

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “~~Expanding Access to~~
5 ~~Low-Cost Generics Act of 2023~~”.

1 **SEC. 2. 180-DAY EXCLUSIVITY PERIOD.**

2 (a) IN GENERAL.—Section 505(j)(5)(B)(iv) of the
3 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
4 355(j)(5)(B)(iv)) is amended—

5 (1) in subclause (I)—

6 (A) by inserting “and subclause (III)”
7 after “subparagraph (D)”; and

8 (B) by inserting before the period at the
9 end the following: “or an applicant whose appli-
10 cation was approved pursuant to subclause
11 (III). If an applicant described in subclause
12 (III) is eligible for effective approval on the
13 same day a tentatively approved first applicant
14 who has requested final approval is determined
15 by the Secretary to be eligible for effective ap-
16 proval by meeting all the approval requirements
17 of this subsection, such applicant described in
18 subclause (III) may not receive effective ap-
19 proval until 180 days after the first applicant
20 begins commercial marketing of the drug.”; and

21 (2) by adding at the end the following new sub-
22 clause:

23 “(III) APPLICANT APPROVAL.—The Sec-
24 retary may approve an application containing a
25 certification described in paragraph
26 (2)(A)(vii)(IV) that is for a drug for which a

1 first applicant has submitted an application
2 containing such a certification, notwithstanding
3 the eligibility of a first applicant for the 180-
4 day exclusivity period described in subclause
5 (II)(aa), if each of the following conditions is
6 met:

7 “(aa) The approval of such applica-
8 tion could be made effective, but for the
9 eligibility of a first applicant for 180-day
10 exclusivity under this clause.

11 “(bb) The applicant of such applica-
12 tion has submitted a certification to the
13 abbreviated new drug application that
14 there are no conditions that would prevent
15 the applicant from commercial marketing
16 within 75 days after the date of approval
17 and that the applicant intends to so mar-
18 ket the drug.

19 “(cc) At least 33 months have passed
20 since the date of submission of an applica-
21 tion for the drug by at least one first ap-
22 plicant.

23 “(dd) Approval of an application for
24 the drug submitted by at least one first ap-
25 plicant is not precluded under clause (iii).

1 “(cc) No application for the drug sub-
2 mitted by any first applicant is effectively
3 approved on the date that the conditions
4 under items (aa), (bb), (cc), and (dd) are
5 all met and maintained.”.

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

10 “(v) SPECIAL APPROVAL STATUS RULE
11 FOR CERTAIN SUBSEQUENT APPLICANTS.—An
12 application that is approved pursuant to sub-
13 clause (III) of subparagraph (B)(iv) is deemed
14 to be tentatively approved and to no longer
15 have an effective approval pursuant to such
16 subclause (III) on the date that is 76 days after
17 the date on which the approval has been made
18 effective pursuant to such subclause (III) if the
19 applicant fails to commercially market such
20 drug within the 75-day period after the date on
21 which the approval is made effective. If the ap-
22 plicant of an application approved pursuant to
23 such subclause (III) submits a notification that
24 it can no longer commence commercial mar-
25 keting within 75 days after the date of ap-

1 proval, as required under subparagraph
2 (B)(iv)(III)(bb), its application is deemed to be
3 tentatively approved and to no longer be effec-
4 tively approved on the date that such a notifica-
5 tion is received. If an applicant does not com-
6 mence commercial marketing within the 75-day
7 period, it shall not be eligible for a subsequent
8 effective approval for the application under sub-
9 clause (III) of subparagraph (B)(iv) unless, in
10 addition to meeting each of the conditions in
11 such subelause (III), it submits a certification
12 to its abbreviated new drug application that an
13 event that could not have been reasonably fore-
14 seen by the applicant prevented it from com-
15 mencing commercial marketing and that it has
16 fully resolved this issue. The applicant shall
17 submit notification to the abbreviated new drug
18 application confirming that such applicant has
19 commenced commercial marketing of the drug
20 not later than one business day after com-
21 mencing such marketing.”.

