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

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A BILL

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

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 ''Efficiency and Transparency in Petitions Act''.

SEC. 2. CITIZEN PETITION AMENDMENTS.

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

(1) in paragraph (1)—

(A) in subparagraph (A)—

(i) in clause (i), by striking ''; and'' and inserting '';'';

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

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

''(ii)(I) the petition is submitted within 1 year of the petitioner first discovering the issue that is the basis for submission of such petition; or

''(II) the Secretary grants a waiver of the 1-year period under subclause (I); and''; and

(B) in subparagraph (H), by adding at the end the following: ''Any subsequent petition or amendment to a petition with respect to the same application under subsection (b)(2) or (j) of this section or section 351(k) of the Public Health Service Act filed by the same person shall include an explanation of why such person did not include the information or allegations contained in the subsequent petition or amendment in the original petition.'';

(2) in paragraph (3)—

(A) in subparagraph (C), by striking ''; and'' and inserting '', and the basis for the determinations of such number of days;'';

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

(C) by adding at the end the following:

''(E) as applicable, the timing of submission of the petition in relation to the expiration of any patents listed under subsection (j)(7) for a drug approved under subsection (c) of this section that is referenced in the application under subsection (b)(2) or (j); and

''(F) the time the Food and Drug Administration expended on the petition.''; and

(3) by adding at the end the following:

''(6) PUBLICATION OF PETITIONS.—The Secretary shall annually publish a list of all petitions that were submitted during the preceding 12-month period.''.

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