

114TH CONGRESS
1ST SESSION

S. 1421

To amend the Federal Food, Drug, and Cosmetic Act to authorize a 6-month extension of certain exclusivity periods in the case of approved drugs that are subsequently approved for a new indication to prevent, diagnose, or treat a rare disease or condition, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MAY 21, 2015

Mr. HATCH (for himself and Ms. KLOBUCHAR) 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 to authorize a 6-month extension of certain exclusivity periods in the case of approved drugs that are subsequently approved for a new indication to prevent, diagnose, or treat a rare disease or condition, 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 “Orphan Product Ex-
5 tensions Now Accelerating Cures and Treatments Act of
6 2015”.

1 **SEC. 2. EXTENSION OF EXCLUSIVITY PERIODS FOR A DRUG**
 2 **APPROVED FOR A NEW INDICATION FOR A**
 3 **RARE DISEASE OR CONDITION.**

4 (a) IN GENERAL.—Chapter V of the Federal Food,
 5 Drug, and Cosmetic Act is amended by inserting after sec-
 6 tion 505E the following:

7 **“SEC. 505F. EXTENSION OF EXCLUSIVITY PERIODS FOR A**
 8 **DRUG APPROVED FOR A NEW INDICATION**
 9 **FOR A RARE DISEASE OR CONDITION.**

10 “(a) DESIGNATION.—

11 “(1) IN GENERAL.—The Secretary shall des-
 12 ignate a drug as a drug approved for a new indica-
 13 tion to prevent, diagnose, or treat a rare disease or
 14 condition for purposes of granting the extensions
 15 under subsection (b) if—

16 “(A) prior to approval of an application or
 17 supplemental application for the new indication,
 18 the drug was approved or licensed for mar-
 19 keting under section 505(c) of this Act or sec-
 20 tion 351(a) of the Public Health Service Act,
 21 but was not so approved or licensed for the new
 22 indication;

23 “(B)(i) the sponsor of the approved or li-
 24 censed drug files an application or a supple-
 25 mental application for approval of the new indi-

1 cation for use of the drug to prevent, diagnose,
2 or treat the rare disease or condition; and

3 “(ii) the Secretary approves the application
4 or supplemental application; and

5 “(C) the application or supplemental appli-
6 cation for the new indication contains the con-
7 sent of the applicant to notice being given by
8 the Secretary under paragraph (4) respecting
9 the designation of the drug.

10 “(2) REVOCATION OF DESIGNATION.—

11 “(A) IN GENERAL.—Except as provided in
12 subparagraph (B), a designation under this
13 subsection shall not be revoked for any reason.

14 “(B) EXCEPTION.—The Secretary may re-
15 voke a designation of a drug under paragraph
16 (1) if the Secretary finds that the application or
17 supplemental application resulting in such des-
18 ignation contained an untrue statement of ma-
19 terial fact.

20 “(3) NOTIFICATION PRIOR TO DISCONTINUANCE
21 OF PRODUCTION FOR SOLELY COMMERCIAL REA-
22 SONS.—A designation of a drug under paragraph (1)
23 shall be subject to the condition that the sponsor of
24 the drug will notify the Secretary of any discontinu-
25 ance of the production of the drug for solely com-

1 mercial reasons at least one year before such dis-
2 continuance.

3 “(4) NOTICE TO PUBLIC.—Notice respecting
4 the designation of a drug under paragraph (1) shall
5 be made available to the public.

6 “(b) EXTENSION.—If the Secretary designates a
7 drug as a drug approved for a new indication for a rare
8 disease or condition, as described in subsection (a)(1)—

9 “(1)(A) the 4-, 5-, and 7½-year periods de-
10 scribed in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii)
11 of section 505, the 3-year periods described in
12 clauses (iii) and (iv) of subsection (c)(3)(E) and
13 clauses (iii) and (iv) of subsection (j)(5)(F) of sec-
14 tion 505, and the 7-year period described in section
15 527, as applicable, shall be extended by 6 months;
16 or

17 “(B) the 4- and 12-year periods described in
18 subparagraphs (A) and (B) of section 351(k)(7) of
19 the Public Health Service Act and the 7-year period
20 described in section 527, as applicable, shall be ex-
21 tended by 6 months; and

22 “(2)(A) if the drug is the subject of a listed
23 patent for which a certification has been submitted
24 under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of
25 section 505 or a listed patent for which a certifi-

