# CRS Report for Congress



# Dietary Supplements: Commission Report and FDA Regulation

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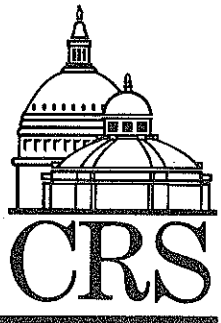

**ABSTRACT**

This report reviews the recommendations in the final report of the Commission on Dietary Supplement Labels. In addition, it provides a brief description of the commission's creation and the Food and Drug Administration's rulemaking on issues addressed in the commission's recommendations. Congress may consider whether to mandate the recommendations for an over-the-counter drug review of botanicals, elimination of the disclosure statement, and additional regulatory and research funding. This report is an update of CRS report 97-937 and is not expected to be updated further.

# Dietary Supplements: Commission Report and FDA Regulation

## Summary

The Dietary Supplement Health and Education Act of 1994 (DSHEA, P.L. 103-417, enacted October 24, 1994) addressed several issues specific to the information provided with dietary supplement products. In response to the controversy that arose concerning the authorization of health claims on supplement products, DSHEA established a commission to make recommendations on the health information provided on supplement labels and promotional literature available in stores. The presidentially appointed Commission on Dietary Supplement Labels released its report in November 1997.

Although product safety was not in its charge, the commission recommended that the entire supplement industry accept responsibility for assuring the safety of these products. It also recommended that the scientific standard and procedure for the authorization of health claims for dietary supplements should be the same as for conventional foods. With regard to statements of nutritional support on supplement labels, the commission made recommendations on the scope of such statements, the information in the letters of notification to the Food and Drug Administration concerning their use, and the substantiation files needed to support them. It recommended that FDA undertake active monitoring of the consumer literature available in conjunction with the sale of these products. While the commission recognized that properly labeled botanicals should continue to be marketed as supplements, it recommended that FDA establish a review panel for botanical products that manufacturers propose for drug uses. It recommended that supplement labeling information be evaluated for its usefulness through consumer research and that health professionals should become more knowledgeable about the appropriate uses of these products to assist consumers. The commission recommended that the supplement industry consider establishing an expert advisory panel to provide scientific review of label statements and claims, and guidance to industry on safety, benefits, and appropriate labeling of specific products. It recommended that federal agencies continue to support research on the health benefits of supplements, with particular focus on botanicals. The commission recommended that the National Institutes of Health's Office of Dietary Supplements (ODS) needed to be an effective focal point for research and understanding of the health benefits of these products, as well as an adviser to other agencies on a broad range of supplement issues. It recommended that ODS be funded at its authorized level.

Since the commission completed its work, FDA has published final rules that provide guidance for the content of notification letters and proposed rules that define the criteria for determining when a statement constitutes a permitted structure/function claim. The agency also published its views on the commission's recommendations.

In reviewing the commission's recommendations, Congress may consider whether additional financial resources are required for implementation. Statutory changes would be needed to implement the recommendations to eliminate the disclaimer for structure/function claims and create a review panel for drug claims.

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# Dietary Supplements: Commission Report and FDA Regulation

The Dietary Supplement Health and Education Act of 1994 (DSHEA, P.L. 103-417, enacted October 24, 1994) established a commission to make recommendations on certain information provided on dietary supplement labels and promotional literature available in stores. In November 1997, the Commission on Dietary Supplement Labels released the report on its findings and recommendations on supplement safety, health claims, statements of nutritional support and their substantiation, publications at the point of sales, botanical products, consumer education and understanding, expert review panels, and research issues. This report provides a brief review of the recommendations contained in the commission's report and the Food and Drug Administration's (FDA) regulations responding to those recommendations. It also identifies several issues Congress may consider implementing as a result of the commission's recommendations. This report is an update of CRS report 97-937.

