

An hourglass-shaped graphic with a globe inside. The top bulb is dark blue, and the bottom bulb is light blue. The globe is centered in the narrow neck of the hourglass. The text is centered within the hourglass shape.

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*Dietary Supplements: Legislative and Regulatory Status*

Donna V. Porter, Domestic Social Policy Division

Updated July 11, 2002

**Abstract.** This report reviews the statutory changes that the Dietary Supplements Health and Education Act of 1994 contained and the status and impact of their implementation by the federal agencies responsible, particularly the Food and Drug Administration. Numerous bills addressing dietary supplement regulation have been introduced in the 107th Congress, although no further action has yet been taken on them.

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# Report for Congress

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## **Dietary Supplements: Legislative and Regulatory Status**

**Updated July 11, 2002**

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# Dietary Supplements: Legislative and Regulatory Status

## Summary

Congress enacted the Dietary Supplement Health and Education Act (DSHEA) of 1994. DSHEA addressed supplement definitions, safety, ingredient and nutrition labeling, supplement claims, good manufacturing practices, statements of nutritional support, new dietary ingredients, created a supplement commission, and established an Office of Dietary Supplements at the National Institutes of Health.

Since DSHEA's passage, which changed the safety standard and placed the burden of proof for supplement safety on the agency, FDA has issued alerts on several supplements to warn consumers of possible safety problems. The agency has received hundreds of adverse reports allegedly caused by the use of ephedrine alkaloids, although no final action has been taken on regulating this product. The Inspector General has issued a report that evaluates and makes recommendations on the effectiveness of the supplement adverse event reporting system.

In January 2000, FDA issued a 10-year strategic plan for regulation of dietary supplements, which was a list of issues that the agency plans to address: safety, labeling, boundaries among product categories, enforcement, science-based decision-making, and stakeholder outreach. In December 2000, FDA announced it had contracted with the National Academy of Sciences to study and provide a protocol for the agency to use in reviewing supplement safety, as part of the 10-year plan. In May 2002, FDA submitted to Congress a report on the cost of implementing the strategic plan.

FDA's regulation of supplements has been affected by *Pearson v. Shalala*, a lawsuit filed by supplement manufacturers who challenged FDA's general health claims regulation of supplements and decision not to authorize four specific health claims. The U.S. Court of Appeals held that the First Amendment does not permit the agency to reject health claims that it determines to be potentially misleading, unless FDA also reasonably determines that no disclaimer would eliminate the potential deception. The court directed the agency to reconsider the four claims, and FDA has since allowed two claims with qualifiers.

The Federal Trade Commission (FTC) issued an advertising guide for the supplement industry in 1998. FTC addressed such issues as identifying claims and interpreting their meaning, claim substantiation and related issues, to ensure its enforcement efforts are as consistent as possible with the provisions of DSHEA and its enabling laws.

On an international level, the U.N.'s Codex Alimentarius has initiated an effort to provide standards and guidelines for vitamin and mineral products, which could serve as a blueprint for countries wishing to adopt standards into their own laws. The European Commission has proposed a directive for these same products which, if adopted by its member countries, would affect supplements sold in those nations.

Numerous bills addressing dietary supplement regulation have been introduced in the 107<sup>th</sup> Congress, although no further action has yet been taken on them.

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# Dietary Supplements: Legislative and Regulatory Status

Passage of the Dietary Supplements Health and Education Act of 1994 (DSHEA – P.L. 103-417) changed the regulatory framework for dietary supplements in the United States. This report reviews the statutory changes that DSHEA contained and the status and impact of their implementation by the federal agencies responsible, particularly the Food and Drug Administration (FDA), within the Department of Health and Human Services. Oversight of this legislation is likely to be an issue for the 107<sup>th</sup> Congress.

## Background

Following passage of the Nutrition Labeling and Education Act of 1990 (NLEA – P.L. 101-535), the dietary supplement industry had a number of concerns about the impact of NLEA implementation on supplement products. NLEA was the comprehensive legislation requiring nutrition labeling on most food products, including dietary supplements, and allowing nutrient content and health claims to be made on food products, if certain relatively strict criteria were met. The law required that information on specific nutrients be listed on food labels, regardless of whether the nutrients were present.

While dietary supplements were regulated under the category of food, certain NLEA provisions were likely to prove inappropriate or impractical for compliance by supplement manufacturers. For example, the nutrition facts panel on the food label required the listing of several nutrients rarely present in many supplements, such as protein, fat, and carbohydrate, which would appear with zeros as the amount contained in the products. This requirement would take up considerable space on the relatively small supplement packages. At the same time, many nutrient and herbal ingredients that were present would not be allowed to be listed on the nutrition facts panel, because they were not on the government's list of nutrients with recognized consumption standards.

For claims, the strict criteria that the Act specified for either a nutrient content or health claim to be made were expected to be virtually impossible for supplement manufacturers to meet. Both types of claims required prior authorization by FDA, through the use of a petition process, before they were allowed to appear in product labeling. A health claim was allowed only if the agency determined that there was significant scientific agreement based on the totality of the publicly available evidence that a relationship exists between a nutrient and the risk of disease. NLEA gave FDA the discretion to determine whether supplements should make health claims under the same standard and procedure as conventional foods. The agency determined that the same standard and procedure for making health claims should be

followed by both supplements and conventional foods, in part because many substances for which claims would be made (i.e., vitamin C or calcium) were contained in both types of products. However, there is a dearth of peer-reviewed literature on the relationship between most supplement ingredients and health conditions that might be used to support health claims.

Finally, NLEA listed 10 nutrient and disease relationships that FDA was to review for possible authorization as health claims. Prior to passage of the Act, FDA had proposed regulations for six of the 10 relationships listed in the Act for review. The additional four relationships concerned supplement ingredients (folate, zinc, omega-3 fatty acids, and antioxidants), which were added to the Act at the request of the supplement industry. When FDA reviewed the 10 relationships, it initially authorized six claims and has since authorized a total of 13 health claims for food products. The agency initially did not authorize the four claims that were specific to dietary supplements. Since then, the health claim for folate has been authorized, along with a fortification requirement for folate in certain foods. The other three claims continue to be reviewed by the agency (see discussion of the *Pearson* case below).

In April 1991, then-FDA Commissioner Kessler convened an FDA Dietary Supplement Task Force to examine the issues regarding dietary supplements and develop a regulatory framework for these products that would best serve the public health. The Task Force was established following FDA's ban of the amino acid L-Tryptophan, after nearly 1500 cases of illness and 39 deaths were allegedly caused by use of this supplement product.<sup>1</sup> The Task Force considered such issues as how to ensure the safety of supplements, limit the potential for fraud, and ensure that the marketing of supplements did not act as a disincentive for drug development.

