117TH CONGRESS
2D SESSION

S. 4090

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

APRIL 26, 2022

Mr. DURBIN (for himself and Mr. BRAUN) 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 2022''.

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 inserting after section 403C of such Act the following:

"SEC. 403D. DIETARY SUPPLEMENT LISTING REQUIREMENT.

''(a) IN GENERAL.—Each dietary supplement shall be listed with the Secretary in accordance with this section.

''(b) LISTING SUBMISSIONS.—

''(1) IN GENERAL.—Each responsible person, or, if the responsible person is a foreign entity, the United States agent, shall submit to the Secretary in accordance with this section the following information for each dietary supplement that will be marketed:

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

''(B) The full name, address, and telephone number for the responsible person, and the name and e-mail address of the owner, operator, or agent in charge of the responsible person.

''(C) The full name, address, telephone number, and e-mail address for the United States agent, if the responsible person is a foreign entity.

''(D) The full business name and address of all locations at which the responsible person manufactures, packages, labels, or holds the dietary supplement.

''(E) An electronic copy of the label for the dietary supplement, and an electronic copy of the package insert, if any.

''(F) A list of all ingredients in the dietary supplement required to appear on the label under sections 101.4 and 101.36 of title 21, Code of Federal Regulations, including—

''(i) the amount per serving of each listed ingredient, if such information is required to appear on the label; and

''(ii) if required by section 101.36 of title 21, Code of Federal Regulations, the percent of the daily value of each listed ingredient.

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

''(H) The conditions of use.

"(I) Warnings and precautions.

"(J) Statements regarding major food allergens, as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(qq)).

"(K) The dosage form, such as pill, capsule, liquid, or powder.

"(L) Any claim that—

"(i) characterizes the relationship of any nutrient which is of the type required by section 403(q)(1) or section (q)(2) to be in the label or labeling of the food to a disease or a health-related condition; or

"(ii) is subject to notification under section 403(r)(6) that appears in the supplement's labeling.

"(M) The unique dietary supplement identifier for the product, provided in accordance with paragraph (3).

"(2) FORMAT.—A listing submitted under this section shall be in such electronic form and manner as the Secretary may prescribe. The Secretary shall promptly confirm, electronically, receipt of a complete listing under this section.

"(3) UNIQUE LISTING IDENTIFICATION NUMBERS.—

"(A) IN GENERAL.—The Secretary shall establish a unique dietary supplement identifier system that shall be used by the responsible person under this section.

"(B) RESERVATION OF NUMBERS.—The system shall allow a responsible person to reserve multiple dietary supplement identifier numbers in advance of listing.

"(C) USE REQUIREMENT.—Any unique dietary supplement identifier shall be used only in connection with the product for which the identifier was used during the listing process.

"(4) SUBMISSION DATES.—A responsible person under this section shall report to the Secretary the listing information described in paragraph (1) pursuant to the following timelines:

"(A) IN GENERAL.—

"(i) EXISTING DIETARY SUPPLEMENTS.—In the case of a dietary supplement that is being offered in interstate commerce on the date that is 18 months after the date of enactment of the Dietary Supplement Listing Act of 2022, a listing

for each such dietary supplement formulation introduced or delivered for introduction into interstate commerce by the responsible person for commercial distribution shall be submitted by the responsible person with the Secretary under this section not later than 60 days after the date that is 18 months after the date of enactment of such Act.

''(ii) NEW DIETARY SUPPLEMENTS.—In the case of a dietary supplement that is not being offered in interstate commerce on the date that is 18 months after the date of enactment. of the Dietary Supplement Listing Act of 2022, a listing for each such dietary supplement formulation introduced or delivered for introduction into interstate commerce by the responsible person for commercial distribution which has not been included in any listing previously submitted by the responsible person to the Secretary under this section shall be submitted to the Secretary prior to introducing the dietary supplement into interstate commerce.

''(B) REFORMULATIONS.—A listing of each dietary supplement formulation introduced by the responsible person for commercial distribution that has a label that differs for such dietary supplement from the representative label provided under subsection (a) with respect to the product name, amount of dietary ingredients, or other distinguishing characteristics such as dosage form (such as pill, capsule, liquid, or powder) shall be submitted to the Secretary not later than 15 business days after introducing the dietary supplement with the change into interstate commerce.

''(C) DISCONTINUED DIETARY SUPPLEMENTS.—If the responsible person has discontinued the commercial marketing of a dietary supplement formulation included in a listing submitted by the responsible person under subparagraph (A) or (B), the responsible person shall report to the Secretary the date of such discontinuance, within 90 days of the discontinuance of the dietary supplement.

''(5) SUPPLIER INFORMATION RECORD KEEPING REQUIREMENT.—Each responsible person subject to the requirements of this subsection shall maintain a

record of the full business name and address from which the responsible person receives any 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. The responsible person shall make this information available to the Secretary within 72 hours of request from the Secretary.

''(c) ELECTRONIC DATABASE.—Beginning not later than 2 years after the Secretary specifies a unique dietary supplement identifier system pursuant to subsection (b)(3), the Secretary shall maintain an electronic database that—

''(1) is publicly accessible;

''(2) is populated with information regarding dietary supplements that is provided under this section or any other provision of this Act; and

''(3) enables the public to search the database by a dietary supplement's unique dietary supplement identifier or other field of information or combination of fields.

''(d) AUTHORIZATION OF APPROPRIATIONS.—For purposes of conducting activities under this section and hiring personnel to carry out this section, there are au-

thorized to be appropriated $4,000,000 for fiscal year 2022 and $1,000,000 for each of fiscal years 2023 through 2026.''.

(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 is required to file a listing under section 403D and such responsible person has not made a listing 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:

''(fff) 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.''.

(d) RULE OF CONSTRUCTION.—Nothing in the amendments made by subsections (a) through subsection (c) shall be construed to expand the existing authorities of the Food and Drug Administration, other than as specified in such amendments. This subsection shall not be construed to—

(1) limit the existing authorities of the Food and Drug Administration; or

(2) limit the authorities specified in the amendments made by subsections (a) through subsection (c).

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