

103^D CONGRESS
1ST SESSION

H. R. 3650

To amend the Federal Food, Drug, and Cosmetic Act to assure access to dietary supplements and to amend the Dietary Supplement Act of 1992 to extend the moratorium with respect to the issuance of regulations on dietary supplements, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 22, 1993

Mr. WAXMAN (for himself and Mr. DINGELL) 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 assure access to dietary supplements and to amend the Dietary Supplement Act of 1992 to extend the moratorium with respect to the issuance of regulations on 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 Access and Claims Moratorium Act of 1993”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds the following:

1 (1) Many consumers use vitamins, minerals,
2 herbs, amino acids, and other dietary supplements.

3 (2) There has been a public campaign to con-
4 vince consumers that the Food and Drug Adminis-
5 tration intends to require prescriptions for many die-
6 tary supplements, or that the FDA will otherwise
7 act to take these products off the market.

8 (3) Due to public concern, it is appropriate for
9 Congress to assure consumers that they will have ac-
10 cess to the dietary supplements that are currently on
11 the market.

12 (4) The dietary supplement industry is con-
13 cerned that the Nutrition Labeling and Education
14 Act of 1990 will prohibit health claims on dietary
15 supplements. Congress shall extend the moratorium
16 on FDA actions under such Act with respect to
17 dietary supplements.

18 **TITLE I—ACCESS TO DIETARY** 19 **SUPPLEMENTS**

20 **SEC. 101. REFERENCE.**

21 Whenever in this title an amendment or repeal is ex-
22 pressed in terms of an amendment to, or repeal of, a sec-
23 tion or other provision, the reference shall be considered
24 to be made to a section or other provision of the Federal
25 Food, Drug, and Cosmetic Act.

1 **SEC. 102. ACCESS TO DIETARY SUPPLEMENTS.**

2 (a) FDA MAY NOT REQUIRE PRESCRIPTIONS FOR
3 DIETARY SUPPLEMENTS.—Section 503(b) (21 U.S.C.
4 353(b)) is amended by adding at the end the following:

5 “(6) For a dietary supplement marketed on or before
6 November 15, 1993, the Secretary may not, after Novem-
7 ber 15, 1993, require a prescription . For a dietary supple-
8 ment first marketed after November 15, 1993, this sub-
9 section as it was in effect on the date of the enactment
10 of the Dietary Supplement Access and Claims Moratorium
11 Act of 1993 shall apply.”.

12 (b) FDA MAY NOT REQUIRE PREMARKET APPROVAL
13 FOR DIETARY SUPPLEMENTS.—

14 (1) FOOD ADDITIVES.—Section 201(s) (21
15 U.S.C. 321(s)) is amended—

16 (A) by striking out the period at the end
17 of subparagraph (5) and inserting in lieu there-
18 of “; or”; and

19 (B) by adding after subparagraph (5) the
20 following:

21 “(6) any dietary ingredient in a dietary supple-
22 ment.”.

23 (2) DRUGS.—Section 201(g)(1) (21 U.S.C.
24 321(g)(1)) is amended by adding at the end the fol-
25 lowing: “A dietary supplement which was on the

1 market on or before November 15, 1993, and for
2 which no claim is made is not a drug.”.

3 (c) BURDEN OF PROOF ON FDA.—

4 (1) IN GENERAL.—Section 402 (21 U.S.C. 342)
5 is amended by adding at the end the following:

6 “(f) If it contains a dietary ingredient at a level that
7 may be injurious to health or is a dietary supplement
8 which when used in accordance with the conditions of use
9 may be injurious to health.”.

10 (2) CONFORMING AMENDMENT.—Section 402
11 (21 U.S.C. 342) is amended by striking “food” in
12 the matter preceding paragraph (a) and inserting
13 “food or dietary supplement”.

14 (d) DEFINITIONS.—

15 (1) IN GENERAL.—Section 201 (21 U.S.C. 321)
16 is amended by adding at the end the following:

17 “(gg) The term ‘dietary ingredient’ means—

18 “(1) a vitamin,

19 “(2) a mineral,

20 “(3) an herb,

21 “(4) an amino acid, or

22 “(5) other ingredient,

23 contained in a product marketed in the United States as
24 a dietary supplement on or before November 15, 1993.

1 “(hh) The term ‘dietary supplement’ means a product
2 which contains one or more dietary ingredients and—

3 “(1) which is marketed to supplement the diet,

4 “(2) which is intended for use in tablet, cap-
5 sule, powder, softgel, or liquid form and if in liquid
6 form is formulated in a fluid carrier and is intended
7 for ingestion in daily quantities measured in drops
8 or similar small units of measure,

9 “(3) which is not represented for use as conven-
10 tional food or as a sole item of a meal or of the diet,
11 and

12 “(4) which does not include any ingredient
13 other than a vitamin or mineral which has been ap-
14 proved as the active ingredient of a drug.”.

15 (2) SECRETARIAL ACTION.—For purposes of
16 the definitions added by paragraph (1), the Sec-
17 retary of Health and Human Services shall, not
18 later than 180 days after the date of the enactment
19 of this Act, issue a regulation identifying the dietary
20 ingredients which were marketed on or before No-
21 vember 15, 1993.

1 **TITLE II—MORATORIUM ON**
2 **DIETARY SUPPLEMENT CLAIMS**

3 **SEC. 201. REFERENCE.**

4 Whenever in this title an amendment or repeal is ex-
5 pressed in terms of an amendment to, or repeal of, a sec-
6 tion or other provision, the reference shall be considered
7 to be made to a section or other provision of the Prescrip-
8 tion Drug User Fee Act of 1992.

9 **SEC. 202. PROHIBITION OF IMPLEMENTATION.**

10 Section 202(a)(1) (21 U.S.C. 343 note) is amended—

11 (1) by striking “December 15, 1993” and in-
12 serting “June 30, 1994”, and

13 (2) by inserting “amino acids,” after “herbs,”.

14 **SEC. 203. ISSUANCE OF REGULATIONS.**

15 The amendments made by sections 202(a)(2)(B)(i)
16 and 202(a)(2)(B)(ii) (21 U.S.C. 343 note) are each
17 amended—

18 (1) by striking “December 31, 1993” and in-
19 serting “June 30, 1994”, and

20 (2) by inserting “amino acids,” after “herbs,”.

21 **SEC. 204. STATE ENFORCEMENT.**

22 The amendment made by section 202(a)(3) (21
23 U.S.C. 343 note) is amended by striking “to such dietary
24 supplement on December 31, 1993” and inserting “to die-
25 tary supplements of vitamins, minerals, herbs, amino

1 acids, or other similar nutritional substances on June 30,
2 1994”.

3 **SEC. 205. CLAIM APPROVAL.**

4 Section 202(b) (21 U.S.C. 343 note) is amended—

5 (1) by striking “December 15, 1993” and in-
6 serting “June 30, 1994”, and

7 (2) by inserting “amino acids,” after “herbs,”.

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