

103D CONGRESS
2D SESSION

S. 784

AN ACT

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

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Dietary Supplement
5 Health and Education Act of 1994”.

1 **SEC. 2. FINDINGS AND PURPOSE.**

2 (a) FINDINGS.—Congress finds that—

3 (1) improving the health status of United
4 States citizens ranks at the top of the national prior-
5 ities of 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
9 in scientific studies;

10 (3)(A) there is a definitive link between the in-
11 gestion of certain nutrients or dietary supplements
12 and the prevention of chronic diseases such as can-
13 cer, heart disease, 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
20 expensive medical procedures, such as coronary by-
21 pass surgery or angioplasty;

22 (5) preventive health measures, including edu-
23 cation, good nutrition, and appropriate use of safe
24 nutritional supplements will limit the incidence of
25 chronic diseases, and reduce long-term health care
26 expenditures;

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

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

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

10 (8) consumers should be empowered to make
11 choices about preventive health care programs based
12 on data from scientific studies of health benefits re-
13 lated to particular dietary supplements;

14 (9)(A) national surveys have revealed that al-
15 most 50 percent of the 260,000,000 Americans reg-
16 ularly consume dietary supplements of vitamins,
17 minerals, or herbs as a means of improving their nu-
18 trition; and

19 (B) nearly all consumers indicate that dietary
20 supplements should not be regulated as drugs;

21 (10) studies indicate that consumers are placing
22 increased reliance on the use of nontraditional
23 health care providers to avoid the excessive costs of
24 traditional medical services and to obtain more holis-
25 tic 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
4 the United States, and this amount and percentage
5 will continue to increase unless significant efforts
6 are undertaken to reverse the increase;

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

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

12 (C) the estimated 600 dietary supplement man-
13 ufacturers in the United States produce approxi-
14 mately 4,000 products, with total annual sales of
15 such products alone reaching at least
16 \$4,000,000,000;

17 (13) although the Federal Government should
18 take swift action against products that are unsafe or
19 adulterated, the Federal Government should not
20 take any actions to impose regulatory barriers limit-
21 ing or slowing the flow of safe products and needed
22 information to consumers;

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

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

4 (B) a rational Federal framework must be es-
5 tablished to supersede the current ad hoc, patchwork
6 regulatory policy on dietary supplements.

7 (b) PURPOSE.—It is the purpose of this Act to—

8 (1) improve the health status of the people of
9 the United States and help constrain runaway health
10 care spending by ensuring that the Federal Govern-
11 ment erects no regulatory barriers that impede the
12 ability of consumers to improve their nutrition
13 through the free choice of safe dietary supplements;

14 (2) clarify that—

15 (A) dietary supplements are not drugs or
16 food additives;

17 (B) dietary supplements should not be reg-
18 ulated as drugs;

19 (C) regulations relating to food additives
20 are not applicable to dietary supplements and
21 their ingredients used for food additive pur-
22 poses, including stabilizers, processing agents,
23 or preservatives; and

24 (D) the burden of proof is on the Food
25 and Drug Administration to prove that a prod-

1 uct is unsafe before it can be removed from the
2 marketplace;

3 (3) establish a new definition of a dietary sup-
4 plement that differentiates dietary supplements from
5 conventional foods, while recognizing the broad
6 range of food ingredients used to supplement the
7 diet;

8 (4) strengthen the current enforcement author-
9 ity of the Food and Drug Administration by provid-
10 ing to the Administration additional mechanisms to
11 take enforcement action against unsafe or fraudu-
12 lent products;

13 (5) establish a series of labeling requirements
14 that will provide consumers with greater information
15 and assurance about the quality and content of die-
16 tary supplements, while at the same time assuring
17 the consumers the freedom to use the supplements
18 of their choice;

19 (6) provide new administrative and judicial re-
20 view procedures to affected parties if the Food and
21 Drug Administration takes certain actions to enforce
22 dietary supplement requirements; and

23 (7) establish a Commission on Dietary Supple-
24 ment Labels within the executive branch to develop
25 recommendations on a procedure to evaluate health

1 claims for dietary supplements and provide rec-
2 ommendations to the President and the Congress.

