

103D CONGRESS
1ST SESSION

S. 784

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

IN THE SENATE OF THE UNITED STATES

APRIL 7 (legislative day, MARCH 3), 1993

Mr. HATCH (for himself, Mr. REID, and Mr. MURKOWSKI) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

A BILL

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 1993”.

6 **SEC. 2. FINDINGS AND PURPOSE.**

7 (a) FINDINGS.—Congress finds that—

1 (1) improving the health status of United
2 States citizens ranks at the top of the national prior-
3 ities of the Federal Government;

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

8 (3)(A) there is a definitive link between the in-
9 gestion of certain nutrients or dietary supplements
10 and the prevention of chronic diseases such as can-
11 cer, heart disease, and osteoporosis; and

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

17 (4) healthful diets may mitigate the need for
18 expensive medical procedures, such as coronary by-
19 pass surgery or angioplasty;

20 (5) preventive health measures, including edu-
21 cation, good nutrition, and appropriate use of safe
22 nutritional supplements will limit the incidence of
23 chronic diseases, and reduce long-term health care
24 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) recent national surveys have revealed
15 that almost 50 percent of the 260,000,000 Ameri-
16 cans regularly consume dietary supplements of vita-
17 mins, minerals, or herbs as a means of improving
18 their nutrition; 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 treatment of patients;

1 (11) the United States will spend over
2 \$900,000,000,000 on health care in 1993, which is
3 about 12 percent of the Gross National Product of
4 the United States, and this amount and percent 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
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 3,400 products, with total annual sales of
15 such products alone reaching \$4,000,000,000;

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

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

19 (C) regulations relating to food additives
20 should only be applied to dietary supplement in-
21 gredients used for food additive purposes, such
22 as stabilizers, processing agents or preserva-
23 tives;

24 (3) establish a new definition of a dietary sup-
25 plement that differentiates dietary supplements from

1 conventional foods, while recognizing the broad
2 range of food ingredients used to supplement the
3 diet;

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

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

15 (6) establish dietary intake standards based on
16 the amount of nutrients needed to prevent disease;

17 (7) provide new administrative and judicial re-
18 view procedures to affected parties if the Adminis-
19 tration takes certain actions to enforce dietary sup-
20 plement requirements;

21 (8) specify the standards applicable to disease
22 and other health-related claims for dietary supple-
23 ments;

24 (9) reaffirm that dietary supplement labeling
25 may bear information, other than health claims,

1 about the vitamin, mineral, or other dietary prop-
2 erties of the supplement; and

3 (10) establish a new Office of Dietary Supple-
4 ments within the National Institutes of Health to
5 initiate and coordinate research on dietary supple-
6 ments and advise the Secretary and other officials of
7 the Department of Health and Human Services on
8 dietary supplement issues.

9 **SEC. 3. DEFINITIONS.**

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

14 “(gg) The term ‘dietary supplement’ means a food
15 for special dietary use, as defined in section 411(c)(3),
16 that—

17 “(1) includes—

18 “(A) a vitamin;

19 “(B) a mineral;

20 “(C) an herb;

21 “(D) an amino acid;

22 “(E) another ingredient for use by man to
23 supplement the diet by increasing the total die-
24 tary intake; or

1 “(F) a concentrate or extract of any ingre-
2 dient described in clause (A), (B), (C), (D), or
3 (E); and

4 “(2)(A) is intended for ingestion in a form de-
5 scribed in section 411(c)(1)(B)(i); or

6 “(B) complies with section 411(c)(1)(B)(ii).”.

7 (b) EXCLUSION FROM DEFINITION OF DRUG.—Sec-
8 tion 201(g)(1) of the Federal Food, Drug, and Cosmetic
9 Act (21 U.S.C. 321(g)) is amended by adding at the end
10 the following new sentence: “The term ‘drug’ does not in-
11 clude a dietary supplement or an ingredient described in
12 clause (A), (B), (C), (D), (E), or (F) of paragraph (gg)(1)
13 in, or intended for use in, a dietary supplement.”.

