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103D CONGRESS
1ST SESSION

H. R. 1709

To amend the Federal Food, Drug, and Cosmetic Act to establish provisions regarding the composition and labeling of dietary supplements.

IN THE HOUSE OF REPRESENTATIVES

APRIL 7, 1993

Mr. RICHARDSON (for himself, Mr. INHOFE, Mr. TOWNS, Mr. BOEHLERT, Mr. SCHIFF, Mr. FROST, Ms. NORTON, Mr. BOUCHER, Mr. BOEHNER, Mr. PETERSON of Minnesota, Ms. PELOSI, Mr. HALL of Texas, Mr. UPTON, and Mr. PALLONE) introduced the following bill; which was referred to the Committee on Energy and Commerce

JUNE 8, 1993

Additional sponsors: Mr. LAROCCO, Mr. OLVER, Mr. KREIDLER, Mr. INGLIS of South Carolina, Mr. DOOLITTLE, Mr. PASTOR, Mr. BURTON of Indiana, Mr. HOCHBRUECKNER, Mr. PARKER, Mr. SENSENBRENNER, Mr. SPENCE, Ms. VELÁZQUEZ, Mrs. UNSOELD, and Mr. INSLEE

JULY 28, 1993

Additional sponsors: Mr. SKAGGS, Mr. JEFFERSON, Mr. LEWIS of Florida, Mr. COMBEST, Mr. HERGER, Mr. ORTON, Mr. MANZULLO, Mr. RANGEL, Mr. SHAYS, Mr. DEFAZIO, Mr. BARCIA of Michigan, Mr. SWETT, Mr. ZELIFF, Mr. CANADY, Mr. LIPINSKI, Mr. CALLAHAN, Mr. FRANK of Massachusetts, Mr. FARR of California, Mr. NEAL of Massachusetts, Mr. TAUZIN, Mr. MEEHAN, Mr. BEVILL, and Mr. MCHALE

AUGUST 23, 1993

Additional sponsors: Mr. BLUTE, Mr. COX, Mr. YATES, Mr. HASTERT, and Mr. KINGSTON

SEPTEMBER 9, 1993

Additional sponsors: Mr. REYNOLDS, Mr. APPLEGATE, Mr. LINDER, Mrs. KENNELLY, Mr. STEARNS, Mr. MURPHY, Ms. FURSE, Mr. KNOLLENBERG, Mr. MICA, Mr. SARPALIUS, Mrs. FOWLER, Mr. ROTH, Mr. THOMAS of Wyoming, Mr. BONILLA, Ms. WOOLSEY, Mr. GREENWOOD, Mr. COYNE, Mr. DEAL, Mr. KING, Ms. SHEPHERD, Mr. BARLOW, and Ms. ESHOO

OCTOBER 7, 1993

Additional sponsors: Mr. ALLARD, Mr. REGULA, Mr. GOODLATTE, Ms. MOL-

INARI, Mr. CONDIT, Mr. SCHAEFER, Mr. HAMBURG, Mr. CAMP, Mr. ARMEY, Mr. BAKER of California, Mr. DICKEY, Mr. BILBRAY, Mr. MCCOLLUM, Mr. MCCRERY, Mr. TALENT, Mr. MACHTLEY, Mrs. VUCANOVICH, Mr. CLEMENT, Mr. JACOBS, Mr. LEWIS of Georgia, Mr. BROOKS, Mr. KOPETSKI, Mr. GORDON, Mr. PORTMAN, Mr. BROWN of Ohio, Mr. MILLER of Florida, Mr. BROWN of California, Mr. HALL of Ohio, Mr. HINCHEY, Mr. DARDEN, Mr. KILDEE, Mr. KASICH, Mr. MCINNIS, Mr. DORNAN, Mr. FRANKS of Connecticut, Ms. DANNER, Mr. FISH, Ms. MCKINNEY, Mr. REED, Mr. DIAZ-BALART, Mr. DEUTSCH, Mr. ROYCE, Ms. KAPTUR, Mr. GILMAN, Mr. EWING, Mr. SHARP, Ms. DUNN, Mr. LEVY, Mr. GUTIERREZ, Mr. FAWELL, Mr. CALVERT, Mr. DE LA GARZA, Mr. ANDREWS of New Jersey, Mr. GEJDENSON, Mr. HASTINGS, Mr. TAYLOR of Mississippi, Mr. QUILLEN, Ms. BYRNE, Mr. MONTGOMERY, Mr. JOHNSON of Georgia, and Mr. WASHINGTON

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish provisions regarding the composition and labeling of dietary supplements.