3 **SEC. 3. DEFINITIONS.**

4 (a) DEFINITION OF CERTAIN FOODS AS DIETARY
5 SUPPLEMENTS.—Section 201 of the Federal Food, Drug,
6 and Cosmetic Act (21 U.S.C. 321) is amended by adding
7 at the end the following:

8 “(ff) The term ‘dietary supplement’ means—

9 “(1) a product intended to supplement the diet
10 by increasing the total dietary intake that bears or
11 contains one or more of the following dietary ingre-
12 dients:

13 “(A) a vitamin;

14 “(B) a mineral;

15 “(C) an herb or other botanical;

16 “(D) an amino acid;

17 “(E) another dietary substance for use by
18 man to supplement the diet by increasing the
19 total dietary intake; or

20 “(F) a concentrate, metabolite, constitu-
21 ent, extract, or combination of any ingredient
22 described in clause (A), (B), (C), (D), (E) or
23 (F);

24 “(2) 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 and

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

8 “(C) is labeled as a dietary supplement.”.

9 (b) EXCLUSION FROM DEFINITION OF DRUG.—Sec-
10 tion 201(g) of the Federal Food, Drug, and Cosmetic Act
11 (21 U.S.C. 321(g)) is amended by adding at the end the
12 following new subparagraph:

13 “(3) The term ‘drug’ does not include a dietary sup-
14 plement as defined in paragraph (ff), except that—

15 “(A) an article that is approved as a new drug,
16 certified as an antibiotic (under section 355 or 357),
17 or licensed as a biologic (under section 351 of the
18 Public Health Service Act (42 U.S.C. 262 et seq.))
19 and was, prior to such approval, certification or li-
20 cense, marketed as a dietary supplement or as a
21 food, may continue to be offered for sale as a dietary
22 supplement unless the Secretary has issued a regula-
23 tion, after notice and comment, finding that the arti-
24 cle when used as or in a dietary supplement under
25 the conditions of use and dosages set forth in the la-

1 belong for such dietary supplement, is unlawful
2 under section 402(f); and

3 “(B) an article that is approved as a new drug,
4 certified as an antibiotic (under section 355 or 357),
5 or licensed as a biologic (under section 351 of the
6 Public Health Service Act (42 U.S.C. 262 et seq.))
7 and was not prior thereto marketed as a dietary
8 supplement or as a food, may not be considered as
9 a dietary ingredient or dietary supplement unless the
10 Secretary has issued a regulation, after notice and
11 comment, finding that the article would be lawful
12 under section 402(f) under the conditions of use and
13 dosages set forth in the recommended labeling for
14 such article.”.

15 (c) EXCLUSION FROM DEFINITION OF FOOD ADDI-
16 TIVE.—Section 201(s) of the Federal Food, Drug, and
17 Cosmetic Act (21 U.S.C. 321(s)) is amended—

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

19 (4);

20 (2) by striking the period at the end of sub-
21 paragraph (5) and inserting “; or”; and

22 (3) by adding at the end the following new sub-
23 paragraph:

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

1 (d) FORM OF INGESTION.—Section 411(c)(1)(B) of
2 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 350(c)(1)(B)) is amended—

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

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

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

10 Section 402 of the Federal Food, Drug, and Cosmetic
11 Act (21 U.S.C. 342) is amended by adding at the end the
12 following:

13 “(f) If it is a dietary supplement that—

14 “(1) the Secretary finds, after rulemaking, pre-
15 sents a substantial and unreasonable risk of illness
16 or injury under conditions of use recommended or
17 suggested in labeling;

18 “(2) the Secretary declares to pose an imminent
19 and substantial hazard to public health or safety, ex-
20 cept that the authority to make such declaration
21 shall not be delegated and the Secretary shall
22 promptly thereafter convene rulemaking pursuant to
23 section 701(e), (f), and (g) to affirm or withdraw
24 the declaration; or

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

5 In any proceeding under this section, the United States
6 bears the burden of proof on each element to show that
7 a dietary supplement is adulterated.”.

8 **SEC. 5. DIETARY SUPPLEMENT CLAIMS.**

9 (a) SUPPLEMENT CLAIMS.—Chapter IV of the Fed-
10 eral Food, Drug, and Cosmetic Act (21 U.S.C. 341 et
11 seq.) is amended by inserting after section 403A the fol-
12 lowing new section:

13 “DIETARY SUPPLEMENT LABELING EXEMPTIONS

14 “SEC. 403B. An article, another publication, a chap-
15 ter in books, or the official abstract of a peer-reviewed sci-
16 entific publication that appears in the article and was pre-
17 pared by the author or the editors of the publication, re-
18 printed in its entirety, shall not be defined as labeling
19 when used in connection with the sale of dietary supple-
20 ments to consumers when it—

21 “(1) is not false or misleading;

22 “(2) does not promote a particular brand of a
23 dietary supplement;

24 “(3) is displayed or presented, or is displayed
25 or presented with other such items on the same sub-
26 ject matter, so as to present a balanced view of the

1 available scientific information on a dietary supple-
2 ment; and

3 “(4) if displayed in an establishment, is phys-
4 ically separate from the dietary supplements.

