

Table 5

**OBLIGATIONS FOR NUTRITION RESEARCH AND TRAINING BY
AGENCY, FISCAL YEARS 1986 THROUGH 1995
(THOUSANDS OF DOLLARS)**

Agency	1986	1987	1988	1989 ^a	1990	1991	1992	1993 ^b	1994	1995
Department of Health and Human Services (DHHS):										
National Institutes of Health	212,978	260,611	276,195	286,975	292,359	310,810	343,788	373,251	400,701	428,687
Food and Drug Administration	8,143	6,799	10,470	10,063	7,397	10,527	10,958	7,661	2,054	1,464
Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA)	7,548	7,685	7,545	9,603	11,876	18,875	15,019	-	-	-
Centers for Disease Control (CDC)	569	561	537	5,216	5,084	6,006	6,074	5,579	5,633	4,713
National Center for Health Statistics (NCHS)	804	3,885	4,227	-	-	-	-	-	-	-
Health Resources and Services Administration	1,151	1,147	1,625	1,114	959	1,717	1,858	1,025	579	344
Total DHHS	231,193	280,687	300,599	312,971	317,675	347,935	377,698	387,515	408,966	435,208
U.S. Department of Agriculture	61,265	67,601	70,029	65,433	62,467	63,756	70,563	67,435	73,912	84,217
Agency for International Development	4,998	4,364	6,037	6,492	4,147	4,617	4,157	3,958	3,922	6,104
National Science Foundation	-	-	-	-	-	79	19	29	29	41
Department of Veterans Affairs	5,500	2,021	2,816	3,104	2,379	2,139	2,366	4,379	4,076	9,962
Department of Commerce	1,000	946	1,078	989	1,016	937	1,199	981	576	502
Department of Defense	782	533	4,091	421	488	849	3,631	3,176	2,869	3,545
National Aeronautics and Space Administration	-	-	37	-	-	428	679	681	687	855
Total Federal Expenditures	304,738	356,152	384,687	389,410	388,172	420,739	460,311	468,153	495,038	540,436

^a In FY/89, CDC includes NCHS.

^b In FY/93, NIH includes ADAMHA.

Source: This table was modified from information provided by the Human Nutrition Research and Information Management System 13th Progress Report (74, 82).

Support for research from the private sector depends to a considerable degree on the economic return that may be expected from investments in research. While some companies make grants and donate products for research studies, the Commission was unable to obtain any reliable information on the dietary supplement industry's overall investment in research on product efficacy and safety. Public testimony to the Commission indicated that many of the products marketed as dietary supplements do not have patent protection, thus marketing advantages obtained through research are difficult to maintain because the research results would be available to competitors as well as the company supporting the research. The Commission took note of the discussion of research issues related to health claims in the recent Keystone report (80) and believed that the discussion was particularly relevant to consideration of mechanisms for support of research on dietary supplements.

FINDINGS

The Commission reached the following conclusions about research issues related to dietary supplements:

- The dietary supplement industry is diverse, with a number of large companies and several hundred relatively small companies manufacturing and/or marketing dietary supplements. The small size of many companies contributes to limited investment by individual companies in research on product efficacy. These companies have been able to market products either with no label claims or now, under DSHEA, with statements of nutritional support without heavy research investment. It may be difficult for such companies to envision increased economic return on greater research investment. In lieu of investment in research, substantiation of statements of nutritional support has been based on extension of publicly available research, research conducted overseas, or a history of use.
- The Commission heard testimony in its public hearings that most dietary supplements, being natural or generic products, cannot be given effective patent protection. Therefore a manufacturer lacks incentive to expend resources for research that might benefit competitors as well as itself.
- Conducting clinical research to assess the validity of statements of nutritional support could be difficult. A statement that a product provides a feeling of well-being may be confounded with the placebo effect, thus double-blind studies using placebo would be essential to assessing such statements. A statement that a product enhances immune function requires an appropriate challenge using acceptable clinical and biochemical methodology to determine whether the product actually improves resistance to common conditions such as colds and flu. Such research is resource intensive.
- Many dietary supplements claim to improve or optimize the functioning of the human body and do not result in immediate drug-like effects. The "soft" end points of research supporting such claims can make clinical research results ambiguous. The cost of research to

prove moderate benefits is significantly higher than that of research to prove immediate relief of disease symptoms. In addition, identification of benefits for particular segments of the population will require either multiple trials involving each group or large studies that involve several population subgroups.

- For a health claim to be made under NLEA, a considerable body of research must demonstrate that a food or dietary supplement ingredient will reduce risk for a specific disease or condition. The research base must be sufficient to permit significant scientific agreement among qualified scientists. Existing health claims generally have not been based on research supported by a single company, but have relied on research funded by both government and industry. For example, the recently approved health claim that soluble fiber from whole oats reduces the risk of coronary heart disease was based on research supported by NIH and the petitioner over a period of many years.
- Determination of prevention in the general population, or even in a population at risk for developing a specific disease, is more expensive and difficult than determination of an effect in a population with a disease. Determining any relationship between dietary ingredients and disease or risk of developing a disease may require numerous expensive, large-scale clinical trials.

GUIDANCE

- The Commission believes that the public interest would be served by more research that assesses the relationships between dietary supplements and maintenance of health and/or prevention of disease.
- Incentive mechanisms should be developed to encourage the dietary supplement industry to invest in research on products offered to the consumer. FDA might consider a mechanism for review of research conducted to validate a statement of nutritional support so that the label disclaimer mandated by DSHEA could be modified or removed. More consideration is needed of ways to provide sufficient resources to FDA to make it possible for the agency to take on such an additional responsibility.
- The Commission recommends that Federal agencies continue to support research on the health benefits and safety of dietary supplements. Research should be expanded beyond the traditionally supported areas associated with vitamin and mineral supplements and include research on some of the more promising botanical products used as dietary supplements.

