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103D 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.

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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

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# 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.

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

**SECTION 1. SHORT TITLE.**

This Act may be cited as the ''Dietary Supplement Access and Claims Moratorium Act of 1993''.

**SEC. 2. FINDINGS.**

The Congress finds the following:

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

(2) There has been a public campaign to convince consumers that the Food and Drug Administration intends to require prescriptions for many dietary supplements, or that the FDA will otherwise act to take these products off the market.

(3) Due to public concern, it is appropriate for Congress to assure consumers that they will have access to the dietary supplements that are currently on the market.

(4) The dietary supplement industry is concerned that the Nutrition Labeling and Education Act of 1990 will prohibit health claims on dietary supplements. Congress shall extend the moratorium on FDA actions under such Act with respect to dietary supplements.

# TITLE I—ACCESS TO DIETARY SUPPLEMENTS

**SEC. 101. REFERENCE.**

Whenever in this title 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. 102. ACCESS TO DIETARY SUPPLEMENTS.**

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

''(6) For a dietary supplement marketed on or before November 15, 1993, the Secretary may not, after November 15, 1993, require a prescription . For a dietary supplement first marketed after November 15, 1993, this subsection as it was in effect on the date of the enactment of the Dietary Supplement Access and Claims Moratorium Act of 1993 shall apply.''.

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

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

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

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

''(6) any dietary ingredient in a dietary supplement.''.

(2) DRUGS.—Section 201(g)(1) (21 U.S.C. 321(g)(1)) is amended by adding at the end the following: ''A dietary supplement which was on the

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

(c) BURDEN OF PROOF ON FDA.—

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

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

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

(d) DEFINITIONS.—

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

''(gg) The term 'dietary ingredient' means—

''(1) a vitamin,

''(2) a mineral,

''(3) an herb,

''(4) an amino acid, or

''(5) other ingredient,

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

''(hh) The term 'dietary supplement' means a product which contains one or more dietary ingredients and—

''(1) which is marketed to supplement the diet,

''(2) which is intended for use in tablet, capsule, powder, softgel, or liquid form and if in liquid form is formulated in a fluid carrier and is intended for ingestion in daily quantities measured in drops or similar small units of measure,

''(3) which is not represented for use as conventional food or as a sole item of a meal or of the diet, and

''(4) which does not include any ingredient other than a vitamin or mineral which has been approved as the active ingredient of a drug.''.

(2) SECRETARIAL ACTION.—For purposes of the definitions added by paragraph (1), the Secretary of Health and Human Services shall, not later than 180 days after the date of the enactment of this Act, issue a regulation identifying the dietary ingredients which were marketed on or before November 15, 1993.

# TITLE II—MORATORIUM ON DIETARY SUPPLEMENT CLAIMS

**SEC. 201. REFERENCE.**

Whenever in this title 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 Prescription Drug User Fee Act of 1992.

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

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

(1) by striking ''December 15, 1993'' and inserting ''June 30, 1994'', and

(2) by inserting ''amino acids,'' after ''herbs,''.

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

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

(1) by striking ''December 31, 1993'' and inserting ''June 30, 1994'', and

(2) by inserting ''amino acids,'' after ''herbs,''.

**SEC. 204. STATE ENFORCEMENT.**

The amendment made by section 202(a)(3) (21 U.S.C. 343 note) is amended by striking ''to such dietary supplement on December 31, 1993'' and inserting ''to dietary supplements of vitamins, minerals, herbs, amino

acids, or other similar nutritional substances on June 30, 1994''.

**SEC. 205. CLAIM APPROVAL.**

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

(1) by striking ''December 15, 1993'' and inserting ''June 30, 1994'', and

(2) by inserting ''amino acids,'' after ''herbs,''.

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