

## Calendar No. 523

119TH CONGRESS  
2D SESSION**S. 3788**

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

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IN THE SENATE OF THE UNITED STATES

FEBRUARY 5, 2026

Mr. SCOTT of Florida (for himself, Mrs. GILLIBRAND, Mr. TUBERVILLE, Mrs. BRITT, Mr. JOHNSON, Mrs. MOODY, Mr. LEE, Mr. CRAMER, Mr. RISCH, Mr. GRASSLEY, Mr. RICKETTS, Ms. ERNST, and Mr. ARMSTRONG) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

JULY 27, 2026

Reported by Mr. CASSIDY, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]

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**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-~~

1 ability for Base Entity Listings Act” or the “CLEAR LA-  
2 BELS Act”.

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

6 Section 502(b) of the Federal Food, Drug, and Cos-  
7 metic Act (21 U.S.C. 352(b)) is amended—

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

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

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

19 “(B) an accurate”;

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

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

3           “~~(b)(1)~~ If it is a finished drug product in a package  
4           form”; and

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

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

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

13                 “(i) the original manufacturer of each active  
14                 pharmaceutical ingredient;

15                 “(ii) the original manufacturer of the finished  
16                 drug product; and

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

20          “~~(B)~~ In the case of a finished drug product for which  
21          there are multiple potential different manufacturers of the  
22          active pharmaceutical ingredient, the requirements of this  
23          subparagraph shall be satisfied if all such manufacturers  
24          of active pharmaceutical ingredients for the drug product

1 are identified in the labeling or the searchable electronic  
2 portal.

3 “(4) A manufacturer, packer, or distributor required  
4 to furnish information under paragraphs (1), (2), and (3),  
5 in addition to making such information available electroni-  
6 cally, as applicable, shall make such information available  
7 through a package insert, or in paper copy to any indi-  
8 vidual who requests such a copy.

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

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

1 **SEC. 3. EXEMPTION FROM CUSTOMS COUNTRY OF ORIGIN**  
 2 **MARKING REQUIREMENT.**

3 Section 304 of the Tariff Act of 1930 (19 U.S.C.  
 4 1304) is amended by adding at the end the following:

5 “(m) ~~MARKING OF CERTAIN FINISHED DRUG PROD-~~  
 6 ~~UCTS.~~—The marking requirements of subsections (a) and  
 7 (b) shall not apply to articles that are finished drug prod-  
 8 ucts and are marked in accordance with the requirements  
 9 of section 502(b)(2)(A) of the Federal Food, Drug, and  
 10 Cosmetic Act (21 U.S.C. 352(b)(2)(A)).”.

11 **SECTION 1. SHORT TITLE.**

12 *This Act may be cited as the “Consumer Labeling for*  
 13 *Enhanced API Reporting and Legitimate Accountability*  
 14 *for Base Entity Listings Act” or the “CLEAR LABELS*  
 15 *Act”.*

16 **SEC. 2. REQUIRE DRUG LABELS TO INCLUDE ORIGINAL**  
 17 **MANUFACTURER AND SUPPLY CHAIN INFOR-**  
 18 **MATION.**

19 *Section 503 of the Federal Food, Drug, and Cosmetic*  
 20 *Act (21 U.S.C. 353) is amended by adding at the end the*  
 21 *following —*

22 “(i) *ORIGINAL MANUFACTURER AND SUPPLY CHAIN*  
 23 *INFORMATION.*—

24 “(1) *IN GENERAL.*—No person shall introduce or  
 25 deliver for introduction into interstate commerce any  
 26 drug—

1           “(A) if it is an active pharmaceutical ingre-  
 2           dient, unless the label and certificate of analysis  
 3           contain the name and place of business of the  
 4           original manufacturer; or

5           “(B) if it is a finished drug product in a  
 6           package form, unless the label includes, either  
 7           printed directly or made available through elec-  
 8           tronic means, the name and place of business  
 9           of—

10                   “(i) the original manufacturer of each  
 11                   active pharmaceutical ingredient;

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

14                   “(iii) the packer or distributor, if any.

