117TH CONGRESS
1ST SESSION

S. 2910

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

SEPTEMBER 30, 2021

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 2021''.

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 inserting before the period at the end the following: ''or an applicant whose application was approved pursuant to subclause (III). If an applicant described in subclause (III) is eligible for effective approval on the same day a tentatively approved first applicant who has requested final approval is determined by the Secretary to be eligible for effective approval by meeting all the approval requirements of this subsection, such applicant may not receive effective approval until 180 days after the first applicant begins commercial marketing of the drug.''; and

(2) by adding at the end the following new subclause:

''(III) APPLICANT APPROVAL.—The Secretary may approve an application containing a certification described in paragraph (2)(A)(vii)(IV) that is for a drug for which a first applicant has submitted an application containing such a certification, notwithstanding the eligibility of a first applicant for the 180-day exclusivity period described in subclause (II)(aa), if each of the following conditions is met:

''(aa) The approval of such application could be made effective, but for the eligibility of a first applicant for 180-day exclusivity under this clause.

''(bb) At least 30 months have passed since the date of submission of an application for the drug by at least one first applicant.

''(cc) Approval of an application for the drug submitted by at least one first applicant is not precluded under clause (iii).

''(dd) No application for the drug submitted by any first applicant is effectively approved on the date that the conditions under items (aa), (bb), and (cc) are all met, regardless of whether such application is subsequently approved.''.

(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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