

Calendar No. 107

118TH CONGRESS
1ST SESSION**S. 1067**

To amend the Federal Food, Drug, and Cosmetic Act with respect to citizen petitions.

 IN THE SENATE OF THE UNITED STATES

MARCH 29, 2023

Mrs. SHAHEEN (for herself, Ms. COLLINS, Mr. BENNET, Mr. RUBIO, Ms. BALDWIN, 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 citizen petitions.

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 “~~Ensuring Timely Ac-~~
5 ~~cess to Generics Act of 2023~~”.

1 **SEC. 2. ENSURING TIMELY ACCESS TO GENERICS.**

2 Section 505(q) of the Federal Food, Drug, and Cos-
3 metic Act (21 U.S.C. 355(q)) is amended—

4 (1) in paragraph (1)—

5 (A) in subparagraph (A)(i), by inserting “,
6 10.31,” after “10.30”;

7 (B) in subparagraph (E)—

8 (i) by striking “application and” and
9 inserting “application or”;

10 (ii) by striking “If the Secretary” and
11 inserting the following:

12 “(i) IN GENERAL.—If the Secretary”;

13 (iii) by striking the second sentence
14 and inserting the following:

15 “(ii) PRIMARY PURPOSE OF DELAY-
16 ING.—

17 “(I) IN GENERAL.—In deter-
18 mining whether a petition was sub-
19 mitted with the primary purpose of
20 delaying an application, the Secretary
21 may consider the following factors:

22 “(aa) Whether the petition
23 was submitted in accordance with
24 paragraph (2)(B), based on when
25 the petitioner knew or reasonably
26 should have known the relevant

1 information relied upon to form
2 the basis of such petition.

3 “(bb) Whether the petitioner
4 has submitted multiple or serial
5 petitions or supplements to peti-
6 tions raising issues that reason-
7 ably could have been known to
8 the petitioner at the time of sub-
9 mission of the earlier petition or
10 petitions.

11 “(cc) Whether the petition
12 was submitted close in time to a
13 known, first date upon which an
14 application under subsection
15 (b)(2) or (j) of this section or
16 section 351(k) of the Public
17 Health Service Act could be ap-
18 proved.

19 “(dd) Whether the petition
20 was submitted without relevant
21 data or information in support of
22 the scientific positions forming
23 the basis of such petition.

24 “(ee) Whether the petition
25 raises the same or substantially

1 similar issues as a prior petition
2 to which the Secretary has re-
3 sponded substantively already, in-
4 cluding if the subsequent submis-
5 sion follows such response from
6 the Secretary closely in time.

7 “(ff) Whether the petition
8 requests changing the applicable
9 standards that other applicants
10 are required to meet, including
11 requesting testing, data, or label-
12 ing standards that are more on-
13 erous or rigorous than the stand-
14 ards the Secretary has deter-
15 mined to be applicable to the list-
16 ed drug, reference product, or pe-
17 titioner’s version of the same
18 drug.

19 “(gg) The petitioner’s record
20 of submitting petitions to the
21 Food and Drug Administration
22 that have been determined by the
23 Secretary to have been submitted
24 with the primary purpose of
25 delay.

1 “(hh) Other relevant and
2 appropriate factors, which the
3 Secretary shall describe in guid-
4 ance.

5 “(II) GUIDANCE.—The Secretary
6 may issue or update guidance, as ap-
7 propriate, to describe factors the Sec-
8 retary considers in accordance with
9 subclause (I).”;

10 (iv) by adding at the end the fol-
11 lowing:

12 “(iii) REFERRAL TO THE FEDERAL
13 TRADE COMMISSION.—The Secretary shall
14 establish procedures for referring to the
15 Federal Trade Commission any petition or
16 supplement to a petition that the Secretary
17 determines was submitted with the primary
18 purpose of delaying approval of an applica-
19 tion. Such procedures shall include notifi-
20 cation to the petitioner by the Secretary.”;

21 (C) by striking subparagraph (F);

22 (D) by redesignating subparagraphs (G)
23 through (I) as subparagraphs (F) through (H),
24 respectively; and

