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(Original Signature of Member)

117TH CONGRESS
2D SESSION

H. R.

To amend the Federal Food, Drug, and Cosmetic Act to clarify the conditions under which the Secretary of Health and Human Services can approve generic drug applications with labeling temporarily different than the brand name drug, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. CARTER of Georgia introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to clarify the conditions under which the Secretary of Health and Human Services can approve generic drug applications with labeling temporarily different than the brand name drug, 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 “Enhanced Access to
5 Affordable Medicines Act of 2022”.

1 **SEC. 2. CLARIFYING THE CONDITIONS OF GENERIC DRUG**
2 **APPLICATION APPROVAL FOR LAST-MINUTE**
3 **BRAND NAME DRUG LABELING CHANGES.**

4 Section 505(j)(10)(A) of the Federal Food, Drug,
5 and Cosmetic Act (21 U.S.C. 355(j)(10)(A)) is amended
6 by striking clauses (i) through (iv) and inserting the fol-
7 lowing:

8 “(i) the application is otherwise eligible for ap-
9 proval under this subsection except that—

10 “(I)(aa) the listed drug has an active pat-
11 ent, the listed drug has an active exclusivity pe-
12 riod, or there is a delay in approval as de-
13 scribed in paragraph (5)(B)(iii); and

14 “(bb) a revision to the labeling of the listed
15 drug has been approved by the Secretary within
16 90 days of expiration of a patent, exclusivity
17 period, or delay in approval referenced in item
18 (aa); or

19 “(II) a revision to the labeling of the listed
20 drug has been approved by the Secretary, with-
21 in 90 days of when the application is otherwise
22 eligible for approval under this subsection;

23 “(ii) the sponsor of the application agrees to
24 submit revised labeling for the drug that is the sub-
25 ject of the application not later than 60 days after

1 approval under this subsection of the application;
2 and
3 “(iii) the labeling revision described under
4 clause (i) does not include a change to the ‘Warn-
5 ings’ section of the labeling.”.