II

119TH CONGRESS
2D SESSION

S. 3677

To improve transparency and the availability of information regarding dietary supplements by amending the Federal Food, Drug, and Cosmetic Act to require manufacturers of dietary supplements to list dietary supplements with the Food and Drug Administration.

IN THE SENATE OF THE UNITED STATES

JANUARY 15, 2026

Mr. DURBIN introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To improve transparency and the availability of information regarding dietary supplements by amending the Federal Food, Drug, and Cosmetic Act to require manufacturers of dietary supplements to list dietary supplements with the Food and Drug Administration.

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 Listing Act of 2026''.

SEC. 2. REGULATION OF DIETARY SUPPLEMENTS.

(a) IN GENERAL.—Chapter IV of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amended by adding after section 403C of such Act (21 U.S.C. 343–3) the following:

"SEC. 403D. DIETARY SUPPLEMENT LISTING REQUIREMENT.

''(a) IN GENERAL.—Beginning on the date specified in subsection (b)(4), each dietary supplement marketed in the United States shall be listed with the Secretary in accordance with this section. Each such listing shall include, with respect to the dietary supplement, the information specified in subsection (b)(1).

''(b) REQUIREMENTS.—

''(1) IN GENERAL.—The manufacturer, packer, or distributor of a dietary supplement whose name (pursuant to section 403(e)(1)) appears on the label of a dietary supplement marketed in the United States (referred to in this section as the 'responsible person'), or if the responsible person is a foreign entity, the United States agent of such person, shall submit to the Secretary in accordance with this section the following information for a dietary supplement that is marketed in the United States:

"(A) Any name of the dietary supplement and the statement of identity, including brand name and specified flavors, if applicable.

"(B) The name and address of the responsible person and the name and email address of the owner, operator, or agent in charge of the responsible person.

"(C) The name, domestic address, and email address for the United States agent, if the responsible person is a foreign entity.

"(D) The business name and place of business the responsible person provided on the label pursuant to section 403(e)(1).

"(E) An electronic copy of the label for the dietary supplement.

"(F) A list of all ingredients in each such dietary supplement required under sections 101.4 and 101.36, title 21, Code of Federal Regulations (or any successor regulations), to appear on the label of a dietary supplement, including—

"(i) where applicable, ingredients in a proprietary blend as described in section 101.36(c) of title 21, Code of Federal Regulations (or any successor regulations);

''(ii) the amount per serving of each listed dietary ingredient;

''(iii) if required by section 101.36 of title 21, Code of Federal Regulations (or any successor regulations), the percent of the daily value of each listed dietary ingredient; and

''(iv) the amount per serving of dietary ingredients within a proprietary blend (which shall remain confidential and not subject to public disclosure).

''(G) The number of servings per container for each container size.

''(H) The directions for use.

''(I) Warnings, notice, and safe handling statements, as required by section 101.17 of title 21, Code of Federal Regulations (or any successor regulations).

''(J) Allergen statements for major food allergens (pursuant to sections 403(w) and 403(x)).

''(K) The form of the dietary supplement (such as tablets, capsules, powders, liquids, softgels, and gummies).

''(L) Any claim that appears on the label or package insert that—

''(i) characterizes the relationship of any ingredient to a disease or a health-related condition and is described in section 403(r)(1)(B); or

''(ii) is subject to notification under section 403(r)(6), provided that no additional listing or change to listing information is required under this paragraph for any minor variation or modification to a claim for which notification under section 403(r)(6) is not required.

''(M) The dietary supplement product listing number for the dietary supplement provided by the Secretary in accordance with subsection (c).

''(2) FORMAT; NOTIFICATION OF RECEIPT.—

''(A) FORMAT.—The Secretary may require that a listing submitted under paragraph (1) be submitted in an electronic format.

''(B) NOTIFICATION OF RECEIPT.—

''(i) IN GENERAL.—Upon receipt of a listing under paragraph (1), the Secretary

shall promptly notify the responsible person of—

"(I) the receipt of a complete listing; or

"(II) the receipt of a listing that is not complete, together with a statement describing the reasons why the listing is not complete.

"(ii) COMPLETE RECEIPTS DESCRIBED.—A listing under paragraph (1) is deemed complete once all fields of required information have been completed by the responsible person who represents that the product will be marketed in the United States as a dietary supplement.

"(3) LISTING CONTENT.—A single listing submission for a dietary supplement under paragraph (1) may include multiple dietary supplements with identical formulations and forms, or formulations of the same form, that differ only with respect to color, excipients, or flavorings, whether offered in a single package size or in multiple package sizes.