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

SECTION 1. SHORT TITLE AND REFERENCE.

(a) SHORT TITLE.—This Act may be cited as the ''Dietary Supplement Health and Education Act of 1993''.

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

SEC. 2. DEFINITIONS.

(a) DIETARY SUPPLEMENT.—Section 201 (21 U.S.C. 321) is amended by adding at the end the following new paragraph:

''(gg) The term 'dietary supplement' means a food for special dietary use, as defined in section 411(c)(3), that—

''(1) includes one or more—

''(A) vitamins;

''(B) minerals;

''(C) herbs;

''(D) amino acids; or

''(E) other ingredients for use by man to supplement the diet by increasing the total dietary intake, including a concentrate or extract of any article listed in this paragraph; and

''(2) is intended for use in tablet, capsule, powder, softgel, or any other form (including liquid form) that is not represented for use as conventional food or as a sole item of a meal or of the diet.''.

(b) FOOD ADDITIVE.—Section 201(s) (21 U.S.C. 321(s)) is amended—

(1) by striking out the period at the end of subparagraph (5) and inserting in lieu thereof ''; or''; and

(2) by adding after subparagraph (5) the following:

''(6) any dietary ingredients of the kind specified in paragraph (gg)(1) in, or intended for use in, a dietary supplement.

For purposes of subparagraph (6) the term 'dietary ingredient' means an ingredient that is in, or intended for use in, a dietary supplement.''.

SEC. 3. DIETARY SUPPLEMENT LABELING AND COMPOSITION.

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

''(f) If it is a dietary supplement and—

''(1) it contains an unsafe dietary ingredient which is a substance that is intended to be consumed for its dietary properties but which the Secretary has found through rulemaking to present a substantial and unreasonable risk of illness or injury; or

''(2) it contains a dietary ingredient that has not been adequately substantiated for safety by the person identified under section 403(e)(1) or by the raw material manufacturer through—

''(A) evidence of a history of safe use (as part of any prior intended use) and the absence

of substantial information that brings the safety of the ingredient into question; or

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

''(C) by other appropriate means.

A dietary ingredient that is found to be safe for use in a dietary supplement or as a nutrient by the Secretary or by the National Academy of Sciences through the establishment of a recommended dietary allowance or an estimated safe and adequate dietary intake shall be deemed to have met the requirements of this paragraph within the scope of the determination by the Secretary or the National Academy of Sciences.

''(g)(1) If it is a dietary supplement and the Secretary was not notified, in accordance with regulations issued under subparagraph (2), about a significant change in the manufacturing practice which produced the supplement or of potential problems of safety or contamination affecting such practice.

''(2) The Secretary shall promulgate regulations within 18 months of the date of the enactment of this subparagraph to require notification to the Secretary by manufacturers of raw materials utilized in dietary supplements

of significant changes in manufacturing practices of such materials or of any potential problems of safety or contamination arising from any such changes to ensure the safety of such materials.

''(3) Subparagraphs (1) and (2) apply only to manufacturing changes that are substantial and have been shown to present adverse safety consequences. These sections do not apply to routine changes in the formulating and manufacturing of dietary supplements by dietary supplement manufacturers that utilize good manufacturing practices.''.

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

''(s) If it is a dietary supplement and—

''(1) its label fails to list the name and quantity or proportion of each dietary ingredient included in section 201(gg), except that proprietary blends of ingredients may declare the quantity of the total blend;

''(2) its label fails to identify the product as a supplement, as a supplement modified with the name of the ingredient of the kind specified in section 201(gg)(1), or as a dietary supplement;

''(3) it contains an ingredient of the kind specified in section 201(gg)(1)(C) and the labeling fails

to identify the part of the plant from which the ingredient is derived;

''(4) if it purports to be or is represented as a dietary supplement the name of which is listed in a compendium for foods recognized in regulations issued by the Secretary and its composition or strength differs from, or its quality or purity (including tablet or capsule disintegration or dissolution) falls below, the standards set forth in such compendium unless such difference in composition, strength, quality, or purity from the applicable compendium standards is plainly stated on the label; or

''(5) it is not subject to subparagraph (4) and its composition or strength differs from, or its purity or quality (including tablet or capsule disintegration or dissolution) falls below, that which it purports or is represented to have.

