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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.

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.

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 Fairness in Labeling and Advertising Act''.

SEC. 2. LABELING OF DIETARY SUPPLEMENTS.

(a) SENSE OF CONGRESS.—It is the sense of Congress that the proposed rule entitled ''Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Functions of the Body'', published in the Federal Register on April 29, 1998, 63 Fed. Reg. 23624 (to be codified at part 101 of title 21, Code of Federal Regulations) would improperly restrict use of appropriate labeling claims about the effect of a dietary supplement or dietary ingredient on the structure or function of the human body.

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

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

''(d) EXEMPTION FROM REGULATION AS LABELING.—A truthful and accurate summary of 1 or more of the findings of a study or article that has appeared in a peer-reviewed medical, nutritional, or other scientific publication, or in a bona fide medical, nutritional, or other scientific textbook, shall not be subject to regulation as labeling under this Act when used in connection with the sale of a dietary supplement to consumers, even if the

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

SEC. 3. ADVERTISING OF DIETARY SUPPLEMENTS.

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

''(o) ADVERTISING OF DIETARY SUPPLEMENTS AND DIETARY INGREDIENTS.—

''(1) DEFINITIONS.—In this subsection:

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

''(B) DIETARY INGREDIENT.—The term 'dietary ingredient' means an ingredient listed in section 201(ff)(1) (A) through (F) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(ff)(1) (A) through (F)) that is included in, or that is intended to be included in, a dietary supplement.

''(2) EXEMPTIONS FROM REGULATION AS ADVERTISING.—

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

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

''(B) TRUTHFUL AND ACCURATE SUMMARY.—A truthful and accurate summary of 1 or more of the findings of a cited study or article that has appeared in a peer-reviewed medical, nutritional, or other scientific publication, or in a bona fide medical, nutritional, or other scientific textbook, when used in promotion for a dietary supplement or dietary ingredient, shall not be subject to regulation as advertising under the Federal Trade Commission Act.

''(3) ADVERTISER ACCESS TO GOVERNMENT SCIENTIFIC EXPERTS BEFORE A REGULATORY ACTION IS INITIATED.—Before the Commission files any complaint that initiates any administrative or judicial proceeding alleging that an advertisement or advertiser is not in compliance with the Federal Trade Commission Act with respect to any advertising for a dietary supplement or dietary ingredient, or for medical services or health treatments, the Commission shall ensure that the advertiser first—

''(A) has been provided a full and fair opportunity to consult directly with all of the individuals whom the Commission or Commission

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

"(B) has been provided a reasonable time thereafter to communicate with the Commission staff and the Commission with respect to the merits of the experts' views.

"(4) RELIANCE UPON SCIENTIFIC DATA OTHER THAN CONCLUSIVE HUMAN CLINICAL STUDIES.—It is not inherently or presumptively deceptive, unfair, lacking in substantiation, or otherwise improper for advertising about a dietary supplement or dietary ingredient, or about medical services or health treatments, to describe, mention, or rely upon in vitro laboratory studies, animal feeding studies, human epidemiological studies, human clinical studies that are of a preliminary nature and do not provide a conclusive finding, meta-analyses, review articles, or other bona fide medical, nutritional, or other scientific texts if the advertising is truthful, not misleading, and reveals the nature of the study or other information.

"(5) CONSENT AGREEMENTS.—In any case in which the Commission enters into a consent agreement concerning advertising about a dietary supple-

ment or dietary ingredient, or about medical services or health treatments, the agreement shall apply only to the particular dietary supplements/ingredients and particular health-related conditions, or to the particular medical services or health treatments, or to other particular matters, that are subjects of the complaint.''.

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