II

110TH CONGRESS
2D SESSION

S. 3633

To amend the Federal Food, Drug, and Cosmetic Act to require country of origin labeling on prescription and over-the-counter drugs.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 26 (legislative day, SEPTEMBER 17), 2008

Mr. BROWN introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require country of origin labeling on prescription and over-the-counter drugs.

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 ''Transparency in Drug Labeling Act''.

SEC. 2. COUNTRY OF ORIGIN LABELING FOR DRUGS.

(a) IN GENERAL.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:

''(aa)(1) If it is a drug subject to section 503(b)(1) in final dosage form, unless the labeling of such drug bears the following 2 separate lists:

''(A) The identity of the country of manufacture of each active ingredient of the drug, listed in descending order based on the percentage of the number of active ingredients in the final dosage form manufactured in such countries.

''(B) The identity of the country of manufacture of each inactive ingredient of the drug, listed in descending order based on the percentage of the number of inactive ingredients in the final dosage form manufactured in such countries.

''(2) If it is a nonprescription drug (as defined in section 760), unless the label of such drug bears the following 2 separate lists:

''(A) The identity of the country of manufacture of each active ingredient of the drug, listed in descending order based on the percentage of the number of active ingredients in such drug manufactured in such countries.

''(B) The identity of the country of manufacture of each inactive ingredient of the drug, listed in descending order based on the percentage of the

number of inactive ingredients in such drug manufactured in such countries.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on the date that is 180 days after the date of enactment of this Act.

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