NIH OFFICE OF DIETARY SUPPLEMENTS

DSHEA established the Office of Dietary Supplements within NIH for the purpose of exploring the potential role of dietary supplements as a significant part of the

efforts of the United States to improve health care, and to promote scientific study of the benefits of dietary supplements in maintaining health and preventing chronic disease.

Most of the duties outlined by DSHEA for ODS are related to conducting, coordinating, or compiling the results of scientific research. ODS is directed by the Act to conduct and coordinate scientific research relating to dietary supplements within NIH, to coordinate funding for such research, to collect and compile the results of scientific research on dietary supplements, and to compile a database of such research. In addition, DSHEA directs ODS to "...serve as the principal advisor to the Secretary and to the Assistant Secretary for Health and provide advice to the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of Food and Drugs on issues..." relating to safety, benefits, and labeling of dietary supplements.

The Commission observes that ODS has so far not been provided with sufficient staffing or funds to achieve these goals. While an annual budget of \$5 million was authorized by DSHEA in 1994, the Commission notes that currently, ODS has an annual budget of about \$1 million. Much of its work over recent months has focused on assessment of priorities among several mandated tasks; collection and organization of information concerning research activities, both within NIH and throughout other Federal agencies; and gathering information on research needs.

The development of a strategic plan has been a major activity of ODS. A draft plan has been developed with the assistance of industry, the scientific community, and others. The final plan will probably not be available until after the Commission completes this report. Nevertheless, the Commission believes that critical evaluation of the ODS strategic plan for research will be essential if the intent of DSHEA is to be realized fully.

ODS has great potential, but has so far been unable to reach that potential due to inadequate staffing and funding. If adequate resources can be provided, the Commission believes ODS could play a valuable role in providing consumers with information about dietary supplements. In this report, the Commission is urging manufacturers to provide consumers and health professionals with more information regarding the substantiation for statements of nutritional support and regarding the safety of products. ODS could serve as a depository for that information, which could be compiled into a useful database.

FINDINGS

The Commission recognizes a need for ODS to be more proactive in fulfilling its purposes, including promotion of scientific studies on potential roles of dietary supplements in health promotion and disease prevention. Appropriations as authorized by DSHEA are essential if ODS is to meet these mandates of the Act.

RECOMMENDATIONS

- ODS should strive to be an effective focal point for research on and understanding of the health effects of dietary supplements.
- ODS should place greater emphasis on its assigned role of advising other government agencies on a broad range of issues relating to dietary supplements.
- Congress should fund ODS at the level authorized by DSHEA.

Chapter V

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Appendix A

DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT OF 1994

Public Law 103-417
103d Congress

An Act

To amend the Federal Food, Drug, and Cosmetic Act to establish standards with respect to dietary supplements, and for other purposes.

Oct. 25, 1994
[S. 784]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Dietary Supplement Health and Education Act of 1994.
21 USC 301 note.

SECTION 1. SHORT TITLE; REFERENCE; TABLE OF CONTENTS.

(a) **SHORT TITLE.**—This Act may be cited as the “Dietary Supplement Health and Education Act of 1994”.

(b) **REFERENCE.**—Whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act.

(c) **TABLE OF CONTENTS.**—The table of contents of this Act is as follows:

- Sec. 1. Short title; reference; table of contents.
- Sec. 2. Findings.
- Sec. 3. Definitions.
- Sec. 4. Safety of dietary supplements and burden of proof on FDA.
- Sec. 5. Dietary supplement claims.
- Sec. 6. Statements of nutritional support.
- Sec. 7. Dietary supplement ingredient labeling and nutrition information labeling.
- Sec. 8. New dietary ingredients.
- Sec. 9. Good manufacturing practices.
- Sec. 10. Conforming amendments.
- Sec. 11. Withdrawal of the regulations and notice.
- Sec. 12. Commission on dietary supplement labels.
- Sec. 13. Office of dietary supplements.

SEC. 2. FINDINGS.

21 USC 321 note.

Congress finds that—

(1) improving the health status of United States citizens ranks at the top of the national priorities of the Federal Government;

(2) the importance of nutrition and the benefits of dietary supplements to health promotion and disease prevention have been documented increasingly in scientific studies;

(3)(A) there is a link between the ingestion of certain nutrients or dietary supplements and the prevention of chronic diseases such as cancer, heart disease, and osteoporosis; and

(B) clinical research has shown that several chronic diseases can be prevented simply with a healthful diet, such as a diet that is low in fat, saturated fat, cholesterol, and sodium, with a high proportion of plant-based foods;

(4) healthful diets may mitigate the need for expensive medical procedures, such as coronary bypass surgery or angioplasty;

(5) preventive health measures, including education, good nutrition, and appropriate use of safe nutritional supplements will limit the incidence of chronic diseases, and reduce long-term health care expenditures;

(6)(A) promotion of good health and healthy lifestyles improves and extends lives while reducing health care expenditures; and

(B) reduction in health care expenditures is of paramount importance to the future of the country and the economic well-being of the country;

(7) there is a growing need for emphasis on the dissemination of information linking nutrition and long-term good health;

(8) consumers should be empowered to make choices about preventive health care programs based on data from scientific studies of health benefits related to particular dietary supplements;

(9) national surveys have revealed that almost 50 percent of the 260,000,000 Americans regularly consume dietary supplements of vitamins, minerals, or herbs as a means of improving their nutrition;

(10) studies indicate that consumers are placing increased reliance on the use of nontraditional health care providers to avoid the excessive costs of traditional medical services and to obtain more holistic consideration of their needs;

