Calendar No. 108

118TH CONGRESS
1ST SESSION

S. 1114

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

IN THE SENATE OF THE UNITED STATES

MARCH 30, 2023

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

JUNE 22, 2023

Reported by Mr. SANDERS, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

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

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 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) 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) The applicant of such application has submitted a certification to the 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 ap-

proval, 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 commence 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.~~

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 commence 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 ap-

plicant 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.

SEC. 3. INCREASING TRANSPARENCY IN GENERIC DRUG APPLICATIONS.

(a) IN GENERAL.—Section 505(j)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(3)) is amended by adding at the end the following:

"(H)(i) Upon request (in controlled correspondence or an analogous process) by a person that has submitted or intends to submit an abbreviated application under this subsection for a drug that is required by regulation to contain one or more of the same inactive ingredients in the same concentration as the listed drug referred to, or for which the Secretary determines there is a scientific jus-

tification for an approach that is in vitro, in whole or in part, to be used to demonstrate bioequivalence for a drug if such a drug contains one or more of the same inactive ingredients in the same concentration as the listed drug referred to, or on the Secretary's own initiative during the review of an application under this subsection for such a drug, the Secretary shall inform the person whether such drug is qualitatively and quantitatively the same as the listed drug.

"(ii) Notwithstanding section 301(j), if the Secretary determines that such drug is not qualitatively or quantitatively the same as the listed drug, the Secretary shall identify and disclose to the person—

"(I) the ingredient or ingredients that cause the drug not to be qualitatively or quantitatively the same as the listed drug; and

"(II) for any ingredient for which there is an identified quantitative deviation, the amount of such deviation.

"(iii) If the Secretary determines that such drug is qualitatively and quantitatively the same as the listed drug, the Secretary shall not change or rescind such determination after the submission of an abbreviated application for such drug under this subsection unless—

"(I) the formulation of the listed drug has been changed and the Secretary has determined that the prior listed drug formulation was withdrawn for reasons of safety or effectiveness; or

"(II) the Secretary makes a written determination that the prior determination must be changed because an error has been identified.

"(iv) If the Secretary makes a written determination described in clause (iii)(II), the Secretary shall provide notice and a copy of the written determination to the person making the request under clause (i).

"(v) Except as set forth in clauses (i) and (ii), nothing in this subparagraph shall be construed to authorize the disclosure of nonpublic qualitative or quantitative information about the ingredients in a listed drug, or to affect the status, if any, of such information as trade secret or confidential commercial information for purposes of section 301(j) of this Act, section 552 of title 5, United States Code, or section 1905 of title 18, United States Code.".

(b) GUIDANCE.—

(1) IN GENERAL.—Not later than one year after the date of enactment of this Act, the Secretary of Health and Human Services shall issue draft guidance, or update guidance, describing how the Secretary will determine whether a drug is qualitatively

and quantitatively the same as the listed drug (as such terms are used in section 505(j)(3)(H) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a)), including with respect to assessing pH adjusters.

(2) PROCESS.—In issuing guidance under this subsection, the Secretary of Health and Human Services shall—

(A) publish draft guidance;

(B) provide a period of at least 60 days for comment on the draft guidance; and

(C) after considering any comments received and not later than one year after the close of the comment period on the draft guidance, publish final guidance.

(c) APPLICABILITY.—Section 505(j)(3)(H) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), applies beginning on the date of enactment of this Act, irrespective of the date on which the guidance required by subsection (b) is finalized.

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