1 ~~(E)~~ in subparagraph ~~(H)~~, as so redesignated, by striking “submission of this petition”
2 and inserting “submission of this document”;
3 ~~(2)~~ in paragraph ~~(2)~~—

4 (A) by redesignating subparagraphs (A)
5 through (C) as subparagraphs (C) through (E),
6 respectively;

7 (B) by inserting before subparagraph (C),
8 as so redesignated, the following:

9 “(A) IN GENERAL.—A person shall submit
10 a petition to the Secretary under paragraph (1)
11 before filing a civil action in which the person
12 seeks to set aside, delay, rescind, withdraw, or
13 prevent submission, review, or approval of an
14 application submitted under subsection (b)(2)
15 or (j) of this section or section 351(k) of the
16 Public Health Service Act. Such petition and
17 any supplement to such a petition shall describe
18 all information and arguments that form the
19 basis of the relief requested in any civil action
20 described in the previous sentence.

21 “(B) TIMELY SUBMISSION OF CITIZEN PE-
22 TITION.—A petition and any supplement to a
23 petition shall be submitted within 60 days after
24 the person knew, or reasonably should have
25

1 known, the information that forms the basis of
 2 the request made in the petition or supple-
 3 ment.”;

4 (C) in subparagraph (C), as so redesign-
 5 nated—

6 (i) in the heading, by striking “WITH-
 7 IN 150 DAYS”;

8 (ii) in clause (i), by striking “during
 9 the 150-day period referred to in para-
 10 graph (1)(F),”;

11 (iii) by amending clause (ii) to read as
 12 follows:

13 “(ii) on or after the date that is 151
 14 days after the date of submission of the
 15 petition, the Secretary approves or has ap-
 16 proved the application that is the subject
 17 of the petition without having made such a
 18 final decision.”;

19 (D) by amending subparagraph (D), as so
 20 redesignated, to read as follows:

21 “(D) DISMISSAL OF CERTAIN CIVIL AC-
 22 TIONS.—

23 “(i) PETITION.—If a person files a
 24 civil action against the Secretary in which
 25 a person seeks to set aside, delay, rescind,

1 withdraw, or prevent submission, review, or
2 approval of an application submitted under
3 subsection (b)(2) or (j) of this section or
4 section 351(k) of the Public Health Service
5 Act without complying with the require-
6 ments of subparagraph (A), the court shall
7 dismiss without prejudice the action for
8 failure to exhaust administrative remedies.

9 “(ii) TIMELINESS.—If a person files a
10 civil action against the Secretary in which
11 a person seeks to set aside, delay, rescind,
12 withdraw, or prevent submission, review, or
13 approval of an application submitted under
14 subsection (b)(2) or (j) of this section or
15 section 351(k) of the Public Health Service
16 Act without complying with the require-
17 ments of subparagraph (B), the court shall
18 dismiss with prejudice the action for fail-
19 ure to timely file a petition.

20 “(iii) FINAL RESPONSE.—If a civil ac-
21 tion is filed against the Secretary with re-
22 spect to any issue raised in a petition time-
23 ly filed under paragraph (1) in which the
24 petitioner requests that the Secretary take
25 any form of action that could, if taken, set

1 aside, delay, rescind, withdraw, or prevent
 2 submission, review, or approval of an appli-
 3 cation submitted under subsection (b)(2)
 4 or (j) of this section or section 351(k) of
 5 the Public Health Service Act before the
 6 Secretary has taken final agency action on
 7 the petition within the meaning of sub-
 8 paragraph (C), the court shall dismiss
 9 without prejudice the action for failure to
 10 exhaust administrative remedies.”; and

11 (E) in clause (iii) of subparagraph (E), as
 12 so redesignated, by striking “as defined under
 13 subparagraph (2)(A)” and inserting “within the
 14 meaning of subparagraph (C)”;

15 (3) in paragraph (4)—

16 (A) by striking “EXCEPTIONS” in the
 17 paragraph heading and all that follows through
 18 “~~This subsection does~~” and inserting “EXCEP-
 19 TIONS.—This subsection does”;

20 (B) by striking subparagraph (B); and

21 (C) by redesignating clauses (i) and (ii) as
 22 subparagraphs (A) and (B), respectively, and
 23 adjusting the margins accordingly.

