

115TH CONGRESS  
1ST SESSION

# S. 1509

To amend the Federal Food, Drug, and Cosmetic Act to authorize an extension of exclusivity periods for certain drugs that are approved for a new indication for a rare disease or condition, and for other purposes.

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## IN THE SENATE OF THE UNITED STATES

JUNE 29, 2017

Mr. HATCH (for himself and Mr. MENENDEZ) 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 amend the Federal Food, Drug, and Cosmetic Act to authorize an extension of exclusivity periods for certain drugs that are approved for a new indication for 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 Products Ex-  
5 tension Now Accelerating Cures and Treatments Act of  
6 2017”.

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.—The Federal Food, Drug, and  
5 Cosmetic Act is amended by inserting after section 505F  
6 of such Act (21 U.S.C. 355g) the following:

7 **“SEC. 505G. 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 under section  
19 505(c) of this Act or section 351(a) of the Pub-  
20 lic Health Service Act but was not so approved  
21 or licensed for the new indication;

22 “(B)(i) the sponsor of the approved or li-  
23 censed drug files an application or a supple-  
24 mental application for approval of the new indi-  
25 cation for use of the drug to prevent, diagnose,  
26 or treat the rare disease or condition; and

1           “(ii) the Secretary approves the application  
2 or supplemental application; and

3           “(C) the application or supplemental appli-  
4 cation for the new indication contains the con-  
5 sent of the applicant to public notice under  
6 paragraph (3) with respect to the designation of  
7 the drug.

8           “(2) REVOCATION OF DESIGNATION.—

9           “(A) IN GENERAL.—Except as provided in  
10 subparagraph (B), a designation under para-  
11 graph (1) shall not be revoked for any reason.

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

18           “(3) NOTICE TO PUBLIC.—The Secretary shall  
19 provide public notice of the designation of a drug  
20 under paragraph (1).

21           “(b) EXTENSION.—

22           “(1) IN GENERAL.—If the Secretary designates  
23 a drug as a drug approved for a new indication for  
24 a rare disease or condition, as described in sub-  
25 section (a)(1)—

1           “(A)(i) the 4-, 5-, and 7½-year periods de-  
2           scribed in subsections (c)(3)(E)(ii) and  
3           (j)(5)(F)(ii) of section 505, the 3-year periods  
4           described in clauses (iii) and (iv) of subsection  
5           (c)(3)(E) and clauses (iii) and (iv) of subsection  
6           (j)(5)(F) of section 505, and the 7-year period  
7           described in section 527, as applicable, shall be  
8           extended by 6 months; or

9           “(ii) the 4- and 12-year periods described  
10          in subparagraphs (A) and (B) of section  
11          351(k)(7) of the Public Health Service Act and  
12          the 7-year period described in section 527, as  
13          applicable, shall be extended by 6 months; and

14          “(B)(i) if the drug is the subject of a listed  
15          patent for which a certification has been sub-  
16          mitted under subsection (b)(2)(A)(ii) or  
17          (j)(2)(A)(vii)(II) of section 505 or a listed pat-  
18          ent for which a certification has been submitted  
19          under subsection (b)(2)(A)(iii) or  
20          (j)(2)(A)(vii)(III) of section 505, the period  
21          during which an application may not be ap-  
22          proved under section 505(c)(3) or section  
23          505(j)(5)(B) shall be extended by a period of 6  
24          months after the date the patent expires (in-  
25          cluding any patent extensions); or

1           “(ii) if the drug is the subject of a listed  
2           patent for which a certification has been sub-  
3           mitted under subsection (b)(2)(A)(iv) or  
4           (j)(2)(A)(vii)(IV) of section 505, and in the pat-  
5           ent infringement litigation resulting from the  
6           certification the court determines that the pat-  
7           ent is valid and would be infringed, the period  
8           during which an application may not be ap-  
9           proved under section 505(c)(3) or section  
10          505(j)(5)(B) shall be extended by a period of 6  
11          months after the date the patent expires (in-  
12          cluding any patent extensions).

