Chapter I

Dietary Supplement Health And Education Act of 1994

The Dietary Supplement Health and Education Act of 1994 (DSHEA, or the Act) (Appendix A) was enacted by Congress following public debate concerning the importance of dietary supplements in promoting health, the need for consumers to have access to current and accurate information about supplements, and controversy over the Food and Drug Administration's (FDA) regulatory approach to this product category. Signing DSHEA into law on October 25, 1994, President Clinton said:

> After several years of intense efforts, manufacturers, experts in nutrition, and legislators, acting in a conscientious alliance with consumers at the grassroots level, have moved successfully to bring common sense to the treatment of dietary supplements under regulation and law. (12)

The issues and debates that led to the passage of DSHEA have been discussed by a number of authors (7,88,90,122-125,136). Despite extensive public debate during the consideration of DSHEA, the official legislative history for the Act is limited (134) (see Chapter I Endnote).

DSHEA amends the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA) to alter the way dietary supplements are regulated and labeled. This chapter provides an overview of the provisions of DSHEA and discusses the scope of this report.

MAJOR PROVISIONS

The following provisions of DSHEA are contained in the 13 sections of the Act (Appendix A).

1. Short Title, Reference, Table of Contents

Section 1 provides introductory information on the Act.

2. Congressional Findings

In Section 2 of DSHEA, Congress identifies 15 findings that established the rationale for DSHEA and that were meant to establish a conceptual framework for Federal regulatory policy regarding dietary supplements. Integral to the legislative changes was Congress' finding that "improving the health status of United States citizens ranks at the top of the national priorities of the Federal government."

3. Definitions

DSHEA for the first time defines dietary supplements by law. According to Section 3 of the Act, the term "dietary supplement":

> (1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:
>
> (A) a vitamin;
> (B) a mineral;
> (C) an herb or other botanical;
> (D) an amino acid;

(E) a dietary supplement used by man to supplement the diet by increasing the total dietary intake; or

(F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E).

According to DSHEA, a dietary supplement is a product that is labeled as a dietary supplement and is not represented for use as a conventional food or as a sole item of a meal or the diet.

The definition describes the variety of forms—capsule, powder, softgel, gelcap, tablet, liquid, or other form—in which these products can be ingested. This section of DSHEA specifically excludes dietary supplements from the definition of food additives in Section 409 of FDCA.

4. Safety of Dietary Supplements and Burden of Proof on FDA

DSHEA establishes separate standards for the safety of dietary supplements by describing the conditions under which dietary supplements are adulterated (unsafe). DSHEA applies the existing food standards for adulteration to dietary supplements but requires that such a determination be based on conditions of use recommended or suggested on the product label or, in the absence of such recommendations or suggestions, on ordinary conditions of use. For new dietary supplement ingredients (those marketed after October 15, 1994), products may be found to be adulterated if there is inadequate information to provide reasonable assurance that such an ingredient does not present a significant or unreasonable risk of illness or injury. In making such a determination, the burden of proof rests with the Federal government.

5. Dietary Supplement Claims

Under Section 5 of DSHEA, information about a dietary supplement, such as "a publication, including an article, a chapter in a book, or an official abstract of a peer-reviewed scientific publication that appears in an article and was prepared by the author or the editors of the publication, which is reprinted in its entirety, shall not be defined as labeling when used in connection with the sale of a dietary supplement" under certain conditions. Such a publication may be used in connection with the sale as long as it is truthful and not misleading; does not promote a particular manufacturer or brand of dietary supplement; presents a balanced view or is displayed or presented with other such items on the same subject matter so as to present a balanced view of the available scientific information; and does not have appended to it any information by sticker or any other means. DSHEA also requires that when such third-party information is used in an establishment, it may not be displayed next to the supplement product but must be physically separated from the supplement.

6. Statements of Nutritional Support

Section 6 of DSHEA amends the Nutrition Labeling and Education Act of 1990 (NLEA) health claims provisions of FDCA to allow dietary supplement labels to carry any of four types of statements of nutritional support without obtaining premarketing authorization from FDA. According to DSHEA, an acceptable statement of nutritional support is one that:

> . . . claims a benefit related to a classical nutrient deficiency and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function of humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient.

