

119TH CONGRESS
2D SESSION

H. R. 8269

To amend the Federal Food, Drug, and Cosmetic Act to require drug labeling to include original manufacturer and supply chain information.

IN THE HOUSE OF REPRESENTATIVES

APRIL 14, 2026

Mr. MCCORMICK (for himself and Ms. DELAURO) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require drug labeling to include original manufacturer and supply chain information.

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 “Consumer Labeling
5 for Enhanced API Reporting and Legitimate Account-
6 ability for Base Entity Listings Act” or the “CLEAR LA-
7 BELS Act”.

1 **SEC. 2. REQUIRE DRUG LABELING TO INCLUDE ORIGINAL**
2 **MANUFACTURER AND SUPPLY CHAIN INFOR-**
3 **MATION.**

4 Section 502(b) of the Federal Food, Drug, and Cos-
5 metic Act (21 U.S.C. 352(b)) is amended to read as fol-
6 lows:

7 “(b)(1) If it is a finished drug product in a package
8 form, unless it bears a label containing—

9 “(A) the name, place of business, and unique
10 facility identifier of the manufacturer, packer, or
11 distributor or a link, barcode, QR code, or other
12 means to access a searchable electronic portal con-
13 taining such information; and

14 “(B) an accurate statement of the quantity of
15 the contents in terms of weight, measure, or numer-
16 ical count, provided that under this clause reason-
17 able variations shall be permitted, and exemptions as
18 to small packages shall be established, by regulations
19 prescribed by the Secretary.

20 “(2) If it is an active pharmaceutical ingredient, un-
21 less any accompanying label and certificate of analysis
22 contains the name, place of business, and unique facility
23 identifier of the original manufacturer.

24 “(3)(A) If it is a finished drug product, unless its
25 labeling contains the name, place of business, and unique
26 facility identifier of—

1 “(i) the original manufacturer of each active
2 pharmaceutical ingredient;

3 “(ii) the original manufacturer of the finished
4 drug product; and

5 “(iii) the packer or distributor, if any,
6 or a link, barcode, QR code, or other means to access a
7 searchable electronic portal containing such information.

8 “(B) In the case of a finished drug product for which
9 there are multiple potential different manufacturers of the
10 active pharmaceutical ingredient, the requirements of this
11 subparagraph shall be satisfied if all such manufacturers
12 of active pharmaceutical ingredients for the drug product
13 are identified in the labeling or the searchable electronic
14 portal.

15 “(4) A manufacturer, packer, or distributor required
16 to furnish information under subparagraphs (1), (2), and
17 (3), in addition to making such information available elec-
18 tronically, as applicable, shall make such information
19 available through a package insert, or in paper copy to
20 any individual who requests such a copy.

21 “(5) For purposes of this paragraph, the term ‘origi-
22 nal manufacturer’, means the single last establishment to
23 conduct substantial manufacturing activities prior to in-
24 troduction of the active pharmaceutical ingredient or fin-
25 ished drug product into interstate commerce.

1 “(6) The Secretary shall issue regulations to imple-
2 ment subparagraphs (2) and (3) and may provide for rea-
3 sonable variations in the implementation of, or an alter-
4 native placement for, the labeling requirements under such
5 subparagraphs, including by electronic means. Such regu-
6 lations shall take effect on a date determined by the Sec-
7 retary and not earlier than 1 year after the date of publi-
8 cation of the final regulations, and shall apply with respect
9 to drugs manufactured on or after the effective date of
10 such regulations.”.

11 **SEC. 3. EXEMPTION FROM CUSTOMS COUNTRY OF ORIGIN**
12 **MARKING REQUIREMENT.**

13 Section 304 of the Tariff Act of 1930 (19 U.S.C.
14 1304) is amended by adding at the end the following:

15 “(m) MARKING OF CERTAIN FINISHED DRUG PROD-
16 UCTS.—The marking requirements of subsections (a) and
17 (b) shall not apply to articles that are finished drug prod-
18 ucts and are marked in accordance with the requirements
19 of section 502(b)(3)(A) of the Federal Food, Drug, and
20 Cosmetic Act.”.

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