

In the House of Representatives, U. S.,

October 7 (legislative day, October 6), 1994.

Resolved, That the bill from the Senate (S. 784) entitled “An Act to amend the Federal Food, Drug, and Cosmetic Act to establish standards with respect to dietary supplements, and for other purposes”, do pass with the following

AMENDMENT:

Strike out all after the enacting clause and insert:

1 ***SECTION 1. SHORT TITLE; REFERENCE; TABLE OF CON-***
2 ***TENTS.***

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

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

10 *(c) TABLE OF CONTENTS.—The table of contents of this*
11 *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.

1 **SEC. 2. FINDINGS.**

2 *Congress finds that—*

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

6 *(2) the importance of nutrition and the benefits*
7 *of dietary supplements to health promotion and dis-*
8 *ease prevention have been documented increasingly in*
9 *scientific studies;*

10 *(3)(A) there is a link between the ingestion of*
11 *certain nutrients or dietary supplements and the pre-*
12 *vention of chronic diseases such as cancer, heart dis-*
13 *ease, and osteoporosis; and*

14 *(B) clinical research has shown that several*
15 *chronic diseases can be prevented simply with a*
16 *healthful diet, such as a diet that is low in fat, satu-*
17 *rated fat, cholesterol, and sodium, with a high pro-*
18 *portion of plant-based foods;*

19 *(4) healthful diets may mitigate the need for ex-*
20 *pensive medical procedures, such as coronary bypass*
21 *surgery or angioplasty;*

22 *(5) preventive health measures, including edu-*
23 *cation, good nutrition, and appropriate use of safe*

1 *nutritional supplements will limit the incidence of*
2 *chronic diseases, and reduce long-term health care ex-*
3 *penditures;*

4 *(6)(A) promotion of good health and healthy life-*
5 *styles improves and extends lives while reducing*
6 *health care expenditures; and*

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

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

13 *(8) consumers should be empowered to make*
14 *choices about preventive health care programs based*
15 *on data from scientific studies of health benefits relat-*
16 *ed to particular dietary supplements;*

17 *(9) national surveys have revealed that almost*
18 *50 percent of the 260,000,000 Americans regularly*
19 *consume dietary supplements of vitamins, minerals,*
20 *or herbs as a means of improving their nutrition;*

21 *(10) studies indicate that consumers are placing*
22 *increased reliance on the use of nontraditional health*
23 *care providers to avoid the excessive costs of tradi-*
24 *tional medical services and to obtain more holistic*
25 *consideration of their needs;*

1 (11) the United States will spend over
2 \$1,000,000,000,000 on health care in 1994, which is
3 about 12 percent of the Gross National Product of the
4 United States, and this amount and percentage will
5 continue to increase unless significant efforts are un-
6 dertaken to reverse the increase;

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

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

11 (C) the estimated 600 dietary supplement manu-
12 facturers in the United States produce approximately
13 4,000 products, with total annual sales of such prod-
14 ucts alone reaching at least \$4,000,000,000;

15 (13) although the Federal Government should
16 take swift action against products that are unsafe or
17 adulterated, the Federal Government should not take
18 any actions to impose unreasonable regulatory bar-
19 riers limiting or slowing the flow of safe products and
20 accurate information to consumers;

21 (14) dietary supplements are safe within a broad
22 range of intake, and safety problems with the supple-
23 ments are relatively rare; and

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

4 (B) a rational Federal framework must be estab-
5 lished to supersede the current ad hoc, patchwork reg-
6 ulatory policy on dietary supplements.

7 **SEC. 3. DEFINITIONS.**

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

11 “(ff) The term ‘dietary supplement’—

12 “(1) means a product (other than tobacco) in-
13 tended to supplement the diet that bears or contains
14 one or more of the following dietary ingredients:

15 “(A) a vitamin;

16 “(B) a mineral;

17 “(C) an herb or other botanical;

18 “(D) an amino acid;

19 “(E) a dietary substance for use by man to
20 supplement the diet by increasing the total die-
21 tary intake; or

22 “(F) a concentrate, metabolite, constituent,
23 extract, or combination of any ingredient de-
24 scribed in clause (A), (B), (C), (D), or (E);

25 “(2) means a product that—

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

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

4 “(B) is not represented for use as a conven-
5 tional food or as a sole item of a meal or the
6 diet; and

