

119TH CONGRESS
1ST SESSION

S. 3014

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

IN THE SENATE OF THE UNITED STATES

OCTOBER 16, 2025

Mrs. SHAHEEN (for herself and Ms. COLLINS) 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 2025”.

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 the relevant
23 information relied upon to form
24 the basis of such petition.

1 “(bb) When the petition was
2 submitted in relation to when the
3 petitioner reasonably should have
4 known the relevant information
5 relied upon to form the basis of
6 such petition.

7 “(cc) Whether the petitioner
8 has submitted multiple or serial
9 petitions or supplements to peti-
10 tions raising issues that reason-
11 ably could have been known to
12 the petitioner at the time of sub-
13 mission of the earlier petition or
14 petitions.

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

23 “(ee) Whether the petition
24 was submitted without relevant
25 data or information in support of

1 the scientific positions forming
2 the basis of such petition.

3 “(ff) Whether the petition
4 raises the same or substantially
5 similar issues as a prior petition
6 to which the Secretary has re-
7 sponded substantively already, in-
8 cluding if the subsequent submis-
9 sion follows such response from
10 the Secretary closely in time.

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

23 “(hh) The petitioner’s
24 record of submitting petitions to
25 the Food and Drug Administra-

1 tion that have been determined
2 by the Secretary to have been
3 submitted with the primary pur-
4 pose of delay.

5 “(ii) Other relevant and ap-
6 propriate factors, which the Sec-
7 retary shall describe in guidance.

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

13 (C) by striking subparagraph (F);

14 (D) by redesignating subparagraphs (G)
15 through (I) as subparagraphs (F) through (H),
16 respectively; and

17 (E) in subparagraph (H), as so redesign-
18 ated, by striking “submission of this petition”
19 and inserting “submission of this document”;

20 (2) in paragraph (2)—

21 (A) by redesignating subparagraphs (A)
22 through (C) as subparagraphs (C) through (E),
23 respectively;

24 (B) by inserting before subparagraph (C),
25 as so redesignated, the following:

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

“(B) TIMELY SUBMISSION OF CITIZEN PETITION.—A petition and any supplement to a petition shall be submitted within 180 days after the person knew the information that forms the basis of the request made in the petition or supplement.”;

(C) in subparagraph (C), as so redesignated—

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

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

1 (iii) by amending clause (ii) to read as
 2 follows:

3 “(ii) on or after the date that is 151
 4 days after the date of submission of the
 5 petition, the Secretary approves or has ap-
 6 proved the application that is the subject
 7 of the petition without having made such a
 8 final decision.”;

9 (D) by amending subparagraph (D), as so
 10 redesignated, to read as follows:

11 “(D) DISMISSAL OF CERTAIN CIVIL AC-
 12 TIONS.—

13 “(i) PETITION.—If a person files a
 14 civil action against the Secretary in which
 15 a person seeks to set aside, delay, rescind,
 16 withdraw, or prevent submission, review, or
 17 approval of an application submitted under
 18 subsection (b)(2) or (j) of this section or
 19 section 351(k) of the Public Health Service
 20 Act without complying with the require-
 21 ments of subparagraph (A), the court shall
 22 dismiss without prejudice the action for
 23 failure to exhaust administrative remedies.

24 “(ii) TIMELINESS.—If a person files a
 25 civil action against the Secretary in which

1 a person seeks to set aside, delay, rescind,
2 withdraw, or prevent submission, review, or
3 approval of an application submitted under
4 subsection (b)(2) or (j) of this section or
5 section 351(k) of the Public Health Service
6 Act without complying with the require-
7 ments of subparagraph (B), the court shall
8 dismiss with prejudice the action for fail-
9 ure to timely file a petition.

10 “(iii) FINAL RESPONSE.—If a civil ac-
11 tion is filed against the Secretary with re-
12 spect to any issue raised in a petition time-
13 ly filed under paragraph (1) in which the
14 petitioner requests that the Secretary take
15 any form of action that could, if taken, set
16 aside, delay, rescind, withdraw, or prevent
17 submission, review, or approval of an appli-
18 cation submitted under subsection (b)(2)
19 or (j) of this section or section 351(k) of
20 the Public Health Service Act before the
21 Secretary has taken final agency action on
22 the petition within the meaning of sub-
23 paragraph (C), the court shall dismiss
24 without prejudice the action for failure to
25 exhaust administrative remedies.”; and

1 (E) in clause (iii) of subparagraph (E), as
2 so redesignated, by striking “as defined under
3 subparagraph (2)(A)” and inserting “within the
4 meaning of subparagraph (C)”;
5 (3) in paragraph (4)—

6 (A) by striking “EXCEPTIONS” in the
7 paragraph heading and all that follows through
8 “This subsection does” and inserting “EXCEP-
9 TIONS.—This subsection does”;

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

11 (C) by redesignating clauses (i) and (ii) as
12 subparagraphs (A) and (B), respectively, and
13 adjusting the margins accordingly.

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