"(4) TIMING.—

"(A) IN GENERAL.—

"(i) DIETARY SUPPLEMENTS ON THE MARKET.—In the case of a dietary supplement that is being offered in interstate commerce on or before January 1, 2027, a listing for each such dietary supplement introduced or delivered for introduction into interstate commerce shall be submitted by the responsible person to the Secretary under this subsection not later than 18 months after the date of enactment of the Dietary Supplement Listing Act of 2026.

"(ii) NEW DIETARY SUPPLEMENTS.—In the case of a dietary supplement that is not being offered in interstate commerce on or before January 1, 2027, a listing for each such dietary supplement introduced or delivered for introduction into interstate commerce that has not been included in any listing previously submitted by the responsible person to the Secretary under this subsection shall be submitted to the Secretary at the time of introduction into interstate commerce.

"(B) DISCONTINUED DIETARY SUPPLEMENTS.—The responsible person shall notify

the Secretary not later than 1 year after the date the responsible person discontinues the introduction into interstate commerce of a dietary supplement required to be listed with the Secretary under paragraph (1).

''(C) CHANGES TO EXISTING LISTINGS.—The responsible person shall submit to the Secretary any change or modification to listing information submitted under paragraph (1) included on the label of a dietary supplement not later than 30 days after the dietary supplement with the change or modification is first introduced into interstate commerce.

''(5) ADDITIONAL INFORMATION.—The responsible person shall provide, upon request from the Secretary, not later than 10 calendar days after such request—

''(A) the full business name and physical and mailing address of all locations at which the responsible person manufactures, packages, labels, or holds the dietary supplement; and

''(B) the full business name and physical and mailing address from which the responsible person receives a dietary ingredient or combination of dietary ingredients that the responsible

person uses in the manufacture of the dietary supplement or, if applicable, from which the responsible person receives the dietary supplement.

"(c) PRODUCT LISTING NUMBER AND DIETARY SUPPLEMENT ELECTRONIC DATABASE.—

"(1) DIETARY SUPPLEMENT PRODUCT LISTING NUMBER.—The Secretary shall provide each dietary supplement listed in accordance with subsection (b)(1) a dietary supplement product listing number, which may apply to multiple dietary supplements with identical formulations, or formulations that differ only with respect to color, excipients, or flavorings, including dietary supplements offered in a single package size or in multiple package sizes. The Secretary shall provide a process for a responsible person to reserve dietary supplement listing numbers in advance of listing under subsection (b)(1).

"(2) ELECTRONIC DATABASE.—Not later than 2 years after the date of enactment of the Dietary Supplement Listing Act of 2026, the Secretary shall establish and maintain an electronic database that is publicly available and contains information submitted under subsection (b)(1) (except for the infor-

mation submitted under subparagraph (B), (C), and (F)(iv) of such subsection). The Secretary shall make such information maintained in the electronic database publicly searchable, including by dietary supplement product listing number, and by any field of information or combination of fields of information provided under subsection (b)(1) (except for the information submitted under subparagraph (B), (C), and (F)(iv) of such subsection).

''(3) CONFIDENTIAL INFORMATION.—In response to a request under section 552 of title 5, United States Code, information described in subparagraph (B), (C), and (F)(iv) of subsection (b)(1) that is derived from a listing under this section, and information described in subparagraph (b)(5), shall be withheld under section 552(b)(3) of title 5, United States Code.

''(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed—

''(1) to limit the authority of the Secretary to inspect or copy records or to require the establishment and maintenance of records under any other provision of this Act;

''(2) to authorize the disclosure of information that is prohibited from disclosure under section

301(j) of this Act or section 1905 of title 18, United States Code, or that is subject to withholding under section 552(b)(4) of title 5, United States Code;

''(3) to authorize or permit the release in the public database, or to make subject to disclosure under section 552 of title 5, United States Code, information that discloses the identity or location of a specific registered person or facility not identified on the label, or the quantity of any individual ingredients in a proprietary blend; or

''(4) to grant the Secretary authority to require the approval of a dietary supplement prior to marketing.

''(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated $7,872,984 for fiscal year 2026, and $6,615,000 for each of fiscal years 2027 through 2030, for purposes of conducting the activities under this section and hiring personnel required to carry out this section.''.

(b) MISBRANDING.—Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amended by adding at the end the following:

''(z) If it is a dietary supplement for which a responsible person or the United States agent of such a person is required under section 403D to file a listing, file a

change to an existing listing, or provide additional information to the Secretary, and such person or agent has failed to comply with any such requirements under section 403D with respect to such dietary supplement.''.

(c) NEW PROHIBITED ACT.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

''(jjj) The introduction or delivery for introduction into interstate commerce of a dietary supplement that has been prepared, packed, or held using the assistance of, or at the direction of, a person debarred under section 306.''.

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