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

9 “(3) does—

10 “(A) include an article that is approved as
11 a new drug under section 505, certified as an
12 antibiotic under section 507, or licensed as a bio-
13 logic under section 351 of the Public Health
14 Service Act (42 U.S.C. 262) and was, prior to
15 such approval, certification, or license, marketed
16 as a dietary supplement or as a food unless the
17 Secretary has issued a regulation, after notice
18 and comment, finding that the article, when used
19 as or in a dietary supplement under the condi-
20 tions of use and dosages set forth in the labeling
21 for such dietary supplement, is unlawful under
22 section 402(f); and

23 “(B) not include—

24 “(i) an article that is approved as a
25 new drug under section 505, certified as an

1 *antibiotic under section 507, or licensed as*
 2 *a biologic under section 351 of the Public*
 3 *Health Service Act (42 U.S.C. 262), or*

4 “(ii) *an article authorized for inves-*
 5 *tigation as a new drug, antibiotic, or bio-*
 6 *logical for which substantial clinical inves-*
 7 *tigations have been instituted and for which*
 8 *the existence of such investigations has been*
 9 *made public,*

10 *which was not before such approval, certification, li-*
 11 *censing, or authorization marketed as a dietary sup-*
 12 *plement or as a food unless the Secretary, in the Sec-*
 13 *retary’s discretion, has issued a regulation, after no-*
 14 *tice and comment, finding that the article would be*
 15 *lawful under this Act.*

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

19 (b) *EXCLUSION FROM DEFINITION OF FOOD ADDI-*
 20 *TIVE.—Section 201(s) (21 U.S.C. 321(s)) is amended—*

21 (1) *by striking “or” at the end of subparagraph*

22 (4);

23 (2) *by striking the period at the end of subpara-*
 24 *graph (5) and inserting “; or”; and*

1 (3) by adding at the end the following new sub-
2 paragraph:

3 “(6) an ingredient described in paragraph (ff)
4 in, or intended for use in, a dietary supplement.”.

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

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

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

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

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

15 “(f)(1) If it is a dietary supplement or contains a die-
16 tary ingredient that—

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

19 “(i) conditions of use recommended or sug-
20 gested in labeling, or

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

24 “(B) is a new dietary ingredient for which there
25 is inadequate information to provide reasonable as-

1 *surance that such ingredient does not present a sig-*
2 *nificant or unreasonable risk of illness or injury;*

3 *“(C) the Secretary declares to pose an imminent*
4 *hazard to public health or safety, except that the au-*
5 *thority to make such declaration shall not be dele-*
6 *gated and the Secretary shall promptly after such a*
7 *declaration initiate a proceeding in accordance with*
8 *sections 554 and 556 of title 5, United States Code,*
9 *to affirm or withdraw the declaration; or*

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

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

19 *“(2) Before the Secretary may report to a United*
20 *States attorney a violation of paragraph (1)(A) for a civil*
21 *proceeding, the person against whom such proceeding would*
22 *be initiated shall be given appropriate notice and the op-*
23 *portunity to present views, orally and in writing, at least*
24 *10 days before such notice, with regard to such proceeding.”.*

1 **SEC. 5. DIETARY SUPPLEMENT CLAIMS.**

2 Chapter IV (21 U.S.C. 341 et seq.) is amended by in-
 3 serting after section 403A the following new section:

4 “DIETARY SUPPLEMENT LABELING EXEMPTIONS

5 “SEC. 403B. (a) IN GENERAL.—A publication, includ-
 6 ing an article, a chapter in a book, or an official abstract
 7 of a peer-reviewed scientific publication that appears in an
 8 article and was prepared by the author or the editors of
 9 the publication, which is reprinted in its entirety, shall not
 10 be defined as labeling when used in connection with the sale
 11 of a dietary supplement to consumers when it—

12 “(1) is not false or misleading;

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

15 “(3) is displayed or presented, or is displayed or
 16 presented with other such items on the same subject
 17 matter, so as to present a balanced view of the avail-
 18 able scientific information on a dietary supplement;

19 “(4) if displayed in an establishment, is phys-
 20 ically separate from the dietary supplements; and

21 “(5) does not have appended to it any informa-
 22 tion by sticker or any other method.