## Background

The Dietary Supplement Health and Education Act of 1994 addressed several issues specific to the labeling and information to be provided with dietary supplement products. Those products were defined in the law to include vitamins, minerals, amino acids, herbs and botanicals, and other dietary ingredients added to supplement the total diet. The act placed the burden of proof for safety on the federal government, established the manner in which promotional literature is provided at the point of sale, specified types of statements of nutritional support allowed on labels, defined and described the conditions of use of new dietary ingredients, specified certain labeling requirements, and directed that rules for good manufacturing practices be established. In addition, the act established an office of dietary supplements at the National Institutes of Health (NIH) to coordinate scientific research related to these products and advise other federal agencies on issues related to the regulation and promotion of these products.

The Commission on Dietary Supplement Labels was created by DSHEA in response to the controversy that arose concerning the authorization of health claims following the enactment of the Nutrition Labeling and Education Act of 1990 (NLEA, P.L. 103-535). NLEA had provided the Secretary of the Department of Health and Human Services (DHHS) with the discretion to determine whether conventional foods and dietary supplements should have the same or separate standards and procedures for the review and authorization of health claims. When FDA proposed regulations for the same standard and process for the authorization of health claims for conventional foods and supplements, the supplement industry mounted a consumer campaign to press Congress to enact legislation that would require a specific review of the appropriate standards and procedures for claims and statements of nutritional

support for their unique products. The consumer campaign had a significant influence on DSHEA enactment in 1994.

The seven-member, presidentially appointed commission was announced in October 1995 and chartered in February 1996. It was set up as an independent entity sponsored by the DHHS Secretary under the standards set forth for the formation and use of federal advisory committees. Its charge was to conduct a study on, and provide recommendations for, the regulation of label claims and nutritional statements on supplements, including the use of promotional literature provided at the point of sale. The commission was to evaluate how supplement manufacturers could best provide truthful, scientifically valid, and not misleading information about their products so that consumers can make informed and appropriate health care choices for themselves and their families. The act mandated that, within two years of enactment, a report was to be submitted to the President and Congress.

In the course of its deliberations, the commission held open public meetings in several locations around the country, taking oral and written testimony from more than 87 organizations and individuals who presented views on the issues outlined in the commission's charge. Meeting notices were published in advance in the *Federal Register* and a record of the proceedings was kept according to federal regulations. The commission requested comments on its June 1997 draft report from all interested parties, even though this opportunity was not required under the provisions of the law.[1] After considering these comments while making technical amendments to the report, the commission issued its final report in November 1997.

## Recommendations in the Final Report

The commission's final report contains recommendations on nine issues which are reviewed in brief in this section. Each section provides the panel's rationale for the recommendations. The full report provides a review of the pertinent legislative and regulatory history, the demographics of consumer use, and the characteristics of the industry that manufactures these products.[2]

**Safety of Dietary Supplements.** Although the issue of product safety was not part of the original charge, the commission considered it of primary importance that all marketed supplements should be safe. The commission recommended that manufacturers and the supplement industry as a whole accept full responsibility for assuring the safety of these products. It also urged FDA, the industry, and scientific and consumer groups to work together to improve passive postmarketing surveillance systems, including the voluntary adverse reactions reporting systems, to ensure that any safety problems are identified and promptly corrected. The commission recommended that manufacturers include, where appropriate, health warnings in product information for consumers. It urged FDA to use its authority to take swift enforcement action to address potential safety issues. The commission recognized

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[1] Department of Health and Human Services, Public Health Service, *Commission on Dietary Supplement Labels; Draft Report* (June 1997), 117.

[2] Department of Health and Human Services, Public Health Service, *Commission on Dietary Supplement Labels; Final Report* (November 1997), 121.

that the agency and its state counterparts may need additional resources to develop the necessary evidence that shows an unreasonable risk from using a supplement currently on the market.

**NLEA Health Claims in Dietary Supplement Labeling.** The commission was specifically charged with determining whether any changes should be made in NLEA's health claims provision for dietary supplements. As required by NLEA, FDA developed a petition process for health claims, whereby an interested party may request that the agency establish regulations authorizing a claim that characterizes the relationship between a nutrient and a disease or health-related condition. The petition must include "the totality of publicly available scientific evidence" that addresses the claim sought in the petition. The agency is required to determine whether the available evidence on the relationship meets the standard of significant scientific agreement (SSA) in order to authorize a health claim for foods. SSA is not defined in statute and its interpretation is the subject of considerable controversy. The commission recommended that the NLEA-defined process for authorizing health claims be the same for supplements and conventional foods. It determined that the statutory standard of SSA for evaluating the evidence substantiating a claim is appropriate and serves the public interest, as long as it is not strictly interpreted as requiring unanimous or near unanimous scientific support. Finally, the commission recommended that FDA should ensure that broad input is obtained from independent scientific experts and other agencies in determining the degree to which SSA exists for a particular claim.

