117TH CONGRESS
1ST SESSION

S. ____

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

IN THE SENATE OF THE UNITED STATES

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 _____

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-

1   sponded substantively already, in-

2   cluding if the subsequent submis-

3   sion follows such response from

4   the Secretary closely in time.

5   "(ff) Whether the petition

6   requests changing the applicable

7   standards that other applicants

8   are required to meet, including

9   requesting testing, data, or label-

10   ing standards that are more on-

11   erous or rigorous than the stand-

12   ards the Secretary has deter-

13   mined to be applicable to the list-

14   ed drug, reference product, or pe-

15   titioner's version of the same

16   drug.

17   "(gg) The petitioner's record

18   of submitting petitions to the

19   Food and Drug Administration

20   that have been determined by the

21   Secretary to have been submitted

22   with the primary purpose of

23   delay.

24   "(hh) Other relevant and

25   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 redesig-

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 redesig-

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)''; and
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.