AMENDMENT NO._____ Calendar No._____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—118th Cong., 1st Sess.

S. 1114

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

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended to be proposed by _____

Viz:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Expanding Access to Low-Cost Generics Act of 2023''.

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)—

(A) by inserting ''and subclause (III)'' after ''subparagraph (D)''; and

(B) 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 described in subclause (III) shall 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) The applicant of such application has submitted a certification to its abbreviated new drug application that there are no conditions that would prevent the applicant from commercial marketing within 75 days after the date of approval and that the applicant intends to so market the drug.

"(cc) At least 33 months have passed since the date of submission of an application for the drug by at least one first applicant.

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

"(ee) No application for the drug submitted by any first applicant is effectively approved on the date that the conditions under items (aa), (bb), (cc), and (dd) are all met and maintained.".

(b) SPECIAL APPROVAL STATUS RULE FOR CERTAIN SUBSEQUENT APPLICANTS.—Section 505(j)(5)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355 (j)(5)(D)) is amended at the end by adding the following:

"(v) SPECIAL APPROVAL STATUS RULE FOR CERTAIN SUBSEQUENT APPLICANTS.—An application that is approved pursuant to subclause (III) of subparagraph (B)(iv) is deemed to be tentatively approved and to no longer have an effective approval pursuant to such subclause (III) on the date that is 76 days after the date on which the approval has been made effective pursuant to such subclause (III) if the applicant fails to commercially market such drug within the 75-day period after the date on which the approval is made effective. If the applicant of an application approved pursuant to such subclause (III) submits a notification that it can no longer commence commercial marketing within 75 days after the date of approval, as required under subparagraph (B)(iv)(III)(bb), its application is deemed to be tentatively approved and to no longer be effectively approved on the date that such a notification is received. If an applicant does not com-

mence commercial marketing within the 75-day period, it shall not be eligible for a subsequent effective approval for the application under subclause (III) of subparagraph (B)(iv) unless, in addition to meeting each of the conditions in such subclause (III), it submits a certification to its abbreviated new drug application that an event that could not have been reasonably foreseen by the applicant prevented it from commencing commercial marketing and that it has fully resolved this issue. The applicant shall submit notification to the abbreviated new drug application confirming that such applicant has commenced commercial marketing of the drug not later than one business day after commencing such marketing.''.

(c) APPLICABILITY.—The amendments made by subsections (a) and (b) 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 505(j) was made before such date of enactment.