

116TH CONGRESS
1ST SESSION

S. 660

To address abuse of the Food and Drug Administration’s citizen petition process by brand drug manufacturers.

IN THE SENATE OF THE UNITED STATES

MARCH 5, 2019

Mr. BRAUN introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To address abuse of the Food and Drug Administration’s citizen petition process by brand drug manufacturers.

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 “Efficiency and Trans-
5 parency in Petitions Act”.

6 **SEC. 2. CITIZEN PETITION AMENDMENTS.**

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)—

10 (A) in subparagraph (A)—

1 (i) in clause (i), by striking “; and”
2 and inserting “;”;

3 (ii) by redesignating clause (ii) as
4 clause (iii); and

5 (iii) by inserting after clause (i) the
6 following:

7 “(ii)(I) the petition is submitted with-
8 in 1 year of the petitioner first discovering
9 the issue that is the basis for submission
10 of such petition; or

11 “(II) the Secretary grants a waiver of
12 the 1-year period under subclause (I);
13 and”; and

14 (B) in subparagraph (H), by adding at the
15 end the following: “Any subsequent petition or
16 amendment to a petition with respect to the
17 same application under subsection (b)(2) or (j)
18 of this section or section 351(k) of the Public
19 Health Service Act filed by the same person
20 shall include an explanation of why such person
21 did not include the information or allegations
22 contained in the subsequent petition or amend-
23 ment in the original petition.”;

24 (2) in paragraph (3)—

1 (A) in subparagraph (C), by striking “;
 2 and” and inserting “, and the basis for the de-
 3 terminations of such number of days;”;

4 (B) in subparagraph (D), by striking the
 5 period and inserting a semicolon; and

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

7 “(E) as applicable, the timing of submis-
 8 sion of the petition in relation to the expiration
 9 of any patents listed under subsection (j)(7) for
 10 a drug approved under subsection (c) of this
 11 section that is referenced in the application
 12 under subsection (b)(2) or (j); and

13 “(F) the time the Food and Drug Admin-
 14 istration expended on the petition.”; and

15 (3) by adding at the end the following:

16 “(6) PUBLICATION OF PETITIONS.—The Sec-
 17 retary shall annually publish a list of all petitions
 18 that were submitted during the preceding 12-month
 19 period.”.

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