

103^D CONGRESS
1ST SESSION

H. R. 2923

To amend the Federal Food, Drug, and Cosmetic Act to revise the regulation of dietary supplements.

IN THE HOUSE OF REPRESENTATIVES

AUGUST 6, 1993

Mrs. COLLINS of Illinois introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to revise the regulation 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; REFERENCE.**

4 This Act may be cited as the “Dietary Supplement
5 Consumer Protection Act of 1993”.

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

1 **SEC. 2. DEFINITIONS.**

2 Section 201 (21 U.S.C. 321) is amended by adding
3 at the end the following:

4 “(gg) The term ‘dietary supplement’ means an article
5 that is—

6 “(1) intended to supplement the diet,

7 “(2) is, or contains, a vitamin, mineral, or an
8 herb or similar nutritional substance, including a
9 concentrate or extract of a vitamin, mineral, or other
10 nutritional substance, and

11 “(3)(A) is intended for ingestion in a form de-
12 scribed in paragraph (1)(B)(i) or (2) of section
13 411(c) or in another similar form, or

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

15 “(hh) The term ‘dietary ingredient’ means a vitamin,
16 mineral, or herb or other similar nutritional substance the
17 intended use of which results, or may reasonably be ex-
18 pected to result, directly or indirectly, in its becoming a
19 component or otherwise affecting the characteristics of
20 any dietary supplement.”.

21 **SEC. 3. DEFINITIONS AND STANDARDS OF IDENTITY.**

22 Section 401 (21 U.S.C. 341) is amended—

23 (1) in the first sentence, by inserting “or die-
24 tary supplement” after “establishing for any food”,
25 and

1 (2) in the fourth sentence, by inserting “or die-
2 tary supplement” after “any food” and by inserting
3 “or dietary supplements” after “class of food”.

4 **SEC. 4. ADULTERATION.**

5 Section 402 (21 U.S.C. 342) is amended—

6 (1) by inserting “or dietary supplement” after
7 “food” before paragraph (a), and

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

9 “(f) If it is a dietary supplement and it is, or con-
10 tains, any dietary ingredient which is unsafe within the
11 meaning of section 413.

12 “(g) If it is a dietary supplement and it does not meet
13 the quality factor requirements prescribed by the Sec-
14 retary under this paragraph. The Secretary shall, by regu-
15 lation, establish requirements for quality factors for die-
16 tary supplements as appropriate.

17 “(h)(1) If it is a dietary supplement and the process-
18 ing of such dietary supplement is not in compliance with
19 the good manufacturing practices and the quality control
20 procedures established by the Secretary under subpara-
21 graph (2).

22 “(2) The Secretary shall, by regulation, establish
23 good manufacturing practices for dietary supplements, in-
24 cluding quality control procedures that the Secretary de-

1 termines are necessary to assure that a dietary supple-
2 ment—

3 “(A) provides the vitamin, mineral, or herb or
4 other nutritional substance it claims to provide in its
5 label or labeling, and

6 “(B) is manufactured in a manner designed to
7 prevent adulteration.”.

8 **SEC. 5. MISBRANDING.**

9 Section 403 (21 U.S.C. 343) is amended—

10 (1) by inserting “or dietary supplement” after
11 “food” before paragraph (a),

12 (2) in paragraph (a)(2), by inserting “or die-
13 tary supplement” after “food”,

14 (3) in paragraph (b), by inserting “or dietary
15 supplement” after “another food”,

16 (4) in paragraph (g), by inserting “or dietary
17 supplement” after “food” each place it occurs,

18 (5) in paragraph (h), by inserting “or dietary
19 supplement” after “food” each place it occurs,

20 (6) in paragraph (i)(1), by inserting “or dietary
21 supplement” after “food”,

22 (7) in paragraph (r)(1), by inserting “or dietary
23 supplement” after “food” each place it occurs and
24 by inserting “or dietary ingredient” after “nutrient”
25 each place it occurs,

1 (8) in paragraph (r)(1)(B), by inserting “or any
2 dietary supplement” after “food” and by striking
3 out “or (5)(D)”,

4 (9) in paragraph (r)(3)(A)(ii), by inserting “or
5 dietary supplement” after “food” each place it oc-
6 curs and by inserting “or dietary ingredient” after
7 “nutrient”,