In its final 1992 report to the Commissioner, the Task Force concluded that safety should be the overriding concern for FDA in developing a regulatory framework for this class of products.<sup>2</sup> Specific recommendations included regulatory changes for vitamin and minerals, amino acids and other products regulated as supplements, and a number of cross-cutting issues such as: good manufacturing practices, purity and identity, bioavailability, a consumer education program, a compliance program for FDA district offices, compliance with all NLEA provisions, partnerships with nongovernmental experts on scientific issues, an adverse event reaction reporting system, action against misleading product names that implied therapeutic properties, compliance with tamper-resistant and child-proof packaging, coordination with the Federal Trade Commission, coordination with state agencies to regulate supplements, and sharing FDA's policies with the international community. The report and a request for public comment was published in the

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<sup>1</sup> CRS Report 91-758, *L-Tryptophan—Health Problems, Production and Regulatory Status: Proceedings of a CRS Seminar*, by Donna V. Porter. (Archived, available upon request to CRS)

<sup>2</sup> U.S. Food and Drug Administration. Dietary Supplements Task Force. Final Report, May 1992. 93 p.

*Federal Register*,<sup>3</sup> as an advanced notice of proposed rulemaking (ANPR). The supplement industry raised concerns about the notice and the content of the Task Force report.

At that time, the agency viewed supplement ingredients as unapproved and present in products that were formulated and used as either drugs or food additives. The supplement industry viewed the ingredients in their products as having had a long history of use, similar to many food ingredients that were viewed as safe, and therefore, not needing the type of safety testing required for food additives and drug ingredients.

## Congressional Action Since 1992

Ultimately the issues of nutrition labeling, claims and safety led to the passage of DSHEA. In 1992, Congress passed the Dietary Supplement Act (P.L. 102-571), which prohibited the Secretary of the Department of Health and Human Services from implementing the provisions of NLEA that affected dietary supplements. The only NLEA provision allowed to be implemented for supplements was the one concerning authorized health claims. The 1992 Act also required that several reports be prepared for Congress in preparation for subsequent legislation. These provisions included a report prepared by FDA that reviewed the agency's enforcement priorities and practices for supplements;<sup>4</sup> a report prepared by the General Accounting Office that reviewed the management activities of FDA related to supplements, compared to other products regulated by the agency;<sup>5</sup> a report prepared by the Office of Technology Assessment that reviewed the relationship between the regulatory systems affecting the development and sale of dietary supplements and health outcomes (uncompleted); and a report prepared by the Library of Congress that reviewed the efforts of industrialized nations to regulate the manufacture and sale of supplements and the effect of these regulatory efforts on human health.<sup>6</sup> The rationale for these reports was the perception that FDA had taken a disproportionate amount of regulatory action against supplements compared to the other products that it regulated, and that the regulation of supplements in other industrialized countries was a seamless process that provided lessons that Congress might consider for adoption.

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<sup>3</sup> U.S. Food and Drug Administration. Dietary Supplements. Advance Notice of Proposed Rulemaking. *Federal Register* v. 58, June 18, 1993. p. 33690-33751.

<sup>4</sup> U.S. Food and Drug Administration. Enforcement Report: *Statement of the Enforcement Priorities and Practices of the Food and Drug Administration Under Section 409 of the Federal Food, Drug and Cosmetic Act with Respect to Dietary Supplements of Vitamins, Minerals, Herbs and Other Similar Substances*. May 12, 1993. 86 p.

<sup>5</sup> U.S. General Accounting Office. *FDA Regulation: Compliance by Dietary Supplement and Conventional Food Establishments*. Report to Congressional Committees. Washington, D.C., June 13, 1994. 16 p.

<sup>6</sup> U.S. Library of Congress. Law Library. LL 94-3. Dietary Supplements. Report for Congress, February 1994. 79 p.

Before the four reports requested in the 1992 Act were completed, however, Congress passed DSHEA in 1994. The dietary supplement industry had, through health foods stores and other retail outlets, promoted a successful grass-roots campaign to get consumers to sign letters to Members of Congress seeking support for dietary supplement legislation. In exchange, consumers were offered discounts on supplement product purchases.<sup>7</sup> The letters sought relief from the presumed threat that FDA was going to ban certain supplements and require prescriptions for any supplements left on the market. Some supplement retailers staged “black Mondays” where they draped certain supplements in black and refused to sell them on a given day in an effort to convince consumers to sign the form letters. Reportedly, thousands of letters were received by each congressional office as a result of this campaign. There is no evidence that FDA at that time, had plans either to ban most dietary supplements or require prescriptions for their use, nor did the agency have the authority or resources to implement such a policy.

While numerous bills on dietary supplement regulation were introduced in the 103rd Congress, bills introduced in the House (H.R.1709) and Senate (S.784) by Congressman Bill Richardson and Senator Orrin Hatch, respectively, became the focus of debate. There was considerable debate before the Act was passed by unanimous consent in both chambers. In addition, a “Congressional Statement of Agreement” entered into the *Congressional Record* for October 7, 1994, stated that there would be no other reports or statements considered to be legislative history for the bill,<sup>8</sup> a decision which appears to have complicated implementation of the Act. Provisions of the bill are addressed below in the section on implementation.

## Implementation of DSHEA

The implementation of DSHEA has been a piecemeal process because of the diverse provisions in the Act. Discussion in this section is in the chronological order in which the promulgation of regulations for the provisions was completed, rather than the order of the provisions in the Act. For more information on DSHEA, see CRS Report 94-965, *Dietary Supplement Health and Education Act, P.L. 103-417*. (Archived, available upon request from CRS).

**Definitions.** The Act defined a dietary supplement for the first time as meaning a product (other than tobacco) intended to supplement the diet that 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 humans to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combinations of any ingredient described above. The definition further provides that a supplement is a product that is intended for human ingestion as a tablet, capsule, powder, softgel, gelcap, liquid or some other form, is not represented for use as a conventional food or as a sole item of a meal in the diet,

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<sup>7</sup> Giorgianni, A., *Health Food Stores Plan Protest Day*. The Hartford Courant. June 18, 1993, p. D8.

<sup>8</sup> Congressional Statement of Agreement on DSHEA. Dietary Supplement Health and Education Act of 1994. P.L. 103-417. 140 *Congressional Record*. October 7, 1994. S. 14801.



and must be labeled as a dietary supplement. A product marketed as a dietary supplement cannot have been on the market as a new drug or biologic prior to being marketed as a dietary supplement or food. Finally, the Act specifically excluded a dietary supplement or its ingredients from the definition of a food additive.

**Implementation.** Because this section of DSHEA provided specific language defining dietary supplement, FDA did not promulgate regulations. Instead the agency adopted the language from the Act directly into its regulations.

**Safety.** Prior to DSHEA, FDA's primary safety standard for a dietary supplement was whether it failed the general food safety standard; i.e., that it bears or contains any poisonous or deleterious substance which may render it injurious to health. Under DSHEA, the safety standard itself was amended so that a supplement or a dietary ingredient was to be considered unsafe, if it presented a significant or unreasonable risk of illness or injury, under the conditions of use recommended or suggested in labeling, or under ordinary conditions of use. A new dietary ingredient for which there is inadequate information to provide assurance that it does not present a significant or unreasonable risk of illness or injury would be considered unsafe. In situations where the Secretary declares that an ingredient poses an imminent hazard to public health or safety, the department must promptly follow the declaration with a statement that either affirms or withdraws the declaration. The Act placed the burden of proof of showing that a dietary supplement is unsafe on the U.S. government, rather than on the manufacturers. Before the Secretary may report to the Department of Justice that a supplement is unsafe for civil proceedings, the individual against whom the proceeding will be initiated is to be given at least 10 days notice and opportunity to present both oral and written views before the proceedings begin.