(11) the United States will spend over \$1,000,000,000,000 on health care in 1994, which is about 12 percent of the Gross National Product of the United States, and this amount and percentage will continue to increase unless significant efforts are undertaken to reverse the increase;

(12)(A) the nutritional supplement industry is an integral part of the economy of the United States;

(B) the industry consistently projects a positive trade balance; and

(C) the estimated 600 dietary supplement manufacturers in the United States produce approximately 4,000 products, with total annual sales of such products alone reaching at least \$4,000,000,000;

(13) although the Federal Government should take swift action against products that are unsafe or adulterated, the Federal Government should not take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers;

(14) dietary supplements are safe within a broad range of intake, and safety problems with the supplements are relatively rare; and

(15)(A) legislative action that protects the right of access of consumers to safe dietary supplements is necessary in order to promote wellness; and

(B) a rational Federal framework must be established to supersede the current ad hoc, patchwork regulatory policy on dietary supplements.

SEC. 3. DEFINITIONS.

(a) **DEFINITION OF CERTAIN FOODS AS DIETARY SUPPLEMENTS.**—Section 201 (21 U.S.C. 321) is amended by adding at the end the following:

“(ff) The term ‘dietary supplement’—

“(1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

“(A) a vitamin;

“(B) a mineral;

“(C) an herb or other botanical;

“(D) an amino acid;

“(E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or

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

“(2) means a product that—

“(A)(i) is intended for ingestion in a form described in section 411(c)(1)(B)(i); or

“(ii) complies with section 411(c)(1)(B)(ii);

“(B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and

“(C) is labeled as a dietary supplement; and

“(3) does—

“(A) include an article that is approved as a new drug under section 505, certified as an antibiotic under section 507, or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262) and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section 402(f); and

“(B) not include—

“(i) an article that is approved as a new drug under section 505, certified as an antibiotic under section 507, or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262), or

“(ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public,

which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this Act.

Except for purposes of section 201(g), a dietary supplement shall be deemed to be a food within the meaning of this Act.”.

(b) **EXCLUSION FROM DEFINITION OF FOOD ADDITIVE.**—Section 201(s) (21 U.S.C. 321(s)) is amended—

(1) by striking “or” at the end of subparagraph (4);

(2) by striking the period at the end of subparagraph (5) and inserting “; or”; and

(3) by adding at the end the following new subparagraph:
“(6) an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement.”.

(c) FORM OF INGESTION.—Section 411(c)(1)(B) (21 U.S.C. 350(c)(1)(B)) is amended—

(1) in clause (i), by inserting “powder, softgel, gelcap,” after “capsule.”; and

(2) in clause (ii), by striking “does not simulate and”.

SEC. 4. SAFETY OF DIETARY SUPPLEMENTS AND BURDEN OF PROOF ON FDA.

Section 402 (21 U.S.C. 342) is amended by adding at the end the following:

“(f)(1) If it is a dietary supplement or contains a dietary ingredient that—

“(A) presents a significant or unreasonable risk of illness or injury under—

“(i) conditions of use recommended or suggested in labeling, or

“(ii) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use;

“(B) is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury;

“(C) the Secretary declares to pose an imminent hazard to public health or safety, except that the authority to make such declaration shall not be delegated and the Secretary shall promptly after such a declaration initiate a proceeding in accordance with sections 554 and 556 of title 5, United States Code, to affirm or withdraw the declaration; or

“(D) is or contains a dietary ingredient that renders it adulterated under paragraph (a)(1) under the conditions of use recommended or suggested in the labeling of such dietary supplement.

In any proceeding under this subparagraph, the United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated. The court shall decide any issue under this paragraph on a de novo basis.

Notification.

“(2) Before the Secretary may report to a United States attorney a violation of paragraph (1)(A) for a civil proceeding, the person against whom such proceeding would be initiated shall be given appropriate notice and the opportunity to present views, orally and in writing, at least 10 days before such notice, with regard to such proceeding.”.

SEC. 5. DIETARY SUPPLEMENT CLAIMS.

Chapter IV (21 U.S.C. 341 et seq.) is amended by inserting after section 403A the following new section:

“DIETARY SUPPLEMENT LABELING EXEMPTIONS

21 USC 343-2.

“SEC. 403B. (a) IN GENERAL.—A publication, including an article, a chapter in a book, or an official abstract of a peer-reviewed scientific publication that appears in an article and was prepared

by the author or the editors of the publication, which is reprinted in its entirety, shall not be defined as labeling when used in connection with the sale of a dietary supplement to consumers when it—

“(1) is not false or misleading;

“(2) does not promote a particular manufacturer or brand of a dietary supplement;

“(3) is displayed or presented, or is displayed or presented with other such items on the same subject matter, so as to present a balanced view of the available scientific information on a dietary supplement;

“(4) if displayed in an establishment, is physically separate from the dietary supplements; and

“(5) does not have appended to it any information by sticker or any other method.

“(b) APPLICATION.—Subsection (a) shall not apply to or restrict a retailer or wholesaler of dietary supplements in any way whatsoever in the sale of books or other publications as a part of the business of such retailer or wholesaler.

“(c) BURDEN OF PROOF.—In any proceeding brought under subsection (a), the burden of proof shall be on the United States to establish that an article or other such matter is false or misleading.”

SEC. 6. STATEMENTS OF NUTRITIONAL SUPPORT.

Section 403(r) (21 U.S.C. 343(r)) is amended by adding at the end the following:

“(6) For purposes of paragraph (r)(1)(B), a statement for a dietary supplement may be made if—

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

“(B) the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading, and

“(C) the statement contains, prominently displayed and in boldface type, the following: ‘This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.’