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

17 (1) by striking “or” at the end of subparagraph
18 (4);

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

21 (3) by adding at the end the following:

22 “(6) an ingredient described in clause (A), (B),
23 (C), (D), (E), or (F) of paragraph (gg)(1) in, or in-
24 tended 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 after “capsule,”; and

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

8 **SEC. 4. SAFETY OF DIETARY SUPPLEMENTS.**

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

12 “(f) If it is a dietary supplement that contains an
13 ingredient that is intended to be consumed for its dietary
14 properties and—

15 “(1) the Secretary finds, after rulemaking, that
16 the ingredient presents a substantial and unreason-
17 able risk of illness or injury; or

18 “(2) no manufacturer of the supplement, or
19 manufacturer of the raw material comprising the in-
20 gredient, has adequately substantiated the safety of
21 the ingredient—

22 “(A) through evidence of a history of safe
23 use of the ingredient (as part of any intended
24 use prior to the use of the ingredient in such
25 dietary supplement), and through the absence

1 of substantial information that brings the safety
2 of the ingredient into question;

3 “(B) by well-designed scientific studies
4 conducted in a manner that is consistent with
5 generally recognized scientific procedures and
6 principles; or

7 “(C) by other appropriate means,

8 unless—

9 “(i) the Secretary has established, in consulta-
10 tion with the Director of the Centers for Disease
11 Control and Prevention, the Director of the National
12 Institutes of Health, and the National Academy of
13 Sciences, a recommended dietary allowance, or an
14 estimated safe and adequate dietary intake level,
15 with respect to the ingredient;

16 “(ii) the Secretary has determined, prior to the
17 date of enactment of this paragraph, that the ingre-
18 dient has been generally recognized as safe; or

19 “(iii) the ingredient is used in conformity with
20 a regulation relating to food additives that is de-
21 scribed in section 409(a)(2) and is issued prior to
22 the date of enactment of this paragraph.”.

1 **SEC. 5. REPORT ON IMPACT OF SIGNIFICANT CHANGES IN**
2 **MANUFACTURING PRACTICES.**

3 (a) STUDY.—The Director of the Office of Dietary
4 Supplements shall conduct a study relating to significant
5 changes in the manufacturing practices of manufacturers
6 of raw materials utilized in dietary supplements. In con-
7 ducting the study, the Director shall analyze the extent
8 to which such changes pose a risk to public safety.

9 (b) REPORT.—Not later than 3 years after the date
10 of enactment of this Act, the Director of the Office of Die-
11 tary Supplements shall prepare and submit to the Com-
12 mittee on Energy and Commerce of the House of Rep-
13 resentatives and the Committee on Labor and Human Re-
14 sources of the Senate a report containing—

15 (1) the results of the study described in sub-
16 section (a); and

17 (2) any recommendations for legislative reform.

18 **SEC. 6. DIETARY INTAKE STANDARDS.**

19 (a) NUTRITION INFORMATION.—Section 403(q)(1)
20 (21 U.S.C. 343(q)(1)) is amended—

21 (1) by striking the period at the end of clause
22 (E) and inserting “, or”; and

23 (2) by adding after clause (E) the following:

24 “(F) a declaration of the percent of a daily ref-
25 erence amount for each nutrient specified in clauses

1 (D) and (E), stated as a ‘Percent Daily Value’ pro-
2 vided by a serving of the food.’’.

3 (b) REGULATIONS.—

4 (1) IN GENERAL.—

5 (A) DAILY VALUE.—Subject to subpara-
6 graph (B), the Secretary of Health and Human
7 Services shall, by regulation, determine, based
8 on the dietary guidance provided by the Depart-
9 ment of Agriculture, the Department of Health
10 and Human Services, the Centers for Disease
11 Control and Prevention, the National Institutes
12 of Health, and other authoritative public health
13 organizations, a daily value for each nutrient
14 specified in clauses (D) and (E) of section
15 403(q)(1) of the Federal Food, Drug, and Cos-
16 metic Act. The daily value shall reflect the daily
17 intake of each such nutrient that will promote
18 optimal health and minimize the risk of disease
19 or other health-related conditions.

20 (B) LIMITATION.—The daily value deter-
21 mined by the Secretary under subparagraph (A)
22 shall, in every appropriate case, be no less than
23 the United States Recommended Daily Allow-
24 ances established by the Food and Nutrition
25 Board of the National Academy of Sciences for

1 the age and sex group most at risk of nutri-
2 tional deficiencies of any particular nutrient.

3 (2) TIMING.—Except as provided in paragraph
4 (4), the Secretary of Health and Human Services
5 shall issue proposed regulations under paragraph (1)
6 no later than 12 months after the date of the enact-
7 ment of this Act and shall issue final regulations no
8 later than 24 months after such date.