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

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

5 **SEC. 6. STATEMENTS OF NUTRITIONAL SUPPORT.**

6 Section 403(r) (21 U.S.C. 343(r)) is amended by add-
 7 ing at the end the following:

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

10 “(A) the statement claims a benefit related to a
 11 classical nutrient deficiency disease and discloses the
 12 prevalence of such disease in the United States, de-
 13 scribes the role of a nutrient or dietary ingredient in-
 14 tended to affect the structure or function in humans,
 15 characterizes the documented mechanism by which a
 16 nutrient or dietary ingredient acts to maintain such
 17 structure or function, or describes general well-being
 18 from consumption of a nutrient or dietary ingredient,

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

22 “(C) the statement contains, prominently dis-
 23 played and in boldface type, the following: ‘This state-
 24 ment has not been evaluated by the Food and Drug

1 *Administration. This product is not intended to diag-*
 2 *nose, treat, cure, or prevent any disease.’*

3 *A statement under this subparagraph may not claim to di-*
 4 *agnose, mitigate, treat, cure, or prevent a specific disease*
 5 *or class of diseases. If the manufacturer of a dietary supple-*
 6 *ment proposes to make a statement described in the first*
 7 *sentence of this subparagraph in the labeling of the dietary*
 8 *supplement, the manufacturer shall notify the Secretary no*
 9 *later than 30 days after the first marketing of the dietary*
 10 *supplement with such statement that such a statement is*
 11 *being made.”*

12 **SEC. 7. DIETARY SUPPLEMENT INGREDIENT LABELING AND**
 13 **NUTRITION INFORMATION LABELING.**

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

16 “(s) If—

17 “(1) it is a dietary supplement; and

18 “(2)(A) the label or labeling of the supplement

19 *fails to list—*

20 “(i) the name of each ingredient of the sup-

21 *plement that is described in section 201(ff); and*

22 “(ii)(I) the quantity of each such ingredi-

23 *ent; or*

1 “(II) with respect to a proprietary blend of
2 such ingredients, the total quantity of all ingre-
3 dients in the blend;

4 “(B) the label or labeling of the dietary supple-
5 ment fails to identify the product by using the term
6 ‘dietary supplement’, which term may be modified
7 with the name of such an ingredient;

8 “(C) the supplement contains an ingredient de-
9 scribed in section 201(ff)(1)(C), and the label or label-
10 ing of the supplement fails to identify any part of the
11 plant from which the ingredient is derived;

12 “(D) the supplement—

13 “(i) is covered by the specifications of an of-
14 ficial compendium;

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

17 “(iii) fails to so conform; or

18 “(E) the supplement—

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

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

24 “(II) fails to meet the quality (including
25 tablet or capsule disintegration), purity, or

1 *compositional specifications, based on validated*
2 *assay or other appropriate methods, that the*
3 *supplement is represented to meet.”.*

4 (b) *SUPPLEMENT LISTING ON NUTRITION LABEL-*
5 *ING.—Section 403(q)(5)(F) (21 U.S.C. 343(q)(5)(F)) is*
6 *amended to read as follows:*

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

12 “(i) nutrition information shall first list those
13 dietary ingredients that are present in the product in
14 a significant amount and for which a recommenda-
15 tion for daily consumption has been established by the
16 Secretary, except that a dietary ingredient shall not
17 be required to be listed if it is not present in a sig-
18 nificant amount, and shall list any other dietary in-
19 gredient present and identified as having no such rec-
20 ommendation;

21 “(ii) the listing of dietary ingredients shall in-
22 clude the quantity of each such ingredient (or of a
23 proprietary blend of such ingredients) per serving;

24 “(iii) the listing of dietary ingredients may in-
25 clude the source of a dietary ingredient; and

1 “(iv) the nutrition information shall imme-
 2 diately precede the ingredient information required
 3 under subclause (i), except that no ingredient identi-
 4 fied pursuant to subclause (i) shall be required to be
 5 identified a second time.”.

6 (c) *PERCENTAGE LEVEL CLAIMS*.—Section 403(r)(2)
 7 (21 U.S.C. 343(r)(2)) is amended by adding after clause
 8 (E) the following:

9 “(F) Subclause (i) clause (A) does not apply to a state-
 10 ment in the labeling of a dietary supplement that character-
 11 izes the percentage level of a dietary ingredient for which
 12 the Secretary has not established a reference daily intake,
 13 daily recommended value, or other recommendation for
 14 daily consumption.”

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

17 (1) by striking “vitamins or minerals” and in-
 18 serting “dietary supplement ingredients described in
 19 section 201(ff)”;

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

22 (3) by striking subparagraph (B).

