

106TH CONGRESS  
1ST SESSION

# H. R. 3305

To require the Commissioner of Food and Drugs to issue revised regulations relating to dietary supplement labeling, to amend the Federal Trade Commission Act to provide that certain types of advertisements for dietary supplements are proper, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 10, 1999

Mr. BURTON of Indiana introduced the following bill; which was referred to the Committee on Commerce

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## A BILL

To require the Commissioner of Food and Drugs to issue revised regulations relating to dietary supplement labeling, to amend the Federal Trade Commission Act to provide that certain types of advertisements for dietary supplements are proper, 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 Fairness in Labeling and Advertising Act”.

1 **SEC. 2. LABELING OF DIETARY SUPPLEMENTS.**

2 (a) SENSE OF CONGRESS.—It is the sense of Con-  
3 gress that the proposed rule entitled “Regulations on  
4 Statements Made for Dietary Supplements Concerning the  
5 Effect of the Product on the Structure or Functions of  
6 the Body”, published in the Federal Register on April 29,  
7 1998, 63 Fed. Reg. 23624 (to be codified at part 101 of  
8 title 21, Code of Federal Regulations) would improperly  
9 restrict use of appropriate labeling claims about the effect  
10 of a dietary supplement or dietary ingredient on the struc-  
11 ture or function of the human body.

12 (b) EFFECT OF REGULATIONS.—The proposed rule  
13 described in subsection (a) shall not take effect.

14 (c) DIETARY SUPPLEMENT LABELING EXEMP-  
15 TIONS.—Section 403B of the Federal Food, Drug, and  
16 Cosmetic Act (21 U.S.C. 343–2) is amended by adding  
17 at the end the following:

18 “(d) EXEMPTION FROM REGULATION AS LABEL-  
19 ING.—A truthful and accurate summary of 1 or more of  
20 the findings of a study or article that has appeared in a  
21 peer-reviewed medical, nutritional, or other scientific pub-  
22 lication, or in a bona fide medical, nutritional, or other  
23 scientific textbook, shall not be subject to regulation as  
24 labeling under this Act when used in connection with the  
25 sale of a dietary supplement to consumers, even if the

1 summary is included in written, printed, or graphic matter  
2 that accompanies the dietary supplement.”.

3 **SEC. 3. ADVERTISING OF DIETARY SUPPLEMENTS.**

4 Section 5 of the Federal Trade Commission Act (15  
5 U.S.C. 45) is amended by adding at the end the following:

6 “(o) ADVERTISING OF DIETARY SUPPLEMENTS AND  
7 DIETARY INGREDIENTS.—

8 “(1) DEFINITIONS.—In this subsection:

9 “(A) DIETARY SUPPLEMENT.—The term  
10 ‘dietary supplement’ has the meaning given that  
11 term by section 201(ff) of the Federal Food,  
12 Drug, and Cosmetic Act (21 U.S.C. 321(ff)).

13 “(B) DIETARY INGREDIENT.—The term  
14 ‘dietary ingredient’ means an ingredient listed  
15 in section 201(ff)(1) (A) through (F) of the  
16 Federal Food, Drug, and Cosmetic Act (21  
17 U.S.C. 321(ff)(1) (A) through (F)) that is in-  
18 cluded in, or that is intended to be included in,  
19 a dietary supplement.

20 “(2) EXEMPTIONS FROM REGULATION AS AD-  
21 VERTISING.—

22 “(A) LABELING.—Insofar as a publication  
23 is exempt from regulation as labeling pursuant  
24 to section 403B of the Federal Food, Drug, and  
25 Cosmetic Act (21 U.S.C. 343–2) the publication

1 is also exempt from regulation as advertising  
2 under the Federal Trade Commission Act.

3 “(B) TRUTHFUL AND ACCURATE SUM-  
4 MARY.—A truthful and accurate summary of 1  
5 or more of the findings of a cited study or arti-  
6 cle that has appeared in a peer-reviewed med-  
7 ical, nutritional, or other scientific publication,  
8 or in a bona fide medical, nutritional, or other  
9 scientific textbook, when used in promotion for  
10 a dietary supplement or dietary ingredient, shall  
11 not be subject to regulation as advertising  
12 under the Federal Trade Commission Act.

13 “(3) ADVERTISER ACCESS TO GOVERNMENT  
14 SCIENTIFIC EXPERTS BEFORE A REGULATORY AC-  
15 TION IS INITIATED.—Before the Commission files  
16 any complaint that initiates any administrative or  
17 judicial proceeding alleging that an advertisement or  
18 advertiser is not in compliance with the Federal  
19 Trade Commission Act with respect to any adver-  
20 tising for a dietary supplement or dietary ingredient,  
21 or for medical services or health treatments, the  
22 Commission shall ensure that the advertiser first—

23 “(A) has been provided a full and fair op-  
24 portunity to consult directly with all of the indi-  
25 viduals whom the Commission or Commission

1 staff have relied upon or intend to rely upon as  
2 nutritional, medical, or other scientific experts  
3 with respect to the particular allegations; and

4 “(B) has been provided a reasonable time  
5 thereafter to communicate with the Commission  
6 staff and the Commission with respect to the  
7 merits of the experts’ views.

8 “(4) RELIANCE UPON SCIENTIFIC DATA OTHER  
9 THAN CONCLUSIVE HUMAN CLINICAL STUDIES.—It  
10 is not inherently or presumptively deceptive, unfair,  
11 lacking in substantiation, or otherwise improper for  
12 advertising about a dietary supplement or dietary in-  
13 gredient, or about medical services or health treat-  
14 ments, to describe, mention, or rely upon in vitro  
15 laboratory studies, animal feeding studies, human  
16 epidemiological studies, human clinical studies that  
17 are of a preliminary nature and do not provide a  
18 conclusive finding, meta-analyses, review articles, or  
19 other bona fide medical, nutritional, or other sci-  
20 entific texts if the advertising is truthful, not mis-  
21 leading, and reveals the nature of the study or other  
22 information.

23 “(5) CONSENT AGREEMENTS.—In any case in  
24 which the Commission enters into a consent agree-  
25 ment concerning advertising about a dietary supple-

1       ment or dietary ingredient, or about medical services  
2       or health treatments, the agreement shall apply only  
3       to the particular dietary supplements/ingredients  
4       and particular health-related conditions, or to the  
5       particular medical services or health treatments, or  
6       to other particular matters, that are subjects of the  
7       complaint.”.

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