

116TH CONGRESS
1ST SESSION

H. R. 2455

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

IN THE HOUSE OF REPRESENTATIVES

MAY 1, 2019

Mr. JOYCE of Pennsylvania (for himself and Mr. BRINDISI) introduced the following bill; which was referred to the Committee on Energy and Commerce

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

petitioner has not provided comment
other than through the petition;

“(VII) whether the petition re-
quests 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, ref-
erence product, or petitioner’s version
of the same drug;

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

“(IX) other relevant consider-
ations, 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 Administra-
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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