

119TH CONGRESS
2D SESSION

H. R. 10336

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

SEPTEMBER 10, 2026

Mrs. HARSHBARGER 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 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.

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 Innovation Act”.

1 **SEC. 2. CLARIFICATION OF DRUG PRECLUSION WITH RE-**
2 **SPECT TO FOOD AND DIETARY SUPPLE-**
3 **MENTS.**

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

7 “(ll) The introduction or delivery for introduction
8 into interstate commerce of any food (including a dietary
9 supplement) to which has been added a drug approved
10 under section 505 of this Act, a biological product licensed
11 under section 351 of the Public Health Service Act, or
12 a drug or biological product for which Phase 2 or Phase
13 3 (as such terms are described in section 312.21(b) of title
14 21, Code of Federal Regulations (or successor regula-
15 tions)) clinical investigations have been instituted and for
16 which the existence of such investigations has been made
17 public, unless—

18 “(1) the drug or biological product was mar-
19 keted in the United States before October 15, 1994,
20 as or in—

21 “(A) food; or

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

1 “(2) such drug or biological product was mar-
2 keted as food or in a dietary supplement before—

3 “(A) any approval of the drug under sec-
4 tion 505;

5 “(B) any licensure of the biological product
6 under such section 351; or

7 “(C) any Phase 2 or Phase 3 clinical inves-
8 tigation involving the use of the substance as a
9 drug or biological product has been instituted
10 and the existence of such investigation has been
11 made public;

12 “(3) each Phase 2 or Phase 3 clinical investiga-
13 tion referred to in the matter preceding subpara-
14 graph (1) has been on inactive status, withdrawn, or
15 both for a continuous period of at least seven years
16 preceding the addition of the drug or biological prod-
17 uct in food (including a dietary supplement), or the
18 sponsor has publicly announced discontinuation of
19 drug development activities;

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

22 “(5) the use of the drug or the biological prod-
23 uct in the food (including a dietary supplement) is
24 to enhance the safety of the food to which the drug
25 or the biological product is added or applied and not

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

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

5 “(B) a regulation listing or affirming con-
6 ditions under which the use of the drug or bio-
7 logical product in food is generally recognized
8 as safe;

9 “(C) the conditions of use identified in a
10 notification to the Secretary of a claim of ex-
11 emption from the premarket approval require-
12 ments for food additives based on the notifier’s
13 determination that the use of the drug or bio-
14 logical product in food is generally recognized
15 as safe, provided that the Secretary has not
16 questioned the general recognition of safety de-
17 termination in a letter to the notifier; or

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

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

24 “(7) the Secretary, in the Secretary’s discre-
25 tion, has issued an administrative order through a

1 proceeding initiated by the Secretary approving the
2 use of such drug or biological product in food (in-
3 cluding a dietary supplement).”.

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

8 **“SEC. 413A. DETERMINATIONS MADE WITH RESPECT TO**
9 **DRUG PRECLUSION OF FOOD AND DIETARY**
10 **SUPPLEMENTS.**

11 “(a) STANDARDS OF EVALUATION.—For purposes of
12 determining whether a drug (including a biological prod-
13 uct) has been added to a food (including a dietary supple-
14 ment) for purposes of section 301(l)(1) or (2), the Sec-
15 retary shall consider any difference between such drug and
16 the substance when added to such food, including with re-
17 spect to—

18 “(1) route of administration;

19 “(2) recommended dosage and serving amount;

20 “(3) concentration or composition; or

21 “(4) the degree of safety of the substance when
22 added to—

23 “(A) a food; or

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

1 etary supplements as described in section
2 402(ff).

3 “(b) JUDICIAL REVIEW.—

4 “(1) IMMEDIATELY REVIEWABLE.—A warning
5 letter, response to a notification submitted pursuant
6 to section 101.93(a) of title 21, Code of Federal
7 Regulations (or successor regulations), response to
8 information provided pursuant to section 413(a)(2)
9 of this Act, or statement made on a website con-
10 trolled by the Secretary, finding or otherwise assert-
11 ing that the introduction or delivery for introduction
12 into interstate commerce of a food (including a die-
13 tary supplement) violates section 301(ll) of this Act
14 shall be immediately reviewable by a court of juris-
15 diction under applicable law, irrespective of whether
16 such warning letter, response, or statement is con-
17 sidered to be final agency action under chapter 7 of
18 title 5, United States Code.

19 “(2) BURDEN OF PROOF.—In any action for
20 which immediate review is sought pursuant to para-
21 graph (1), the United States shall bear the burden
22 of proof to show that such introduction or delivery
23 for introduction would violate such section 301(ll).”.

24 (c) CONFORMING CHANGES TO DEFINITION OF DIE-
25 TARY SUPPLEMENT.—Section 201(ff) of the Federal

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

3 (1) in subparagraph (1)(F), by adding “and” at
4 the end;

5 (2) in subparagraph (2)(C), by striking “; and”
6 at the end and inserting a period; and

7 (3) by striking “(3) does—” and all that fol-
8 lows through “would be lawful under this Act.”.

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