

116TH CONGRESS
1ST SESSION

S. 1209

To amend the Federal Food, Drug, and Cosmetic Act with respect to approval of abbreviated new drug applications.

IN THE SENATE OF THE UNITED STATES

APRIL 11, 2019

Mr. CASSIDY (for himself and Mr. DURBIN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to approval of abbreviated new drug applications.

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 “Reforming
5 Evergreening and Manipulation that Extends Drug Years
6 Act” or the “REMEDY Act”.

7 **SEC. 2. AMENDMENTS TO ANDA APPROVAL PROVISION.**

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

1 (1) in subsection (e)(3)(C), by inserting “in the
2 case of a certification with respect to a patent that
3 claims a drug substance (and not in the case of a
4 certification with respect to a patent that claims a
5 drug product or method of use for a drug, except
6 that, in the case of a patent that claims a drug sub-
7 stance and a drug product or method of use, this
8 subparagraph shall apply, but only to the extent the
9 patent claims a drug substance),” after “imme-
10 diately unless,”; and

11 (2) in subsection (j)(5)(B)(iii), by inserting “in
12 the case of a certification with respect to a patent
13 that claims a drug substance (and not in the case
14 of a certification with respect to a patent that claims
15 a drug product or method of use for a drug, except
16 that, in the case of a patent that claims a drug sub-
17 stance and a drug product or method of use, this
18 clause shall apply, but only to the extent the patent
19 claims a drug substance),” after “immediately un-
20 less,”.

21 (b) ORANGE BOOK UPDATES WITH RESPECT TO IN-
22 VALIDATED PATENTS.—

23 (1) IN GENERAL.—Section 505(j)(7)(A) of the
24 Federal Food, Drug, and Cosmetic Act (21 U.S.C.

1 355(j)(7)(A)) is amended by adding at the end the
2 following:

3 “(iv) In the case of a listed drug for which the
4 list under clause (i) includes a patent that claims the
5 drug or a use for such drug, and where the Under
6 Secretary of Commerce for Intellectual Property and
7 Director of the United States Patent and Trade-
8 mark Office has cancelled any claim of the patent
9 relating to such drug or such use pursuant to a de-
10 termination by the Patent Trial and Appeal Board
11 in an inter partes review conducted under chapter
12 31 of title 35, United States Code, or a post-grant
13 review conducted under chapter 32 of that title, and
14 any such cancellation, if appealed, has been upheld
15 upon appeal, the holder of the applicable approved
16 application shall notify the Secretary of such can-
17 cellation, and the revisions required under clause
18 (iii) shall include striking the patent from the list
19 with respect to such drug.”.

20 (2) NO EFFECT ON FIRST APPLICANT EXCLU-
21 SIVITY PERIOD.—Section 505(j)(5)(B)(iv)(I) is
22 amended by adding at the end the following: “This
23 subclause shall apply even if a patent is stricken
24 from the list under paragraph (7)(A), pursuant to
25 the second sentence of clause (iii) of such paragraph,

1 provided that, at the time that the first applicant
2 submitted an application under this subsection con-
3 taining a certification described in paragraph
4 (2)(A)(vii)(IV), the patent that was the subject of
5 such certification was included in such list with re-
6 spect to the listed drug.”.

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