A statement under this subparagraph may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. If the manufacturer of a dietary supplement proposes to make a statement described in the first sentence of this subparagraph in the labeling of the dietary supplement, the manufacturer shall notify the Secretary no later than 30 days after the first marketing of the dietary supplement with such statement that such a statement is being made.”

SEC. 7. DIETARY SUPPLEMENT INGREDIENT LABELING AND NUTRITION INFORMATION LABELING.

(a) MISBRANDED SUPPLEMENTS.—Section 403 (21 U.S.C. 343) is amended by adding at the end the following:

“(s) If—

“(1) it is a dietary supplement; and
 “(2)(A) the label or labeling of the supplement fails to list—

“(i) the name of each ingredient of the supplement that is described in section 201(ff); and

“(ii)(I) the quantity of each such ingredient; or

“(II) with respect to a proprietary blend of such ingredients, the total quantity of all ingredients in the blend;
 “(B) the label or labeling of the dietary supplement fails to identify the product by using the term ‘dietary supplement’, which term may be modified with the name of such an ingredient;

“(C) the supplement contains an ingredient described in section 201(ff)(1)(C), and the label or labeling of the supplement fails to identify any part of the plant from which the ingredient is derived;

“(D) the supplement—

“(i) is covered by the specifications of an official compendium;

“(ii) is represented as conforming to the specifications of an official compendium; and

“(iii) fails to so conform; or

“(E) the supplement—

“(i) is not covered by the specifications of an official compendium; and

“(ii)(I) fails to have the identity and strength that the supplement is represented to have; or

“(II) fails to meet the quality (including tablet or capsule disintegration), purity, or compositional specifications, based on validated assay or other appropriate methods, that the supplement is represented to meet.”

(b) SUPPLEMENT LISTING ON NUTRITION LABELING.—Section 403(q)(5)(F) (21 U.S.C. 343(q)(5)(F)) is amended to read as follows:

“(F) A dietary supplement product (including a food to which section 411 applies) shall comply with the requirements of subparagraphs (1) and (2) in a manner which is appropriate for the product and which is specified in regulations of the Secretary which shall provide that—

“(i) nutrition information shall first list those dietary ingredients that are present in the product in a significant amount and for which a recommendation for daily consumption has been established by the Secretary, except that a dietary ingredient shall not be required to be listed if it is not present in a significant amount, and shall list any other dietary ingredient present and identified as having no such recommendation;

“(ii) the listing of dietary ingredients shall include the quantity of each such ingredient (or of a proprietary blend of such ingredients) per serving;

“(iii) the listing of dietary ingredients may include the source of a dietary ingredient; and

“(iv) the nutrition information shall immediately precede the ingredient information required under subclause (i), except that no ingredient identified pursuant to subclause (i) shall be required to be identified a second time.”

(c) PERCENTAGE LEVEL CLAIMS.—Section 403(r)(2) (21 U.S.C. 343(r)(2)) is amended by adding after clause (E) the following:

“(F) Subclause (i) clause (A) does not apply to a statement in the labeling of a dietary supplement that characterizes the percentage level of a dietary ingredient for which the Secretary has not established a reference daily intake, daily recommended value, or other recommendation for daily consumption.”

(d) VITAMINS AND MINERALS.—Section 411(b)(2) (21 U.S.C. 350(b)(2)) is amended—

(1) by striking “vitamins or minerals” and inserting “dietary supplement ingredients described in section 201(ff)”;

(2) by striking “(2)(A)” and inserting “(2)”; and

(3) by striking subparagraph (B).

(e) EFFECTIVE DATE.—Dietary supplements—

(1) may be labeled after the date of the enactment of this Act in accordance with the amendments made by this section, and

(2) shall be labeled after December 31, 1996, in accordance with such amendments.

21 USC 343
note.

SEC. 8. NEW DIETARY INGREDIENTS.

Chapter IV of the Federal Food, Drug, and Cosmetic Act is amended by adding at the end the following:

“NEW DIETARY INGREDIENTS

“SEC. 413. (a) IN GENERAL.—A dietary supplement which contains a new dietary ingredient shall be deemed adulterated under section 402(f) unless it meets one of the following requirements:

21 USC 350b.

“(1) The dietary supplement contains only dietary ingredients which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered.

“(2) There is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides the Secretary with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

The Secretary shall keep confidential any information provided under paragraph (2) for 90 days following its receipt. After the expiration of such 90 days, the Secretary shall place such information on public display, except matters in the information which are trade secrets or otherwise confidential, commercial information.

Classified
information.

“(b) PETITION.—Any person may file with the Secretary a petition proposing the issuance of an order prescribing the conditions under which a new dietary ingredient under its intended conditions of use will reasonably be expected to be safe. The Secretary shall make a decision on such petition within 180 days of the date the petition is filed with the Secretary. For purposes of chapter 7 of title 5, United States Code, the decision of the Secretary shall be considered final agency action.

“(c) DEFINITION.—For purposes of this section, the term ‘new dietary ingredient’ means a dietary ingredient that was not mar-

keted in the United States before October 15, 1994 and does not include any dietary ingredient which was marketed in the United States before October 15, 1994.”.

SEC. 9. GOOD MANUFACTURING PRACTICES.

Section 402 (21 U.S.C. 342), as amended by section 4, is amended by adding at the end the following:

“(g)(1) If it is a dietary supplement and it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations, including regulations requiring, when necessary, expiration date labeling, issued by the Secretary under subparagraph (2).