22 (c) **APPLICABILITY.**—The amendments made by sub-
23 sections (a) and (b) shall apply only with respect to an
24 application filed under section 505(j) of the Federal Food,
25 Drug, and Cosmetic Act (21 U.S.C. 355(j)) after the date

1 of enactment of this Act that identifies a listed drug for
 2 which no certification under paragraph (2)(A)(vii)(IV) of
 3 such section 505(j) was made before such date of enact-
 4 ment.

5 **SECTION 1. SHORT TITLE.**

6 *This Act may be cited as the “Expanding Access to*
 7 *Low-Cost Generics Act of 2023”.*

8 **SEC. 2. 180-DAY EXCLUSIVITY PERIOD.**

9 *(a) IN GENERAL.—Section 505(j)(5)(B)(iv) of the Fed-*
 10 *eral Food, Drug, and Cosmetic Act (21 U.S.C.*
 11 *355(j)(5)(B)(iv)) is amended—*

12 *(1) in subclause (I)—*

13 *(A) by inserting “and subclause (III)” after*
 14 *“subparagraph (D)”;* and

15 *(B) by inserting before the period at the end*
 16 *the following: “or an applicant whose applica-*
 17 *tion was approved pursuant to subclause (III).*
 18 *If an applicant described in subclause (III) is el-*
 19 *igible for effective approval on the same day a*
 20 *tentatively approved first applicant who has re-*
 21 *quested final approval is determined by the Sec-*
 22 *retary to be eligible for effective approval by*
 23 *meeting all the approval requirements of this*
 24 *subsection, such applicant described in subclause*
 25 *(III) shall not receive effective approval until*

1 180 days after the first applicant begins com-
2 mercial marketing of the drug.”; and

3 (2) by adding at the end the following new sub-
4 clause:

5 “(III) *APPLICANT APPROVAL.*—The Sec-
6 retary may approve an application containing a
7 certification described in paragraph
8 (2)(A)(vii)(IV) that is for a drug for which a
9 first applicant has submitted an application
10 containing such a certification, notwithstanding
11 the eligibility of a first applicant for the 180-day
12 exclusivity period described in subclause
13 (II)(aa), if each of the following conditions is
14 met:

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

19 “(bb) The applicant of such application has
20 submitted a certification to its abbreviated new
21 drug application that there are no conditions
22 that would prevent the applicant from commer-
23 cial marketing within 75 days after the date of
24 approval and that the applicant intends to so
25 market the drug.

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

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

7 “(ee) *No application for the drug submitted*
 8 *by any first applicant is effectively approved on*
 9 *the date that the conditions under items (aa),*
 10 *(bb), (cc), and (dd) are all met and main-*
 11 *tained.”.*

12 **(b) SPECIAL APPROVAL STATUS RULE FOR CERTAIN**
 13 **SUBSEQUENT APPLICANTS.—***Section 505(j)(5)(D) of the*
 14 *Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
 15 *355(j)(5)(D)) is amended at the end by adding the fol-*
 16 *lowing:*

17 “(v) **SPECIAL APPROVAL STATUS RULE**
 18 **FOR CERTAIN SUBSEQUENT APPLICANTS.—**
 19 *An application that is approved pursuant*
 20 *to subclause (III) of subparagraph (B)(iv)*
 21 *is deemed to be tentatively approved and to*
 22 *no longer have an effective approval pursu-*
 23 *ant to such subclause (III) on the date that*
 24 *is 76 days after the date on which the ap-*
 25 *proval has been made effective pursuant to*

1 *such subclause (III) if the applicant fails to*
2 *commercially market such drug within the*
3 *75-day period after the date on which the*
4 *approval is made effective. If the applicant*
5 *of an application approved pursuant to*
6 *such subclause (III) submits a notification*
7 *that it can no longer commence commercial*
8 *marketing within 75 days after the date of*
9 *approval, as required under subparagraph*
10 *(B)(iv)(III)(bb), its application is deemed*
11 *to be tentatively approved and to no longer*
12 *be effectively approved on the date that such*
13 *a notification is received. If an applicant*
14 *does not commence commercial marketing*
15 *within the 75-day period, it shall not be eli-*
16 *gible for a subsequent effective approval for*
17 *the application under subclause (III) of sub-*
18 *paragraph (B)(iv) unless, in addition to*
19 *meeting each of the conditions in such sub-*
20 *clause (III), it submits a certification to its*
21 *abbreviated new drug application that an*
22 *event that could not have been reasonably*
23 *foreseen by the applicant prevented it from*
24 *commencing commercial marketing and*
25 *that it has fully resolved this issue. The ap-*

