

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

A BILL

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

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 “Accelerating New
5 Pharmaceutical Competition Act”.

6 **SEC. 2. DRUGS APPROVED IN CERTAIN FOREIGN COUN-**
7 **TRIES.**

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

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

3 “(7) An application described in paragraph (2) may
4 rely upon investigations conducted in a country listed
5 under subparagraph (A) or designated under subpara-
6 graph (B) of section 802(b)(1), including premarket clin-
7 ical and nonclinical investigations and postmarket surveil-
8 lance studies, if the drug that is the subject of such appli-
9 cation has been approved in such country.”; and

10 (2) in subsection (c)—

11 (A) in paragraph (1), by striking “Within”
12 and inserting “Except as provided in paragraph
13 (5), within”; and

14 (B) by adding at the end the following:

15 “(5) In the case of an application that relies on inves-
16 tigations conducted in a foreign country, as described in
17 subsection (b)(7), within 90 days after the filing of such
18 application under subsection (b), the Secretary shall ap-
19 prove the application if the Secretary finds that none of
20 the grounds for denying approval specified in subsection
21 (d) applies or take action described in paragraph (1)(B).
22 If the Secretary does not approve the application or take
23 such other action within such 90-day period, the applica-
24 tion shall be considered approved under this subsection.”.

1 **SEC. 3. APPROVAL OF GENERIC DRUGS.**

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

10 (b) EXPEDITED GENERIC REVIEW.—Section
11 505(j)(5) of the Federal Food, Drug, and Cosmetic Act
12 (21 U.S.C. 355(j)(5)) is amended—

13 (1) in subparagraph (A), by striking “Within”
14 and inserting “Except as provided in subparagraph
15 (G), within”; and

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

17 “(G)(i) The Secretary shall prioritize the review, and
18 act not later than 150 calendar days after the date of the
19 submission of an application, or supplement to an applica-
20 tion, in the case of an application or supplement to an
21 application described in clause (ii).

22 “(ii) Clause (i) shall apply to an application or sup-
23 plement to an application under this subsection with re-
24 spect to which the applicable listed drug, or another drug
25 approved under this subsection with reference to such list-
26 ed drug—

1 “(I) has been introduced into interstate com-
2 merce by not more than one manufacturer or spon-
3 sor in the 3-month period immediately preceding the
4 date of submission of such application or supplement
5 and with respect to which tentative approval has
6 been granted for not more than 2 applications under
7 this subsection; or
8 “(II) has been included on the drug shortage
9 list under section 506E.”.

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