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2D SESSION

S. 4827

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

JULY 29, 2024

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

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.

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 Listing Act of 2024”.

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

2 (a) IN GENERAL.—Chapter IV of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amend-
4 ed by adding after section 403C of such Act (21 U.S.C.
5 343–3) the following:

6 **“SEC. 403D. DIETARY SUPPLEMENT LISTING REQUIRE-**
7 **MENT.**

8 “(a) IN GENERAL.—Beginning on the date specified
9 in subsection (b)(4), each dietary supplement marketed in
10 the United States shall be listed with the Secretary in ac-
11 cordance with this section. Each such listing shall include,
12 with respect to the dietary supplement, the information
13 specified in subsection (b)(1).

14 “(b) REQUIREMENTS.—

15 “(1) IN GENERAL.—The manufacturer, packer,
16 or distributor of a dietary supplement whose name
17 (pursuant to section 403(e)(1)) appears on the label
18 of a dietary supplement marketed in the United
19 States (referred to in this section as the ‘responsible
20 person’), or if the responsible person is a foreign en-
21 tity, the United States agent of such person, shall
22 submit to the Secretary in accordance with this sec-
23 tion the following information for a dietary supple-
24 ment that is marketed in the United States:

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

4 “(B) The name and address of the respon-
5 sible person and the name and email address of
6 the owner, operator, or agent in charge of the
7 responsible person.

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

11 “(D) The business name and place of busi-
12 ness the responsible person provided on the
13 label pursuant to section 403(e)(1).

14 “(E) An electronic copy of the label for the
15 dietary supplement.

16 “(F) A list of all ingredients in each such
17 dietary supplement required under sections
18 101.4 and 101.36, title 21, Code of Federal
19 Regulations (or any successor regulations), to
20 appear on the label of a dietary supplement, in-
21 cluding—

22 “(i) where applicable, ingredients in a
23 proprietary blend as described in section
24 101.36(e) of title 21, Code of Federal Reg-
25 ulations (or any successor regulations);

1 “(ii) the amount per serving of each
2 listed dietary ingredient;

3 “(iii) if required by section 101.36 of
4 title 21, Code of Federal Regulations (or
5 any successor regulations), the percent of
6 the daily value of each listed dietary ingre-
7 dient; and

8 “(iv) the amount per serving of die-
9 tary ingredients within a proprietary blend.

10 “(G) The number of servings per container
11 for each container size.

12 “(H) The directions for use.

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

17 “(J) Allergen statements for major food al-
18 lergens (pursuant to sections 403(w) and
19 403(x)).

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

23 “(L) Any claim that appears on the label,
24 package insert, or website of the responsible
25 person who submits the listing that—

1 “(i) characterizes the relationship of
2 any ingredient to a disease or a health-re-
3 lated condition and is described in section
4 403(r)(1)(B); or

5 “(ii) is subject to notification under
6 section 403(r)(6).

7 “(M) The dietary supplement product list-
8 ing number for the dietary supplement provided
9 by the Secretary in accordance with subsection
10 (c).

11 “(2) FORMAT.—The Secretary may require that
12 a listing submitted under paragraph (1) be sub-
13 mitted in an electronic format. Upon receipt of a
14 complete listing under paragraph (1), the Secretary
15 shall promptly notify the responsible person of the
16 receipt of such listing. A listing is deemed complete
17 once all fields of required information have been
18 completed by the responsible person who represents
19 that the product will be marketed in the United
20 States as a dietary supplement.

21 “(3) LISTING CONTENT.—A single listing sub-
22 mission for a dietary supplement under paragraph
23 (1) may include multiple dietary supplements with
24 identical formulations and forms, or formulations of
25 the same form, that differ only with respect to color,

1 excipients, or flavorings, whether offered in a single
2 package size or in multiple package sizes.

3 “(4) TIMING.—

4 “(A) IN GENERAL.—

5 “(i) DIETARY SUPPLEMENTS ON THE
6 MARKET.—In the case of a dietary supple-
7 ment that is being offered in interstate
8 commerce on or before January 1, 2025, a
9 listing for each such dietary supplement in-
10 troduced or delivered for introduction into
11 interstate commerce shall be submitted by
12 the responsible person to the Secretary
13 under this subsection not later than 18
14 months after the date of enactment of the
15 Dietary Supplement Listing Act of 2024.