1 **SECTION 1. SHORT TITLE.**

2 *This Act may be cited as the “Ensuring Timely Access*
 3 *to Generics Act of 2023”.*

4 **SEC. 2. ENSURING TIMELY ACCESS TO GENERICS.**

5 *Section 505(q) of the Federal Food, Drug, and Cos-*
 6 *metic Act (21 U.S.C. 355(q)) is amended—*

7 *(1) in paragraph (1)—*

8 *(A) in subparagraph (A)(i), by inserting “,*
 9 *10.31,” after “10.30”;*

10 *(B) in subparagraph (E)—*

11 *(i) by striking “application and” and*
 12 *inserting “application or”;*

13 *(ii) by striking “If the Secretary” and*
 14 *inserting the following:*

15 *“(i) IN GENERAL.—If the Secretary”;*

16 *and*

17 *(iii) by striking the second sentence*
 18 *and inserting the following:*

19 *“(ii) PRIMARY PURPOSE OF DELAY-*
 20 *ING.—*

21 *“(I) IN GENERAL.—In deter-*
 22 *mining whether a petition was sub-*
 23 *mitted with the primary purpose of de-*
 24 *laying an application, the Secretary*
 25 *may consider the following factors:*

1 “(aa) Whether the petition
2 was submitted in accordance with
3 paragraph (2)(B), based on when
4 the petitioner knew the relevant
5 information relied upon to form
6 the basis of such petition.

7 “(bb) When the petition was
8 submitted in relation to when the
9 petitioner reasonably should have
10 known the relevant information
11 relied upon to form the basis of
12 such petition.

13 “(cc) Whether the petitioner
14 has submitted multiple or serial
15 petitions or supplements to peti-
16 tions raising issues that reason-
17 ably could have been known to the
18 petitioner at the time of submis-
19 sion of the earlier petition or peti-
20 tions.

21 “(dd) Whether the petition
22 was submitted close in time to a
23 known, first date upon which an
24 application under subsection
25 (b)(2) or (j) of this section or sec-

1 *tion 351(k) of the Public Health*
2 *Service Act could be approved.*

3 *“(ee) Whether the petition*
4 *was submitted without relevant*
5 *data or information in support of*
6 *the scientific positions forming the*
7 *basis of such petition.*

8 *“(ff) Whether the petition*
9 *raises the same or substantially*
10 *similar issues as a prior petition*
11 *to which the Secretary has re-*
12 *sponded substantively already, in-*
13 *cluding if the subsequent submis-*
14 *sion follows such response from*
15 *the Secretary closely in time.*

16 *“(gg) Whether the petition*
17 *requests changing the applicable*
18 *standards that other applicants*
19 *are required to meet, including re-*
20 *questing testing, data, or labeling*
21 *standards that are more onerous*
22 *or rigorous than the standards the*
23 *Secretary has determined to be*
24 *applicable to the listed drug, ref-*

1 *erence product, or petitioner’s*
2 *version of the same drug.*

3 *“(hh) The petitioner’s record*
4 *of submitting petitions to the*
5 *Food and Drug Administration*
6 *that have been determined by the*
7 *Secretary to have been submitted*
8 *with the primary purpose of*
9 *delay.*

10 *“(ii) Other relevant and ap-*
11 *propriate factors, which the Sec-*
12 *retary shall describe in guidance.*

13 *“(II) GUIDANCE.—The Secretary*
14 *may issue or update guidance, as ap-*
15 *propriate, to describe factors the Sec-*
16 *retary considers in accordance with*
17 *subclause (I).”;*

18 *(C) by striking subparagraph (F);*

19 *(D) by redesignating subparagraphs (G)*
20 *through (I) as subparagraphs (F) through (H),*
21 *respectively; and*

22 *(E) in subparagraph (H), as so redesign-*
23 *ated, by striking “submission of this petition”*
24 *and inserting “submission of this document”;*

25 *(2) in paragraph (2)—*

1 (A) by redesignating subparagraphs (A)
2 through (C) as subparagraphs (C) through (E),
3 respectively;

4 (B) by inserting before subparagraph (C),
5 as so redesignated, the following:

6 “(A) *IN GENERAL.*—A person shall submit a
7 petition to the Secretary under paragraph (1)
8 before filing a civil action in which the person
9 seeks to set aside, delay, rescind, withdraw, or
10 prevent submission, review, or approval of an
11 application submitted under subsection (b)(2) or
12 (j) of this section or section 351(k) of the Public
13 Health Service Act. Such petition and any sup-
14 plement to such a petition shall describe all in-
15 formation and arguments that form the basis of
16 the relief requested in any civil action described
17 in the previous sentence.