Subparagraph (4) is not to be construed as prohibiting a dietary supplement from representing that it meets U.S. Pharmacopeia standards for dietary supplements if it meets such standards. Such a supplement shall not be deemed a drug because of such a representation.''.

(c) COMPOSITIONAL LIMITS.—Section 411 (21 U.S.C. 350) is amended by adding at the end the following:

''(d)(1) Except as provided in paragraph (2), the Secretary may not—

''(A) establish under section 201(n), 401, or 403 maximum limits on the potency of any dietary supplement or any dietary ingredient of the kind specified in section 201(gg);

''(B) classify any dietary supplement or any ingredient of the kind specified in section 201(gg) as a drug solely because it exceeds the level of potency that the Secretary determines is nutritionally rational or useful; or

''(C) limit, under section 201(n), 401, or 403, in a dietary supplement the combination or number of ingredients of the kind specified in section 201(gg).

''(2) Paragraph (1) does not apply in the case of a dietary supplement represented (other than in conformity with section 403(r)(5)(D)) for use by individuals in the treatment or management of specific diseases or disorders, by children, or by pregnant or lactating women. For purposes of this paragraph, the term 'children' means individuals who are under the age of 12 years.''.

SEC. 4. CLAIMS.

Section 403(r)(5)(D) (21 U.S.C. 343(r)(5)(D)) is amended to read as follows:

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

''(ii) Labeling of a dietary supplement may characterize the relationship between the supplement and a disease or other condition of the body if—

''(I) the supplement contains one or more nutrients for which a claim of the type described in subparagraph (1)(B) has been authorized by the Secretary pursuant to subparagraph (3)(B) and such characterization is consistent with the claim authorized by the Secretary, unless the Secretary determines, through rulemaking based upon the totality of publicly available scientific evidence, that consumption of the nutrient in a dietary supplement would not tend to reduce the risk of disease or other health-related condition in a manner similar to the consumption of such nutrient in conventional foods; or

''(II) such characterization accurately represents the current state of scientific evidence concerning the relationship between the supplement or dietary ingredient of the supplement and a disease or other health-related condition, taking into account the totality of scientific evidence (including evidence

from well-designed studies conducted in a manner consistent with generally recognized scientific principles).

This clause does not prohibit the labeling of a dietary supplement from providing truthful and non-misleading information, measured by the standard set forth in subclause (II), concerning its vitamin, mineral, or other dietary properties, including nutritional information about the manner in which those dietary properties affect physiological processes of the body or prevent or repair damage caused by diet or other environmental factors and does not authorize the Secretary to establish a prior restraint on the use of any labeling that is subject to subclause (II).

''(iii) At least 30 days before the introduction into interstate commerce of any label, consumer package, or literature in the package containing a claim described in subclause (ii), or before the making of such a claim through any other means, a person responsible for marketing the dietary supplement to which such claim refers shall provide notification to the Secretary of the wording of such claim if such claim has not previously been made for such dietary supplement by such person. Documentation that is intended to support such claim may be submitted with such notice. The Secretary may not impose any addi-

tional pre-market requirement, including requirements or requests for further documentation.''.

SEC. 5. DIETARY INTAKE STANDARDS.

(a) NUTRITION INFORMATION.—Section 403(q)(1) (21 U.S.C. 343(q)(1)) is amended by striking the period at the end of subparagraph (E) and inserting in lieu thereof ``, or'' and by adding after that subparagraph the following:

''(F) a declaration of the percent of a daily reference amount for each nutrient specified in subparagraphs (D) and (E), stated as a 'Percent Daily Value' provided by a serving of that food.''.

(b) REGULATIONS.—

(1) IN GENERAL.—

(A) DAILY VALUE.—Subject to subparagraph (B), the Secretary of Health and Human Services shall, by regulation, determine, based on the dietary guidance provided by the Department of Agriculture, the Department of Health and Human Services, the Centers for Disease Control, the National Institutes of Health, and other authoritative public health organizations, a daily value for each nutrient specified in subparagraphs (1)(D) and (1)(E) of section 403(q) of the Federal Food, Drug, and Cosmetic Act

which shall reflect the daily intake of each such nutrient that will promote optimal health and minimize the risk of disease or other health-related condition.

