the names of the seven individuals the President intends to appoint to the Commission. The members include nutritionists, industry representatives, a pharmacognosist, and attorneys.

The Commission will submit a final report including recommendations and legislation related to label claims for dietary supplements to the President and Congress within two years of convening.

OFFICE OF DIETARY SUPPLEMENTS

The HHS Secretary will establish an office within the National Institutes of Health to explore the potential role of supplements to improve health care in the U.S. The office will also promote scientific study of

supplements and their value in preventing chronic diseases; collect and compile scientific research, including data from foreign sources and the NIH Office of Alternative Medicine; serve as a scientific adviser to HHS and FDA; and compile a database of scientific research on supplements and individual nutrients.

EFFECTIVE DATE

DSHEA's provisions for use of nutritional support statements and third-party literature became effective when the law was signed. The effective date for other labeling provisions and any FDA implementing regulations is after December 31, 1996, although manufacturers may label their products consistent with provisions of DSHEA until that date.

This document was issued on December 1, 1995.
For more recent information on Dietary Supplements
See http://www.cfsan.fda.gov/~dms/supplmnt.html