8 (10) in paragraph (r)(3)(B)(ii)(I), by inserting
9 “or dietary supplements” after “food” and by insert-
10 ing “or dietary ingredient” after “(q)(2)”,

11 (11) in paragraph (r)(3)(B)(ii)(II), by inserting
12 “or dietary ingredient” after “nutrient”,

13 (12) in paragraph (r)(5), by striking out clause
14 (D), and

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

16 “(s) If it is a dietary supplement, unless its label and
17 labeling contain the date after which it should no longer
18 be consumed as prescribed by the Secretary by regulation.

19 “(t) If it is a dietary supplement, unless its label and
20 labeling contain, where appropriate, a statement regarding
21 possible adverse effects as prescribed by the Secretary by
22 regulation. Such a statement shall indicate the level, if
23 any, at which a dietary supplement can cause adverse ef-
24 fects and the specific nature of any adverse effects and

1 shall identify segments of the population, including the el-
2 derly and children, that may be affected.”.

3 **SEC. 6. SAFETY PROVISIONS AND NOTIFICATION REQUIRE-**
4 **MENTS FOR DIETARY INGREDIENTS.**

5 Subchapter IV of chapter 4 is amended by adding
6 at the end the following:

7 “DIETARY INGREDIENTS SAFETY

8 “SEC. 413. (a) A dietary ingredient shall, with re-
9 spect to any particular or intended use of such ingredient,
10 be deemed unsafe for the purposes of section 402(f) un-
11 less—

12 “(1) there is in effect, and it and its use or in-
13 tended use are in conformity with, a regulation is-
14 sued under this section prescribing the conditions
15 under which such dietary ingredient may be safely
16 used,

17 “(2) such ingredient is generally recognized,
18 among experts qualified by adequate training and
19 experience to evaluate its safety, as having been ade-
20 quately shown through scientific procedures to be
21 safe under the conditions of its intended use, or

22 “(3) in the case of a dietary ingredient in use
23 in a dietary supplement before August 5, 1993, it
24 has been adequately shown, through either scientific
25 procedures or experience based on common use in a
26 dietary supplement, to be safe under the conditions

1 of its intended use pending completion of the review
2 required by subsection (f).

3 “(b) Any person may with respect to any intended
4 use of a dietary ingredient file with the Secretary a peti-
5 tion proposing the issuance of a regulation prescribing the
6 conditions under which such ingredient may be safely
7 used. The Secretary shall by regulation establish require-
8 ments for petitions submitted under this subsection.

9 “(c) The Secretary shall by order—

10 “(1) establish a regulation (whether or not in
11 accord with the regulation proposed by the peti-
12 tioner) prescribing, with respect to one or more pro-
13 posed uses of the dietary ingredient involved, the
14 conditions under which such ingredient may be safe-
15 ly used, including specifications as to the—

16 “(A) particular dietary supplement or
17 classes of dietary supplements in which such in-
18 gredient may be used,

19 “(B) the maximum quantity which may be
20 used or permitted in the dietary supplement,

21 “(C) the manner in which such ingredient
22 may be added to or used in the dietary supple-
23 ment, and

24 “(D) any directions or other labeling or
25 packaging requirements for such ingredient

1 supplement or ingredient may be adulterated or mis-
2 branded, such manufacturer, distributor, or retailer shall
3 promptly notify the Secretary of such knowledge.”.

4 **SEC. 7. ADVISORY COMMITTEE.**

5 The Secretary of Health and Human Services shall
6 establish an advisory committee, in accordance with the
7 Federal Advisory Committee Act, to assist in the imple-
8 mentation of the amendments made by this Act.

9 **SEC. 8. RESEARCH.**

10 (a) ESTABLISHMENT.—The Director of the National
11 Institutes of Health shall expand and intensify programs
12 with respect to research and related activities regarding
13 dietary supplements.

14 (b) AUTHORIZATION OF APPROPRIATIONS.—For the
15 purpose of carrying out subsection (a), there are author-
16 ized to be appropriated \$10,000,000 for fiscal year 1994
17 and such sums as may be necessary for each of the fiscal
18 years 1995 through 1997.

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