23 (e) *EFFECTIVE DATE*.—Dietary supplements—

1 (1) may be labeled after the date of the enact-
2 ment of this Act in accordance with the amendments
3 made by this section, and

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

6 **SEC. 8. NEW DIETARY INGREDIENTS.**

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

9 “NEW DIETARY INGREDIENTS

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

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

18 “(2) There is a history of use or other evidence
19 of safety establishing that the dietary ingredient when
20 used under the conditions recommended or suggested
21 in the labeling of the dietary supplement will reason-
22 ably be expected to be safe and, at least 75 days before
23 being introduced or delivered for introduction into
24 interstate commerce, the manufacturer or distributor
25 of the dietary ingredient or dietary supplement pro-
26 vides the Secretary with information, including any

1 *citation to published articles, which is the basis on*
2 *which the manufacturer or distributor has concluded*
3 *that a dietary supplement containing such dietary in-*
4 *gredient will reasonably be expected to be safe.*

5 *The Secretary shall keep confidential any information pro-*
6 *vided under paragraph (2) for 90 days following its receipt.*
7 *After the expiration of such 90 days, the Secretary shall*
8 *place such information on public display, except matters*
9 *in the information which are trade secrets or otherwise con-*
10 *fidential, commercial information.*

11 “(b) *PETITION.*—Any person may file with the Sec-
12 *retary a petition proposing the issuance of an order pre-*
13 *scribing the conditions under which a new dietary ingredi-*
14 *ent under its intended conditions of use will reasonably be*
15 *expected to be safe. The Secretary shall make a decision on*
16 *such petition within 180 days of the date the petition is*
17 *filed with the Secretary. For purposes of chapter 7 of title*
18 *5, United States Code, the decision of the Secretary shall*
19 *be considered final agency action.*

20 “(c) *DEFINITION.*—For purposes of this section, the
21 *term ‘new dietary ingredient’ means a dietary ingredient*
22 *that was not marketed in the United States before October*
23 *15, 1994 and does not include any dietary ingredient which*
24 *was marketed in the United States before October 15,*
25 *1994.”*

1 **SEC. 9. GOOD MANUFACTURING PRACTICES.**

2 *Section 402 (21 U.S.C. 342), as amended by section*
3 *4, is amended by adding at the end the following:*

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

9 *“(2) The Secretary may by regulation prescribe good*
10 *manufacturing practices for dietary supplements. Such reg-*
11 *ulations shall be modeled after current good manufacturing*
12 *practice regulations for food and may not impose standards*
13 *for which there is no current and generally available ana-*
14 *lytical methodology. No standard of current good manufac-*
15 *turing practice may be imposed unless such standard is in-*
16 *cluded in a regulation promulgated after notice and oppor-*
17 *tunity for comment in accordance with chapter 5 of title*
18 *5, United States Code.”.*

19 **SEC. 10. CONFORMING AMENDMENTS.**

20 *(a) SECTION 201.—The last sentence of section*
21 *201(g)(1) (21 U.S.C. 321(g)(1)) is amended to read as fol-*
22 *lows: “A food or dietary supplement for which a claim, sub-*
23 *ject to sections 403(r)(1)(B) and 403(r)(3) or sections*
24 *403(r)(1)(B) and 403(r)(5)(D), is made in accordance with*
25 *the requirements of section 403(r) is not a drug solely be-*
26 *cause the label or the labeling contains such a claim. A food,*

1 *dietary ingredient, or dietary supplement for which a truth-*
2 *ful and not misleading statement is made in accordance*
3 *with section 403(r)(6) is not a drug under clause (C) solely*
4 *because the label or the labeling contains such a statement.”.*

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

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

10 (c) *SECTION 403.—Section 403 (21 U.S.C. 343), as*
11 *amended by section 7, is amended by adding after para-*
12 *graph (s) the following:*

13 “*A dietary supplement shall not be deemed misbranded sole-*
14 *ly because its label or labeling contains directions or condi-*
15 *tions of use or warnings.”.*

16 ***SEC. 11. WITHDRAWAL OF THE REGULATIONS AND NOTICE.***

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

1 **SEC. 12. COMMISSION ON DIETARY SUPPLEMENT LABELS.**

2 (a) *ESTABLISHMENT.*—There shall be established as an
 3 independent agency within the executive branch a commis-
 4 sion to be known as the Commission on Dietary Supple-
 5 ment Labels (hereafter in this section referred to as the
 6 “Commission”).

7 (b) *MEMBERSHIP.*—

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

11 (2) *EXPERTISE REQUIREMENT.*—The members of
 12 the Commission shall consist of individuals with ex-
 13 pertise and experience in dietary supplements and in
 14 the manufacture, regulation, distribution, and use of
 15 such supplements. At least three of the members of the
 16 Commission shall be qualified by scientific training
 17 and experience to evaluate the benefits to health of the
 18 use of dietary supplements and one of such three
 19 members shall have experience in pharmacognosy,
 20 medical botany, traditional herbal medicine, or other
 21 related sciences. Members and staff of the Commission
 22 shall be without bias on the issue of dietary supple-
 23 ments.