**Scope of Statements of Nutritional Support.** DSHEA allows supplement labels to bear statements of nutritional support without preauthorization by FDA, if certain conditions are met. Statements of nutritional support address the benefit a dietary ingredient provides related to the effects of a nutrient deficiency, the role or mechanism it is intended to affect in the structure or function of a body organ or system, or the contribution to general well-being from its use. These statements are allowed for supplements, as long as no therapeutic claim is made and they appear with a disclaimer statement that they have not been evaluated by FDA. The commission recommended that statements of nutritional support provide useful consumer information on a product's intended use and that such statements be truthful and not misleading and supported by scientifically valid evidence. It also recommended that these statements be permitted when they indicate the role of an ingredient in affecting the structure or function of a body system or organ, as long as they do not suggest that the supplement will prevent disease or provide medical treatment for a condition. The commission recommended that statements should not be made suggesting that the product has the ability to restore normal or correct abnormal function, which may imply the presence of disease. It recommended that structure/function statements remain distinct from NLEA health claims, by not stating or implying a link between the use of a supplement and the prevention of a specific disease or health-related condition. In addition, the commission recommended that statements of nutritional support should not refer to specific diseases, disorders, or classes of disease or use drug-related terms, which might suggest a product's ability to diagnose, treat, prevent, cure or mitigate a medical problem. Finally, it recommended that, resources permitting, FDA should continue to provide guidance to manufacturers by responding to notification letters when the agency deems a proposed statement of nutritional support to be inappropriate.

**Notification Letters for Statements of Nutritional Support.** The provisions of DSHEA require supplement manufacturers that make statements of nutritional support to notify FDA within 30 days after marketing a supplement with such a statement. However, the law is silent on the specific information to be provided to the agency. The commission recommended that letters of notification be placed on the public docket at FDA and outlined specific information that it believes the letters should contain, including the purpose of the letter; name, address, and telephone number of the manufacturer; name and description of the product; identification of the ingredient(s) to which the statement applies; and the intended use of the product. Furthermore, it recommended that manufacturers should provide statements of affirmation that they have substantiation for the statement of nutritional support and that the product does not represent a significant or unreasonable risk of illness on the labeling information for conditions of use. Finally, the commission suggested that manufacturers use these guidelines in preparing their agency notification letters.

**Substantiation Files for Statements of Nutritional Support.** DSHEA required manufacturers who make a statement of nutritional support to have in their files substantiation that the statements are truthful and not misleading. The law does not, however, define "substantiation," which would likely vary depending on the statement made, or the amount of evidence needed to support such a statement. The commission did not reach a consensus on the amount of evidence needed to constitute substantiation or the degree to which this information should be available to FDA. It did, however, recommend that the following information be placed in the manufacturer's substantiation files for each claim: copy of the notification letter; identity and quantity of the dietary ingredients that are the subject of the statement; key evidence to substantiate the statement of nutritional support, including an interpretive summary by qualified experts; evidence substantiating the product's safety; evidence that good manufacturing practices were followed; and qualifications of the experts who reviewed the safety and efficacy evidence.

**Publications Exempt from Classification as Labeling When Used in Connection With Sales.** DSHEA directed the commission to study and make recommendations on the regulation and evaluation of the literature made available in connection with the sale of supplements. Under DSHEA, this literature was exempted from the labeling regulations under certain conditions. The commission determined that meeting the conditions specified in the act may be difficult, especially the requirement that the literature provide a balanced view of the available scientific evidence. While the provision on literature dissemination may have been written with scientific articles in mind, these articles generally are not consumer-oriented. Most literature to which this provision applies is likely to have been written specifically for consumers. The commission recommended that FDA undertake active monitoring of these publications to learn more about the information being provided to consumers. It also recommended that regulatory guidance be provided for the preparation of consumer materials, if necessary.

