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(Original Signature of Member)

117TH CONGRESS
2D SESSION

H. R. 6973

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.

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 ''Enhanced Access to Affordable Medicines Act of 2022''.

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

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

''(i) the application is otherwise eligible for approval under this subsection except that—

''(I)(aa) the listed drug has an active patent, the listed drug has an active exclusivity period, or there is a delay in approval as described in paragraph (5)(B)(iii); and

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

''(II) a revision to the labeling of the listed drug has been approved by the Secretary, within 90 days of when the application is otherwise eligible for approval under this subsection;

''(ii) the sponsor of the application agrees to submit revised labeling for the drug that is the subject of the application not later than 60 days after

approval under this subsection of the application; and

''(iii) the labeling revision described under clause (i) does not include a change to the 'Warnings' section of the labeling.''.