16 “(ii) NEW DIETARY SUPPLEMENTS.—

17 In the case of a dietary supplement that is
18 not being offered in interstate commerce
19 on or before January 1, 2025, a listing for
20 each such dietary supplement introduced
21 or delivered for introduction into interstate
22 commerce that has not been included in
23 any listing previously submitted by the re-
24 sponsible person to the Secretary under
25 this subsection shall be submitted to the

1 Secretary at the time of introduction into
2 interstate commerce.

3 “(B) DISCONTINUED DIETARY SUPPLE-
4 MENTS.—The responsible person shall notify
5 the Secretary not later than 1 year after the
6 date the responsible person discontinues the in-
7 troduction into interstate commerce of a dietary
8 supplement required to be listed with the Sec-
9 retary under paragraph (1).

10 “(C) CHANGES TO EXISTING LISTINGS.—
11 The responsible person shall submit to the Sec-
12 retary any change or modification to listing in-
13 formation submitted under paragraph (1) in-
14 cluded on the label of a dietary supplement not
15 later than 30 days after the dietary supplement
16 with the change or modification is first intro-
17 duced into interstate commerce.

18 “(5) ADDITIONAL INFORMATION.—The respon-
19 sible person shall provide, upon request from the
20 Secretary, not later than 10 calendar days after
21 such request—

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

1 “(B) the full business name and physical
2 and mailing address from which the responsible
3 person receives a dietary ingredient or combina-
4 tion of dietary ingredients that the responsible
5 person uses in the manufacture of the dietary
6 supplement or, if applicable, from which the re-
7 sponsible person receives the dietary supple-
8 ment.

9 “(c) PRODUCT LISTING NUMBER AND DIETARY SUP-
10 PLEMENT ELECTRONIC DATABASE.—

11 “(1) DIETARY SUPPLEMENT PRODUCT LISTING
12 NUMBER.—The Secretary shall provide each dietary
13 supplement listed in accordance with subsection
14 (b)(1) a dietary supplement product listing number,
15 which may apply to multiple dietary supplements
16 with identical formulations, or formulations that dif-
17 fer only with respect to color, excipients, or
18 flavorings, including dietary supplements offered in
19 a single package size or in multiple package sizes.
20 The Secretary shall provide a process for a respon-
21 sible person to reserve dietary supplement listing
22 numbers in advance of listing under subsection
23 (b)(1).

24 “(2) ELECTRONIC DATABASE.—Not later than
25 2 years after the date of enactment of the Dietary

1 Supplement Listing Act of 2024, the Secretary shall
2 establish and maintain an electronic database that is
3 publicly available and contains information sub-
4 mitted under subsection (b)(1) (except for the infor-
5 mation submitted under subparagraph (B), (C), and
6 (F)(iv) of such subsection). The Secretary shall
7 make such information maintained in the electronic
8 database publicly searchable, including by dietary
9 supplement product listing number, and by any field
10 of information or combination of fields of informa-
11 tion provided under subsection (b)(1) (except for the
12 information submitted under subparagraph (B), (C),
13 and (F)(iv) of such subsection).

14 “(3) CONFIDENTIAL INFORMATION.—In re-
15 sponse to a request under section 552 of title 5,
16 United States Code, information described in sub-
17 paragraph (B), (C), and (F)(iv) of subsection (b)(1)
18 that is derived from a listing under this section, and
19 information described in subparagraph (b)(5), shall
20 be withheld under section 552(b)(3) of title 5,
21 United States Code.

22 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-
23 tion shall be construed—

24 “(1) to limit the authority of the Secretary to
25 inspect or copy records or to require the establish-

1 ment and maintenance of records under any other
2 provision of this Act;

3 “(2) to authorize the disclosure of information
4 that is prohibited from disclosure under section
5 301(j) of this Act or section 1905 of title 18, United
6 States Code, or that is subject to withholding under
7 section 552(b)(4) of title 5, United States Code; or

8 “(3) to grant the Secretary authority to require
9 the approval of a dietary supplement prior to mar-
10 keting.

11 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
12 is authorized to be appropriated \$7,872,984 for fiscal year
13 2024, and \$6,615,000 for each of fiscal years 2025
14 through 2028, for purposes of conducting the activities
15 under this section and hiring personnel required to carry
16 out this section.”.

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

20 “(z) If it is a dietary supplement for which a respon-
21 sible person or the United States agent of such a person
22 is required under section 403D to file a listing, file a
23 change to an existing listing, or provide additional infor-
24 mation to the Secretary, and such person or agent has

1 failed to comply with any such requirements under section
2 403D with respect to such dietary supplement.”.

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

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

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