**Botanical Products.** Traditionally botanical supplement products have been used for preventive and therapeutic purposes. Under certain circumstances, their medical use is supported by scientific evidence. The commission suggested that more study was needed regarding the establishment of an alternative system for regulating botanical products that are used for purposes other than supplementing the diet, but

that cannot meet over-the-counter (OTC) drug requirements. The commission believed that such a system should consider the types of disclaimers that might apply and the appropriateness of such a system within the U.S. regulatory framework. It concluded that a comprehensive evaluation of regulatory systems for botanical remedies used in other countries is also needed. As a result, the commission recognized that botanicals should continue to be marketed as supplements when properly labeled. It recommended that FDA establish an OTC review panel for botanical products that are proposed for drug uses by manufacturers.

**Information for Consumers and Health Professionals.** The commission was charged by DSHEA to determine how best to provide consumers with information that will allow them to make informed and appropriate health care choices. It recommended that supplement labeling be evaluated in additional research to determine whether consumers actually want and can utilize the information provided under the existing FDA regulations, DSHEA requirements, and the commission's recommendations. Additionally, the commission believed that all health care professionals should become more knowledgeable about supplements and assist consumers in making appropriate decisions concerning their use. Finally, the commission urged manufacturers to make publicly available for their products balanced and nonmisleading summaries of the evidence substantiating statements of nutritional support and product safety for the intended use at stated dosages.

**Need for Industry Expert Advice on Safety, Label Statements and Claims.** Despite the different regulatory requirements for labeling statements of nutritional support, health claims, and drug claims, these messages may, in reality, seem similar to consumers. Therefore, the commission recommended that the supplement industry consider establishing an expert advisory committee to provide scientific review of label statements and claims. It also recommended that such a committee provide guidance to the industry regarding the safety, benefit, and appropriate labeling of specific products. Further, the commission suggested that such a committee might be funded by industry trade associations or established as an independent entity funded by grants and/or some form of user fees.

**Research Issues.** In considering the scientific evidence supporting the health benefits of supplements, the commission made several observations related to research on these products, constraints on such research and incentives for manufacturers to make investments in research. It indicated that consumers would be better served by more research that assesses the relationships between supplements and maintenance of health and/or preventing disease. The commission also believed that incentive mechanisms should be developed to encourage the industry to invest in research on consumer products. It recommended that federal agencies continue to support research on the health benefits of supplements, including expanding attention on botanical products.

**NIH Office of Dietary Supplements.** DSHEA required NIH to establish an office of dietary supplements to conduct and coordinate scientific research related to supplements, coordinate funding for this research, collect and compile in a database the results of scientific research on supplements, and serve as advisor to other governmental agencies relating to the safety, benefits and labeling of these products. The commission recommended that the NIH Office of Dietary Supplement (ODS),

that was created as a result of DSHEA, strive to be an effective focal point for research and understanding of the health benefits derived from supplements. In addition, it recommended that ODS place greater emphasis on its assigned role of advising other agencies on a broad range of issues relating to supplements. Finally, the commission recommended that Congress fund ODS at the level ($5M) authorized by DSHEA.

## FDA's Regulatory Activities Following the Commission's Work

In September 1997, FDA issued numerous supplement labeling regulations that resulted from passage of DSHEA. As part of these labeling rules, the agency published a final rule that provides guidelines for the content of notification letters sent to the agency by manufacturers making statements of nutritional support.[3] The rule specifies that the notification submission should contain an original and two copies of the following information: name and address of the manufacturer, packer or distributor of the supplement bearing the statement; text of the statement; name of the dietary ingredient that is the subject of the statement; name of the supplement, including the brand; and the signature of the responsible individual who can certify to the accuracy of the information presented. The commission's final report was not completed before FDA finalized the rule on notification procedures. Nevertheless, the final language in this rule seems to reflect the recommendations in the commission's draft report, which had been released in June 1997. The final report contained essentially the same recommendations concerning notification letters.

