

104TH CONGRESS
1ST SESSION

H. R. 1951

To amend the Federal Food, Drug, and Cosmetic Act to allow food and dietary supplement manufacturers to communicate truthful, nonmisleading information to consumers concerning the nutritional content and disease prevention benefits of their products, to repeal or clarify rules enacted by the Dietary Supplement Health and Education Act of 1994, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 28, 1995

Mr. PALLONE (for himself, Mr. HASTERT, Mr. RICHARDSON, Mr. FRISA, and Mr. DEFAZIO) introduced the following bill; which was referred to the Committee on Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to allow food and dietary supplement manufacturers to communicate truthful, nonmisleading information to consumers concerning the nutritional content and disease prevention benefits of their products, to repeal or clarify rules enacted by the Dietary Supplement Health and Education Act of 1994, 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,*

1 **SECTION 1. SHORT TITLE; REFERENCE.**

2 (a) SHORT TITLE.—This Act may be cited as the
3 “Food and Dietary Supplement Consumer Information
4 Act of 1995”.

5 (b) REFERENCE.—Whenever in this Act an amend-
6 ment or repeal is expressed in terms of an amendment
7 to, or repeal of, a section or other provision, the reference
8 shall be considered to be made to a section or other provi-
9 sion of the Federal Food, Drug, and Cosmetic Act.

10 **SEC. 2. AUTHORIZING TRUTHFUL CLAIMS THAT ARE NOT**
11 **MISLEADING.**

12 (a) CLAIMS PERMITTED.—Section 403B (21 U.S.C.
13 343–2) is amended to read as follows:

14 “FOOD AND DIETARY SUPPLEMENT LABELING RULE

15 “SEC. 403B. If the labeling or advertising for a food
16 or dietary supplement contains a claim or other informa-
17 tion that characterizes the relationship of such food or die-
18 tary supplement to a disease or health-related condition,
19 or characterizes the relationship of the presence or ab-
20 sence of any substance in such food or dietary supplement
21 to a disease or health-related condition, such food or die-
22 tary supplement may not be deemed to be adulterated or
23 misbranded by reason of such claim or other information,
24 if such claim or other information is truthful and not mis-
25 leading.”.

1 (b) CONFORMING REPEALER.—Section 403(r)(6) (21
2 U.S.C. 343(r)(6)) (pertaining to allowable statements of
3 nutritional support) is repealed.

4 **SEC. 3. REPEAL OF RULE ENACTED BY THE DIETARY SUP-**
5 **PLEMENT HEALTH AND EDUCATION ACT OF**
6 **1994 PERTAINING TO A FOOD OR DIETARY**
7 **SUPPLEMENT THAT IS ALSO MARKETED AS A**
8 **NEW DRUG, ANTIBIOTIC, OR BIOLOGIC.**

9 Section 201(ff) (21 U.S.C. 321(ff)) is amended—

10 (1) in paragraph (1), by inserting “and” after
11 the semicolon at the end;

12 (2) in paragraph (2)(C), by striking “; and”
13 and inserting a period; and

14 (3) by striking paragraph (3).

15 **SEC. 4. REPEAL OF DIETARY INGREDIENT RULE.**

16 (a) Section 413 (21 U.S.C. 350b) is repealed.

17 (b) Section 402(f) (21 U.S.C. 342(f)) is amended by
18 striking subparagraph (B) and redesignating subpara-
19 graphs (C) and (D) as subparagraphs (B) and (C), respec-
20 tively.

21 **SEC. 5. FOODS AND DIETARY SUPPLEMENTS NOT TO BE**
22 **TREATED AS DRUGS.**

23 (a) Section 201(g)(1) (21 U.S.C. 321(g)(1)) is
24 amended—

1 (1) by striking the last two sentences and in-
2 sserting, “Neither a food nor a dietary supplement
3 shall be deemed to be a drug.”; and

4 (2) in clause (C), by striking “(other than
5 food)”.

6 (b) Section 201(ff) (21 U.S.C. 321(ff)), as amended
7 by section 3, is further amended by striking the last sen-
8 tence (pertaining to the deeming of a dietary supplement
9 to be a food).

10 **SEC. 6. ADULTERATED DIETARY SUPPLEMENT: CLARIFICA-**
11 **TION OF TEST.**

12 Section 402(f) (21 U.S.C. 342(f)), as amended by
13 section 4, is further amended in paragraph (1)(A) by
14 striking “significant or unreasonable risk” and inserting
15 “substantial and unreasonable risk”.

16 **SEC. 7. REGULATION OF FOODS AND DIETARY SUPPLE-**
17 **MENTS UNDER STATE LAW.**

18 Chapter IV (21 U.S.C. 341 et seq.) is amended by
19 inserting after section 403B the following:

20 “STATE REGULATION OF FOOD AND DIETARY
21 SUPPLEMENTS

22 “SEC. 403C. (a) No State or political subdivision of
23 a State may deem a food or dietary supplement to be a
24 drug, or directly or indirectly establish under any author-
25 ity, or continue in effect, a requirement applicable to such
26 food or dietary supplement as though it were a drug.

1 “(b) If the labeling or advertising of a food or dietary
2 supplement contains a claim or other information that
3 complies with section 403B, no State or political subdivi-
4 sion of a State may deem such food or dietary supplement
5 to be adulterated, misbranded, or otherwise rendered out
6 of compliance with the law of such State or political sub-
7 division, by reason of such claim.”.

8 **SEC. 8. COMMISSION ON DIETARY SUPPLEMENT LABELS**
9 **ABOLISHED.**

10 The Commission on Dietary Supplement Labels, es-
11 tablished under the Dietary Supplement Health and Edu-
12 cation Act of 1994, Public Law 103–417, is abolished, and
13 section 12 of that Act is repealed.

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