

117TH CONGRESS
1ST SESSION

S. 562

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

IN THE SENATE OF THE UNITED STATES

MARCH 3, 2021

Mrs. SHAHEEN (for herself, Mr. CASSIDY, Mr. BENNET, and Mr. RUBIO) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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 2021”.

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

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

9 (1) in paragraph (1)—

1 (A) in subparagraph (A)(i), by inserting “,
2 10.31,” after “10.30”;

3 (B) in subparagraph (E)—

4 (i) by striking “application and” and
5 inserting “application or”;

6 (ii) by striking “If the Secretary” and
7 inserting the following:

8 “(i) IN GENERAL.—If the Secretary”;
9 and

10 (iii) by striking the second sentence
11 and inserting the following:

12 “(ii) PRIMARY PURPOSE OF DELAY-
13 ING.—

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

19 “(aa) Whether the petition
20 was submitted in accordance with
21 paragraph (2)(B), based on when
22 the petitioner knew or reasonably
23 should have known the relevant
24 information relied upon to form
25 the basis of such petition.

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

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

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

22 “(ee) Whether the petition
23 raises the same or substantially
24 similar issues as a prior petition
25 to which the Secretary has re-

sponded substantively already, including if the subsequent submission follows such response from the Secretary closely in time.

“(ff) Whether the petition requests changing the applicable standards that other applicants are required to meet, including requesting testing, data, or labeling standards that are more onerous or rigorous than the standards the Secretary has determined to be applicable to the listed drug, reference product, or petitioner’s version of the same drug.

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

“(hh) Other relevant and appropriate factors, which the

1 Secretary shall describe in guid-
2 ance.

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

8 (C) by adding at the end the following:

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

18 (D) by striking subparagraph (F);

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

22 (F) in subparagraph (H), as so redesign-
23 nated, 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
7 a 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)
12 or (j) of this section or section 351(k) of the
13 Public Health Service Act. Such petition and
14 any supplement to such a petition shall describe
15 all information and arguments that form the
16 basis of the relief requested in any civil action
17 described in the previous sentence.

18 “(B) TIMELY SUBMISSION OF CITIZEN PE-
19 TITION.—A petition and any supplement to a
20 petition shall be submitted within 60 days after
21 the person knew, or reasonably should have
22 known, the information that forms the basis of
23 the request made in the petition or supple-
24 ment.”;

1 (C) in subparagraph (C), as so redesignated—
 2 nated—

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

5 (ii) in clause (i), by striking “during
 6 the 150-day period referred to in para-
 7 graph (1)(F),”; and

8 (iii) by amending clause (ii) to read as
 9 follows:

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

16 (D) by amending subparagraph (D), as so
 17 redesignated, to read as follows:

18 “(D) DISMISSAL OF CERTAIN CIVIL AC-
 19 TIONS.—

20 “(i) PETITION.—If a person files a
 21 civil action against the Secretary in which
 22 a person seeks to set aside, delay, rescind,
 23 withdraw, or prevent submission, review, or
 24 approval of an application submitted under
 25 subsection (b)(2) or (j) of this section or

1 section 351(k) of the Public Health Service
2 Act without complying with the require-
3 ments of subparagraph (A), the court shall
4 dismiss without prejudice the action for
5 failure to exhaust administrative remedies.

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

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

1 or (j) of this section or section 351(k) of
 2 the Public Health Service Act before the
 3 Secretary has taken final agency action on
 4 the petition within the meaning of sub-
 5 paragraph (C), the court shall dismiss
 6 without prejudice the action for failure to
 7 exhaust administrative remedies.”; and

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

12 (3) in paragraph (4)—

13 (A) by striking “EXCEPTIONS” and all that
 14 follows through “This subsection does” and in-
 15 serting “EXCEPTIONS.—This subsection does”;

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

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

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