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117TH CONGRESS
1ST SESSION

H. R. 2831

To amend the Federal Food, Drug, and Cosmetic Act to provide for the prompt approval of drugs when safety information is added to labeling, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 26, 2021

Ms. BARRAGÁN introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for the prompt approval of drugs when safety information is added to labeling, and for other purposes.

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 ''Prompt Approval of Safe Generic Drugs Act''.

SEC. 2. HEADING.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

''(z) PROMPT APPROVAL OF DRUGS WHEN SAFETY INFORMATION IS ADDED TO LABELING.—

''(1) GENERAL RULE.—A drug for which an application has been submitted or approved under subsection (b)(2) or (j) shall not be considered ineligible for approval under this section or misbranded under section 502 on the basis that the labeling of the drug omits safety information, including contraindications, warnings, precautions, dosing, administration, or other information pertaining to safety, when the omitted safety information is protected by exclusivity under clause (iii) or (iv) of subsection (c)(3)(E), clause (iii) or (iv) of subsection (j)(5)(F), or section 527(a), or by an extension of such exclusivity under section 505A or 505E.

''(2) LABELING.—Notwithstanding clauses (iii) and (iv) of subsection (c)(3)(E), clauses (iii) and (iv) of subsection (j)(5)(F), or section 527, the Secretary shall require that the labeling of a drug approved pursuant to an application submitted under subsection (b)(2) or (j) that omits safety information described in paragraph (1) include a statement of any appropriate safety information that the Secretary considers necessary to assure safe use.

"(3) AVAILABILITY AND SCOPE OF EXCLUSIVITY.—This subsection does not affect—

"(A) the availability or scope of exclusivity or an extension of exclusivity described in subparagraph (A) or (B) of section 505A(o)(3);

"(B) the question of the eligibility for approval under this section of any application described in subsection (b)(2) or (j) that omits any other aspect of labeling protected by exclusivity under—

"(i) clause (iii) or (iv) of subsection (c)(3)(E);

"(ii) clause (iii) or (iv) of subsection (j)(5)(F); or

"(iii) section 527(a); or

"(C) except as expressly provided in paragraphs (1) and (2), the operation of this section or section 527.".

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