**Implementation.** Because this section of DSHEA provided specific language on the safety standard, procedures for a regulatory action and the burden of proof of safety for supplements, FDA did not promulgate regulations. Instead the agency adopted the language from the Act directly into its regulations. Proving "a significant and unreasonable risk to health" after it is on the market is considerably more difficult than demonstrating that a product or its ingredients are safe in controlled situations prior to marketing. Placing the burden of proof on the agency to demonstrate that a marketed supplement is unsafe was a significant departure from the policy for other FDA regulated products for which the manufacturer must demonstrate safety before they are allowed on the market. Additionally, no resources were provided to the agency to implement this provision. There is no requirement for safety or efficacy testing of dietary supplement ingredients that have been on the market since before DSHEA passage. Therefore, there is no database on which to determine whether problems that seem to or are alleged to arise from the use of certain supplements are a serious problem or anticipated side effect on which the agency could base its determination that a supplement or ingredient may be unsafe.

**Withdrawal of ANPR.** DSHEA declared the June 18, 1993, ANPR null and void, and of no force or effect. The Act required FDA to publish a notice to this effect in the *Federal Register*. The ANPR notice had contained the FDA Task Force on Dietary Supplements' published report (mentioned above) along with the agency's

request for comments on the issues raised in the report, particularly on the safety and use of amino acids.

**Implementation.** FDA published a notice of the withdrawal of the ANPR and the report on December 6, 1994.<sup>9</sup>

**Ingredient and Nutrition Labeling.** The Act required that a dietary supplement product label provide the name and quantity of each ingredient, state that it is a dietary supplement, and identify the portion of the plant that is the source of an herbal ingredient. The product is required to meet the identity and strength information that is stated on the label. Required nutrition information is to list first the ingredients and the quantity present in significant amount for ingredients which have a recognized recommendation for daily consumption, followed by ingredients for which there is no recognized recommendation for intake. Labeling statements that characterize the percentage level of a dietary ingredient contained in a supplement are exempt from the regulations on percentage level when the Secretary has not established a standard for the daily consumption of that ingredient. The Act allowed this information to appear on supplement products upon enactment of the law and it required all products to be so labeled by December 31, 1996.

**Implementation.** FDA published the proposed rules on several aspects of nutrition and ingredient labeling for supplements on December 28, 1995.<sup>10</sup> The agency published final regulations on a number of issues for ingredient and nutrition labeling of dietary supplements on September 23, 1997.<sup>11</sup> These final rules addressed statements of identity, nutrition labeling and ingredient labeling, label format, requirements for nutrient content claims, health claims and statements of nutritional support and definitions of high potency, and antioxidants for use in nutrient content claims for both supplements and conventional foods. The final implementation date was March 23, 1999.

**Commission on Dietary Supplement Labels.** DSHEA required that a seven-member presidential commission be appointed to study and provide recommendations for the regulation of label claims and statements for supplements, including the use of literature provided at the point of sale and procedures for evaluating claims. Commission members were to be individuals with expertise and experience in the manufacture, regulation, distribution, and use of supplement products, with at least three members qualified by scientific training and experience to evaluate the benefits to health of supplement use. The Commission was given administrative powers to conduct hearings, and secure necessary information from

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<sup>9</sup> U.S. Food and Drug Administration. Regulation of Dietary Supplements; Withdrawal of Advance Notice of Proposed Rulemaking. *Federal Register*. v. 59, no. 233. December 6, 1994, p. 52644.

<sup>10</sup> U.S. Food and Drug Administration. Food Labeling; Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements. Proposed Rule. *Federal Register*. v. 60, no. 249, December 28, 1995. p. 67194-67224.

<sup>11</sup> U.S. Food and Drug Administration Food Labeling; Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements. Final Rule. *Federal Register*. v. 62, no. 185, September 23, 1997. p. 49825-49892.

federal agencies. It had 2 years to prepare and submit to the President and the Congress a final report on the study, including any recommendations for legislation. The Secretary of Health and Human Services had 90 days following issuance of the report to publish a notice of proposed rulemaking on any recommendations for changes contained in the final report of the Commission. Any rulemaking was to be completed in 2 years after the issuance of the report.

The final report of the Commission on Dietary Supplement Labels was published in November 1997.<sup>12</sup> It contained recommendations in the form of guidance on safety, labeling, NLEA claims on labeling, scope of statements of nutritional support, notification letters and substantiation files for statements of nutritional support, publications exempt from labeling regulations, and botanical products. In addition, the Commission made recommendations regarding information for consumers and health professionals, the need for industry expert advice on key issues, future research, and the National Institutes of Health's Office of Dietary Supplements. One issue that had generated considerable discussion prior to enactment of DSHEA was whether supplements should be required to use the same standards and procedures as conventional foods to make health claims, and the Commission concluded that supplements and conventional foods should use the same standards and procedures. For additional information on the Commission on Dietary Supplement Labels work and report, see CRS Report 97-937, *Dietary Supplements: Commission Report and FDA Regulation*. (Archived, available upon request from CRS)

**Implementation.** FDA published a notice on the Commission's report on April 29, 1998.<sup>13</sup> The agency's comments agreed in general with the Commission's report and indicated willingness to work with appropriate parties to implement the Commission's recommendations. However, FDA did indicate that agency funding levels and statutory constraints prevented implementation of some recommendations.

**Supplement Claims.** DSHEA created a new provision that exempted from labeling regulations any publication, including an article, book chapter, or official abstract of a peer-reviewed scientific publication that appears in an article and was prepared by the authors or editors of the publication which is reprinted in its entirety, when used in connection with the sale of supplements to consumers. Such literature is not to be false or misleading, cannot promote a particular brand of a supplement, must be presented with such items on the same subject matter as to present a balanced view of the available scientific information on a given supplement, is displayed physically separate from the supplements in a retail establishment, and is not appended to a supplement product by any means. This set of criteria does not apply to books or other publications that are sold as part of the business of the retailer or wholesaler. The Act places the burden of proof on the federal government to establish that an article or other such matter is false or misleading.

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<sup>12</sup> Department of Health and Human Services. Public Health Service. Report of the Commission on Dietary Supplements Labels. November 1997. 121p.

<sup>13</sup> U.S. Food and Drug Administration. Dietary Supplements; Comments on the Commission on Dietary Supplements Labels. Notice. *Federal Register*. v. 63, no. 82, April 29 1998. p. 23633.

**Implementation.** FDA did not promulgate rules related to the third party literature available in retail operations that is exempt from labeling regulations. There is neither a monitoring program, nor resources available for the agency to initiate such a program. The requirement that balanced information be available is difficult to enforce because, beyond scientific papers that are not generally consumer friendly, materials that provide information on the benefits of using a particular supplement or ingredient are generally written by those who are being paid to promote the product and have no incentive for providing balanced information. The difficulty in applying the requirements of this provision was considered by the Commission on Dietary Supplements, which suggested proactive monitoring to evaluate practices and determine the need for regulatory guidance.

