114TH CONGRESS
2D SESSION

S. 3387

To provide for the fast track review of certain generic drugs.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 22, 2016

Mr. COTTON 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 provide for the fast track review of certain generic drugs.

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 ''Safely Advancing Valuable and Inexpensive New Generic Solutions Act'' or the ''SAVINGS Act''.

SEC. 2. FAST TRACK REVIEW FOR CERTAIN GENERIC DRUGS.

Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is amended by adding at the end the following:

''(11)(A) Notwithstanding any other provision of law, the Secretary shall prioritize the review of a qualifying application under this subsection and shall, within 150 days of the initial receipt of such qualifying application, take final agency action on the application.

''(B) For purposes of this paragraph, the term 'qualifying application' means an application—

''(i) that does not contain a certification under subclause (IV) of paragraph (2)(A)(vii);

''(ii) that may contain a certification under subclause (III) of paragraph (2)(A)(vii) only if such certification asserts that an existing patent will expire not more than 5 months after the date of such certification;

''(iii) for a drug where the reference drug is a drug for which there is no exclusivity period in effect, including an exclusivity period under paragraph (5)(F), or under section 505A, section 527, or section 505E; and

''(iv) for a drug where the reference drug has not been the reference drug for more than one other drug that—

''(I) is approved under this subsection; and

''(II) has been introduced into interstate commerce in the 3-month period preceding the date of the qualifying application.

''(C) Notwithstanding any other provision of this paragraph and regardless of the date of submission, a qualifying application shall lose status as an application for priority review, and the Secretary's timeline for taking action on such an application described in subparagraph (A) shall no longer apply, if the application no longer meets the definition of a qualifying application.''.

SEC. 3. TRANSPARENCY.

(a) IN GENERAL.—Not later than 6 months after enactment and every 6 months thereafter, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives containing the information described in subsection (c).

(b) DEFINITION.—In this section the term ''generic fast track review'' means review under paragraph (11) of section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)), as added by section 2 of this Act.

(c) CONTENTS OF REPORT.—The report described in subsection (a) shall include the following information:

(1) The number of applications in the most recent 6-month period that are subject to generic fast track review, and which of those applications—

(A) are for a drug where the reference drug has not been the reference drug for any other application that is approved under subsection (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355);

(B) are for a drug where the reference drug has been the reference drug for not more than one other application that is approved under subsection (j) of such section; and

(C) are for a drug that is on the drug shortage list established under section 506E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356e).

(2) The average and median time before an applicant receives an approval decision for an application subject to generic fast track review.

(3) The number of applications subject to generic fast track review that were approved.

(4) At the time such report is submitted, the number of applications subject to fast track review—

(A) that have been withdrawn by the applicant;

(B) that have been granted tentative approval;

(C) with respect to which the Food and Drug Administration has requested additional information from the sponsor of the application;

(D) that are awaiting review by the Food and Drug Administration after additional information has been supplied, as described in subparagraph (C); and

(E) with respect to which the Food and Drug Administration has recorded reception of the application but has yet to contact the sponsor regarding the status of the application.

(5) A prediction of how long the Food and Drug Administration will take to respond to such applications that are awaiting review with either an approval or a rejection, and how many of such applications are expected to be withdrawn by the applicant.

(6) The average review time for such applications that are receiving generic fast track review versus the standard review period.

(7) The information described in paragraphs (1) through (6) with respect to applications for drugs under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) that are subject to another form of priority review or fast-track review.

(8) An annual accounting of how the Food and Drug Administration has spent the fees it has received under part 7 of subchapter C of chapter VII of such Act (21 U.S.C. 379f et seq.) to include the proportion of such fees that such Administration has spent on personnel costs.

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