114TH CONGRESS
2D SESSION

S. 3466

To allow sponsors of certain new drug applications to rely upon investigations conducted in certain foreign countries, and for other purposes.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 29, 2016

Mr. PAUL 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 allow sponsors of certain new drug applications to rely upon investigations conducted in certain foreign countries, and for other purposes.

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 ''Accelerating New Pharmaceutical Competition Act''.

SEC. 2. DRUGS APPROVED IN CERTAIN FOREIGN COUNTRIES.

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

(1) in subsection (b), by adding at the end the following:

''(7) An application described in paragraph (2) may rely upon investigations conducted in a country listed under subparagraph (A) or designated under subparagraph (B) of section 802(b)(1), including premarket clinical and nonclinical investigations and postmarket surveillance studies, if the drug that is the subject of such application has been approved in such country.''; and

(2) in subsection (c)—

(A) in paragraph (1), by striking ''Within'' and inserting ''Except as provided in paragraph (5), within''; and

(B) by adding at the end the following:

''(5) In the case of an application that relies on investigations conducted in a foreign country, as described in subsection (b)(7), within 90 days after the filing of such application under subsection (b), the Secretary shall approve the application if the Secretary finds that none of the grounds for denying approval specified in subsection (d) applies or take action described in paragraph (1)(B). If the Secretary does not approve the application or take such other action within such 90-day period, the application shall be considered approved under this subsection.''.

SEC. 3. APPROVAL OF GENERIC DRUGS.

(a) STAYS IN THE CASE IF PATENT INFRINGEMENT LAWSUITS.—Section 505(j)(5)(B)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)(iii)) is amended by striking ''the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i)'' and inserting ''the date upon final judgment is entered in such action''.

(b) EXPEDITED GENERIC REVIEW.—Section 505(j)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) is amended—

(1) in subparagraph (A), by striking ''Within'' and inserting ''Except as provided in subparagraph (G), within''; and

(2) by adding at the end the following:

''(G)(i) The Secretary shall prioritize the review, and act not later than 150 calendar days after the date of the submission of an application, or supplement to an application, in the case of an application or supplement to an application described in clause (ii).

''(ii) Clause (i) shall apply to an application or supplement to an application under this subsection with respect to which the applicable listed drug, or another drug approved under this subsection with reference to such listed drug—

"(I) has been introduced into interstate commerce by not more than one manufacturer or sponsor in the 3-month period immediately preceding the date of submission of such application or supplement and with respect to which tentative approval has been granted for not more than 2 applications under this subsection; or

"(II) has been included on the drug shortage list under section 506E.".

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