5 This section shall not apply to or restrict a retailer or
6 wholesaler of dietary supplements in any way whatsoever
7 in the sale of books or other publications as a part of the
8 business of such retailer or wholesaler. In any proceeding
9 under this section, the burden of proof shall be on the
10 United States to establish that an article or other such
11 matter is false or misleading.”.

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

13 Section 403(r)(1) of the Federal Food, Drug, and
14 Cosmetic Act (21 U.S.C. 343(r)(1)) is amended by adding
15 the following new sentence at the end:“For purposes of
16 this subparagraph, a statement for a dietary supplement
17 shall not be considered a claim of the relationship of a
18 nutrient or dietary ingredient to a disease or health-relat-
19 ed condition if the statement does not claim to diagnose,
20 prevent, mitigate, treat, or cure a specific disease or class
21 of diseases. A statement for a dietary supplement may be
22 made if the statement claims a benefit related to a classi-
23 cal nutrient deficiency disease and discloses the prevalence
24 of such disease in the United States, describes the role
25 of a nutrient or dietary ingredient intended to affect the

1 structure or function in humans, characterizes the docu-
2 mented mechanism by which a nutrient or dietary ingredi-
3 ent acts to maintain such structure or function, or de-
4 scribes general well-being from consumption of a nutrient
5 or dietary ingredient.”.

6 **SEC. 7. CONFORMING AMENDMENTS.**

7 (a) SECTION 201.—The next to the last sentence of
8 section 201(g)(1) of the Federal Food, Drug, and Cos-
9 metic Act (21 U.S.C. 321(g)(1)) (as amended by section
10 3(b)) is amended to read as follows: “A food or dietary
11 supplement for which a claim, subject to section
12 403(r)(1)(B) and 403(r)(3) or section 403(r)(1)(B) and
13 403(r)(5)(D), is made in accordance with the require-
14 ments of section 403(r) is not a drug solely because the
15 label or the labeling contains such a claim. A food, dietary
16 ingredient, or dietary supplement for which a truthful and
17 nonmisleading statement is made in accordance with sec-
18 tion 403(r)(1) is not a drug solely because the label or
19 the labeling contains such a statement.”.

20 (b) SECTION 403.—Section 403 (21 U.S.C. 343) is
21 amended by adding at the end the following:
22 “A dietary supplement shall not be deemed misbranded
23 solely because its label or labeling contains directions or
24 conditions of use or warnings.”.

1 **SEC. 8. ADMINISTRATIVE AND JUDICIAL REVIEW.**

2 The Federal Food, Drug, and Cosmetic Act is amend-
3 ed by adding at the end of chapter III (21 U.S.C. 331
4 et seq.) the following new section:

5 **“SEC. 311. WARNING LETTERS.**

6 “Any warning letter or similar written threat of en-
7 forcement under the Federal Food, Drug, and Cosmetic
8 Act constitutes final agency action for the purpose of ob-
9 taining judicial review under chapter 7 of title 5, United
10 States Code, if the matter with respect to such letter or
11 threat is not resolved within 60 days from the date such
12 letter or threat is delivered to any person subject to this
13 Act. In any proceeding for judicial review of a warning
14 letter or similar written threat of enforcement under the
15 Act, the United States bears the burden of proof on each
16 element of each alleged violation of law described.”.

17 **SEC. 9. WITHDRAWAL OF THE REGULATIONS AND NOTICE.**

18 (a) IN GENERAL.—The advance notice of proposed
19 rulemaking concerning dietary supplements published in
20 the Federal Register of June 18, 1993 (58 FR 33690–
21 33700), the notices of proposed rulemaking concerning
22 nutrition labeling for dietary supplements and nutrient
23 content claims for dietary supplements published in the
24 Federal Register of June 18, 1993 (58 FR 33715–33731
25 and 58 FR 33731–33751), and the final rules and notices
26 published in the Federal Register of January 4, 1994 con-

1 cerning nutrition labeling for dietary supplements and nu-
2 trient content claims for dietary supplements (59 FR 354-
3 378 and 378-395) are null and void and of no force or
4 effect insofar as they apply to dietary supplements. Final
5 regulations and notices published in the Federal Register
6 of January 4, 1994 concerning health claims for dietary
7 supplements under the Nutrition Labeling and Education
8 Act of 1990 (59 FR 395-426) shall not be affected by
9 this section and shall remain in effect until 120 days after
10 the date of the submission of the final report of the Com-
11 mission established under section 11 to the President and
12 to Congress, or 28 months after the date of enactment
13 of this Act, whichever is earlier.

