116TH 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

Mr. GARDNER (for himself, Mrs. SHAHEEN, and Mr. CASSIDY) introduced the following bill; which was read twice and referred to the Committee on

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Ensuring Timely Access to Generics Act of 2019''.

SEC. 2. CITIZEN PETITIONS.

Section 505(q)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(q)(1)) is amended—

(1) in subparagraph (E)—

(A) by striking ''If the Secretary'' and inserting the following:

''(i) IN GENERAL.—If the Secretary'';

(B) by striking the second sentence and inserting the following:

''(ii) FACTORS.—In determining whether a petition was submitted with the primary purpose of delaying the approval of an application, the Secretary shall consider—

''(I) whether it appears, based on the date that relevant information relied upon in the petition became known to the petitioner (or reasonably should have been known to the petitioner), as certified by the petitioner in accordance with subparagraph (H), that the petitioner has taken an unreasonable length of time to submit the petition;

''(II) whether the petitioner has submitted multiple or serial petitions raising issues that reasonably could have been known to the petitioner at

the time of submission of the earlier petition or petitions;

''(III) whether the petition was submitted close in time to a known, first date upon which an application under subsection (b)(2) of this section or section 351(k) of the Public Health Service Act could be approved;

''(IV) whether the petition was submitted without any data or information in support of the scientific positions set forth in the petition;

''(V) whether the petition raises the same or substantially similar issues as a prior petition to which the Secretary has responded substantively already, particularly if the subsequent submission follows the earlier response closely in time;

''(VI) whether the petition concerns standards for approval of a drug for which the Secretary has provided an opportunity for public input, such as draft or final product-specific guidance applicable to the drug, and the

petitioner has not provided comment other than through the petition;

''(VII) whether the petition requests that other applicants meet standards for testing, data, or labeling for a drug that are more onerous or rigorous than the standards applicable to, as applicable, the listed drug, reference product, or petitioner's version of the same drug;

''(VIII) the history of the petitioner with the Food and Drug Administration, such as whether the petitioner has a history of submitting petitions that the Secretary has determined were submitted with the primary purpose of delay; and

''(IX) other relevant considerations, as the Secretary may describe in guidance.''; and

(C) by adding at the end the following:

''(iii) PUBLIC AVAILABILITY.—The Secretary shall publish on the internet website of the Food and Drug Administration a list of any petitions that the Sec-

retary determines were submitted for the primary purpose of delaying the approval of an application.

''(iv) REFERRAL TO THE FEDERAL TRADE COMMISSION.—The Secretary shall establish procedures for referring to the Federal Trade Commission any petition or supplement to a petition that the Secretary determines was submitted with the primary purpose of delaying approval of an application. Such procedures shall include notification to the petitioner and an opportunity for the petitioner to respond to the Secretary prior to referral to the Federal Trade Commission.''; and

(2) by adding at the end the following:

''(J) TIMELINE FOR SUBMITTING PETITIONS.—The Secretary may establish a time period after the relevant information relied upon in a petition became known to the petitioner (or reasonably should have been known to a petitioner), as certified by the petitioner in accordance with subparagraph (H), and any petition that is submitted after such time period has passed shall be summarily denied.''.