

103^D CONGRESS
2^D 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, Mr. MURKOWSKI, Mr. CRAIG, Mr. DURENBERGER, Mr. GORTON, Mr. WALLOP, Mr. GRASSLEY, Mr. THURMOND, Mr. D'AMATO, Mr. COATS, Mr. SIMPSON, Mr. KEMPTHORNE, Mr. BENNETT, Mr. DOMENICI, Mr. SMITH, Mr. JEFFORDS, Mr. GREGG, Mr. BURNS, Mr. NICKLES, Mr. PELL, Mr. MCCAIN, Mr. FAIRCLOTH, Ms. MIKULSKI, Mr. HELMS, Mr. DOLE, Mr. GRAMM, Mr. BINGAMAN, Mr. CAMPBELL, Mr. DASCHLE, Mr. INOUE, Mr. MACK, Mr. COVERDELL, Mr. SIMON, Ms. MOSELEY-BRAUN, Mr. HATFIELD, Mr. HOLLINGS, Mr. PRESSLER, Mrs. HUTCHISON, Mr. DORGAN, Mr. McCONNELL, Mr. BOND, Mr. STEVENS, Mr. SPECTER, Mr. HEFLIN, Mr. MATHEWS, Mr. LOTT, Mr. BROWN, Mr. DECONCINI, Mr. JOHNSTON, Mr. AKAKA, Mr. BOREN, Mr. CHAFEE, Mrs. BOXER, Mr. EXON, Mr. SHELBY, Mr. FORD, Mr. SASSER, Mr. LEAHY, Mr. ROTH, Mr. NUNN, Mr. DANFORTH, Mr. KOHL, Mr. WOFFORD, Mr. FEINGOLD, and Mr. HARKIN) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

AUGUST 13 (legislative day, AUGUST 11), 1994

Committee discharged

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—

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

11 (2) the importance of nutrition and the benefits
12 of dietary supplements to health promotion and dis-
13 ease prevention have been documented increasingly
14 in scientific studies;

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

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

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

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

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

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

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

18 (8) consumers should be empowered to make
19 choices about preventive health care programs based
20 on data from scientific studies of health benefits re-
21 lated to particular dietary supplements;

22 (9)(A) recent national surveys have revealed
23 that almost 50 percent of the 260,000,000 Ameri-
24 cans regularly consume dietary supplements of vita-

1 mins, minerals, or herbs as a means of improving
2 their nutrition; and

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

5 (10) studies indicate that consumers are placing
6 increased reliance on the use of nontraditional
7 health care providers to avoid the excessive costs of
8 traditional medical services and to obtain more holis-
9 tic treatment of patients;

10 (11) the United States will spend over
11 \$900,000,000,000 on health care in 1993, which is
12 about 12 percent of the Gross National Product of
13 the United States, and this amount and percent will
14 continue to increase unless significant efforts are un-
15 dertaken to reverse the increase;

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

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

21 (C) the estimated 600 dietary supplement man-
22 ufacturers in the United States produce approxi-
23 mately 3,400 products, with total annual sales of
24 such products alone reaching \$4,000,000,000;

1 (13) although the Federal Government should
2 take swift action against products that are unsafe or
3 adulterated, the Federal Government should not
4 take any actions to impose regulatory barriers limit-
5 ing or slowing the flow of safe products and needed
6 information to the marketplace and consumers;

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

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

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

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

17 (1) improve the health status of the people of
18 the United States and help constrain runaway health
19 care spending by ensuring that the Federal Govern-
20 ment erects no regulatory barriers that impede the
21 ability of consumers to improve their nutrition
22 through the free choice of safe dietary supplements;

23 (2) clarify that—

24 (A) dietary supplements are not drugs or
25 food additives;

1 (B) dietary supplements should not be reg-
2 ulated as drugs; and

3 (C) regulations relating to food additives
4 should only be applied to dietary supplement in-
5 gredients used for food additive purposes, such
6 as stabilizers, processing agents or preserva-
7 tives;

8 (3) establish a new definition of a dietary sup-
9 plement that differentiates dietary supplements from
10 conventional foods, while recognizing the broad
11 range of food ingredients used to supplement the
12 diet;