The legislation requires supplement manufacturers to have substantiation of such label claims and to notify FDA within 30 days after first marketing a product with a statement of nutritional support that such a

statement is being made. The label must also carry a disclaimer "prominently displayed and in boldface type" that states:

> **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.**

7. Dietary Supplement Ingredient Labeling and Nutrition Information Labeling

Section 7 of the Act imposes specific requirements for supplement labels. It specifies some circumstances under which dietary supplements would be misbranded. It provides that supplement labels must list the name and quantity of each ingredient. In the case of a proprietary blend, the "total quantity of all ingredients in the blend" may be provided.

DSHEA requires that, if a dietary supplement purports to conform to the standards of a particular compendium, it must actually do so. Official compendiums identified by FDCA or Federal regulations include the U.S. Pharmacopeia (USP) and the Food Chemicals Codex. Otherwise, the identity and quality of the product must be as stated on the label.

With respect to nutrition labeling, DSHEA permits the inclusion of substances without a Reference Daily Intake (RDI) or Daily Recommended Value (DRV). The nutrition label must include the quantity of each dietary ingredient per serving. The sources of the dietary ingredients may be stated on the nutrition label or in a separate ingredient list. In the case of botanicals, the label must indicate the part of the plant used in the ingredient. Nutrient content claims for dietary supplements can be based on RDIs or DRVs (98), but DSHEA specifically permits percentage level claims for ingredients where a Daily Value (DV) is not established.

8. New Dietary Ingredients

According to Section 8 of DSHEA, the term "new dietary ingredient" means "a dietary ingredient that was not marketed in the United States before October 15, 1994, and does not include any dietary ingredient which was marketed in the United States before October 15, 1994."

This section describes the conditions under which a new dietary ingredient may be used in a dietary supplement. Unless an ingredient has been "present in the food supply as an article used for food in a form in which the food has not been chemically altered," the manufacturer must provide FDA with information, based on a history of use or other evidence of safety, supporting the conclusion that the product "will reasonably be expected to be safe." This information must be provided at least 75 days before introducing a new dietary ingredient into interstate commerce.

9. Good Manufacturing Practices

In addition to laying the foundation for a regulatory framework for dietary supplements and their ingredients, DSHEA, under Section 9, provides FDA with the authority to promulgate good manufacturing practice (GMP) regulations for supplements. The Act stipulates that any new GMP regulations must be modeled after current food GMP regulations and go through the required rulemaking process, allowing for public notice and comment.

10. Conforming Amendments

Section 10 of DSHEA makes changes necessary for conformance in relevant sections of FDCA. It amends Section 201 of FDCA to provide that a food or dietary supplement that bears a statement of nutritional support in accordance with DSHEA is not a drug solely because the label or labeling bears such a statement. Section 301 of FDCA is modified to make the introduction of unsafe dietary supplements into interstate

commerce a violation. Section 403 is amended to state that a dietary supplement is not misbranded solely because the label includes directions, conditions of use, or warnings.

11. Withdrawal of the Regulations and Notice

Under Section 11 of DSHEA, the Secretary of the Department of Health and Human Services (HHS) is directed to issue regulations rendering null and void the June 1993 Advance Notice of Proposed Rulemaking (ANPR) concerning dietary supplements (49-52).

12. Commission on Dietary Supplement Labels

Section 12 of DSHEA mandates the appointment by the President of a commission to study and make recommendations concerning label claims and statements for dietary supplements (THE COMMISSION ON DIETARY SUPPLEMENT LABELS of this Chapter).

13. Office of Dietary Supplements

Section 13 of DSHEA establishes an Office of Dietary Supplements (ODS) within the National Institutes of Health (NIH). According to the Act, the purpose of ODS is to explore more fully the potential role of dietary supplements as a significant part of the efforts of the United States to improve health care and to promote scientific study of the benefits of dietary supplements in maintaining health and preventing chronic disease and other health-related conditions.