1 *plicant shall submit notification to the ab-*
2 *breivated new drug application confirming*
3 *that such applicant has commenced com-*
4 *mercial marketing of the drug not later*
5 *than one business day after commencing*
6 *such marketing.”.*

7 *(c) APPLICABILITY.—The amendments made by sub-*
8 *sections (a) and (b) shall apply only with respect to an*
9 *application filed under section 505(j) of the Federal Food,*
10 *Drug, and Cosmetic Act (21 U.S.C. 355(j)) after the date*
11 *of enactment of this Act that identifies a listed drug for*
12 *which no certification under paragraph (2)(A)(vii)(IV) of*
13 *such section 505(j) was made before such date of enactment.*

14 **SEC. 3. INCREASING TRANSPARENCY IN GENERIC DRUG AP-**
15 **PLICATIONS.**

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

19 *“(H)(i) Upon request (in controlled correspondence or*
20 *an analogous process) by a person that has submitted or*
21 *intends to submit an abbreviated application under this*
22 *subsection for a drug that is required by regulation to con-*
23 *tain one or more of the same inactive ingredients in the*
24 *same concentration as the listed drug referred to, or for*
25 *which the Secretary determines there is a scientific jus-*

1 *tification for an approach that is in vitro, in whole or in*
2 *part, to be used to demonstrate bioequivalence for a drug*
3 *if such a drug contains one or more of the same inactive*
4 *ingredients in the same concentration as the listed drug re-*
5 *ferred to, or on the Secretary's own initiative during the*
6 *review of an application under this subsection for such a*
7 *drug, the Secretary shall inform the person whether such*
8 *drug is qualitatively and quantitatively the same as the*
9 *listed drug.*

10 “(ii) Notwithstanding section 301(j), if the Secretary
11 determines that such drug is not qualitatively or quan-
12 titatively the same as the listed drug, the Secretary shall
13 identify and disclose to the person—

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

17 “(II) for any ingredient for which there is an
18 identified quantitative deviation, the amount of such
19 deviation.

20 “(iii) If the Secretary determines that such drug is
21 qualitatively and quantitatively the same as the listed drug,
22 the Secretary shall not change or rescind such determina-
23 tion after the submission of an abbreviated application for
24 such drug under this subsection unless—

1 “(I) the formulation of the listed drug has been
2 changed and the Secretary has determined that the
3 prior listed drug formulation was withdrawn for rea-
4 sons of safety or effectiveness; or

5 “(II) the Secretary makes a written determina-
6 tion that the prior determination must be changed be-
7 cause an error has been identified.

8 “(iv) If the Secretary makes a written determination
9 described in clause (iii)(II), the Secretary shall provide no-
10 tice and a copy of the written determination to the person
11 making the request under clause (i).

12 “(v) Except as set forth in clauses (i) and (ii), nothing
13 in this subparagraph shall be construed to authorize the dis-
14 closure of nonpublic qualitative or quantitative information
15 about the ingredients in a listed drug, or to affect the status,
16 if any, of such information as trade secret or confidential
17 commercial information for purposes of section 301(j) of
18 this Act, section 552 of title 5, United States Code, or sec-
19 tion 1905 of title 18, United States Code.”.

20 (b) GUIDANCE.—

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

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

6 (2) *PROCESS.—In issuing guidance under this*
7 *subsection, the Secretary of Health and Human Serv-*
8 *ices shall—*

9 (A) *publish draft guidance;*

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

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

16 (c) *APPLICABILITY.—Section 505(j)(3)(H) of the Fed-*
17 *eral Food, Drug, and Cosmetic Act, as added by subsection*
18 *(a), applies beginning on the date of enactment of this Act,*
19 *irrespective of the date on which the guidance required by*
20 *subsection (b) is finalized.*

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118TH CONGRESS
1ST Session

S. 1114

A BILL

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

JUNE 22, 2023

Reported with an amendment