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(Original Signature of Member)

119TH CONGRESS
2D SESSION

H. R. _____

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

Mr. MCCORMICK introduced the following bill; which was referred to the Committee on _____

A BILL

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

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 ''Consumer Labeling for Enhanced API Reporting and Legitimate Accountability for Base Entity Listings Act'' or the ''CLEAR LABELS Act''.

SEC. 2. REQUIRE DRUG LABELING TO INCLUDE ORIGINAL MANUFACTURER AND SUPPLY CHAIN INFORMATION.

Section 502(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(b)) is amended to read as follows:

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

''(A) the name, place of business, and unique facility identifier of the manufacturer, packer, or distributor or a link, barcode, QR code, or other means to access a searchable electronic portal containing such information; and

''(B) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count, provided that under this clause reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

''(2) If it is an active pharmaceutical ingredient, unless any accompanying label and certificate of analysis contains the name, place of business, and unique facility identifier of the original manufacturer.

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

''(i) the original manufacturer of each active pharmaceutical ingredient;

''(ii) the original manufacturer of the finished drug product; and

''(iii) the packer or distributor, if any,

or a link, barcode, QR code, or other means to access a searchable electronic portal containing such information.

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

''(4) A manufacturer, packer, or distributor required to furnish information under subparagraphs (1), (2), and (3), in addition to making such information available electronically, as applicable, shall make such information available through a package insert, or in paper copy to any individual who requests such a copy.

''(5) For purposes of this paragraph, the term 'original manufacturer', means the single last establishment to conduct substantial manufacturing activities prior to introduction of the active pharmaceutical ingredient or finished drug product into interstate commerce.

''(6) The Secretary shall issue regulations to implement subparagraphs (2) and (3) and may provide for reasonable variations in the implementation of, or an alternative placement for, the labeling requirements under such subparagraphs, including by electronic means. Such regulations shall take effect on a date determined by the Secretary and not earlier than 1 year after the date of publication of the final regulations, and shall apply with respect to drugs manufactured on or after the effective date of such regulations.''.

SEC. 3. EXEMPTION FROM CUSTOMS COUNTRY OF ORIGIN MARKING REQUIREMENT.

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

''(m) MARKING OF CERTAIN FINISHED DRUG PRODUCTS.—The marking requirements of subsections (a) and (b) shall not apply to articles that are finished drug products and are marked in accordance with the requirements of section 502(b)(3)(A) of the Federal Food, Drug, and Cosmetic Act.''.