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AMENDMENT NO._____ Calendar No._____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—119th Cong., 2d Sess.

S. 3788

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

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended to be proposed by _____

Viz:

Strike all after the enacting clause and insert the following:

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 LABELS TO INCLUDE ORIGINAL MANUFACTURER AND SUPPLY CHAIN INFORMATION.

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

"(i) ORIGINAL MANUFACTURER AND SUPPLY CHAIN INFORMATION.—

"(1) IN GENERAL.—No person shall introduce or deliver for introduction into interstate commerce any drug—

"(A) if it is an active pharmaceutical ingredient, unless the label and certificate of analysis contain the name and place of business of the original manufacturer; or

"(B) if it is a finished drug product in a package form, unless the label includes, either printed directly or made available through electronic means, the name and place of business 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.

"(2) MULTIPLE ORIGINAL MANUFACTURERS.—In the case of a finished drug product for which there are multiple different original manufacturers of an active pharmaceutical ingredient, the requirements of paragraph (1)(B)(i) shall be satisfied if the label includes, either printed directly or made available through electronic means, the name and place of business of each applicable original manufacturer of the active pharmaceutical ingredient for the applicable drug product lot.

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

"(4) DEFINITION OF ORIGINAL MANUFACTURER.—For purposes of this subsection, the term 'original manufacturer', means the establishment that conducts the majority of the significant phases of manufacturing (chemical, physical, or biological manipulation) to produce the active pharmaceutical ingredient or the finished dosage form.".

SEC. 3. PENALTIES.

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

"(10)(A) Any person who fails to comply with the requirements of section 503(i) shall be subject to a civil monetary penalty in an amount not to exceed 25 percent of the total value of the drug product lot or lots involved.

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

"(i) the size of the business of such person and the gravity of the violation;

"(ii) whether such person received written notice of the noncompliance in advance of such proceeding and was provided an opportunity by the Secretary to correct the violation following such notice; and

"(iii) whether such person acted in good faith to correct the violation following any such notice.".

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

SEC. 4. AGENCY COORDINATION REGARDING FDA AND CUSTOMS COUNTRY OF ORIGIN REQUIREMENTS.

In carrying out the amendments made by this Act, the Commissioner of Food and Drugs shall coordinate with the Commissioner of the U.S. Customs and Border Protection on efforts to address the potential administrative burden on manufacturers of active pharmaceutical ingredients and finished drug products related to any potential overlap with, or duplication or conflict between, the requirements of such amendments and section 304 of the Tariff Act of 1930 (19 U.S.C. 1304). Such coordination may include the establishment of mechanisms to facilitate the sharing of relevant information between the Food and Drug Administration and U.S. Customs and Border Protection to ensure compliance with such amendments and such section 304, and joint rulemaking, if determined by such commissioners to be appropriate.

SEC. 5. CONFIDENTIALITY.

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

SEC. 6. EFFECTIVE DATE.

The amendments made by this Act shall apply to active pharmaceutical ingredients and finished drug products that are manufactured and packaged on or after the date that is 5 years after the date of enactment of this Act.