“(2) The Secretary may by regulation prescribe good manufacturing practices for dietary supplements. Such regulations shall be modeled after current good manufacturing practice regulations for food and may not impose standards for which there is no current and generally available analytical methodology. No standard of current good manufacturing practice may be imposed unless such standard is included in a regulation promulgated after notice and opportunity for comment in accordance with chapter 5 of title 5, United States Code.”.

SEC. 10. CONFORMING AMENDMENTS.

(a) SECTION 201.—The last sentence of section 201(g)(1) (21 U.S.C. 321(g)(1)) is amended to read as follows: “A food or dietary supplement for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) or sections 403(r)(1)(B) and 403(r)(5)(D), is made in accordance with the requirements of section 403(r) is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) is not a drug under clause (C) solely because the label or the labeling contains such a statement.”.

(b) SECTION 301.—Section 301 (21 U.S.C. 331) is amended by adding at the end the following:

“(u) The introduction or delivery for introduction into interstate commerce of a dietary supplement that is unsafe under section 413.”.

(c) SECTION 403.—Section 403 (21 U.S.C. 343), as amended by section 7, is amended by adding after paragraph (s) the following: “A dietary supplement shall not be deemed misbranded solely because its label or labeling contains directions or conditions of use or warnings.”.

SEC. 11. WITHDRAWAL OF THE REGULATIONS AND NOTICE.

The advance notice of proposed rulemaking concerning dietary supplements published in the Federal Register of June 18, 1993 (58 FR 33690-33700) is null and void and of no force or effect insofar as it applies to dietary supplements. The Secretary of Health and Human Services shall publish a notice in the Federal Register to revoke the item declared to be null and void and of no force or effect under subsection (a).

SEC. 12. COMMISSION ON DIETARY SUPPLEMENT LABELS.

(a) ESTABLISHMENT.—There shall be established as an independent agency within the executive branch a commission to be known as the Commission on Dietary Supplement Labels (hereafter in this section referred to as the “Commission”).

Federal
Register,
publication.

21 USC 343
note.

(b) MEMBERSHIP.—

(1) COMPOSITION.—The Commission shall be composed of 7 members who shall be appointed by the President.

(2) EXPERTISE REQUIREMENT.—The members of the Commission shall consist of individuals with expertise and experience in dietary supplements and in the manufacture, regulation, distribution, and use of such supplements. At least three of the members of the Commission shall be qualified by scientific training and experience to evaluate the benefits to health of the use of dietary supplements and one of such three members shall have experience in pharmacognosy, medical botany, traditional herbal medicine, or other related sciences. Members and staff of the Commission shall be without bias on the issue of dietary supplements.

(c) FUNCTIONS OF THE COMMISSION.—The Commission shall conduct a study on, and provide recommendations for, the regulation of label claims and statements for dietary supplements, including the use of literature in connection with the sale of dietary supplements and procedures for the evaluation of such claims. In making such recommendations, the Commission shall evaluate how best to provide truthful, scientifically valid, and not misleading information to consumers so that such consumers may make informed and appropriate health care choices for themselves and their families.

(d) ADMINISTRATIVE POWERS OF THE COMMISSION.—

(1) HEARINGS.—The Commission may hold hearings, sit and act at such times and places, take such testimony, and receive such evidence as the Commission considers advisable to carry out the purposes of this section.

(2) INFORMATION FROM FEDERAL AGENCIES.—The Commission may secure directly from any Federal department or agency such information as the Commission considers necessary to carry out the provisions of this section.

(3) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section.

(e) REPORTS AND RECOMMENDATIONS.—

(1) FINAL REPORT REQUIRED.—Not later than 24 months after the date of enactment of this Act, the Commission shall prepare and submit to the President and to the Congress a final report on the study required by this section.

(2) RECOMMENDATIONS.—The report described in paragraph (1) shall contain such recommendations, including recommendations for legislation, as the Commission deems appropriate.

(3) ACTION ON RECOMMENDATIONS.—Within 90 days of the issuance of the report under paragraph (1), the Secretary of Health and Human Services shall publish in the Federal Register a notice of any recommendation of Commission for changes in regulations of the Secretary for the regulation of dietary supplements and shall include in such notice a notice of proposed rulemaking on such changes together with an opportunity to present views on such changes. Such rulemaking shall be completed not later than 2 years after the date of the issuance of such report. If such rulemaking is not completed on or before the expiration of such 2 years, regulations of the Secretary published in 59 FR 395-426 on January 4, 1994, shall not be in effect.

Federal
Register,
publication.

SEC. 13. OFFICE OF DIETARY SUPPLEMENTS.

(a) **IN GENERAL.**—Title IV of the Public Health Service Act is amended by inserting after section 485B (42 U.S.C. 287c-3) the following:

“Subpart 4—Office of Dietary Supplements

42 USC 287c-11. **“SEC. 485C. DIETARY SUPPLEMENTS.**

“(a) **ESTABLISHMENT.**—The Secretary shall establish an Office of Dietary Supplements within the National Institutes of Health.

“(b) **PURPOSE.**—The purposes of the Office are—

“(1) to explore more fully the potential role of dietary supplements as a significant part of the efforts of the United States to improve health care; and

“(2) to promote scientific study of the benefits of dietary supplements in maintaining health and preventing chronic disease and other health-related conditions.