18 “(B) *TIMELY SUBMISSION OF CITIZEN PETI-*
19 *TION.*—A petition and any supplement to a peti-
20 tion shall be submitted within 180 days after the
21 person knew the information that forms the basis
22 of the request made in the petition or supple-
23 ment.”;

24 (C) in subparagraph (C), as so redesign-
25 ated—

1 (i) in the heading, by striking “WITHIN
2 150 DAYS”;

3 (ii) in clause (i), by striking “during
4 the 150-day period referred to in paragraph
5 (1)(F),”; and

6 (iii) by amending clause (ii) to read as
7 follows:

8 “(ii) on or after the date that is 151
9 days after the date of submission of the peti-
10 tion, the Secretary approves or has ap-
11 proved the application that is the subject of
12 the petition without having made such a
13 final decision.”;

14 (D) by amending subparagraph (D), as so
15 redesignated, to read as follows:

16 “(D) DISMISSAL OF CERTAIN CIVIL AC-
17 TIONS.—

18 “(i) PETITION.—If a person files a
19 civil action against the Secretary in which
20 a person seeks to set aside, delay, rescind,
21 withdraw, or prevent submission, review, or
22 approval of an application submitted under
23 subsection (b)(2) or (j) of this section or sec-
24 tion 351(k) of the Public Health Service Act
25 without complying with the requirements of

1 *subparagraph (A), the court shall dismiss*
2 *without prejudice the action for failure to*
3 *exhaust administrative remedies.*

4 “(ii) *TIMELINESS.*—*If a person files a*
5 *civil action against the Secretary in which*
6 *a person seeks to set aside, delay, rescind,*
7 *withdraw, or prevent submission, review, or*
8 *approval of an application submitted under*
9 *subsection (b)(2) or (j) of this section or sec-*
10 *tion 351(k) of the Public Health Service Act*
11 *without complying with the requirements of*
12 *subparagraph (B), the court shall dismiss*
13 *with prejudice the action for failure to time-*
14 *ly file a petition.*

15 “(iii) *FINAL RESPONSE.*—*If a civil ac-*
16 *tion is filed against the Secretary with re-*
17 *spect to any issue raised in a petition time-*
18 *ly filed under paragraph (1) in which the*
19 *petitioner requests that the Secretary take*
20 *any form of action that could, if taken, set*
21 *aside, delay, rescind, withdraw, or prevent*
22 *submission, review, or approval of an appli-*
23 *cation submitted under subsection (b)(2) or*
24 *(j) of this section or section 351(k) of the*
25 *Public Health Service Act before the Sec-*

1 *retary has taken final agency action on the*
2 *petition within the meaning of subpara-*
3 *graph (C), the court shall dismiss without*
4 *prejudice the action for failure to exhaust*
5 *administrative remedies.”; and*

6 *(E) in clause (iii) of subparagraph (E), as*
7 *so redesignated, by striking “as defined under*
8 *subparagraph (2)(A)” and inserting “within the*
9 *meaning of subparagraph (C)”;* and

10 *(3) in paragraph (4)—*

11 *(A) by striking “EXCEPTIONS” in the para-*
12 *graph heading and all that follows through “This*
13 *subsection does” and inserting “EXCEPTIONS.—*
14 *This subsection does”;*

15 *(B) by striking subparagraph (B); and*

16 *(C) by redesignating clauses (i) and (ii) as*
17 *subparagraphs (A) and (B), respectively, and*
18 *adjusting the margins accordingly.*

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A BILL

To amend the Federal Food, Drug, and Cosmetic
Act with respect to citizen petitions.

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