**Office of Dietary Supplements.** The Act required that the Secretary establish an Office of Dietary Supplements (ODS) within the National Institutes of Health (NIH). The purpose of the Office is to explore the potential role of dietary supplements as a significant part of the efforts to improve health care and promote scientific study of the benefits of dietary supplements in maintaining health and preventing chronic disease. ODS is to conduct and coordinate scientific research within NIH relating to supplements and the extent to which their use can limit or reduce the risk of chronic disease. The Office is to collect and compile the results of scientific research relating to supplements, including from foreign sources and the NIH Office of Alternative Medicine (OAM). ODS is to serve as the principal advisor to the Department on issues related to supplements, including dietary intake regulations, safety of supplements, claims for disease prevention, and labeling and composition issues. Finally, the Office is to compile a database of scientific research on supplements and individual nutrients, and coordinate funding for supplement research within NIH. For FY1994, the Act authorized \$5 million and permanently authorized such sums as may be needed in subsequent fiscal years.

**Implementation.** The Office of Dietary Supplements (ODS) was established in November 1995. It has developed and published a strategic plan,<sup>14</sup> conducted workshops and conferences on numerous dietary supplement ingredients, and established an ad hoc advisors group. ODS has created the International Bibliographic Information on Dietary Supplements (IBIDS) database and continues development of the Computer Access to Research on Dietary Supplements (CARDS) database. It began publishing an annual bibliography of significant advances in dietary supplement research in 2000.<sup>15</sup> In 1996, the Office announced its first research enhancement awards and the number of awards has expanded annually. In collaboration with the NIH National Center for Complementary and Alternative Medicine (formerly OAM), ODS has established Centers for Dietary Supplement research in four NIH-supported universities to study the health effects of botanicals.

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<sup>14</sup> National Institutes of Health. Office of the Director. *Merging Quality Science with Supplement Research*. A Strategic Plan for the Office of Dietary Supplements, September 1998. 34 p.

<sup>15</sup> National Institutes of Health. Office of Dietary Supplements. *Consumer Healthcare Products Association*. Annual Bibliography of Significant Advances in Dietary Supplement Research, 1999. 18p.

**Good Manufacturing Practices.** The Act provided that a dietary supplement not prepared, packed, or held under conditions that meet current good manufacturing practice regulations, including expiration date labeling where necessary, would be considered to be unsafe. The Secretary was allowed, by regulation, to prescribe good manufacturing practices (gmps) for supplements. Such rules were to be modeled after the current gmps for foods and were not to impose standards for which there was no current and generally available analytical methodology. No standard of current gmps was allowed to be imposed, unless that standard was in a regulation that had been promulgated with opportunity for notice and comment.

**Implementation.** FDA published an advanced notice of proposed rulemaking on February 6 1997.<sup>16</sup> This notice contained an industry-submitted document that outlined suggested good manufacturing practices that were based primarily on current food gmps, as well as some additional requirements that industry considered essential to the manufacture of safe and properly labeled supplements. FDA requested comments from all interested parties on the need for and specific requirements in supplements gmps. In addition, the agency sought comments on a number of additional issues: specific defect action levels, appropriate testing requirements, certification standards for sanitation, need for quality control procedures, medical followup for injury or illness reports, procedures for potential safety concerns, specific controls for computer controlled operations, appropriateness of hazard analysis and critical control points system, and specific segments of the supplement industry. The deadline for comments was May 7, 1997. The numerous comments received by FDA provided no clear consensus on the direction that the agency should take. As a result, the agency formed a working group of the FDA Food Advisory Committee to discuss and provide direction to resolve the outstanding questions.<sup>17</sup> The proposed regulations on good manufacturing practices are currently under review by the Bush Administration.

**Statements of Nutritional Support.** DSHEA allowed certain informational messages to be made when the claim benefit related to: 1) a classical nutrient deficiency and its prevalence in the United States, 2) describing the role of a supplement ingredient to affect human structure or function, 3) a documented mechanism of a supplement ingredient to affect human structure or function, or 4) describing general well-being from consumption of a nutrient or dietary ingredient. The manufacturer making such claims was required to have scientific evidence substantiating that the claim was truthful and not misleading. In addition, the statement was required to contain a disclaimer prominently displayed and in boldface type stating that the statements had not been evaluated by FDA and that the product was not intended to diagnose, treat, cure, or prevent any disease. The manufacturer wishing to make this type of claim was required to notify FDA, no later than 30 days

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<sup>16</sup> U.S. Food and Drug Administration. *Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Supplements*. Proposed rule. *Federal Register*. v.62, no.25, Part IV, February 6, 1997. p. 5700-5709.

<sup>17</sup> U.S. Food and Drug Administration. Food Advisory Committee. *Ingredient Identity Testing Records and Retention*. Draft Report, June 25, 1999. 35 p.

after the first marketing of the supplement with this type of informational statement, that such claim is being made.

**Implementation.** FDA proposed rules on statements of nutritional support after the Commission on Dietary Supplements issued its report which had recommended that the agency needed to provide specific guidelines for manufacturers and distributors wishing to make such statements. The proposed regulations addressed how to identify the types of statements that may be made without prior FDA review of the effect of supplements on the structure and function of the body, and how to distinguish these statements from drug claims.<sup>18</sup> However, the proposal received over 235,000 comments with the majority of concerns voiced by the supplement industry that the proposed definition for disease was too narrow to allow most claims to be made, while most comments from the health community either supported the rule or believed that it was not restrictive enough. In response to the significant questions raised in comments on the proposed rule, FDA convened a public meeting on August 4, 1999 to address three major issues: the definition of disease, claims related to natural states (such as pregnancy and menopause) and implied structure/function claims.<sup>19</sup> In the final rule published January 6, 2000, the agency defined the types of supplement statements that can be made concerning structure or function of the body, without prior authorization as health claims.<sup>20</sup> It also provided the criteria for determining when a supplement statement is a claim to diagnose, cure, mitigate, treat or prevent disease, i.e., a drug claim which requires prior approval. On February 22, 2001, FDA announced in the *Federal Register* that it was seeking comments on the types of information that should be included in a guidance document applying the regulations on structure/function statements made for dietary supplements.<sup>21</sup> A separate guidance document on the scientific evidence required for the substantiation of claims is expected to be developed at a later date.

**New Dietary Ingredients.** DSHEA contained provisions for new dietary ingredients that included any ingredient that was not marketed in the United States before October 15, 1994 and excluded ingredients that were marketed in the United States before DSHEA passed. A new dietary ingredient was allowed only if it had been used in a food in a form that had not been chemically altered and there was a history of use or other evidence of safety under the conditions of use recommended. At least 75 days before it is introduced into interstate commerce, the manufacturer or distributor of the supplement or ingredient is to provide the Secretary with

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<sup>18</sup> U.S. 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*. v. 63, no. 82, April 29, 1998. p. 23624-23632.