“(c) **DUTIES.**—The Director of the Office of Dietary Supplements shall—

“(1) conduct and coordinate scientific research within the National Institutes of Health relating to dietary supplements and the extent to which the use of dietary supplements can limit or reduce the risk of diseases such as heart disease, cancer, birth defects, osteoporosis, cataracts, or prostatism;

“(2) collect and compile the results of scientific research relating to dietary supplements, including scientific data from foreign sources or the Office of Alternative Medicine;

“(3) serve as the principal advisor to the Secretary and to the Assistant Secretary for Health and provide advice to the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of Food and Drugs on issues relating to dietary supplements including—

“(A) dietary intake regulations;

“(B) the safety of dietary supplements;

“(C) claims characterizing the relationship between—

“(i) dietary supplements; and

“(ii)(I) prevention of disease or other health-related conditions; and

“(II) maintenance of health; and

“(D) scientific issues arising in connection with the labeling and composition of dietary supplements;

“(4) compile a database of scientific research on dietary supplements and individual nutrients; and

“(5) coordinate funding relating to dietary supplements for the National Institutes of Health.

“(d) **DEFINITION.**—As used in this section, the term ‘dietary supplement’ has the meaning given the term in section 201(ff) of the Federal Food, Drug, and Cosmetic Act.

“(e) **AUTHORIZATION OF APPROPRIATIONS.**—There are authorized to be appropriated to carry out this section \$5,000,000 for fiscal year 1994 and such sums as may be necessary for each subsequent fiscal year.”

PUBLIC LAW 103-417—OCT. 25, 1994

108 STAT. 4335

(b) CONFORMING AMENDMENT.—Section 401(b)(2) of the Public Health Service Act (42 U.S.C. 281(b)(2)) is amended by adding at the end the following:

“(E) The Office of Dietary Supplements.”

Approved October 25, 1994.

LEGISLATIVE HISTORY—S. 784

CONGRESSIONAL RECORD, Vol. 140 (1994):

Aug. 13, considered and passed Senate.

Oct. 6, considered and passed House, amended.

Oct. 7, Senate concurred in House amendment.

WEEKLY COMPILATION OF PRESIDENTIAL DOCUMENTS, Vol. 30 (1994):

Oct. 25, Presidential statement.

Appendix B

CHARTER OF THE COMMISSION ON DIETARY SUPPLEMENT LABELS



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

CHARTER COMMISSION ON DIETARY SUPPLEMENT LABELS

PURPOSE

The Secretary of Health and Human Services, in order to meet the intent of The Dietary Supplement Health and Education Act of 1994, P.L. 103-417, Section 12, is establishing a Commission on Dietary Supplement Labels that will develop recommendations for the regulation of label claims and statements for dietary supplements. The Commission is to evaluate how best to provide truthful, scientifically valid, and not misleading information to consumers so that such consumers may make appropriate health care choices for themselves and their families.

The Commission on Dietary Supplement Labels is established for the single, time-limited task of conducting a study on the regulation of label claims and statements for dietary supplements and providing a final report to the Secretary of the Department of Health and Human Services (HHS), the President, and the Congress on its findings and possible recommendations.

AUTHORITY

42 U.S. Code 217a, Section 222 of the Public Health Service Act, as amended. The Commission is governed by the provision of Public Law 92-463, as amended (5 U.S.C., Appendix 2), which sets forth standards for the formation and use of advisory committees.

FUNCTION

The Commission on Dietary Supplement Labels shall conduct a study on, and provide recommendations for, the regulation of label claims and statements for dietary supplements, including the use of literature in connection with the sale of dietary supplements and procedures for the evaluation of such claims. In making such recommendations, the Commission shall evaluate how best to provide truthful, scientifically valid, and not misleading information to consumers so that such consumers may make informed and appropriate health care choices for themselves and their families.

The Commission may hold hearings, sit and act at such times and places, take such testimony, and receive such evidence as the Commission considers advisable to carry out the

purposes of this section. The Commission may secure directly from any Federal department or agency such information as the Commission considers necessary to carry out its charge.

STRUCTURE

The Commission shall consist of seven members, including the chairperson, appointed by the President. Members shall possess expertise and experience in dietary supplements and in the manufacture, regulation, distribution, and use of such supplements. At least three of the members shall be qualified by scientific training and experience to evaluate the benefits to health of the use of dietary supplements and one of such three members shall have experience in pharmacognosy, medical botany, traditional herbal medicine, or other related fields.

MEETINGS

Meetings shall be held at the call of the Chair with the advance approval of a Government official, who shall also approve the agenda. It is anticipated that the Commission will meet six (6) to eight (8) times. A Government official shall be present at all meetings.

Meetings shall be open to the public except as determined otherwise by the Secretary; and, records of the proceedings kept as required by applicable laws and Departmental regulations. Notice of all meetings shall be given to the public.

COMPENSATION

Members shall not receive compensation for their service but shall be paid travel and per diem expenses in accordance with Standard Government Travel Regulations.

ANNUAL COST ESTIMATE

The estimated annual cost of operating the Commission, including travel and per diem expenses for members, but excluding staff support, is \$277,243. The estimated annual person years of staff support required is 2.5 at an estimated annual cost of \$138,535.

REPORTS

The Commission shall prepare a final report to the Secretary of HHS, the President, the Speaker of the House of Representatives, and the President of the Senate that includes the results of its study and any findings or recommendations the Commission may choose to make, including recommendations for legislation.

In the event a portion of a meeting is closed to the public, a report shall be prepared which shall contain, as a minimum, a list of the members and their business addresses, the Commissions functions, dates and places of meetings, and a summary of the Commission

activities and recommendations made during the fiscal year. A copy of the report shall be provided to the Department Committee Management Officer.

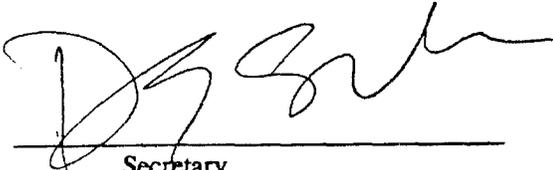
TERMINATION DATE

Unless renewed by appropriate action prior to its expiration, the Commission on Dietary Supplement Labels will terminate after delivery of its final report to the Secretary, the President, and the Congress, or two years from the date this charter is approved, whichever is sooner.