9 (3) PENDING DAILY VALUES.—Pending the is-
10 suaunce of final regulations under paragraph (1), the
11 daily values for the nutrients declared under section
12 403(q)(1)(F) of the Federal Food, Drug, and Cos-
13 metic Act shall be the values specified in sections
14 101.9(c)(8) and 101.9(c)(9) of title 21, Code of Fed-
15 eral Regulations, as in effect on the date of the en-
16 actment of this Act.

17 (4) ASSISTANCE.—

18 (A) REVIEW AND STUDIES.—To assist the
19 Secretary of Health and Human Services in is-
20 suing regulations under paragraph (1), the Di-
21 rector of the Congressional Research Service, in
22 consultation with the Director of the Office of
23 Technology Assessment, shall review existing
24 scientific data and conduct any necessary
25 studies.

1 (B) PURPOSE.—Such review and studies
2 shall determine the amount of each nutrient
3 specified in clauses (D) and (E) of section
4 403(q)(1) of the Federal Food, Drug, and Cos-
5 metic Act that would be provided by the diets
6 recommended by the Department of Agri-
7 culture, the Department of Health and Human
8 Services, the Centers for Disease Control and
9 Prevention, the National Institutes of Health,
10 and other authoritative public health organiza-
11 tions, to minimize the risk of disease and other
12 health-related conditions and to promote opti-
13 mal health.

14 (C) TIMING.—Such review and studies
15 shall be completed no later than 9 months after
16 the date of the enactment of this Act. If the
17 Congressional Research Service does not com-
18 plete such review and studies within 9 months
19 after the date of enactment of this Act, the
20 time prescribed by paragraph (2) for the issu-
21 ance of proposed and final regulations shall be
22 extended by a period equal to the additional
23 time required by such Office to complete such
24 review and studies.

1 **SEC. 7. DIETARY SUPPLEMENT CLAIMS.**

2 Section 403(r) of the Federal Food, Drug, and Cos-
3 metic Act (21 U.S.C. 343(r)) is amended by striking sub-
4 paragraph (5)(D) and inserting the following:

5 “(D) A subparagraph (1)(B) claim made with respect
6 to a dietary supplement shall not be subject to subpara-
7 graph (3).

8 “(6)(A) A claim made in the label or labeling of a
9 dietary supplement may characterize the relationship be-
10 tween the supplement and a disease or other health-related
11 condition if—

12 “(i)(I) the Secretary has authorized, under sub-
13 paragraph (3)(B), a claim of the type described in
14 subparagraph (1)(B) for any nutrient contained in
15 the supplement, with respect to the disease or other
16 health-related condition;

17 “(II) such characterization is consistent with
18 the claim authorized by the Secretary; and

19 “(III) the Secretary has not determined, after
20 rulemaking based on the totality of scientific evi-
21 dence (including evidence from well-designed studies
22 conducted in a manner consistent with generally rec-
23 ognized scientific principles), that consumption of
24 the nutrient in a dietary supplement would not tend
25 to reduce the risk of the disease or other health-re-

1 lated condition in a similar manner as would con-
2 sumption of the nutrient in conventional foods; or

3 “(ii) such characterization accurately represents
4 the state of scientific evidence, as of the date of the
5 evaluation of the claim, concerning the relationship
6 between the supplement or ingredient of the supple-
7 ment and the disease or other health-related condi-
8 tion, taking into account the totality of scientific evi-
9 dence (including evidence from well-designed studies
10 conducted in a manner consistent with generally rec-
11 ognized scientific principles).

12 “(B) Nothing in this subparagraph shall—

13 “(i) prohibit the inclusion, in the label or label-
14 ing of a dietary supplement, of truthful and
15 nonmisleading information concerning the vitamin,
16 mineral, or other dietary properties of the supple-
17 ment (including nutritional information about the
18 manner in which the dietary properties affect proc-
19 esses of the body, or prevent or repair damage
20 caused by diet or other environmental factors); or

21 “(ii) permit the Secretary to establish any re-
22 quirement that such a claim made in the label or la-
23 beling of a dietary supplement be approved by the
24 Secretary before the claim may be used.”.

1 **SEC. 8. REPORT ON NOTIFICATION REGARDING NEW**
2 **CLAIMS.**

3 (a) STUDY.—

4 (1) IN GENERAL.—The Director of the Office of
5 Dietary Supplements shall conduct a study regard-
6 ing the desirability of a notification requirement re-
7 lating to new claims about dietary supplements.

