

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

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”.

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

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

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

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

8 (iv) by adding at the end the fol-
9 lowing:

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

19 (C) by striking subparagraph (F);

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

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

1 (2) in paragraph (2)—

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

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

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

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

1 (C) in subparagraph (C), as so redesignig-
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” in the
14 paragraph heading and all that follows through
15 “This subsection does” and inserting “EXCEP-
16 TIONS.—This subsection does”;

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

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

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