APPROVED:

FEB 13 1996

Date



Secretary

Appendix C

COMMISSION PROCEDURES

COMMISSION PROCEDURES

The Dietary Supplement Health and Education Act (DSHEA), signed into law on October 25, 1994, mandated the establishment of the Commission on Dietary Supplement Labels. The appointments of the seven members of the Commission were confirmed by the President on November 9, 1995. The Commission received its charter from the Secretary of Health and Human Services on February 13, 1996.

From February 1996, to August 1997, the Commission held nine meetings. The first four meetings focused on obtaining comments, data, and information from interested individuals and organizations. In addition, the Commission invited testimony from the Food and Drug Administration (FDA), the Federal Trade Commission (FTC), and several organizations that represent consumer groups as well as the dietary supplement and food industries. Based in part on the testimony received during the course of the eight meetings, the Commission continually revised its list of key issues. Each of these key issues was assigned to an ad hoc subcommittee of the Commission or to the Commission staff for further research and study, and for development of draft materials for discussion by the full Commission at subsequent meetings.

Meeting # 1. February 16, 1996, Washington, D.C. The Commission agreed on procedural aspects and the scope of work. Testimony was received from the Food and Drug Administration, the Office of Dietary Supplements of the National Institutes of Health, and three interested organizations. The former two discussed their responsibilities under DSHEA; the latter three provided their perspectives on the scope and responsibilities of the Commission.

Meeting # 2. March 8, 1996, Salt Lake City, Utah. Nineteen individuals, representing consumers, manufacturers, retailers, and dietary supplement industry organizations, addressed the Commission, commenting on the Commission's charge and discussing issues they thought should be considered by the Commission.

Meeting # 3. April 26, 1996, San Francisco, California. Sixteen individuals and organizations provided comments to the Commission. Four represented dietary supplement producers, three presenters had specific information and comments on herbs and phytomedicines, three others offered comments and information from the perspective of educational institutions, five presented views of consumers, and one provided a view as a registered dietitian. Two ad hoc Subcommittees discussed key issues for Commission consideration and reviewed health claim regulations; both ad hoc Subcommittees reported to the full Commission. The Commission agreed that the meeting on June 6, 1996, in Orlando, Florida would complete the oral testimony component of the Commission's efforts and June 30, 1996 would be the cutoff date for submission of public comments.

Meeting # 4. June 6, 1996, Orlando, Florida. Thirteen persons, representing scientific societies, consumer organizations, State government officials, and supplement manufacturers, presented information and views to the Commission. Ad hoc Subcommittee reported to Commission on current regulations governing label statements. Commission agreed to extend the deadline for public input of written submissions to August 30, 1996.

Meeting # 5. September 19 and 20, 1996, Reston, Virginia. Written comments submitted to the Commission as of the extended deadline date, August 30, 1996, were summarized; a number of recurrent themes were noted. These included safety issues; effects of label statements; truthfulness of label statements; consumer information; content, and review of, and access to the substantiation files supporting product label statements; possible use of external third-party review panels; regulatory categorizations of botanical products; and clarification of what constitutes a structure/function type of statement of nutritional support. Commission discussions focused on the process, procedures, and guidelines for review of label claims and petitions for marketing herbals and botanicals. A representative from the Division of Over-The-Counter Drug Products, FDA, answered questions concerning the possible application of the over-the-counter drug review process to botanical dietary supplements that make preventive or treatment claims. A representative from the Division of Advertising Practices, FTC, provided an overview of the agency's regulatory procedures for dealing with dietary supplements and foods. Summaries of the progress of several ad hoc subcommittees held since June 7, 1996, were reviewed by the full Commission.

Meeting # 6. October 24 and 25, 1996, Washington, D.C. The Commission reviewed and reached tentative agreement on findings and recommendations about several key issues: safety of dietary supplements, literature at point of sale, content of notification letters, and regulatory management of dietary supplements in other countries. In addition, the Commission discussed regulatory options for herbals and botanicals and explored issues relating to structure/function statements and health claims raised by the content of notification letters.

Meeting # 7. December 16, 1996, Washington, D.C. The Commission met to review draft materials on events that led to passage of DSHEA and characteristics of consumer use of dietary supplements. Drafts of tentative findings and possible recommendations for the Commission's report were reviewed. The Commission decided to revise these findings and recommendations and have the redrafts recirculated to the full Commission prior to the meeting on March 4, 1997. The Commission approved the establishment of an Information Response Center to handle inquiries from the public. The Commission discussed the possibility of making a draft of the report available for public comment.

Meeting # 8. March 4, 1997, Baltimore, Maryland. The Commission invited testimony from specific groups that had testified previously on the regulatory management of botanical remedies and possible use of third-party evaluation of dietary supplement label statements. Five presenters represented various trade organizations in the dietary supplement and food industries, two represented public interest groups, and two represented scientific and professional groups. In addition, the Commission discussed revised drafts of sections of the report. Comments on revised drafts of the findings and recommendations were forwarded to the Executive staff for inclusion in the draft report of the Commission. The Commission agreed to make the draft report available for public comments.

Revisions of the several sections of the draft report prepared by individual Commission members and the staff were circulated to the full Commission from March 5 to May 23, 1997. With the agreement of the Commission members, the publicly available draft report was prepared and

released for public comment. Submission of written comments from all interested parties was solicited.

