

119TH CONGRESS
1ST SESSION

S. 2620

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

JULY 31, 2025

Mr. DURBIN (for himself and Mr. CASSIDY) 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 PROVISIONS.**

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

(1) in subsection (c)(2) by adding at the end the following: “With respect to a drug approved on or after the date of enactment of the Reforming Evergreening and Manipulation that Extends Drug Years Act, when a holder of an approved application first files information under this paragraph with respect to one or more patents described in subsection (b)(1)(A)(viii), the holder shall select one such patent with respect to which the owner or licensee may be eligible for the thirty-month period under paragraph (3)(C) or subsection (j)(5)(B)(iii), as applicable; for purposes of paragraphs (3)(C) and (3)(E)(ii) and subsections (j)(5)(B)(iii) and (j)(5)(F)(ii), such patent shall be referred to as the ‘covered patent’. The selection of such covered patent may not be changed or amended.”;

(2) in subsection (c)(3)(C)—

(A) in the matter preceding clause (i)—

(i) by striking “an action is brought for infringement” and all that follows through the period at the end of the first sentence and inserting “with respect to a drug approved under this subsection before the date of enactment of the Reforming Evergreening and Manipulation that Ex-

1 tends Drug Years Act, an action is
2 brought for infringement of any patent
3 that is the subject of the certification and
4 for which information was submitted to the
5 Secretary under paragraph (2) before the
6 date on which the application (excluding
7 an amendment or supplement to the appli-
8 cation) was submitted, or, with respect to
9 a drug approved under this subsection on
10 or after the date of enactment of the Re-
11 forming Evergreening and Manipulation
12 that Extends Drug Years Act, an action is
13 brought for infringement of the covered
14 patent (as described in paragraph (2)) that
15 is the subject of the certification and for
16 which information was submitted to the
17 Secretary under paragraph (2) before the
18 date on which the application (excluding
19 an amendment or supplement to the appli-
20 cation) was submitted.”; and

21 (ii) by striking “an action is brought
22 before” and inserting “an action with re-
23 spect to a patent or a covered patent, as
24 applicable, is brought before”; and

1 (B) in clause (i), by striking “decides that
2 the patent” and inserting “decides that the pat-
3 ent or the covered patent, as applicable”;

4 (3) in the second sentence of subsection
5 (c)(3)(E)(ii), by inserting “with respect to any pat-
6 ent for which the requirements are met for the thir-
7 ty-month period described in subparagraph (C)”
8 after “action for patent infringement”;

9 (4) in subsection (j)(5)(B)(iii)—

10 (A) in the matter preceding subclause
11 (I)—

12 (i) by striking “an action is brought
13 for infringement” and all that follows
14 through the period at the end of the first
15 sentence and inserting “with respect to a
16 drug approved under subsection (c) before
17 the date of enactment of the Reforming
18 Evergreening and Manipulation that Ex-
19 tends Drug Years Act, an action is
20 brought for infringement of any patent
21 that is the subject of the certification and
22 for which information was submitted to the
23 Secretary under subsection (c)(2) before
24 the date on which the application (exclud-
25 ing an amendment or supplement to the

1 application), which the Secretary later de-
2 termines to be substantially complete, was
3 submitted, or, with respect to a drug ap-
4 proved under subsection (c) on or after the
5 date of enactment of the Reforming
6 Evergreening and Manipulation that Ex-
7 tends Drug Years Act, an action is
8 brought for infringement of the covered
9 patent (as described in subsection (c)(2))
10 that is the subject of the certification and
11 for which information was submitted to the
12 Secretary under subsection (c)(2) before
13 the date on which the application (exclud-
14 ing an amendment or supplement to the
15 application), which the Secretary later de-
16 termines to be substantially complete, was
17 submitted.”; and

18 (ii) by striking “an action is brought
19 before” and inserting “an action with re-
20 spect to a patent or a covered patent, as
21 applicable, is brought before”; and

22 (B) in subclause (I), by striking “decides
23 that the patent” and inserting “decides that the
24 patent or covered patent, as applicable,”; and

1 (5) in the second sentence of subsection
2 (j)(5)(F)(ii), by inserting “with respect to any pat-
3 ent for which the requirements are met for the thir-
4 ty-month period described in subparagraph (B)(iii),”
5 after “action for patent infringement”.

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