14 (b) NOTICE OF REVOCATION.—The Secretary of
15 Health and Human Services shall publish notices in the
16 Federal Register to revoke all of the items declared to be
17 null and void and of no force or effect under subsection
18 (a).

19 (c) ISSUANCE OF REGULATIONS.—Notwithstanding
20 any provision of the Nutrition Labeling and Education Act
21 of 1990—

22 (1) no regulation is required to be issued pursu-
23 ant to such Act with respect to dietary supplements
24 of vitamins, minerals, herbs, amino acids, or other
25 similar nutritional substances; and

1 (2) no regulation that is issued in whole or in
2 part pursuant to such Act shall have any force or ef-
3 fect with respect to any dietary supplement of vita-
4 mins, minerals, herbs, amino acids, or other similar
5 nutritional substances unless such regulation is is-
6 sued pursuant to rulemaking proceedings that are
7 initiated by an advance notice of proposed rule-
8 making that is published no earlier than 2 years
9 after the date of enactment of this Act, and followed
10 by, at least, a notice of proposed rulemaking prior
11 to issuance of the final regulation, except insofar as
12 the regulation authorizes the use of labeling about
13 calcium, folic acid, or other matters and does not
14 prohibit the use of any labeling.

15 **SEC. 10. DIETARY SUPPLEMENT INGREDIENT LABELING**
16 **AND NUTRITION INFORMATION LABELING.**

17 (a) MISBRANDED SUPPLEMENTS.—Section 403 of
18 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
19 343) is amended by adding at the end the following new
20 paragraph:

21 “(s) If—

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

23 “(2)(A) the label or labeling of the supplement
24 fails to list—

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

4 “(ii)(I) the quantity of each such ingredi-
5 ent; or

6 “(II) with respect to a proprietary blend of
7 such ingredients, the total quantity of all ingre-
8 dients in the blend;

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

13 “(C) the supplement contains an ingredient de-
14 scribed in section 201(ff) (1)(C), and the label or la-
15 beling of the supplement fails to identify any part of
16 the plant from which the ingredient is derived;

17 “(D) the supplement—

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

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

22 “(iii) fails to so conform; or

23 “(E) the supplement—

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

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

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

9 (b) SUPPLEMENT LISTING ON NUTRITION LABEL-
10 ING.—Section 403(q)(1) of the Federal Food, Drug, and
11 Cosmetic Act (21 U.S.C. 343(q)(1)) is amended by adding
12 at the end the following: “A dietary supplement may bear
13 on the nutrition label or in labeling a listing and quantity
14 of ingredients that have not been deemed essential nutri-
15 ents by the Secretary if such ingredients are prominently
16 identified as not having been shown to be essential or not
17 having an established daily value.”.

18 (c) DIETARY SUPPLEMENT LABELING EXEMP-
19 TIONS.—Section 403(q)(5) of the Federal Food, Drug,
20 and Cosmetic Act (21 U.S.C. 343(q)(5)) is amended by
21 adding at the end the following new clause:

22 “(H) The labels of dietary supplements shall not be
23 required to bear the nutrition information under subpara-
24 graph (1), but shall be required to list immediately above
25 the ingredient listing the amount of nutrients required by

1 the Secretary to be listed pursuant to clause (C), (D) or
2 (E) of subparagraph (1) or clause (A) of subparagraph
3 (2) that are present in significant amounts in the supple-
4 ment.”.

5 (d) VITAMINS AND MINERALS.—Section 411(b)(2) of
6 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
7 350(b)(2)) is amended—

8 (1) by striking “vitamins and minerals” and in-
9 serting “dietary supplement ingredients described in
10 section 201(ff)”;

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

13 (3) by striking subparagraph (B).

14 **SEC. 11. COMMISSION ON DIETARY SUPPLEMENT LABELS.**

15 (a) ESTABLISHMENT.—There shall be established as
16 an independent agency within the executive branch a com-
17 mission to be known as the Commission on Dietary Sup-
18 plement Labels (hereafter in this section referred to as
19 the “Commission”).

