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(Original Signature of Member)

119TH CONGRESS
2D SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act to encourage innovation and increase and protect consumer access with respect to dietary supplements by clarifying the regulatory framework governing drug preclusion, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mrs. HARSHBARGER introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to encourage innovation and increase and protect consumer access with respect to dietary supplements by clarifying the regulatory framework governing drug preclusion, 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 Innovation Act''.

SEC. 2. CLARIFICATION OF DRUG PRECLUSION WITH RESPECT TO FOOD AND DIETARY SUPPLEMENTS.

(a) PROHIBITED ACT.—Section 301(ll) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(ll)) is amended to read as follows:

''(ll) The introduction or delivery for introduction into interstate commerce of any food (including a dietary supplement) to which has been added a drug approved under section 505 of this Act, a biological product licensed under section 351 of the Public Health Service Act, or a drug or biological product for which Phase 2 or Phase 3 (as such terms are described in section 312.21(b) of title 21, Code of Federal Regulations (or successor regulations)) clinical investigations have been instituted and for which the existence of such investigations has been made public, unless—

''(1) the drug or biological product was marketed in the United States before October 15, 1994, as or in—

''(A) food; or

''(B) a product that, if the definition of the term 'dietary supplement' under section 201(ff) had been in effect at the date of marketing, would have met such definition (other than the labeling requirement in section 201(ff)(2)(C));

''(2) such drug or biological product was marketed as food or in a dietary supplement before—

''(A) any approval of the drug under section 505;

''(B) any licensure of the biological product under such section 351; or

''(C) any Phase 2 or Phase 3 clinical investigation involving the use of the substance as a drug or biological product has been instituted and the existence of such investigation has been made public;

''(3) each Phase 2 or Phase 3 clinical investigation referred to in the matter preceding subparagraph (1) has been on inactive status, withdrawn, or both for a continuous period of at least seven years preceding the addition of the drug or biological product in food (including a dietary supplement), or the sponsor has publicly announced discontinuation of drug development activities;

''(4) the drug is a new animal drug whose use is not unsafe under section 512;

''(5) the use of the drug or the biological product in the food (including a dietary supplement) is to enhance the safety of the food to which the drug or the biological product is added or applied and not

to have independent biological or therapeutic effects on humans, and the use is in conformity with—

''(A) a regulation issued under section 409 prescribing conditions of safe use in food;

''(B) a regulation listing or affirming conditions under which the use of the drug or biological product in food is generally recognized as safe;

''(C) the conditions of use identified in a notification to the Secretary of a claim of exemption from the premarket approval requirements for food additives based on the notifier's determination that the use of the drug or biological product in food is generally recognized as safe, provided that the Secretary has not questioned the general recognition of safety determination in a letter to the notifier; or

''(D) a food contact substance notification that is effective under section 409(h);

''(6) such drug or biological product had been marketed for smoking cessation prior to the date of the enactment of the Food and Drug Administration Amendments Act of 2007; or

''(7) the Secretary, in the Secretary's discretion, has issued an administrative order through a

proceeding initiated by the Secretary approving the use of such drug or biological product in food (including a dietary supplement).''.

(b) DETERMINATIONS WITH RESPECT TO DRUG PRECLUSION.—The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended by inserting after section 413 (21 U.S.C. 350b) the following:

''SEC. 413A. DETERMINATIONS MADE WITH RESPECT TO DRUG PRECLUSION OF FOOD AND DIETARY SUPPLEMENTS.

''(a) STANDARDS OF EVALUATION.—For purposes of determining whether a drug (including a biological product) has been added to a food (including a dietary supplement) for purposes of section 301(ll)(1) or (2), the Secretary shall consider any difference between such drug and the substance when added to such food, including with respect to—

''(1) route of administration;

''(2) recommended dosage and serving amount;

''(3) concentration or composition; or

''(4) the degree of safety of the substance when added to—

''(A) a food; or

''(B) a dietary supplement subject to the safety requirements and burden of proof for di-

etary supplements as described in section 402(ff).

''(b) JUDICIAL REVIEW.—

''(1) IMMEDIATELY REVIEWABLE.—A warning letter, response to a notification submitted pursuant to section 101.93(a) of title 21, Code of Federal Regulations (or successor regulations), response to information provided pursuant to section 413(a)(2) of this Act, or statement made on a website controlled by the Secretary, finding or otherwise asserting that the introduction or delivery for introduction into interstate commerce of a food (including a dietary supplement) violates section 301(ll) of this Act shall be immediately reviewable by a court of jurisdiction under applicable law, irrespective of whether such warning letter, response, or statement is considered to be final agency action under chapter 7 of title 5, United States Code.

''(2) BURDEN OF PROOF.—In any action for which immediate review is sought pursuant to paragraph (1), the United States shall bear the burden of proof to show that such introduction or delivery for introduction would violate such section 301(ll).''.

(c) CONFORMING CHANGES TO DEFINITION OF DIETARY SUPPLEMENT.—Section 201(ff) of the Federal

Food, Drug, and Cosmetic Act (21 U.S.C. 321(ff)) is amended—

(1) in subparagraph (1)(F), by adding ''and'' at the end;

(2) in subparagraph (2)(C), by striking ''; and'' at the end and inserting a period; and

(3) by striking ''(3) does—'' and all that follows through ''would be lawful under this Act.''.