In fulfilling its duties, as specified in DSHEA, ODS is to:

- Conduct and coordinate scientific research within NIH relating to dietary supplements and the extent to which their use can limit or reduce the risk of diseases and conditions such as heart disease, cancer, birth defects, osteoporosis, cataracts, and prostatism;
- Collect and compile the results of scientific research relating to dietary supplements, including data from foreign sources or NIH's Office of Alternative Medicine;
- Serve as the principal advisor to the Secretary and the Assistant Secretary for Health and provide advice to the Directors of NIH and the Centers for Disease Control and Prevention (CDC), and the Commissioner of Food and Drugs on issues relating to dietary supplements;
- Compile a database on scientific research on dietary supplements and individual nutrients; and
- Coordinate NIH funding relating to dietary supplements.

THE COMMISSION ON DIETARY SUPPLEMENT LABELS

1. Charge

Section 12 of DSHEA establishes a Commission on Dietary Supplement Labels to develop recommendations for the regulation of label claims and statements for dietary supplements. Specifically, DSHEA directs the Commission to:

> . . . conduct a study on, and provide recommendations for, the regulation of label claims and statements for dietary supplements, including the use of literature in connection with the sale of dietary supplements and procedures for the evaluation of such claims.

The Act stipulates that, in making its recommendations, the Commission is to:

> . . . evaluate how best to provide truthful, scientifically valid, and not misleading information to consumers so that such consumers may make informed and appropriate health care choices for themselves and their families.

DSHEA authorizes the Commission to hold public hearings around the country to collect relevant testimony and evidence.

As mandated by DSHEA, the Commission's seven members are presidential appointees with expertise and experience in the manufacture, regulation, distribution, and use of dietary supplements. DSHEA stipulates that three of the members are to be qualified by scientific training and experience to evaluate the benefits to health of the use of dietary supplements and that one of those three is to have experience in pharmacognosy, medical botany, traditional herbal medicine, or other related sciences. The composition of the Commission meets these requirements.

DSHEA directs the Commission to prepare a final report to the President and Congress that includes the results of its study and any findings or recommendations the Commission may choose to make, including recommendations for additional legislation.

The Act requires that the Secretary of HHS, within 90 days after the Commission issues its report, publish in the Federal Register a notice of any Commission recommendations proposing ". . . changes in regulations of the Secretary for the regulation of dietary supplements . . .", along with a notice of proposed rulemaking on such recommendations. DSHEA also stipulates that the rulemaking process must be completed within two years after the release of the report. It adds that, in the event that HHS fails to complete the rulemaking within two years, the regulations published by FDA on January 4, 1994, pertaining to the general requirements covering health claims for dietary supplements shall become null and void.

2. Charter

DSHEA mandates that the Commission be established as an independent agency within the executive branch. Because funds authorized by DSHEA were not appropriated, the Secretary of HHS allocated departmental funds to cover the operating costs of the Commission. Accordingly, the Commission was chartered by HHS under the Federal Advisory Committee Act, rather than formally established as an independent agency. Congressional sponsors of DSHEA were briefed regarding the reasons for this organizational arrangement.

The appointment of the Commission members was announced by the White House on October 2, 1995. Its charter (Appendix B) was approved by the Secretary on February 13, 1996.

In its discussions at the first and later meetings, the Commission agreed that the congressional mandate in Section 12 of DSHEA should be interpreted broadly. This approach is also indicated in its Charter. Thus, the Commission has considered conceptual issues related to the labeling of dietary supplements, including NLEA health claims and DSHEA statements of nutritional support, and the use of literature in connection with sales. Guidance has also been developed on associated issues, including the suggested information needed by manufacturers to substantiate statements of nutritional support. The safety of dietary supplements has been considered by the Commission because of the relevance of safety to the consumer's ability to make "informed and appropriate health care choices." In addition, the safety and labeling of a supplement are interrelated, because the label indications for use and any warning information affect how the supplement can be used appropriately. As mandated, the Commission also considered the procedures for evaluation of label statements and claims, and possible approaches to their implementation. The report also explores alternatives for manufacturers to make claims for botanical products that might otherwise be made only indirectly as statements of nutritional support. The Commission considered the need for consumer research as part of its

evaluation of how to provide information to consumers to enable them to make informed and appropriate health care choices. Research issues have been addressed because of their relevance to the mandate in Section 12 of DSHEA that directs the Commission to study how to provide consumers with information that is scientifically valid. The Commission concludes that the scope of matters covered in this report, as well as the guidance and recommendations meet the Commission's obligation to report to the President, Congress, and the Secretary, as specified in DSHEA and in the Charter.