13 (4) strengthen the current enforcement author-
14 ity of the Food and Drug Administration by provid-
15 ing to the Administration additional mechanisms to
16 take enforcement action against unsafe or fraudu-
17 lent products;

18 (5) establish a series of labeling requirements
19 that will provide consumers with greater information
20 and assurance about the quality and content of die-
21 tary supplements, while at the same time assuring
22 the consumers the freedom to use the supplements
23 of their choice;

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

1 (7) provide new administrative and judicial re-
2 view procedures to affected parties if the Adminis-
3 tration takes certain actions to enforce dietary sup-
4 plement requirements;

5 (8) specify the standards applicable to disease
6 and other health-related claims for dietary supple-
7 ments;

8 (9) reaffirm that dietary supplement labeling
9 may bear information, other than health claims,
10 about the vitamin, mineral, or other dietary prop-
11 erties of the supplement; and

12 (10) establish a new Office of Dietary Supple-
13 ments within the National Institutes of Health to
14 initiate and coordinate research on dietary supple-
15 ments and advise the Secretary and other officials of
16 the Department of Health and Human Services on
17 dietary supplement issues.

18 **SEC. 3. DEFINITIONS.**

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

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

1 “(1) includes—

2 “(A) a vitamin;

3 “(B) a mineral;

4 “(C) an herb;

5 “(D) an amino acid;

6 “(E) another ingredient for use by man to
7 supplement the diet by increasing the total die-
8 tary intake; or

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

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

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

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

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

1 (1) by striking “or” at the end of subparagraph
2 (4);

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

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

6 “(6) an ingredient described in clause (A), (B),
7 (C), (D), (E), or (F) of paragraph (gg)(1) in, or in-
8 tended for use in, a dietary supplement.”.

9 (d) FORM OF INGESTION.—Section 411(c)(1)(B) of
10 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
11 350(c)(1)(B)) is amended—

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

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

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

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

20 “(f) If it is a dietary supplement that contains an
21 ingredient that is intended to be consumed for its dietary
22 properties and—

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

1 “(2) no manufacturer of the supplement, or
2 manufacturer of the raw material comprising the in-
3 gredient, has adequately substantiated the safety of
4 the ingredient—

5 “(A) through evidence of a history of safe
6 use of the ingredient (as part of any intended
7 use prior to the use of the ingredient in such
8 dietary supplement), and through the absence
9 of substantial information that brings the safety
10 of the ingredient into question;

11 “(B) by well-designed scientific studies
12 conducted in a manner that is consistent with
13 generally recognized scientific procedures and
14 principles; or

15 “(C) by other appropriate means,
16 unless—

17 “(i) the Secretary has established, in consulta-
18 tion with the Director of the Centers for Disease
19 Control and Prevention, the Director of the National
20 Institutes of Health, and the National Academy of
21 Sciences, a recommended dietary allowance, or an
22 estimated safe and adequate dietary intake level,
23 with respect to the ingredient;

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

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

8 **SEC. 5. REPORT ON IMPACT OF SIGNIFICANT CHANGES IN**
9 **MANUFACTURING PRACTICES.**

10 (a) **STUDY.**—The Director of the Office of Dietary
11 Supplements shall conduct a study relating to significant
12 changes in the manufacturing practices of manufacturers
13 of raw materials utilized in dietary supplements. In con-
14 ducting the study, the Director shall analyze the extent
15 to which such changes pose a risk to public safety.

16 (b) **REPORT.**—Not later than 3 years after the date
17 of enactment of this Act, the Director of the Office of Die-
18 tary Supplements shall prepare and submit to the Com-
19 mittee on Energy and Commerce of the House of Rep-
20 resentatives and the Committee on Labor and Human Re-
21 sources of the Senate a report containing—

22 (1) the results of the study described in sub-
23 section (a); and

24 (2) any recommendations for legislative reform.

1 **SEC. 6. DIETARY INTAKE STANDARDS.**

2 (a) NUTRITION INFORMATION.—Section 403(q)(1)
3 (21 U.S.C. 343(q)(1)) is amended—

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

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

7 “(F) a declaration of the percent of a daily ref-
8 erence amount for each nutrient specified in clauses
9 (D) and (E), stated as a ‘Percent Daily Value’ pro-
10 vided by a serving of the food.”.

