

119TH CONGRESS
1ST SESSION

S. _____

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

IN THE SENATE OF THE UNITED STATES

Mr. SCOTT of Florida (for himself and Mrs. GILLIBRAND) introduced the following bill; which was read twice and 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.

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—

6 (1) by striking “containing (1) the name and
7 place of business of the manufacturer, packer, or
8 distributor” and inserting the following: “con-
9 taining—

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

15 (2) in clause (A) (as so designated), by striking
16 “(2) an accurate” and inserting the following:

17 “(B) an accurate”;

18 (3) in clause (B) (as so designated), by striking
19 “count: *Provided*, That under clause (2) of this
20 paragraph reasonable variations” and inserting
21 “count, provided that under this clause, reasonable
22 variations”;

23 (4) by striking “(b) If in a package form” and
24 inserting the following:

25 “(b)(1) If it is a finished drug product in a package
26 form”; and

1 (5) by adding at the end the following:

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

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

9 “(i) the original manufacturer of each active pharma-
10 ceutical ingredient;

11 “(ii) the original manufacturer of the finished drug
12 product; and

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

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

23 “(4) A manufacturer, packer, or distributor required
24 to furnish information under paragraphs (1), (2), and (3),
25 in addition to making such information available electroni-

1 cally, as applicable, shall make such information available
2 through a package insert, or in paper copy to any indi-
3 vidual who requests such a copy.

4 “(5) For purposes of this subsection, the term ‘origi-
5 nal manufacturer’, means the single last establishment to
6 conduct substantial manufacturing activities prior to in-
7 troduction of the active pharmaceutical ingredient or fin-
8 ished drug product into interstate commerce.

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

19 **SEC. 3. EXEMPTION FROM CUSTOMS COUNTRY OF ORIGIN**
20 **MARKING REQUIREMENT.**

21 Section 304 of the Tariff Act of 1930 (19 U.S.C.
22 1304) is amended by adding at the end the following:

23 “(m) MARKING OF CERTAIN FINISHED DRUG PROD-
24 UCTS.—The marking requirements of subsections (a) and
25 (b) shall not apply to articles that are finished drug prod-

1 ucts and are marked in accordance with the requirements
2 of section 502(b)(2)(A) of the Federal Food, Drug, and
3 Cosmetic Act (21 U.S.C. 352(b)(2)(A)).”.