Following publication of the commission's final report, DSHEA specified that FDA had 90 days to publish proposed regulations for label claims on supplement products based on the commission's recommendations. On April 29 1998, FDA published two *Federal Register* notices. The first notice was a proposed rule in which the agency defined the criteria for determining when a statement constitutes a structure/function claim that is permitted and a disease claim which is not permitted.[4] In the proposed rule, the agency defined, for the purpose of health claims, a disease or health-related condition as essentially any deviation from normal structure or function of the body, except for nutrient deficiency diseases. For certain types of supplement statements, FDA described the permitted structure and function statements related to a given nutrient or dietary ingredient that are allowed, as long as no disease claim is made. A further description of types of disease claims that are not allowed was outlined in the proposed regulation. The comment period for this proposed rule closed August 27, 1998.

In the second notice, FDA announced its views on the recommendations and guidance of the Commission on Dietary Supplement Labels and additional

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[3]Department of Health and Human Services, Food and Drug Administration, "Food Labeling; Notification Procedures for Statements on Dietary Supplements. Final Rule," *Federal Register* 62, no. 184 (23 September 1997): 49883.

[4]Department of Health and Human Services, Food and Drug Administration, "Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body. Proposed Rule," *Federal Register* 63, no. 82 (29 April 1998): 23624.

communications sent directly to the agency on the issues that the commission addressed.[5] In general, the agency's comments agree with the guidance and recommendations made in the commission's report. FDA indicated a willingness to work with the appropriate parties, including other governmental agencies, the FDA Food Advisory Committee, and industry, to implement the recommendations. The agency stated, however, that despite the merits of a comprehensive review of the relevant laws, regulations, and policies from other regulatory and advisory authorities around the world, resources are not currently available to undertake such a review. In addition, FDA noted that current law prohibits the agency from adopting the suggestion to eliminate the disclaimer requirement for statements of nutritional support.

Three days before the commission's final report was issued, the Food and Drug Administration Modernization Act of 1997 (FDAMA, P.L. 105-115) was enacted on November 21, 1997. This act primarily focused on the regulation of drugs and medical devices and FDA administrative operations. The title on foods is comparatively short and addressed several issues (food contact substances, food irradiation, and paint on glass and ceramic ware) that have no bearing on supplements. The provisions on nutrient content and health claims may have an effect on supplements. The claims provisions allow a manufacturer to make an authorized claim by notifying FDA that the claim is to be made and providing a copy of the authoritative statement on which it is based. For a statement to be authoritative, it must describe the relationship between a nutrient and disease or health-related condition; it must be published by a scientific body (which is responsible for public health protection or human nutrition research) of either the U.S. government or the National Academy of Sciences; and it must be "currently in effect." At the time of passage, there were several opinions on whether the provisions that allowed claims to be made based on authoritative statements applied to supplements. Although claims based on authoritative statements were not part of its charge, the commission's recommendation that the standard and process for authorizing health claims be the same for supplements and conventional foods essentially suggested that any process used for authorizing claims for conventional foods would also apply to supplements. FDA subsequently published guidance on the use of the notification process for making claims based on authoritative statements under FDAMA.[6] Recent *Federal Register* notices announced that FDA had prohibited the use of nine claims submitted to the agency under the terms of these provisions because FDA determined that the statements used as the basis for the claims did not meet the standard for "authoritative."[7] All these claims were for supplement products made by a single manufacturer.

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[5]Department of Health and Human Services, Food and Drug Administration , " Dietary Supplements; Comments on the Commission on Dietary Supplement Labels. Notice," *Federal Register* 63, no. 82 (29 April 1998), 23633.

[6]Department of Health and Human Services, Food and Drug Administration, *Guidance for Industry. Notification of a Health Claim or Nutrient Content Claims Based on an Authoritative Statement of a Scientific Body* (11 May 1998), 5 p.

[7]Department of Health and Human Services, Food and Drug Administration, "Food Labeling: Health Claims; Interim Final Rules," *Federal Register* 63, no. 119 (28 June 1998): 34083.