<sup>19</sup> U.S. 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*. Notice of Public Meeting; Reopening of Comment Period. *Federal Register*. v. 64, no. 130, July 8, 1999. p. 36824-36826.

<sup>20</sup> U.S. 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*. Final Rule. *Federal Register*. v. 65, no. 4. p. 1000-1050.

<sup>21</sup> U.S. Food and Drug Administration. *Guidance on Applying the Structure/Function Rule; Request for Comments*. *Federal Register*. v. 66, no. 36. p. 11172.

information, including any citation of published articles which led the manufacturer or distributor to conclude that the ingredient will be expected to be safe. The Secretary is to keep confidential any information provided for 90 days following its receipt, before placing it on public display, while maintaining privacy of any information that pertains to trade secrets or otherwise confidential, commercial information. The Act created a mechanism for any person to file with the Secretary a petition, proposing the issuance of an order prescribing the conditions under which a new dietary ingredient, taken under its intended conditions of use, will be reasonably expected to be safe. The Secretary has the responsibility to make a decision on this type of petition within 180 days of its filing. The Secretary's decision is considered to be final agency action on the matter.

**Implementation.** FDA published the final rule on premarket notification for a new dietary ingredient on September 23, 1997.<sup>22</sup> The agency had proposed this rule in September 1996. The regulation requires that certain information be submitted to the agency as part of the notification of a new dietary ingredient, 75 days before it is marketed. FDA will acknowledge receipt of the notification. The regulation became effective on October 23, 1997. To date, the agency has reviewed and allowed about 70 new dietary ingredients to be used in supplement products. In February 2001, FDA published a guidance document on agency notification for new dietary ingredients in supplements.<sup>23</sup>

## FDA Regulatory Actions on Specific Supplement Products

Since passage of DSHEA, FDA has issued alerts on several dietary supplements to warn consumers about possible health and safety problems. Specific alerts have been issued for Tiratricol (a potent thyroid hormone, November 21, 2000);<sup>24</sup> Aristolochic Acid (a potent carcinogen and nephrotoxin, April 6, 2001);<sup>25</sup> St. John's Wort and Indinavire (drug interactions, February 10, 2000);<sup>26</sup> Triax Metabolic Accelerator (potent thyroid hormone, November 11, 1999);<sup>27</sup> Gamma Hydroxybutyric Acid, Gamma Butrolactone, and 1,4 Butanediol (life-threatening cardiovascular

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<sup>22</sup> U.S. Food and Drug Administration. Premarket Notification for a New Dietary Ingredient. Final Rule. *Federal Register*. v. 62, no. 184, September 23, 1997. p.498860-49892.

<sup>23</sup> U.S. Food and Drug Administration. New Dietary Ingredients in Dietary Supplements. [<http://www.cfsan.fda.gov/~dms/ds-ingrd.html>]

<sup>24</sup> U.S. Food and Drug Administration. FDA warns against consuming dietary supplements containing Tiratricol. [<http://www.cfsan.fda.gov/~lrd/tptriac.html>]

<sup>25</sup> U.S. Food and Drug Administration. FDA concerned about botanical products, including dietary supplements, containing Aristolochic Acid. [<http://www.cfsan.fda.gov/~ds-bot.html>]

<sup>26</sup> U.S. Food and Drug Administration. FDA Public Health Advisory: risk of drug interactions with St. John's Wort and Indinavir and other drugs. [<http://www.fda.gov/cder/drug/advisory/stjwort.html>]

<sup>27</sup> U.S. Food and Drug Administration. FDA warns against consuming Triax Metabolic Accelerator. [<http://www.cfsan.fda.gov/~lrd/tptriax.html>]

effects, August 25, 1999),<sup>28</sup> LipoKinetic (serious liver injuries, November 19, 2001),<sup>29</sup> Kava products (liver injury, December 19, 2001),<sup>30</sup> and PC SPES and SPES (undeclared prescription drug ingredients, February 8, 2002).<sup>31</sup>

Ephedrine alkaloids, used for weight loss and body building, is the dietary supplement that has gotten most media attention since passage of DSHEA. FDA has received numerous adverse event reports about its use, issued alerts (March 31, 2000), convened Food Advisory Committee meetings (October 11-12, 1995 and August 27-28, 1996), held a public meeting (August 8, 2000), proposed regulations (June 4, 1997), partially withdrawn regulations (April 3, 2000), and testified before the House Committee on Governmental Reform (May 27, 1999) on this supplement. No final action has been taken by FDA on ephedrine alkaloids. For additional information, see CRS Report RL30750, *Dietary Supplements: Ephedra*.

Recent concern has been raised about mad cow disease and dietary supplements, although so far there is no evidence that a problem exists with supplements containing animal tissue. Because bovine brain tissue is used in certain supplements intended to boost intelligence, sexual drive and energy, the potential exists for transmission of the disease. Supplement manufacturers are not required to provide label information on country of origin or animal tissues used in preparing the products. Completion of the good manufacturing practices regulations could be expected to improve confidence in the control over the source of ingredients used in supplement products containing animal tissue. In November 2000, FDA published a letter to reiterate public health and safety concerns to supplement manufacturers making or importing supplements that contain specific bovine tissues.<sup>32</sup>

On January 30, 2001 FDA published a letter to manufacturers regarding botanicals and other novel ingredients in conventional foods.<sup>33</sup> The letter raised general concerns about whether some herbal and other botanical ingredients that are being added to conventional food may cause the food to be adulterated, because these added ingredients are not being used in accordance with an approved food additive regulation and may not be generally recognized as safe for their intended use.

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<sup>28</sup> U.S. Food and Drug Administration. FDA warns about products containing Gamma Butyrolactone or GBL and asks companies to issue a recall. [<http://www.cfsan.fda.gov/~lrd/tpgbl.html>]

<sup>29</sup> U.S. Food and Drug Administration. FDA Warns Consumers Not To Use the Dietary Supplement LipoKinetix [<http://www.cfsan.fda.gov/~dms/ds-lipo.html>]

<sup>30</sup> U.S. Food and Drug Administration. Letter to Health Professionals about FDA Seeking Information on Liver Injury and Kava Products. [<http://www.cfsan.fda.gov/~dms/ds-ltr27.html>]

<sup>31</sup> U.S. Food and Drug Administration. 2002 Medical Product safety Alerts. PC SPEC and SPES (BotanicLab) [<http://www.fda.gov/medwatch/SAFETY/2002/safety02.html>]

<sup>32</sup> U.S. Food and Drug Administration. Letter to Reiterate Certain Public Health and Safety Concerns to Firms Manufacturing or Importing Dietary Supplements that Contain Specific Bovine Tissues. [<http://www.cfsan.fda.gov/~dms/dspltr05.html>]

<sup>33</sup> U.S. Food and Drug Administration. New Dietary Ingredients in Dietary Supplements. [<http://www.cfsan.fda.gov/~dms/ds-ltr15.html>]



In an effort to improve communication and assist consumers, FDA launched *Tips for the Savvy Supplement User: Making Informed Decisions and Evaluating Information in January 2002*.<sup>34</sup> The website offers basic points to consider in using supplements, tips on searching the web for supplement information, tips and to-do's, and selected references for further information.