20 (b) MEMBERSHIP.—

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

24 (2) EXPERTISE REQUIREMENT.—The members
25 of the Commission shall consist of individuals with

1 expertise and experience in dietary supplements and
2 in the manufacture, regulation, distribution, and use
3 of such supplements. At least three of the members
4 of the Commission shall be qualified by scientific
5 training and experience to evaluate the benefits to
6 health of the use of dietary supplements and one of
7 such three members shall have experience in phar-
8 macognosy, medical botany, traditional herbal medi-
9 cine, or other related sciences. No member of the
10 Commission shall be biased against dietary supple-
11 ments.

12 (c) FUNCTIONS OF THE COMMISSION.—The Commis-
13 sion shall conduct a study on, and provide recommenda-
14 tions for, the regulation of label claims for dietary supple-
15 ments, including procedures for the evaluation of such
16 claims. In making such recommendations, the Commission
17 shall evaluate how best to provide truthful and
18 nonmisleading information to consumers so that such con-
19 sumers may make informed health care choices for them-
20 selves and their families.

21 (d) REPORTS AND RECOMMENDATIONS.—

22 (1) FINAL REPORT REQUIRED.—Not later than
23 24 months after the date of enactment of this Act,
24 the Commission shall prepare and submit to the

1 President and to the Congress a final report on the
2 study required by this section.

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

7 (e) ADMINISTRATIVE POWERS OF THE COMMIS-
8 SION.—

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

14 (2) INFORMATION FROM FEDERAL AGENCIES.—
15 The Commission may secure directly from any Fed-
16 eral department or agency such information as the
17 Commission considers necessary to carry out the
18 provisions of this section.

19 (3) AUTHORIZATION OF APPROPRIATIONS.—
20 There are authorized to be appropriated such sums
21 as may necessary to carry out the provisions of this
22 section.

1 **SEC. 12. GOOD MANUFACTURING PRACTICES.**

2 Section 402 of the Federal Food, Drug, and Cosmetic
3 Act (21 U.S.C. 342) (as amended by section 4) is further
4 amended by adding at the end the following:

5 “(g)(1) If it is a dietary supplement and it has been
6 prepared, packed, or held under conditions that do not
7 meet current good manufacturing practice regulations is-
8 sued by the Secretary under subparagraph (2).

9 “(2) The Secretary may by regulation prescribe good
10 manufacturing practices for dietary supplements. Such
11 regulations shall be modeled after current good manufac-
12 turing practice regulations for food and may not impose
13 standards for which there is no current and generally
14 available analytical methodology. No standard of current
15 good manufacturing practice may be imposed unless such
16 standard is included in a regulation promulgated after no-
17 tice and opportunity for comment in accordance with the
18 Administrative Procedure Act.”.

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

20 (a) IN GENERAL.—Title IV of the Public Health
21 Service Act is amended by inserting after section 486 (42
22 U.S.C. 287c-3) the following:

1 “Subpart 4—Office of Dietary Supplements

2 **“SEC. 486E. DIETARY SUPPLEMENTS.**

3 “(a) ESTABLISHMENT.—The Secretary shall estab-
4 lish an Office of Dietary Supplements within the National
5 Institutes of Health.

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

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

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

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

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

23 “(2) collect and compile the results of scientific
24 research relating to dietary supplements, including

1 scientific data from foreign sources or the Office of
2 Alternative Medical Practice;

3 “(3) serve as the principal advisor to the Sec-
4 retary and to the Assistant Secretary for Health,
5 and to provide advice to the Director of the National
6 Institutes of Health, the Director of the Centers for
7 Disease Control and Prevention, and the Commis-
8 sioner of Food and Drugs, on issues relating to die-
9 tary supplements including—

10 “(A) dietary intake regulations;

11 “(B) the safety of dietary supplements;

12 “(C) claims characterizing the relationship
13 between—

14 “(i) dietary supplements; and

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

17 “(II) maintenance of health; and

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

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

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

1 “(d) DEFINITION.—As used in this section, the term
2 ‘dietary supplement’ has the meaning given the term in
3 section 201(ff) of the Federal Food, Drug, and Cosmetic
4 Act (21 U.S.C. 321(ff)).

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

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

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

Passed the Senate August 13 (legislative day, Au-
gust 11), 1994.

Attest:

Secretary.

S 784 ES—2

S 784 ES—3

S 784 ES—4

S 784 ES—5