13           “(2) RELATION TO PEDIATRIC AND QUALIFIED  
14          INFECTIOUS DISEASE PRODUCT EXCLUSIVITY.—Any  
15          extension under paragraph (1) of a period shall be  
16          in addition to any extension of the periods under  
17          sections 505A and 505E of this Act and section  
18          351(m) of the Public Health Service Act, as applica-  
19          ble, with respect to the drug.

20           “(c) LIMITATIONS.—Any extension described in sub-  
21          section (b)(1) shall not apply if the drug designated under  
22          subsection (a)(1) has previously received an extension by  
23          operation of subsection (b)(1).

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

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

12 (c) CONFORMING AMENDMENTS.—

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

16 (A) in subsection (b), by adding at the end  
17 the following:

18 “(3) RELATION TO EXCLUSIVITY FOR A DRUG  
19 APPROVED FOR A NEW INDICATION FOR A RARE DIS-  
20 EASE OR CONDITION.—Notwithstanding the ref-  
21 erences in paragraph (1) to the lengths of the exclu-  
22 sivity periods after application of pediatric exclu-  
23 sivity, the 6-month extensions described in para-  
24 graph (1) shall be in addition to any extensions  
25 under section 505G.”; and

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

3 “(3) RELATION TO EXCLUSIVITY FOR A DRUG  
4 APPROVED FOR A NEW INDICATION FOR A RARE DIS-  
5 EASE OR CONDITION.—Notwithstanding the ref-  
6 erences in paragraph (1) to the lengths of the exclu-  
7 sivity periods after application of pediatric exclu-  
8 sivity, the 6-month extensions described in para-  
9 graph (1) shall be in addition to any extensions  
10 under section 505G.”.

11 (2) RELATION TO EXCLUSIVITY FOR NEW  
12 QUALIFIED INFECTIOUS DISEASE PRODUCTS THAT  
13 ARE DRUGS.—Subsection (b) of section 505E of the  
14 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
15 355f) is amended—

16 (A) by amending the subsection heading to  
17 read as follows: “RELATION TO PEDIATRIC EX-  
18 CLUSIVITY AND EXCLUSIVITY FOR A DRUG AP-  
19 PROVED FOR A NEW INDICATION FOR A RARE  
20 DISEASE OR CONDITION.—”; and

21 (B) by striking “any extension of the pe-  
22 riod under section 505A” and inserting “any  
23 extension of the periods under sections 505A  
24 and 505G, as applicable,”.

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

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

14 **SEC. 3. ORPHAN DRUGS.**

15           (a) IN GENERAL.—Section 527 of the Federal Food,  
16 Drug, and Cosmetic Act (21 U.S.C. 360cc) is amended—

17           (1) in subsection (a), in the matter following  
18 paragraph (2), by striking “such drug for such dis-  
19 ease or condition” and inserting “the same drug for  
20 the same disease or condition”;

21           (2) in subsection (b)—

22           (A) in the matter preceding paragraph (1),  
23 by striking “If an application” and all that fol-  
24 lows through “such license if” and inserting  
25 “During the 7-year period described in sub-

1 section (a) for an approved application under  
2 section 505 or license under section 351 of the  
3 Public Health Service Act, the Secretary may  
4 approve an application or issue a license for a  
5 drug that is otherwise the same, as determined  
6 by the Secretary, as the already approved drug  
7 for the same rare disease or condition if”;

8 (B) in paragraph (1), by striking “notice”  
9 and all that follows through “assure” and in-  
10 sserting “of exclusive approval or licensure no-  
11 tice and opportunity for the submission of  
12 views, that during such period the holder of the  
13 exclusive approval or licensure cannot ensure”;  
14 and

15 (C) in paragraph (2), by striking “such  
16 holder provides” and inserting “the holder pro-  
17 vides”; and