## FDA 10-Year Strategic Plan for Supplements

In January 2000, FDA issued a 10-year plan that outlines its strategy for the regulation of dietary supplements.<sup>35</sup> The stated goal is to have a science-based regulatory program fully implementing DSHEA in place by the year 2010, to provide consumers with a high level of confidence in the safety, composition and labeling of dietary supplement products. Under safety issues, the agency has listed adverse event reporting, good manufacturing practices, health hazard evaluations, a supplement safety database, new dietary ingredients, voluntary submissions, and internet surveillance. Labeling issues include resolution of *Pearson v. Shalala* (discussed below), health claims petitions, database and substantiation for structure/function claims, authoritative statements, consumer and marketplace labeling surveys, publications, and small business exemptions. "Boundary" issues concern structure/function claims, supplements vs. drugs, supplements vs. conventional foods, botanicals, supplement exclusions, dual status, combination products, and supplements vs. cosmetics. Enforcement activities will include an enforcement strategy, capacity building, and Federal Trade Commission coordination. Under the science-base, the agency has listed strengthening the science-base, research efforts, dietary supplement ingredient reviews, leveraging resources, consumer and marketplace research, regulatory oversight of human studies, adverse event report monitoring system, claims, and an interagency clearinghouse. Finally, FDA indicates its desire to enhance outreach through the use of advisory committees, additional stakeholder outreach and communication.

In December 2000, FDA announced that it had contracted with the National Academy of Sciences' Institute of Medicine to study and provide an appropriate protocol for the agency to use in reviewing the safety of dietary supplements,<sup>36</sup> as outlined in the 10-year plan. The work is to include development of a proposed framework for categorizing and prioritizing dietary supplement ingredients based on safety issues, a process for developing a review system with specifications for evaluating the safety and role in health of dietary supplement ingredients, and development of at least six prototypes as examples of using the framework. The framework is to include a methodology for evaluating the available peer-reviewed literature with regard to the role of supplement ingredients in health, taking into

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<sup>34</sup> U.S. Food and Drug Administration. Center for Food Safety and Applied Nutrition. Dietary Supplements. *Tips for the Savvy Supplement User: Making Informed Decisions and Evaluating Information*. [<http://www.cfsan.fda.gov/~dms/ds-savvy.html>]

<sup>35</sup> U.S. Food and Drug Administration. Center for Food Safety and Applied Nutrition. *Dietary Supplement Strategy (10-Year Plan)*. January 2000. 14 p.

<sup>36</sup> U.S. Food and Drug Administration. Center for Food Safety and Applied Nutrition. *Letter to Stakeholders Regarding Contract on Dietary Supplement Safety Issues*. Letter and Scope of Work. December 15, 2000. 4 p.

consideration methods other expert bodies have used to categorize and review issues related to safety and possible roles in health of supplements and their ingredients. The contract is to be completed by September 29, 2002.

FDA's Center for Food Safety and Applied Nutrition announced that it was preparing a report that addressed a congressional inquiry about the amount of money that the agency would need to implement the 10-year strategic plan issued in 2000. Reportedly, the request would be for "tens of millions of dollars" for supplement oversight, including adequate inspections of manufacturing operations.<sup>37</sup> The agency indicated its belief that the future of the enforcement program depends on adequate funding in the long term. In a report transmitted to Congress on May 29, 2002, FDA indicated that its base funding for dietary supplements in FY2001 was approximately \$6 million and 46 FTEs (year 2 of the plan).<sup>38</sup> The agency estimates the initial investment cost to implement the strategic plan would range from \$20 million to \$40 million for year 3, followed by an additional investment from \$30 million to \$55 million for year 4 and a final investment from \$40 million to \$65 million for year 5. These estimates are reported in FY2002 current dollars.

## FDA and the *Pearson* Case

Following the determination by the Commission on Dietary Supplement Labels that the same standard and procedure for making health claims should be followed for both supplements and conventional foods, FDA issued final regulations applying the general requirements for health claims on supplements. Subsequently, lawsuits were filed on behalf of a manufacturer that wished to make health claims for several supplements, which were not authorized by the agency. In the case of *Pearson v. Shalala*, the plaintiffs challenged FDA's general health claims regulation for supplements and the agency's decision not to authorize health claims for four specific substance and disease relationships. The claims that were not authorized were: dietary fiber and cancer, antioxidant vitamins and cancer, omega-3 fatty acids and coronary disease, and the comparative claim that .8 milligrams of folate in supplement form is more effective in reducing the risk of neural tube defects than a lower amount in conventional food form.

In 1998, a federal district court ruled for FDA in all respects. However, the U.S. Court of Appeals for the D.C. Circuit reversed the lower court's decision, holding that the First Amendment does not permit the agency to reject health claims that it determines to be potentially misleading, unless FDA also reasonably determines that no disclaimer would eliminate the potential deception. The court invalidated the FDA regulations that prohibited authorization of the four health claims and directed the agency to reconsider the four claims. Further, the court held that the agency was required under the Administrative Procedure Act to clarify the "significant scientific agreement"(SSA) standard for authorizing claims, either by issuing a regulatory

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<sup>37</sup> FDA to Seek Tens of Millions of Dollars to Oversee Supplements. *Inside Washington's FDA Week* v. 7. no.8, February 23, 2001. p 1.

<sup>38</sup> U.S. Food and Drug Administration. Center for Food Safety and Applied Nutrition. Dietary Supplement Strategic Plan Cost Out. Report to Congress. May 29, 2002. 13 p. <http://www.cfsan.fda.gov/~dms/ds-stra2.htm>

definition, or defining it on a case-by-case basis. On March 1, 1999, the government filed a petition for reconsideration by the full Court of Appeals, but the petition was denied on April 2, 1999.

On December 1, 1999, FDA published a notice on its strategy for implementing the *Pearson* court decision.<sup>39</sup> The components of the plan included: a) updating the scientific evidence on the four claims in the case, b) issuing guidance clarifying the SSA standard,<sup>40</sup> c) convening a public meeting to solicit input on changes to FDA's general health claims rules for supplements that were warranted in light of the *Pearson* decision,<sup>41</sup> d) initiating rulemaking to reconsider the general health claims rules in light of the *Pearson* decision, and e) conducting rulemaking on the four *Pearson* health claims. Since then, the agency has completed the first three components of the *Pearson* implementation strategy and issued an interim enforcement strategy for supplement health claims.

Subsequent to that notice, FDA released letters regarding the four *Pearson* health claims. In each case, the agency has provided documentation based on the available scientific evidence that supports its decisions concerning the claims. FDA has continued to deny the claim for fiber and colorectal cancer, which the scientific evidence does not support and stated that use of a qualifier would be misleading.<sup>42</sup> Likewise, the agency continues to deny the comparative claim for folic acid and neural tube defects which also is not supported by scientific evidence and finds the use of a qualifier would be not remedy the statement's untruthfulness.<sup>43</sup> FDA initially allowed the claim for omega-3 fatty acids and coronary heart disease, with a qualifier,<sup>44</sup> but subsequently changed its position to allow a disclaimer that the evidence is inconclusive.<sup>45</sup> The agency also has allowed the claim for folic acid,

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<sup>39</sup> U.S. Food and Drug Administration. Food Labeling; Health Claims and Label Statements for Dietary Supplements; Update to Strategy for Implementation of Pearson Court Decision. *Federal Register* v.65, no.195, October 6, 2000. p. 59855-59857.