11 (b) REGULATIONS.—

12 (1) IN GENERAL.—

13 (A) DAILY VALUE.—Subject to subpara-
14 graph (B), the Secretary of Health and Human
15 Services shall, by regulation, determine, based
16 on the dietary guidance provided by the Depart-
17 ment of Agriculture, the Department of Health
18 and Human Services, the Centers for Disease
19 Control and Prevention, the National Institutes
20 of Health, and other authoritative public health
21 organizations, a daily value for each nutrient
22 specified in clauses (D) and (E) of section
23 403(q)(1) of the Federal Food, Drug, and Cos-
24 metic Act. The daily value shall reflect the daily
25 intake of each such nutrient that will promote

1 optimal health and minimize the risk of disease
2 or other health-related conditions.

3 (B) LIMITATION.—The daily value deter-
4 mined by the Secretary under subparagraph (A)
5 shall, in every appropriate case, be no less than
6 the United States Recommended Daily Allow-
7 ances established by the Food and Nutrition
8 Board of the National Academy of Sciences for
9 the age and sex group most at risk of nutri-
10 tional deficiencies of any particular nutrient.

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

17 (3) PENDING DAILY VALUES.—Pending the is-
18 suance of final regulations under paragraph (1), the
19 daily values for the nutrients declared under section
20 403(q)(1)(F) of the Federal Food, Drug, and Cos-
21 metic Act shall be the values specified in sections
22 101.9(c)(8) and 101.9(c)(9) of title 21, Code of Fed-
23 eral Regulations, as in effect on the date of the en-
24 actment of this Act.

25 (4) ASSISTANCE.—

1 (A) REVIEW AND STUDIES.—To assist the
2 Secretary of Health and Human Services in is-
3 suing regulations under paragraph (1), the Di-
4 rector of the Congressional Research Service, in
5 consultation with the Director of the Office of
6 Technology Assessment, shall review existing
7 scientific data and conduct any necessary
8 studies.

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

22 (C) TIMING.—Such review and studies
23 shall be completed no later than 9 months after
24 the date of the enactment of this Act. If the
25 Congressional Research Service does not com-

plete such review and studies within 9 months after the date of enactment of this Act, the time prescribed by paragraph (2) for the issuance of proposed and final regulations shall be extended by a period equal to the additional time required by such Office to complete such review and studies.

SEC. 7. DIETARY SUPPLEMENT CLAIMS.

Section 403(r) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)) is amended by striking subparagraph (5)(D) and inserting the following:

“(D) A subparagraph (1)(B) claim made with respect to a dietary supplement shall not be subject to subparagraph (3).

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

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

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

1 “(III) the Secretary has not determined, after
2 rulemaking based on the totality of scientific evi-
3 dence (including evidence from well-designed studies
4 conducted in a manner consistent with generally rec-
5 ognized scientific principles), that consumption of
6 the nutrient in a dietary supplement would not tend
7 to reduce the risk of the disease or other health-re-
8 lated condition in a similar manner as would con-
9 sumption of the nutrient in conventional foods; or

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

19 “(B) Nothing in this subparagraph shall—

20 “(i) prohibit the inclusion, in the label or label-
21 ing of a dietary supplement, of truthful and
22 nonmisleading information concerning the vitamin,
23 mineral, or other dietary properties of the supple-
24 ment (including nutritional information about the
25 manner in which the dietary properties affect proc-

1 esses of the body, or prevent or repair damage
2 caused by diet or other environmental factors); or

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

7 **SEC. 8. REPORT ON NOTIFICATION REGARDING NEW**
8 **CLAIMS.**

9 (a) STUDY.—

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

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

15 (A) the need for a requirement that a per-
16 son responsible for marketing a dietary supple-
17 ment provide notification to the Secretary of
18 Health and Human Services before making
19 such a claim;

20 (B) the feasibility of such a requirement;

21 (C) the effect of such a requirement on the
22 marketing of dietary supplements and on the
23 ability of consumers to purchase dietary supple-
24 ments; and

1 (D) such other issues related to the desir-
2 ability of such a requirement as the Director of
3 the Office of Dietary Supplements may deter-
4 mine to be appropriate.

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

11 (1) the results of the study described in sub-
12 section (a); and

13 (2) any recommendations for legislative reform.

