II

116TH CONGRESS
1ST SESSION

S. 3092

To amend the Federal Food, Drug, and Cosmetic Act with respect to the 180-day exclusivity period, and for other purposes.

IN THE SENATE OF THE UNITED STATES

DECEMBER 18, 2019

Ms. SMITH (for herself and Mr. BRAUN) 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 with respect to the 180-day exclusivity period, 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 ''Expanding Access to Low-Cost Generics Act of 2019''.

SEC. 2. 180-DAY EXCLUSIVITY PERIOD.

(a) IN GENERAL.—Section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)(iv)) is amended—

(1) in subclause (I), by striking ''effective on the date that is 180 days after'' and all that follows through the period at the end and inserting the following: ''effective—

''(aa) except as provided in item (bb), on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant; or

''(bb) if, in an infringement action brought in a district court solely against the applicant for the application described in this subclause (or any affiliate of the applicant), or an action in a district court for a declaratory judgment brought by that applicant, with respect to each patent to which a first applicant had submitted and lawfully maintained a certification under paragraph (2)(A)(vii)(IV), the district court decides that each patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), and the applicant for the application de-

scribed in this subclause meets the requirements under subclause (III), immediately upon the district court entering such decision for such applicant.''; and

(2) by adding at the end the following:

''(III) APPLICANT REQUIREMENTS.—The requirements under this subclause are that the applicant for the application described in subclause (I)—

''(aa) does not stay the action described in item (bb) of such subclause;

''(bb) does not agree to be bound by a judgment as to another applicant; and

''(cc) does not request joinder under section 42.122 of title 37, Code of Federal Regulations (or any corresponding similar regulation or ruling), for any petition that the applicant may have filed with respect to the application.''.

(b) APPLICABILITY.—The amendments made by subsection (a) shall apply only with respect to an application filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) after the date of enactment of this Act that identifies a listed drug for which

no certification under paragraph (2)(A)(vii)(IV) of such section was made before such date of enactment.

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