

103<sup>D</sup> CONGRESS  
1<sup>ST</sup> SESSION

# H. R. 509

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

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## IN THE HOUSE OF REPRESENTATIVES

JANUARY 21, 1993

Mr. GALLEGLY (for himself, Mr. INHOFE, Mr. SHAYS, Mr. COX, Mr. TAYLOR of North Carolina, Mr. STUMP, Mr. BURTON of Indiana, Mr. HANSEN, Mr. HUNTER, Mr. HASTERT of Illinois, Mr. UPTON, and Mr. SCHIFF introduced the following bill; which was referred to the Committee on Energy and Commerce

AUGUST 23, 1993

Additional sponsors: Mr. STEARNS, Mr. KLUG, Mr. EMERSON, Mr. MANZULLO, Mr. HANCOCK, Mr. ARMEY, Mr. HERGER, Mr. BAKER of Louisiana, Mr. DELAY, Mr. THOMAS of California, Mr. SKEEN, Mr. BARTLETT of Maryland, Mr. SCHAEFER, Mr. GINGRICH, Mr. FIELDS of Texas, Mr. DREIER, Mr. BOEHNER, Mr. FISH, Mrs. THURMAN, Mr. HEFLEY, Mr. GOSS, Mr. WALSH, Mr. CRANE, Mr. KIM, Mr. MCKEON, Mr. DOOLITTLE, Mr. ROTH, Mr. HYDE, Mr. SMITH of Oregon, Mr. SENBRENNER, Mr. SPENCE, Mr. PACKARD, Mr. CALVERT, and Mr. ROYCE

JANUARY 5, 1994

Additional sponsors: Mr. DUNCAN, Mr. CUNNINGHAM, Mr. DORNAN, Mr. PORTMAN, Mr. QUILLEN, Mr. ISTOOK, Mr. THOMAS of Wyoming, Mr. CAMP, Mr. LINDER, Mr. FRANKS of Connecticut, Mr. PETRI, Mr. WOLF, Mr. RAVENEL, Mr. ROHRABACHER, Mr. ARCHER, Mr. POMBO, and Mr. CRAPO

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to

establish provisions regarding the composition and labeling of dietary supplements.

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 “Health Freedom Act  
5 of 1993”.

6 **SEC. 2. DEFINITIONS.**

7 (a) DIETARY SUPPLEMENT.—Section 201 of the  
8 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)  
9 is amended by adding at the end the following new para-  
10 graph:

11 “(ff) The term ‘dietary supplement’ means an article  
12 that—

13 “(1) includes, and is intended to supplement  
14 the diet with—

15 “(A) a vitamin;

16 “(B) a mineral;

17 “(C) an herb; or

18 “(D) another similar nutritional substance,  
19 including a concentrate or extract of an item  
20 described in clause (A), (B), or (C); and

21 “(2)(A) is intended for ingestion in a form de-  
22 scribed in paragraph (1)(B)(i) or (2) of section  
23 411(c), or another similar form; or

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

1 (b) DRUG.—Section 201(g)(1) of such Act is amend-  
2 ed by adding at the end the following: “A dietary supple-  
3 ment shall not be considered to be a drug solely because  
4 of the potency of a substance in the dietary supplement.  
5 A dietary supplement shall not be considered to be a drug  
6 under clause (B) solely because the labeling or advertising  
7 for the supplement contains a claim, or provides informa-  
8 tion, that is described in section 413(b) and meets the re-  
9 quirements specified in paragraphs (1) and (2) of such  
10 section, or that concerns the potency of a substance in  
11 the supplement.”.

12 (c) FOOD ADDITIVE.—Section 201(s) of such Act is  
13 amended—

14 (1) by redesignating subparagraphs (1) through  
15 (5) as clauses (A) through (E), respectively;

16 (2) by inserting “(1)” after “(s)”; and

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

18 “(2) A substance in a dietary supplement is not a  
19 food additive if the substance is identified in the labeling  
20 of the dietary supplement as a substance provided by the  
21 product to supplement the diet.”.

22 **SEC. 3. DIETARY SUPPLEMENTS.**

23 (a) IN GENERAL.—Chapter IV of the Federal Food,  
24 Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amend-  
25 ed by adding at the end the following new section:

1 **“SEC. 413. LABELING AND ADVERTISING OF DIETARY SUP-**  
2 **PLEMENTS.**

3 “(a) DESCRIPTION.—Notwithstanding any other pro-  
4 vision of this Act, an article that is a dietary supplement  
5 may be described as a dietary supplement in labeling or  
6 advertising.

7 “(b) RELATIONSHIP TO DISEASE OR HEALTH-RE-  
8 LATED CONDITION.—Notwithstanding any other provision  
9 of this Act, labeling or advertising for a dietary supple-  
10 ment may include a claim or other information that char-  
11 acterizes the relationship of the dietary supplement, or of  
12 one or more of the substances provided by the dietary sup-  
13 plement, or of the absence of one or more of the sub-  
14 stances, to a disease or health-related condition, if—

15 “(1) such claim or other information is truthful  
16 and not misleading; and

17 “(2) there is scientific evidence, whether pub-  
18 lished or unpublished, that provides a reasonable  
19 basis for such claim or other information.

20 “(c) PROHIBITION ON PRIOR APPROVAL OR REGULA-  
21 TION.—Notwithstanding any other provision of this Act,  
22 the Secretary shall not establish any requirement that  
23 such a claim or other information that meets the require-  
24 ments specified in paragraphs (1) and (2) of subsection  
25 (b) shall be approved by or conform to a regulation issued

1 by the Secretary before the claim or information may be  
2 used.

3 “(d) ACTIONS.—

4 “(1) RIGHT OF ACTION.—If the Secretary as-  
5 serts that labeling or advertising for a dietary sup-  
6 plement includes such a claim or other information  
7 that fails to comply with paragraph (1) or (2) of  
8 subsection (b), whether the Secretary makes the as-  
9 sertation in a warning letter issued by an officer or  
10 employee of the Department, or in connection with  
11 another action to enforce a provision of this Act, the  
12 manufacturer, processor, packer, distributor, or re-  
13 tailer, of the dietary supplement, or other person to  
14 whom the assertion is addressed, may—

15 “(A) bring an action in a United States  
16 district court in any appropriate judicial district  
17 under section 1391 of title 28, United States  
18 Code, to secure a declaratory judgment regard-  
19 ing the validity of the assertion; and

20 “(B) obtain any other means of judicial re-  
21 view authorized by law.

22 “(2) INFERENCE.—The absence of any action  
23 described in subparagraph (A) or (B) in paragraph  
24 (1) with respect to an assertion shall not establish  
25 any inference that the assertion is valid.”.

1       (b) CONFORMING AMENDMENT.—Section 403(r)(5)  
2 of such Act (21 U.S.C. 343(r)(5)) is amended by striking  
3 clause (D).

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