15           “(2) *MULTIPLE ORIGINAL MANUFACTURERS.*—In  
 16           the case of a finished drug product for which there are  
 17           multiple different original manufacturers of an active  
 18           pharmaceutical ingredient, the requirements of para-  
 19           graph (1)(B)(i) shall be satisfied if the label includes,  
 20           either printed directly or made available through elec-  
 21           tronic means, the name and place of business of each  
 22           applicable original manufacturer of the active phar-  
 23           maceutical ingredient for the applicable drug product  
 24           lot.

1           “(3) *EFFECT OF NONCOMPLIANCE.*—*In the case*  
 2           *of noncompliance with the requirements of paragraph*  
 3           *(1), the Secretary shall have discretion to determine*  
 4           *that such noncompliance constitutes misbranding and*  
 5           *to assess a civil monetary penalty, as described in*  
 6           *section 303(f)(10), except that the Secretary may not*  
 7           *treat a violation of this subsection as a criminal vio-*  
 8           *lation.*

9           “(4) *DEFINITION OF ORIGINAL MANUFAC-*  
 10          *TURER.*—*For purposes of this subsection, the term*  
 11          *‘original manufacturer’ means the establishment that*  
 12          *conducts the majority of the significant phases of*  
 13          *manufacturing (chemical, physical, or biological ma-*  
 14          *nipulation) to produce the active pharmaceutical in-*  
 15          *gredient or the finished dosage form.’.*

16 **SEC. 3. PENALTIES.**

17          (a) *IN GENERAL.*—*Section 303(f) of the Federal Food,*  
 18          *Drug, and Cosmetic Act (21 U.S.C. 333(f)) is amended by*  
 19          *adding at the end the following:*

20          “(10)(A) *Any person who fails to comply with the re-*  
 21          *quirements of section 503(i) shall be subject to a civil mone-*  
 22          *tary penalty in an amount not to exceed 25 percent of the*  
 23          *total value of the drug product lot or lots involved.*

1       “(B) *In determining whether to assess a penalty under*  
 2 *this paragraph against a person, and the amount of such*  
 3 *a penalty, the Secretary shall consider—*

4               “(i) *the size of the business of such person and*  
 5 *the gravity of the violation;*

6               “(ii) *whether such person received written notice*  
 7 *of the noncompliance in advance of such proceeding*  
 8 *and was provided an opportunity by the Secretary to*  
 9 *correct the violation following such notice; and*

10              “(iii) *whether such person acted in good faith to*  
 11 *correct the violation following any such notice.”.*

12       (b) **CONFORMING AMENDMENTS.**—*Section 303(f)(5)(A)*  
 13 *of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*  
 14 *333(f)(5)(A)) is amended by striking “(1), (2), (3), (4), or*  
 15 *(9)” and inserting “(1), (2), (3), (4), (9), or (10)”.*

16 **SEC. 4. AGENCY COORDINATION REGARDING FDA AND CUS-**  
 17 **TOMS COUNTRY OF ORIGIN REQUIREMENTS.**

18       *In carrying out the amendments made by this Act, the*  
 19 *Commissioner of Food and Drugs shall coordinate with the*  
 20 *Commissioner of U.S. Customs and Border Protection on*  
 21 *efforts to address the potential administrative burden on*  
 22 *manufacturers of active pharmaceutical ingredients and*  
 23 *finished drug products related to any potential overlap*  
 24 *with, or duplication or conflict between, the requirements*  
 25 *of such amendments and section 304 of the Tariff Act of*



1 1930 (19 U.S.C. 1304). Such coordination may include the  
2 establishment of mechanisms to facilitate the sharing of rel-  
3 evant information between the Food and Drug Administra-  
4 tion and U.S. Customs and Border Protection to ensure  
5 compliance with such amendments and such section 304,  
6 and joint rulemaking, if determined by such commissioners  
7 to be appropriate.

8 **SEC. 5. CONFIDENTIALITY.**

9       Nothing in the amendments made by this Act shall be  
10 construed as authorizing the Secretary of Health and  
11 Human Services to disclose any information that is a trade  
12 secret or confidential information subject to section  
13 552(b)(4) of title 5, United States Code, or section 1905  
14 of title 18, United States Code.

15 **SEC. 6. EFFECTIVE DATE.**

16       The amendments made by this Act shall apply to ac-  
17 tive pharmaceutical ingredients and finished drug products  
18 that are manufactured and packaged on or after the date  
19 that is 5 years after the date of enactment of this Act.

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