(B) LIMITATION.—The daily value determined by the Secretary under subparagraph (A) shall be no less than the Recommended Daily Allowances established by the Food and Nutrition Board of the National Academy of Sciences for the age and sex group most at risk of nutritional deficiencies of any particular nutrient.

(2) TIMING.—Except as provided in paragraph (4), the Secretary of Health and Human Services shall issue proposed regulations under paragraph (1) no later than 12 months from the date of the enactment of this Act and shall issue final regulations no later than 24 months from such date.

(3) PENDING DAILY VALUES.—Pending the issuance of final regulations under paragraph (1), the daily values for the nutrients declared under section 403(q)(1)(F) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(q)(1)(F)) shall be those specified in sections 101.9(8) and 101.9(9) of regulations published in title 21 of the Code of Federal

Regulations, as in effect on the date of the enactment of this Act.

(4) ASSISTANCE.—To assist the Secretary of Health and Human Services in issuing regulations under paragraph (1), the Director of the Congressional Research Office, in consultation with the Director of the Office of Technology Assessment, shall arrange for that office to review existing scientific data and conduct one or more studies, if necessary, to be completed no later than 9 months from the date of the enactment of this Act, to determine what amount of each nutrient specified in subparagraphs (1)(D) and (1)(E) of section 403(q) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(q) would be provided by the diets recommended by the Department of Agriculture, the Department of Health and Human Services, the Centers for Disease Control, the National Institutes of Health, and other authoritative public health organizations to minimize the risk of disease and other health-related conditions and to promote optimal health. If the Office of Technology Assessment does not complete the studies determined to be necessary within 9 months from the date of the enactment of this Act, the time prescribed by paragraph (2) for the issuance of pro-

posed and final regulations shall be extended by a period equal to the additional time required by such Office to complete such studies.

SEC. 6. APPEAL.

Section 411 (21 U.S.C. 350), as amended by section 3(c), is amended by adding at the end the following:

''(e)(1) If the Secretary asserts that a dietary supplement is in violation of any provision of this Act, whether the assertion is made in a warning letter issued by an officer or employee of the Department of Health and Human Services or in any other manner, the manufacturer, processor, packer, distributor, or retailer of the dietary supplement or any other person to whom the assertion is addressed may, within 60 days, appeal to the Secretary or to an officer or employee of the Department of Health and Human Services assigned by the Secretary to hear such an appeal showing that the assertion is incorrect and should be withdrawn. During the 60-day period after such assertion is made by the Secretary and during pendency of such an appeal, the United States shall not initiate litigation on the matter unless the Secretary concludes that such litigation is required because of an imminent hazard to health. If such an appeal is not resolved to the satisfaction of the appellant, the appellant may—

''(A) bring an action in a United States district court in any appropriate judicial district under section 1391 of title 28, United States Code, to secure a declaratory judgment in which all factual determinations regarding the validity of the assertion in question shall be made de novo; or

''(B) obtain any other means of judicial review authorized by law.

The absence of an action described in subparagraph (A) or (B) shall not establish any inference that an assertion is valid.

''(2) The institution by the United States of a libel of information to condemn a dietary supplement shall constitute final agency action on the part of the Secretary.''.

SEC. 7. OFFICE FOR DIETARY SUPPLEMENTS.

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

''Subpart 4—Office for Dietary Supplements

''SEC. 486E. OFFICE OF DIETARY SUPPLEMENTS.

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

''(b) DUTIES.—The Office for Dietary Supplements shall—

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

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

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

''(A) dietary intake regulations;

''(B) the safety of dietary supplements;

''(C) claims characterizing the relationship between—

''(i) dietary supplements; and

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

''(II) maintenance of health; and

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

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

''(5) coordinate funding relating to dietary supplements for the National Institutes of Health;

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

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

''(c) DEFINITION.—As used in this section, the term 'dietary supplement' has the meaning given the term in section 201(gg) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(gg)).

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

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

''(E) The Office for Dietary Supplements.''.

SEC. 8. EFFECTIVE DATE.

The amendments made by this Act shall take effect on the date of the enactment of this Act, except that the amendments made by section 3 shall take effect 18 months after such date with respect to products labeled after such date.

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