## Potential Impact of the Commission's Recommendations

The Commission on Dietary Supplement Labels addressed issues that are of concern to FDA, the supplement industry, consumers, and Congress. Several recommendations may warrant congressional attention.

The commission addressed, and resolved for the time being, the issue of whether conventional foods and supplements should have the same substantiation standard and regulatory process for the authorization of health claims. With the commission's determination that the same rules should apply to both categories, there would not appear to be a need for changes in the statutory provision that is the basis for the current health claims regulations. A recommendation that separate standards and procedures be established for supplements might have required a change in the law, reopening the debate concerning the equity of having different substantiation standards for nutrients that are present in both foods and supplements. The amendments enacted as part of FDAMA allowing claims to be made based on authoritative statements will apply to both conventional foods and dietary supplements. This conclusion can be drawn based on the commission's recommendation that the same rules should apply to claims for both product categories and the recent *Federal Register* notices concerning FDA's review of supplement claims submitted under those provisions.

The commission's recommendation to establish an OTC review panel for botanical products that are intended for disease prevention and therapeutic use may require congressional action to become effective. The current definition of supplements does not require or allow them or their ingredients to be subjected to the type of safety and effectiveness review required for OTC drugs. The recommendation that such a review be undertaken would seem more likely to be implemented if there were a statutory requirement to do so. Such a statutory change may require the reclassification to drug status of botanicals that make a therapeutic claim. The commission recommended that, for botanical products that cannot meet OTC safety and efficacy standards, a study should be undertaken to establish some alternative system for drug claims for these products. In the current U.S. regulatory framework, an alternative regulatory scheme for making a therapeutic claim when a product does not meet the drug safety and effectiveness standards would most likely require a change in the law. If such a study recommends a new regulatory scheme, further statutory change might be required for its implementation.

The commission suggested that FDA consider reviewing research to validate structure/function claims and other statements of nutritional support so that the currently required disclaimer could be removed. However, current law prevents the agency from adopting this suggestion unless it is amended to eliminate this requirement.

A recurring theme in the commission's final report was the need for financial resources. Several recommendations were predicated on the understanding that they would require, and may not be undertaken until, additional FDA funding is available. The commission's assumption seems to be that it will take additional federal funding to implement its recommendations, although no information is provided on the amount of funding currently available for supplement regulatory activities. Also, there

is no indication in the commission's report of the source of funding or its availability for these tasks. Specifically, in the areas of safety review, swift enforcement of safety regulations, regulatory guidance, letters of notification, and expansion of supplement research, the report called for these activities to be undertaken as funding permits. In addition, the recommendations regarding postmarket surveillance, broad review input on claims, promotional literature enforcement, proactive monitoring of publications, OTC review, consumer research, federal research support, and ODS full funding also represent resource-intensive activities, requiring funds that may not be available in current operating funds. The recommendation to create an expert review panel for label statements, claims and guidance to the industry regarding the safety, benefit and appropriate labeling of specific products is the only one that specifically suggested industry support might be provided for its implementation.

Regardless of the merits of the individual recommendations in the commission's final report, the practical reality of implementing them remains uncertain, if implementation requires resources that the agency does not have available. DSHEA required FDA to implement new regulatory activities related to dietary supplements. However, Congress did not, in general, authorize additional funding for completion of those tasks nor have funds been appropriated. As a result, the agency's existing manpower and financial resources within the Center for Food Safety and Applied Nutrition have been used to maintain its routine regulatory functions, while simultaneously adding implementation of the regulatory requirements for dietary supplements under DSHEA.[8] The commission's report seems to emphasize that the DSHEA-mandated tasks need to be done, but recognizes that they are unlikely to be done, or done well, until adequate funding is provided. Since Congress has, to date, not provided additional funding for these tasks, FDA has had to perform them using existing budgetary resources. If Congress decides to enact these recommendations, it will need to determine whether to provide the agency with additional funding or direct that the tasks be accomplished within the existing budget allocations.

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[8]Department of Health and Human Services, Public Health Service, *Commission on Dietary Supplement Labels; Final Report*(November 1997), 121.