<sup>40</sup> U.S. Food and Drug Administration. Guidance for Industry Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements. [<http://www.cfsan.fda.gov/~dms/ssaguide.html>].

<sup>41</sup> U.S. Food and Drug Administration. Food Labeling; Dietary Supplement Health Claims; Public Meeting Concerning Implementation of Pearson Court Decision and Whether Claims of Effects on Existing Disease May Be Made as Health Claims. Announcement of Public Meeting. *Federal Register* v. 65, no. 52, March 16, 2000. p. 14219-14223.

<sup>42</sup> U.S. Food and Drug Administration. Letter Regarding Dietary Supplement Health Claim for Fiber with Respect to Colorectal Cancer. To Jonathan Emord. October 10, 2000. 21 p.

<sup>43</sup> U.S. Food and Drug Administration. Letter Regarding Dietary Supplement Health Claim for Folic Acid with Respect to Neural Tube Defects. To Jonathan Emord. October 10, 2000. 15 p.

<sup>44</sup> U.S. Food and Drug Administration. Letter Regarding Dietary Supplement Health Claim for Omega-3 Fatty Acids and Coronary Heart Disease. To Jonathan Emord. October 31, 2000. 30 p.

<sup>45</sup> U.S. Food and Drug Administration. Letter Regarding Dietary Supplement Health Claim for Omega-3 Fatty Acids and Coronary Heart Disease. To Jonathan Emord. February 8, (continued...)

vitamin B6 and vitamin B12 and vascular disease, with a qualifier.<sup>46</sup> FDA completed its review of the petition for a health claim for antioxidants and cancer, and concluded that there is no significant scientific agreement for a relationship between antioxidant vitamins and certain types of cancer or individual cancers. And therefore, the agency finds that any health claim relating antioxidant vitamins and reduced risk of cancer is inherently misleading and cannot be made non-misleading with a disclaimer or other qualifying language.<sup>47</sup>

## Inspector General's Report on Dietary Supplements

In April 2001, the HHS Inspector General (IG) released its findings and recommendations on FDA's adverse events reporting system for dietary supplements and its effectiveness as a consumer protection tool.<sup>48</sup> The report finds that FDA's adverse event reports (AERs) system detects relatively few adverse events due to underreporting, and has difficulty generating signals of possible public health concerns because of the limited information for the AERs that are collected. In addition, FDA lacks vital information to adequately assess signals of possible public health concerns generated by the AERs system, which is limited by a lack of clinical information on both safety studies and consumer use. The IG determined that as a result of the dearth of information in all aspects of the AERs system, FDA rarely takes safety actions.

The IG recommendations included facilitating greater detection of adverse events by requiring supplement manufacturers to report serious adverse events to FDA. The IG also said the agency should obtain the Poison Control Centers AERs for supplements, and health professionals and consumers need to be better informed about the AERs system for supplements. A second recommendation was to obtain more information on AERs in order to generate stronger signals of public health concerns by educating health professionals about the importance of including medical information in AERs, requiring supplement manufacturers and their products to be registered with FDA, notify manufacturers when FDA receives a serious AER, emphasize to health professionals and consumers the importance of providing a way to identify the alleged injured party, and develop a new computer database to track and analyze AERs.

In order to obtain vital information to adequately assess signals generated by the AERs system, the report recommends that FDA issue guidance on the type of safety

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<sup>45</sup> (...continued)

2002. FDA Week. February 15, 2002. p. 14.

<sup>46</sup> U.S. Food and Drug Administration. Letter Regarding Dietary Supplement Health Claim for Folic Acid, Vitamin B6 and Vitamin B12 and Vascular Disease. To Jonathan Emord. November 28, 2000. 37 p.

<sup>47</sup> U.S. Food and Drug Administration. Letter Regarding Petition for Health Claim: Antioxidants and Cancer. To Jonathan Emord. May 4, 2001. 99 p.

<sup>48</sup> Dept. of Health and Human Services. Office of Inspector General. Adverse Event Reporting for Dietary Supplements: An Inadequate Safety Valve. OEI-01-00-00180. April 2001. 110p.

information that manufacturers should include in the 75-day premarket notification requirements for some new supplement ingredients, explore use of a monograph system for supplements containing safety information on particular ingredients, collaborate with NIH in setting a research agenda addressing safety issues, assist industry and U.S. Pharmacopeia in standardizing supplement ingredients particularly for botanicals, and expedite the development and implementation of GMPs for supplement manufacturers. Finally, the IG report recommended disclosure of more useful information to the public about dietary supplement AERs.

## Federal Trade Commission and Supplement Advertising

Although DSHEA applied to the labeling of dietary supplements, which is regulated by FDA, the Federal Trade Commission (FTC) issued an advertising guide for the dietary supplement industry following its passage.<sup>49</sup> FDA has responsibility for claims in product labeling and FTC has responsibility for claims in product advertising. The two agencies work closely together under a liaison agreement to ensure that their enforcement efforts are consistent to the fullest extent possible under their respective laws. In the advertising guide, FTC has addressed such issues as identifying claims and interpreting meaning conveyed in the advertising message, substantiating claims and other issues (testimonials and expert endorsements, traditional use, use of the DSHEA disclaimer, and third party literature).

Since release of this 1998 Supplement Advertising Guide, FTC reports having stepped up its enforcement activities and that 17 cases in which the Commission took action have been settled.<sup>50</sup> Included were claims for remedies for serious diseases that were not supported by competent and reliable scientific substantiation, safety problems without warning statements, and a few cases in which monetary relief was required. Some serious conditions for which claims were made included cancer, AIDS, arthritis, attention deficit/hyperactivity disorder (ADHD), and weight loss. An additional 20 active investigations involving supplement products are underway, focusing on similar enforcement concerns: safety, lack of scientific support for claims, widespread national advertising claims of unproven products, and internet fraud.

## Codex Alimentarius and European Union Activities

Several efforts are underway to develop international guidelines for supplements containing vitamins and minerals. The Codex Alimentarius is an international intergovernmental body responsible for the implementation of the United Nation's Joint Food and Agriculture Organization/World Health Organization's Food Standards Program. Its committees meet on a regular basis to draft standards and guidelines that affect various aspects of food trade. The Committee on Nutrition and Foods for Special Dietary Uses is responsible for determining the need to develop

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<sup>49</sup> U.S. Federal Trade Commission. Bureau of Consumer Protection. *Dietary Supplements: An Advertising Guide for Industry*. 25 p.