14 **SEC. 9. DIETARY SUPPLEMENT LABELING.**

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

18 “(s) If—

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

20 “(2)(A) the label or labeling of the supplement
21 fails to list—

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

1 “(ii)(I) the quantity of each such ingredi-
2 ent; or

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

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

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

10 “(ii) by a general term such as the term
11 ‘dietary’;

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

16 “(D) the supplement—

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

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

21 “(iii) fails to so conform; or

22 “(E) the supplement—

23 “(i) is not covered by the specifications of
24 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 **SEC. 10. PROHIBITION ON CERTAIN REGULATORY ACTIONS.**

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

12 (1) in the title, by striking “VITAMINS AND MIN-
13 ERALS” and inserting “VITAMINS, MINERALS, AND
14 DIETARY SUPPLEMENTS”; and

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

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

17 “(A) the Secretary may not establish, under
18 section 201(n), 401, or 403, maximum limits on the
19 potency of any dietary supplement, or any ingredient
20 that is described in clause (A), (B), (C), (D), (E),
21 or (F) of section 201(gg)(1) within such a supple-
22 ment;

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

1 “(C) the Secretary may not limit, under section
2 201(n), 401, or 403, the combination or number of
3 such ingredients within a dietary supplement.

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

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

9 “(ii) children; or

10 “(iii) pregnant or lactating women.

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

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

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

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

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

23 “(b) REVIEW OF VIOLATIONS.—

24 “(1) DETERMINATION OF VIOLATION.—

1 “(A) INFORMAL HEARING.—If the Sec-
2 retary determines that an affected party has
3 violated a provision of this Act with respect to
4 a dietary supplement, whether the Secretary
5 makes the determination in a warning letter is-
6 sued by an officer or employee of the Depart-
7 ment or in connection with another action to
8 enforce a provision of this Act, the Secretary
9 shall provide notice to the affected party of the
10 opportunity to obtain a determination on the
11 record after opportunity for an agency hearing
12 regarding the alleged violation. The affected
13 party may request such a hearing not later
14 than 60 days after receiving the notice.

15 “(B) NOTIFICATION.—Not later than 30
16 days after the date on which the hearing is
17 held, the Secretary shall notify the affected
18 party whether the determination of the violation
19 has been affirmed, modified, or revoked. Such
20 notification shall constitute final agency action.

21 “(C) PROHIBITION ON ACTION.—The Unit-
22 ed States may not bring an action in any Fed-
23 eral court relating to the matter that is the sub-
24 ject of the determination until 60 days after the
25 Secretary provides notification under subpara-

graph (B), unless the Secretary demonstrates that the dietary supplement involved in the matter poses an imminent hazard to health.

“(D) RIGHT OF ACTION.—Not later than 60 days after receipt of the notification under subparagraph (B), an affected party who receives notification of an adverse decision under subparagraph (B) may—

“(i) bring an action in a district court of the United States in any appropriate judicial district under section 1391 of title 28, United States Code, seeking de novo review of the final agency action regarding the validity of the determination; or

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

“(E) INFERENCE.—The absence of any request for a hearing under subparagraph (A), or of an action described in subparagraph (D), with respect to such a determination shall not establish any inference that the determination is valid.

“(2) SEIZURES.—

1 “(A) INSTITUTION OF LIBEL OF INFORMA-
 2 TION.—The institution by the United States of
 3 a libel of information for condemnation of a die-
 4 tary supplement, on the basis of a determina-
 5 tion that an affected party has violated a provi-
 6 sion of this Act with respect to the supplement,
 7 shall constitute final agency action by the Sec-
 8 retary or the delegate of the Secretary.

9 “(B) RIGHT OF ACTION.—Not later than
 10 60 days after the United States institutes such
 11 a libel of information with respect to a dietary
 12 supplement, the affected party may—

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

17 “(ii) obtain any other means author-
 18 ized by law of judicial review of the final
 19 agency action.”.

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

21 (a) IN GENERAL.—Title IV of the Public Health
 22 Service Act is amended by inserting after section 486 (42
 23 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(gg) of the Federal Food, Drug, and Cosmetic
4 Act (21 U.S.C. 321(gg)).

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.”.

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