1 cation has been submitted under subsections
2 (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,
3 the period during which an application may not be
4 approved under section 505(c)(3) or section
5 505(j)(5)(B) shall be extended by a period of 6
6 months after the date the patent expires (including
7 any patent extensions); or

8 “(B) if the drug is the subject of a listed patent
9 for which a certification has been submitted under
10 subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of sec-
11 tion 505, and in the patent infringement litigation
12 resulting from the certification the court determines
13 that the patent is valid and would be infringed, the
14 period during which an application may not be ap-
15 proved under section 505(c)(3) or section
16 505(j)(5)(B) shall be extended by a period of 6
17 months after the date the patent expires (including
18 any patent extensions).

19 “(c) RELATION TO PEDIATRIC AND QUALIFIED IN-
20 FECTIOUS DISEASE PRODUCT EXCLUSIVITY.—Any exten-
21 sion under subsection (b) of a period shall be in addition
22 to any extension of the periods under sections 505A and
23 505E of this Act and section 351(m) of the Public Health
24 Service Act, as applicable, with respect to the drug.

1 “(d) LIMITATIONS.—The extension described in sub-
 2 section (b) shall not apply if the drug designated under
 3 subsection (a)(1) has previously received an extension by
 4 operation of subsection (b).

5 “(e) DEFINITION.—In this section, the term ‘rare
 6 disease or condition’ has the meaning given to such term
 7 in section 526(a)(2).”.

8 (b) APPLICATION.—Section 505F of the Federal
 9 Food, Drug, and Cosmetic Act, as added by subsection
 10 (a), applies only with respect to a drug for which an appli-
 11 cation or supplemental application described in subsection
 12 (a)(1)(B)(i) of such section 505F is first approved under
 13 section 505(c) of such Act (21 U.S.C. 355(c)) or section
 14 351(a) of the Public Health Service Act (42 U.S.C.
 15 262(a)) on or after the date of the enactment of this Act.

16 (c) CONFORMING AMENDMENTS.—

17 (1) RELATION TO PEDIATRIC EXCLUSIVITY FOR
 18 DRUGS.—Section 505A of the Federal Food, Drug,
 19 and Cosmetic Act (21 U.S.C. 355a) is amended—

20 (A) in subsection (b), by adding at the end
 21 the following:

22 “(3) RELATION TO EXCLUSIVITY FOR A DRUG
 23 APPROVED FOR A NEW INDICATION FOR A RARE DIS-
 24 EASE OR CONDITION.—Notwithstanding the ref-
 25 erences in subsection (b)(1) to the lengths of the ex-

clusivity periods after application of pediatric exclusivity, the 6-month extensions described in subsection (b)(1) shall be in addition to any extensions under section 505F.”; and

(B) in subsection (c), by adding at the end the following:

“(3) RELATION TO EXCLUSIVITY FOR A DRUG APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION.—Notwithstanding the references in subsection (c)(1) to the lengths of the exclusivity periods after application of pediatric exclusivity, the 6-month extensions described in subsection (c)(1) shall be in addition to any extensions under section 505F.”.

(2) RELATION TO EXCLUSIVITY FOR NEW QUALIFIED INFECTIOUS DISEASE PRODUCTS THAT ARE DRUGS.—Subsection (b) of section 505E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355f) is amended—

(A) by amending the subsection heading to read as follows: “RELATION TO PEDIATRIC EXCLUSIVITY AND EXCLUSIVITY FOR A DRUG APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION”; and

1 (B) by striking “any extension of the pe-
2 riod under section 505A” and inserting “any
3 extension of the periods under sections 505A
4 and 505F, as applicable.”.

5 (3) RELATION TO PEDIATRIC EXCLUSIVITY FOR
6 BIOLOGICAL PRODUCTS.—Section 351(m) of the
7 Public Health Service Act (42 U.S.C. 262(m)) is
8 amended by adding at the end the following:

9 “(5) RELATION TO EXCLUSIVITY FOR A BIO-
10 LOGICAL PRODUCT APPROVED FOR A NEW INDICA-
11 TION FOR A RARE DISEASE OR CONDITION.—Not-
12 withstanding the references in paragraphs (2)(A),
13 (2)(B), (3)(A), and (3)(B) to the lengths of the ex-
14 clusivity periods after application of pediatric exclu-
15 sivity, the 6-month extensions described in such
16 paragraphs shall be in addition to any extensions
17 under section 505F.”.

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