<sup>50</sup> Federal Trade Commission. *Dietary Supplement Advertising Activities*. February 2001. 4 p.

standards and guidelines on the nutritional quality of foods, including supplements. At a 1995 meeting the Committee voted to draft proposed guidelines on vitamins and mineral products, addressing recommendations for minimum and maximum dosages, approved and prohibited ingredients, and labeling claims. At a 1996 meeting, Committee members reached agreement on most issues. However, unresolved was the method to use in setting safe upper dosage levels for vitamins and minerals, in part because different methods result in different levels. After 5 years of debate, this issue remains unresolved, although the Committee continues to work toward completing the guidelines on vitamins and minerals. At the November 2001 meeting, Committee members proposed a preamble to the document on guidelines for vitamins and mineral products. The Committee is seeking comments on the preamble and other changes to the guidelines until the next session meeting scheduled for Berlin in November 2002.

The Codex draft document on guidelines for vitamins and minerals reflects the concern of several governments about the current level of regulation of supplements in some countries. If finalized, the document would represent agreement of the signatory nations that these products should be regulated at some baseline level. The Codex document would not be binding on any member country, unless the guidelines were adopted into the laws of that country. Completion of the Codex document will not dictate the sale, availability or content of supplements marketed in the United States, unless its provisions are enacted into law by Congress. The adoption of the guidelines into law by other countries could affect the export of U.S.-produced supplements to those countries, if U.S. manufactured supplements do not meet the standards set by the regulations of those countries. For further information on this issue, see CRS Report 98-500, *Dietary Supplements: FDA Reform and Codex*.

The European Commission announced in May 2000 that it had adopted a proposal for a directive on food supplements setting out harmonized rules for the sale of vitamins and minerals as dietary supplements. The objectives are to set a general framework and safety rules for vitamins and minerals in the European Union, and to provide consumers with detailed information through labeling on recommended daily consumption, warnings on side effects from excessive use, and a statement that the pills are not a substitute for a varied diet. Health claims are prohibited and products packaged in a way that resembles a pharmaceutical product must carry the statement that "this is not a medicinal product." The proposal contains a positive list of chemical substances authorized for use in the production of vitamins and minerals.

The proposal for a directive on food supplements is part of a package of measures being considered on food safety. The European Parliament and Council of Ministers have to agree for this directive to take effect. If adopted, the directive would become effective on May 31, 2002, allowing the marketing of products complying with its provisions as of June 2002 and prohibiting the marketing of products that do not respect its rules no later than June 2004. It is unclear at this time what impact this directive, if adopted, will have on U.S.-manufactured vitamin and mineral products. The final document was expected to be issued in 2001. However, several EU member countries have blocked completion of the current proposals. The disagreement, not surprisingly, concerns how to set a safe upper level of the vitamins and minerals, the subject of protracted debate in the Codex committee trying to address the same issue.

## Bills in the 107<sup>th</sup> Congress

A number of bills concerned with dietary supplements have been introduced in the 107<sup>th</sup> Congress. Addressed in this report are supplement bills that directly concern supplement regulation and tax exemptions. Several additional bills concerned with ephedra, allowing supplements to be purchased with food stamps, general FDA appropriations to enhance enforcement, access to medical treatment, bioterrorism and importation issues will not be addressed in this report because they are the subject of other CRS publications that address supplements among the other products regulated by FDA.

Senator Harkin and Representative Burton introduced the Dietary Supplement Tax Fairness Act of 2001 (S. 1330 and H.R. 3475). The bills would amend the Internal Revenue Code of 1986 to provide that amounts paid for foods for special dietary use, dietary supplements or medical foods be treated as medical expenses. It was referred to the Senate Committee on Finance and the House Committee on Ways and Means.

The Ginseng Truth in Labeling Act of 2001 (S. 1664 and H.R. 3329) was introduced by Senator Feingold and Congressman Obey. The bills would require the country of origin labeling of the raw agricultural form of ginseng by requiring disclosure in a particular manner and leveling fines for failure to disclose this information. These bills were referred to the Senate Committees on Agriculture, Nutrition and Forestry, Health, Education, Labor and Pensions, and the House Committees on Agriculture, and Energy and Commerce.

The Foods are not Drugs Act (H.R. 2265) was introduced on June 21, 2001 by Representative Paul. The bill would allow consumers greater access to information regarding the health benefits of food and dietary supplements, by allowing foods and dietary supplements to make claims for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or animals. This bill was referred to the House Committee on Energy and Commerce.

On October 9, 2001 Representative Davis introduced the Dietary Supplement Information Act (H.R. 3065). The bill would require that manufacturers of dietary supplements register with FDA and submit reports on adverse experiences regarding their supplement products to the agency, provide for inspection authority for records on dietary supplements, require labeling of supplements with a toll-free telephone number and internet address, and set a deadline for the publication of proposed rules for good manufacturing practices for supplements. It was referred to the House Committee on Energy and Commerce.

In February 2002, Representative Paul introduced a bill to amend FDCA to establish a system independent of FDA for the review of health claims, to define health claims and for other purposes. The Health Information Independence Act of 2002 would extend certain food and nutrition labeling requirements to dietary supplements and would require nutrition labels to include the relationship of a nutrient to the prevention, treatment or cure of a disease. The Secretary of HHS would be required to solicit independent scientific reviewers from the academic community to review, evaluate and make recommendations on a particular nutrient-

disease association based on the available scientific evidence, excluding health claims only if they are unsupported by credible scientific evidence and no disclaimer could eliminate potentially misleading connotations. Reviewers' recommendations would be binding on the Secretary and reviewable only by the U.S. Court of Appeals of D.C. The bill would require the cost of the reviews to be offset against the operating budget of the Department of Health and Human Services. It was referred to the House Committee on Energy and Commerce.

## Interest in the 107<sup>th</sup> Congress

Oversight hearings on DSHEA were expected to be an issue taken up by both chambers during the 107th Congress, although to date only one hearing has been held. On March 20, 2001 the House Committee on Government Reform held a hearing on the current status of DSHEA implementation with particular attention to issues concerning the Codex Alimentarius and the development of supplement-specific GMPs. The nongovernmental and FDA witnesses all agreed that additional funding and other resources are needed for the agency to improve its enforcement activities.

A bipartisan congressional caucus on Complimentary and Alternative Medicine, and Natural Foods was established in the 107<sup>th</sup> Congress. It was designed to educate Members on evolving policy and regulatory issues on alternative health practices and natural foods through seminars and other events. The inclusion of natural foods as a main focus of the caucus indicates the expanding interest in the use of such products as vitamins, minerals, and botanicals to improve or sustain health. Concern that FDA lacks authority and funding to adequately oversee such products has led several trade associations and organizations to pursue private certification and review approaches for these products.

Considerable attention has been raised recently on the issue of FDA funding and adequate appropriations to implement its statutory mandates and other congressional directives on the regulation of dietary supplements. FDA's release of the report to Congress estimating the funding for implementation of the strategic plan for supplement regulation provides additional information to be considered in future appropriations for supplement enforcement. The 2000 House hearing elicited a unanimous response from witnesses on increased appropriations for enforcement activities for dietary supplements. The Inspector General's report provides considerable discussion on the effectiveness of the current supplement adverse events reporting system and makes recommendations on how to improve its usefulness, including adequate resources. Congress may wish to consider what seems to be a general concern from both the agency and others that FDA needs adequate funding in the future, if DSHEA is to be fully implemented.