3. Procedures

Significant events related to activities of the Commission are highlighted in Figure 1. The Commission procedures are described in Appendix C. Individuals and organizations who testified before the Commission at the public hearings or who otherwise provided formal oral or written comments at the request of the Commission through June 24, 1997, are identified in Appendices D and E.

4. Report

Reflecting the charge to the Commission in DSHEA and in the Commission's charter, this report is addressed to the President, Congress, and the Secretary of HHS. Although many aspects of the report will be of interest to other Federal and State agencies, the general public, and the dietary supplement industry, the primary intent is to provide guidance to those who are responsible for the interpretation and the implementation of DSHEA. The organization of the report is as follows:

- Chapter I summarizes the major provisions of DSHEA and the charge to the Commission. A copy of the legislation and Commission charter are Appendices A and B, respectively.
- Chapter II reviews the legislative and regulatory context surrounding DSHEA. It also summarizes key background information related to consumer use of dietary supplements and the supplement industry.
- Chapter III discusses the major findings, guidance, and recommendations developed by the Commission. Topics include the safety of dietary supplements; general information on dietary supplement labels; claims on dietary supplement labels; statements of nutritional support on dietary supplement labels; substantiation of the information and statements on labels; publications used in conjunction with sales that are exempt from classification as labeling; and regulation of botanical products when manufacturers wish to make claims for prevention and treatment of disease.
- Chapter IV presents findings, guidance, and recommendations related to other issues identified by the Commission during its deliberations. Topics include information the public needs to make informed health care choices and how best to make such information available to consumers. The Commission considered mechanisms to improve the ability of manufacturers of dietary supplements and Federal and State regulators to evaluate the safety of products and to support the validity of claims and statements made on the labels of these products. Enforcement issues and research needs related to consumer use of dietary supplements are also discussed.

The findings, guidance, and recommendations of the Commission are presented in each section of Chapters III and IV.

- **Findings** are the conclusions reached by the Commission during its deliberations and are based on the information and data received and reviewed by the Commission.
- **Guidance** represents advice to specific agencies, groups, or individuals. Guidance should be considered by the identified recipients as they develop or implement activities related to the availability of dietary supplements in the marketplace.

- **Recommendations** are indicated as such and identify the intended recipients. Recommendations that call for consideration of changes in existing regulations, development of new regulations, or legislative action are so indicated.

The Commission on Dietary Supplement Labels was aware of the public interest in its work and desired to receive public comment on its draft report. Therefore, a draft report was released for public comment on June 24, 1997. While comments were requested by August 4, 1997, the Commission accepted submissions through September 15, 1997. Approximately 400 comments on the draft report were received from the public and evaluated before completion of this final report.

ENDNOTE

1. Statement of Agreement: "This statement comprises the entire legislative history for the Dietary Supplement Health and Education Act of 1994, S.784. It is the intent of the chief sponsors of the bill (Senators Hatch, Harkin and Kennedy, and Congressmen Richardson, Bliley, Moorhead, Gallegly, Dingell, Waxman) that no other reports or statements be considered as legislative history for the bill.

    1. The bill does not affect the Food and Drug Administration's existing authority under the Federal Food, Drug and Cosmetic Actto prohibit the import or sale of any product marketed as a drug in a foreign country.
    2. In section 201(ff)(3)(B)(ii), added by section 3 of the bill, the term 'substantial clinical investigations' does not include compassionate investigational new drug applications or an investigational new drug application submitted by a physician for a single patient.
    3. Section 403B, added by section 5, does not apply to a summary of a publication other than an official abstract of a peer-reviewed scientific publication.
    4. Section 403(r)(6)(A), added by section 6, does not permit premarket approval or require premarket review by the FDA of any statement permitted under that provision.
    5. In section 413(a)(1), added by section 8, the term 'chemically altered' does not include the following physical modifications: minor loss of volatile components, dehydration, lyophilization, milling, tincture or solution in water, slurry, powder, or solid in suspension."

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Commission on Dietary Supplement Labels