8 (2) CONTENT.—Such study shall examine—

9 (A) the need for a requirement that a per-
10 son responsible for marketing a dietary supple-
11 ment provide notification to the Secretary of
12 Health and Human Services before making
13 such a claim;

14 (B) the feasibility of such a requirement;

15 (C) the effect of such a requirement on the
16 marketing of dietary supplements and on the
17 ability of consumers to purchase dietary supple-
18 ments; and

19 (D) such other issues related to the desir-
20 ability of such a requirement as the Director of
21 the Office of Dietary Supplements may deter-
22 mine to be appropriate.

23 (b) REPORT.—Not later than 3 years after the date
24 of enactment of this Act, the Director of the Office of Die-
25 tary Supplements shall prepare and submit to the Com-
26 mittee on Energy and Commerce of the House of Rep-

1 representatives and the Committee on Labor and Human Re-
2 sources of the Senate a report containing—

3 (1) the results of the study described in sub-
4 section (a); and

5 (2) any recommendations for legislative reform.

6 **SEC. 9. DIETARY SUPPLEMENT LABELING.**

7 Section 403 of the Federal Food, Drug, and Cosmetic
8 Act (21 U.S.C. 343) is amended by adding at the end the
9 following:

10 “(s) If—

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

12 “(2)(A) the label or labeling of the supplement
13 fails to list—

14 “(i) the name of each ingredient of the
15 supplement that is described in clause (A), (B),
16 (C), (D), (E), or (F) of section 201(gg)(1); and

17 “(ii)(I) the quantity of each such ingredi-
18 ent; or

19 “(II) with respect to a proprietary blend of
20 such ingredients, the total quantity of all ingre-
21 dients in the blend;

22 “(B) the label or labeling of the supplement
23 fails to identify the product by using the term ‘sup-
24 plement’, which term may be modified with—

25 “(i) the name of such an ingredient; or

1 “(ii) by a general term such as the term
2 ‘dietary’;

3 “(C) the supplement contains an ingredient de-
4 scribed in section 201(gg)(1)(C), and the label or la-
5 beling of the supplement fails to identify any part of
6 the plant from which the ingredient is derived;

7 “(D) the supplement—

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

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

12 “(iii) fails to so conform; or

13 “(E) the supplement—

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

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

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

1 **SEC. 10. PROHIBITION ON CERTAIN REGULATORY ACTIONS.**

2 Section 411 of the Federal Food, Drug, and Cosmetic
3 Act (21 U.S.C. 350) is amended—

4 (1) in the title, by striking “VITAMINS AND MIN-
5 ERALS” and inserting “VITAMINS, MINERALS, AND
6 DIETARY SUPPLEMENTS”; and

7 (2) by adding at the end the following:

8 “(d)(1) Except as provided in paragraph (2)—

9 “(A) the Secretary may not establish, under
10 section 201(n), 401, or 403, maximum limits on the
11 potency of any dietary supplement, or any ingredient
12 that is described in clause (A), (B), (C), (D), (E),
13 or (F) of section 201(gg)(1) within such a supple-
14 ment;

15 “(B) the Secretary may not classify any dietary
16 supplement or any such ingredient as a drug; and

17 “(C) the Secretary may not limit, under section
18 201(n), 401, or 403, the combination or number of
19 such ingredients within a dietary supplement.

20 “(2)(A) Subparagraphs (A) and (C) of paragraph (1)
21 shall not apply in the case of such a dietary supplement
22 or such an ingredient that is represented for use by—

23 “(i) individuals in the treatment or manage-
24 ment of specific diseases or disorders;

25 “(ii) children; or

26 “(iii) pregnant or lactating women.

1 “(B) For purposes of this paragraph, the term ‘chil-
2 dren’ means individuals who are under the age of 12
3 years.”.

4 **SEC. 11. ADMINISTRATIVE AND JUDICIAL REVIEW.**

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

8 **“SEC. 311. ADMINISTRATIVE AND JUDICIAL REVIEW.**

9 “(a) DEFINITION.—As used in this subsection, the
10 term ‘affected party’ means a manufacturer, processor,
11 packer, distributor, or retailer, of a dietary supplement,
12 or another appropriate person.