Draft Report Release. Consistent with the decision of the Commission on March 8th, the draft report was released on June 24, 1997. There is no requirement for release of a draft report in either DSHEA or the Federal Advisory Committee Act. However, the Commission was aware of the public interest in its work and desired to have an additional period for public comment on the Commission's findings and recommendations. Because the Commission's funding was about to expire at the end of Fiscal Year 1997, only a limited time was available for comments.

Meeting # 9. August 14 and 15, 1997, Reston, Virginia. The Commission reviewed over 400 comments submitted by the public on the draft report. In addition, the Commission identified portions of the draft report that needed further clarification and explanation. The Chair assigned responsibilities for revisions to the Commission members and staff. A revised final draft was prepared and circulated to the Commission members for review and approval.

Final Report Release. The final report of the Commission on Dietary Supplement Labels was delivered to the Office of the President, Congress, and the Secretary of the Department of Health and Human Services on November 24, 1997. The final report is available from the Government Printing Office and is on the Internet at <http://web.health.gov/dietsupp>

Appendix D

**INDIVIDUALS AND ORGANIZATIONS PRESENTING
ORAL TESTIMONY TO THE COMMISSION**

**INDIVIDUALS AND ORGANIZATIONS PRESENTING
ORAL TESTIMONY TO THE COMMISSION**

Meeting #1, Washington, DC, February 16, 1996

Cordaro, John; Council for Responsible Nutrition
Howard, Rae; National Nutritional Foods Association
Marriott, Bernadette M.; Office of Dietary Supplements, National Institutes of Health
Rosenberg, Kenneth M.; Pharmavite Corporation
Scarborough, F. Edward; Center for Food Safety and Applied Nutrition, Food and Drug Administration
Yetley, Elizabeth A.; Center for Food Safety and Applied Nutrition, Food and Drug Administration

Meeting #2, Salt Lake City, UT, March 8, 1996

Anderson, Corey; Trace Minerals Research
Barney, Paul; Spine Institute of Utah
Berg, Dallas; Consumer
Blumenthal, Mark; American Botanical Council
Bowen, Melanie H.; Office of Senator Orrin G. Hatch
Farris, Jim; New Frontiers Market
Forsberg, Scott; Nature's Way Products
Hilton, Matthew; Consumer
Hinrichs, Jeff; Nutraceutical Corporation
Howard, Kenneth M.; Good Earth Natural Foods
Israelsen, Loren D.; Utah Natural Products Alliance
Martin, Greg; Shaperite Concepts Ltd.
Murdock, Ken; National Nutritional Foods Association
Ochsenbein, Steve; Consumer
Prochnow, James R.; Patton Boggs
Richards, Robert L.; Kaire International, Inc.
Scott, Michael; Academy of Clinical Environmental Research & Informational Sciences
Therault, David; Maharishi Ayur-Ved International, Inc.
Welling, Steve; Nature's Herbs

Meeting #3, April 26, 1996, San Francisco, CA

Brandt, Muriel; American Dietetic Association
Calloway, Doris H.; University of California, Berkeley
Hobbs, Christopher; Herbalist
Ikeda, Joanne P.; University of California, Berkeley
Kallman, Burton; National Nutritional Foods Association

Laux, Marcus; Licensed Naturopathic Physician
McGuffin, Michael; American Herbal Products Association
O'Leary, Tom; Rainbow Light Nutritional Systems
Pizzorno, Joseph E., Jr.; Bastyr University
Reinhardt, Jeffrey H.; People For Pure Food
Riedel, Karl; Nature's Life
Schauss, Alexander G.; Citizens For Health
Schiff, Paula; Consumer
Stemet, John; Citizens for Health
Upton, Roy; American Herbalists Guild
Whitman, James; Shaklee Corporation

Meeting #4, June 6, 1996, Orlando, FL

Baker, Dennis; Association of Food and Drug Officials
Camire, Mary Ellen; Institute of Food Technologists
Crawford, Bob; State of Florida, Dept. of Agriculture and Consumer Services
Girardi, Frank A.; Hoffmann-La Roche Inc.
Hildwine, Regina; National Food Processors Association
Jahner, Debra K. W.; Nutrilite
Lawhead, Clara; State of Florida, Dept. of Health and Rehabilitative Services
Martinez, Antonio C., II; Nutritional Health Alliance
Milner, John A.; American Society for Nutritional Sciences
Pazder, Nadine; American Dietetic Association
Silverglade, Bruce; Center for Science in the Public Interest
Trinker, Deborah; Rexall Sundown, Inc.
Woodward, Betsy B.; State of Florida, Dept. Of Agriculture and Consumer Services

Meeting #5, September 19-20, 1996, Reston, VA

Isrealsen, Loren D.; Utah Natural Products Alliance
Mustafa, Anne; Food and Drug Administration
Peeler, C. Lee; Federal Trade Commission

Meeting #6, October 24-25, 1996, Washington, DC

No oral testimony presented

Meeting #7, December 16, 1996, Washington, DC

No oral testimony presented

Meeting #8, March 4, 1997, Baltimore, MD

Chernoff, Ronni; American Dietetic Association

Cordaro, John; Council for Responsible Nutrition

Ford, Michael Q.; Israelsen, Loren D.; Young, Anthony; jointly for American Herbal Products Association, National Nutritional Foods Association, and Utah Natural Products Alliance

Hildwine, Regina; National Food Processors Association

Martinez, Antonio C., II; Nutritional Health Alliance

Milner, John A.; American Society for Nutritional Sciences

Silverglade, Bruce; Center for Science in the Public Interest

Appendix E

**INDIVIDUALS AND ORGANIZATIONS PROVIDING
WRITTEN SUBMISSIONS TO THE COMMISSION**

**INDIVIDUALS AND ORGANIZATIONS PROVIDING
WRITTEN SUBMISSIONS TO THE COMMISSION**

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