24 (c) *FUNCTIONS OF THE COMMISSION.*—The Commis-
 25 sion shall conduct a study on, and provide recommenda-
 26 tions for, the regulation of label claims and statements for

1 *dietary supplements, including the use of literature in con-*
 2 *nection with the sale of dietary supplements and procedures*
 3 *for the evaluation of such claims. In making such rec-*
 4 *ommendations, the Commission shall evaluate how best to*
 5 *provide truthful, scientifically valid, and not misleading in-*
 6 *formation to consumers so that such consumers may make*
 7 *informed and appropriate health care choices for themselves*
 8 *and their families.*

9 (d) *ADMINISTRATIVE POWERS OF THE COMMISSION.—*

10 (1) *HEARINGS.—The Commission may hold*
 11 *hearings, sit and act at such times and places, take*
 12 *such testimony, and receive such evidence as the Com-*
 13 *mission considers advisable to carry out the purposes*
 14 *of this section.*

15 (2) *INFORMATION FROM FEDERAL AGENCIES.—*

16 *The Commission may secure directly from any Fed-*
 17 *eral department or agency such information as the*
 18 *Commission considers necessary to carry out the pro-*
 19 *visions of this section.*

20 (3) *AUTHORIZATION OF APPROPRIATIONS.—*

21 *There are authorized to be appropriated such sums as*
 22 *may be necessary to carry out this section.*

23 (e) *REPORTS AND RECOMMENDATIONS.—*

24 (1) *FINAL REPORT REQUIRED.—Not later than*
 25 *24 months after the date of enactment of this Act, the*

1 *Commission shall prepare and submit to the Presi-*
2 *dent and to the Congress a final report on the study*
3 *required by this section.*

4 (2) *RECOMMENDATIONS.—The report described*
5 *in paragraph (1) shall contain such recommenda-*
6 *tions, including recommendations for legislation, as*
7 *the Commission deems appropriate.*

8 (3) *ACTION ON RECOMMENDATIONS.—Within 90*
9 *days of the issuance of the report under paragraph*
10 *(1), the Secretary of Health and Human Services*
11 *shall publish in the Federal Register a notice of any*
12 *recommendation of Commission for changes in regula-*
13 *tions of the Secretary for the regulation of dietary*
14 *supplements and shall include in such notice a notice*
15 *of proposed rulemaking on such changes together with*
16 *an opportunity to present views on such changes.*
17 *Such rulemaking shall be completed not later than 2*
18 *years after the date of the issuance of such report. If*
19 *such rulemaking is not completed on or before the ex-*
20 *piration of such 2 years, regulations of the Secretary*
21 *published in 59 FR 395–426 on January 4, 1994,*
22 *shall not be in effect.*

1 **SEC. 13. OFFICE OF DIETARY SUPPLEMENTS.**

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

5 “Subpart 4—Office of Dietary Supplements

6 **“SEC. 485C. DIETARY SUPPLEMENTS.**

7 “(a) *ESTABLISHMENT.*—The Secretary shall establish
 8 an Office of Dietary Supplements within the National In-
 9 stitutes of Health.

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

11 “(1) to explore more fully the potential role of
 12 dietary supplements as a significant part of the ef-
 13 forts of the United States to improve health care; and

14 “(2) to promote scientific study of the benefits of
 15 dietary supplements in maintaining health and pre-
 16 venting chronic disease and other health-related con-
 17 ditions.

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

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

1 “(2) collect and compile the results of scientific
2 research relating to dietary supplements, including
3 scientific data from foreign sources or the Office of Al-
4 ternative Medicine;

5 “(3) serve as the principal advisor to the Sec-
6 retary and to the Assistant Secretary for Health and
7 provide advice to the Director of the National Insti-
8 tutes of Health, the Director of the Centers for Disease
9 Control and Prevention, and the Commissioner of
10 Food and Drugs on issues relating to dietary supple-
11 ments including—

12 “(A) dietary intake regulations;

13 “(B) the safety of dietary supplements;

14 “(C) claims characterizing the relationship
15 between—

16 “(i) dietary supplements; and

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

19 “(II) maintenance of health; and

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

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

1 “(5) coordinate funding relating to dietary sup-
2 plements for the National Institutes of Health.

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

6 “(e) AUTHORIZATION OF APPROPRIATIONS.—There are
7 authorized to be appropriated to carry out this section
8 \$5,000,000 for fiscal year 1994 and such sums as may be
9 necessary for each subsequent fiscal year.”.

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

13 “(E) The Office of Dietary Supplements.”.

Attest:

Clerk.

103^D CONGRESS
2^D SESSION

S. 784

AMENDMENT