

116TH CONGRESS  
1ST SESSION

# S. 1169

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

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## IN THE SENATE OF THE UNITED STATES

APRIL 11, 2019

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

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## 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 2019”.

6 **SEC. 2. CITIZEN PETITIONS.**

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

9 (1) in subparagraph (E)—

1 (A) by striking “If the Secretary” and in-  
2 serting the following:

3 “(i) IN GENERAL.—If the Secretary”;

4 (B) by striking the second sentence and in-  
5 serting the following:

6 “(ii) FACTORS.—In determining  
7 whether a petition was submitted with the  
8 primary purpose of delaying the approval  
9 of an application, the Secretary shall con-  
10 sider—

11 “(I) whether it appears, based on  
12 the date that relevant information re-  
13 lied upon in the petition became  
14 known to the petitioner (or reasonably  
15 should have been known to the peti-  
16 tioner), as certified by the petitioner  
17 in accordance with subparagraph (H),  
18 that the petitioner has taken an un-  
19 reasonable length of time to submit  
20 the petition;

21 “(II) whether the petitioner has  
22 submitted multiple or serial petitions  
23 raising issues that reasonably could  
24 have been known to the petitioner at

1 the time of submission of the earlier  
2 petition or petitions;

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

9 “(IV) whether the petition was  
10 submitted without any data or infor-  
11 mation in support of the scientific po-  
12 sitions set forth in the petition;

13 “(V) whether the petition raises  
14 the same or substantially similar  
15 issues as a prior petition to which the  
16 Secretary has responded substantively  
17 already, particularly if the subsequent  
18 submission follows the earlier response  
19 closely in time;

20 “(VI) whether the petition con-  
21 cerns standards for approval of a drug  
22 for which the Secretary has provided  
23 an opportunity for public input, such  
24 as draft or final product-specific guid-  
25 ance applicable to the drug, and the

1 petitioner has not provided comment  
2 other than through the petition;

3 “(VII) whether the petition re-  
4 quests that other applicants meet  
5 standards for testing, data, or labeling  
6 for a drug that are more onerous or  
7 rigorous than the standards applicable  
8 to, as applicable, the listed drug, ref-  
9 erence product, or petitioner’s version  
10 of the same drug;

11 “(VIII) the history of the peti-  
12 tioner with the Food and Drug Ad-  
13 ministration, such as whether the pe-  
14 titioner has a history of submitting  
15 petitions that the Secretary has deter-  
16 mined were submitted with the pri-  
17 mary purpose of delay; and

18 “(IX) other relevant consider-  
19 ations, as the Secretary may describe  
20 in guidance.”; and

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

22 “(iii) PUBLIC AVAILABILITY.—The  
23 Secretary shall publish on the internet  
24 website of the Food and Drug Administra-  
25 tion a list of any petitions that the Sec-

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

4           “(iv) REFERRAL TO THE FEDERAL  
5           TRADE COMMISSION.—The Secretary shall  
6           establish procedures for referring to the  
7           Federal Trade Commission any petition or  
8           supplement to a petition that the Secretary  
9           determines was submitted with the primary  
10          purpose of delaying approval of an applica-  
11          tion. Such procedures shall include notifi-  
12          cation to the petitioner and an opportunity  
13          for the petitioner to respond to the Sec-  
14          retary prior to referral to the Federal  
15          Trade Commission.”; and

16          (2) by adding at the end the following:

17          “(J) TIMELINE FOR SUBMITTING PETI-  
18          TIONS.—The Secretary may establish a time pe-  
19          riod after the relevant information relied upon  
20          in a petition became known to the petitioner (or  
21          reasonably should have been known to a peti-  
22          tioner), as certified by the petitioner in accord-  
23          ance with subparagraph (H), and any petition

1           that is submitted after such time period has  
2           passed shall be summarily denied.”.

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