13 “(b) REVIEW OF VIOLATIONS.—

14 “(1) DETERMINATION OF VIOLATION.—

15 “(A) INFORMAL HEARING.—If the Sec-
16 retary determines that an affected party has
17 violated a provision of this Act with respect to
18 a dietary supplement, whether the Secretary
19 makes the determination in a warning letter is-
20 sued by an officer or employee of the Depart-
21 ment or in connection with another action to
22 enforce a provision of this Act, the Secretary
23 shall provide notice to the affected party of the
24 opportunity to obtain a determination on the
25 record after opportunity for an agency hearing

1 regarding the alleged violation. The affected
2 party may request such a hearing not later
3 than 60 days after receiving the notice.

4 “(B) NOTIFICATION.—Not later than 30
5 days after the date on which the hearing is
6 held, the Secretary shall notify the affected
7 party whether the determination of the violation
8 has been affirmed, modified, or revoked. Such
9 notification shall constitute final agency action.

10 “(C) PROHIBITION ON ACTION.—The Unit-
11 ed States may not bring an action in any Fed-
12 eral court relating to the matter that is the sub-
13 ject of the determination until 60 days after the
14 Secretary provides notification under subpara-
15 graph (B), unless the Secretary demonstrates
16 that the dietary supplement involved in the
17 matter poses an imminent hazard to health.

18 “(D) RIGHT OF ACTION.—Not later than
19 60 days after receipt of the notification under
20 subparagraph (B), an affected party who re-
21 ceives notification of an adverse decision under
22 subparagraph (B) may—

23 “(i) bring an action in a district court
24 of the United States in any appropriate ju-
25 dicial district under section 1391 of title

1 28, United States Code, seeking de novo
2 review of the final agency action regarding
3 the validity of the determination; or

4 “(ii) bring any other action authorized
5 by law seeking judicial review of the final
6 agency action.

7 “(E) INFERENCE.—The absence of any re-
8 quest for a hearing under subparagraph (A), or
9 of an action described in subparagraph (D),
10 with respect to such a determination shall not
11 establish any inference that the determination
12 is valid.

13 “(2) SEIZURES.—

14 “(A) INSTITUTION OF LIBEL OF INFORMA-
15 TION.—The institution by the United States of
16 a libel of information for condemnation of a die-
17 tary supplement, on the basis of a determina-
18 tion that an affected party has violated a provi-
19 sion of this Act with respect to the supplement,
20 shall constitute final agency action by the Sec-
21 retary or the delegate of the Secretary.

22 “(B) RIGHT OF ACTION.—Not later than
23 60 days after the United States institutes such
24 a libel of information with respect to a dietary
25 supplement, the affected party may—

1 “(i) bring an action described in para-
2 graph (1)(D)(i) seeking de novo review of
3 the final agency action regarding the valid-
4 ity of the determination; or

5 “(ii) obtain any other means author-
6 ized by law of judicial review of the final
7 agency action.”.

8 **SEC. 12. OFFICE OF DIETARY SUPPLEMENTS.**

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

12 “Subpart 4—Office of Dietary Supplements

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

14 “(a) ESTABLISHMENT.—The Secretary shall estab-
15 lish an Office of Dietary Supplements within the National
16 Institutes of Health.

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

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

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

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

3 “(1) conduct and coordinate scientific research
4 within the National Institutes of Health relating to
5 dietary supplements and the extent to which the use
6 of dietary supplements can limit or reduce the risk
7 of diseases such as heart disease, cancer, birth de-
8 fects, osteoporosis, cataracts, or prostatism;

9 “(2) collect and compile the results of scientific
10 research relating to dietary supplements, including
11 scientific data from foreign sources or the Office of
12 Alternative Medical Practice;

13 “(3) serve as the principal advisor to the Sec-
14 retary and to the Assistant Secretary for Health,
15 and to provide advice to the Director of the National
16 Institutes of Health, the Director of the Centers for
17 Disease Control and Prevention, and the Commis-
18 sioner of Food and Drugs, on issues relating to die-
19 tary supplements including—

20 “(A) dietary intake regulations;

21 “(B) the safety of dietary supplements;

22 “(C) claims characterizing the relationship

23 between—

24 “(i) dietary supplements; and

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

3 “(II) maintenance of health; and

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

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

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

11 “(d) DEFINITION.—As used in this section, the term
12 ‘dietary supplement’ has the meaning given the term in
13 section 201(gg) of the Federal Food, Drug, and Cosmetic
14 Act (21 U.S.C. 321(gg)).

15 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
16 are authorized to be appropriated to carry out this section
17 \$5,000,000 for fiscal year 1994 and such sums as may
18 be necessary for each subsequent fiscal year.”.

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

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

○

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S 784 IS—3