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(Original Signature of Member)

119TH CONGRESS
1ST SESSION

H. R. _____

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

Ms. BARRAGÁN introduced the following bill; which was referred to the Committee on _____

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.

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 “Prompt Approval of
5 Safe Generic Drugs Act”.

1 **SEC. 2. PROMPT APPROVAL OF DRUGS WHEN SAFETY IN-**
2 **FORMATION IS ADDED TO LABELING.**

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

6 “(aa) PROMPT APPROVAL OF DRUGS WHEN SAFETY
7 INFORMATION IS ADDED TO LABELING.—

8 “(1) GENERAL RULE.—A drug for which an ap-
9 plication has been submitted or approved under sub-
10 section (b)(2) or (j) shall not be considered ineligible
11 for approval under this section or misbranded under
12 section 502 on the basis that the labeling of the
13 drug omits safety information, including contra-
14 indications, warnings, precautions, dosing, adminis-
15 tration, or other information pertaining to safety,
16 when the omitted safety information is protected—

17 “(A) by exclusivity under clause (iii) or (iv)
18 of subsection (c)(3)(E), clause (iii) or (iv) of
19 subsection (j)(5)(F), or section 527(a);

20 “(B) by an extension of such exclusivity
21 under section 505A or 505E; or

22 “(C) by patent.

23 “(2) LABELING.—Notwithstanding clauses (iii)
24 and (iv) of subsection (c)(3)(E), clauses (iii) and (iv)
25 of subsection (j)(5)(F), or section 527, the Secretary
26 shall require that the labeling of a drug approved

1 pursuant to an application submitted under sub-
2 section (b)(2) or (j) that omits safety information
3 described in paragraph (1) include a statement of
4 any appropriate safety information that the Sec-
5 retary considers necessary to assure safe use.

6 “(3) AVAILABILITY AND SCOPE OF EXCLU-
7 SIVITY.—This subsection does not affect—

8 “(A) the availability or scope of exclusivity
9 or an extension of exclusivity described in sub-
10 paragraph (A) or (B) of section 505A(o)(3);

11 “(B) the question of the eligibility for ap-
12 proval under this section of any application de-
13 scribed in subsection (b)(2) or (j) that omits
14 any other aspect of labeling protected by exclu-
15 sivity under—

16 “(i) clause (iii) or (iv) of subsection
17 (c)(3)(E);

18 “(ii) clause (iii) or (iv) of subsection
19 (j)(5)(F); or

20 “(iii) section 527(a); or

21 “(C) except as expressly provided in para-
22 graphs (1) and (2), the operation of this section
23 or section 527.”.