18 (3) by adding at the end the following:

19 “(c) CONDITION OF CLINICAL SUPERIORITY.—

20 “(1) IN GENERAL.—If a sponsor of a drug that  
21 is designated under section 526 and is otherwise the  
22 same, as determined by the Secretary, as an already  
23 approved or licensed drug is seeking exclusive ap-  
24 proval or exclusive licensure described in subsection  
25 (a) for the same rare disease or condition as the al-

1 ready approved drug, the Secretary shall require  
2 such sponsor, as a condition of such exclusive ap-  
3 proval or licensure, to demonstrate that such drug is  
4 clinically superior to any already approved or li-  
5 censed drug that is the same drug.

6 “(2) DEFINITION.—For purposes of paragraph  
7 (1), the term ‘clinically superior’ with respect to a  
8 drug means that the drug provides a significant  
9 therapeutic advantage over and above an already ap-  
10 proved or licensed drug in terms of greater efficacy,  
11 greater safety, or by providing a major contribution  
12 to patient care.

13 “(d) REGULATIONS.—The Secretary may promulgate  
14 regulations for the implementation of subsection (c). Be-  
15 ginning on the date of enactment of the Orphan Products  
16 Extension Now Accelerating Cures and Treatments Act  
17 of 2017, until such time as the Secretary promulgates reg-  
18 ulations in accordance with this subsection, the Secretary  
19 may apply any definitions set forth in regulations that  
20 were promulgated prior to such date of enactment, to the  
21 extent such definitions are not inconsistent with the terms  
22 of this section, as amended by such Act.

23 “(e) DEMONSTRATION OF CLINICAL SUPERIORITY  
24 STANDARD.—To assist sponsors in demonstrating clinical  
25 superiority as described in subsection (c), the Secretary—

1           “(1) upon the designation of any drug under  
2           section 526, shall notify the sponsor of such drug in  
3           writing of the basis for the designation, including, as  
4           applicable, any plausible hypothesis offered by the  
5           sponsor and relied upon by the Secretary that the  
6           drug is clinically superior to a previously approved  
7           drug; and

8           “(2) upon granting exclusive approval or licen-  
9           sure under subsection (a) on the basis of a dem-  
10          onstration of clinical superiority as described in sub-  
11          section (c), shall publish a summary of the clinical  
12          superiority findings.”.

13          (b) **RULE OF CONSTRUCTION.**—Nothing in the  
14          amendments made by subsection (a) shall affect any deter-  
15          mination under sections 526 and 527 of the Federal Food,  
16          Drug, and Cosmetic Act (21 U.S.C. 360bb, 360cc) made  
17          prior to the date of enactment of the Orphan Products  
18          Extension Now Accelerating Cures and Treatments Act  
19          of 2017.

20          **SEC. 4. PEDIATRIC INFORMATION ADDED TO LABELING.**

21          Section 505A(o) of the Federal Food, Drug, and Cos-  
22          metic Act (21 U.S.C. 355a(o)) is amended—

23                  (1) in the subsection heading, by striking

24                  “UNDER SECTION 505(j)”;

25                  (2) in paragraph (1)—

1 (A) by striking “under section 505(j)” and  
2 inserting “under subsection (b)(2) or (j) of sec-  
3 tion 505”; and

4 (B) by striking “or by exclusivity under  
5 clause (iii) or (iv) of section 505(j)(5)(F)” and  
6 inserting “, or by exclusivity under clause (iii)  
7 or (iv) of section 505(j)(5)(F), clauses (iii) and  
8 (iv) of section 505(c)(3)(E), or section 527(a),  
9 or by an extension of such exclusivity under this  
10 section or section 505E”;

11 (3) in paragraph (2), in the matter preceding  
12 subparagraph (A)—

13 (A) by inserting “clauses (iii) and (iv) of  
14 section 505(c)(3)(E), or section 527,” after  
15 “section 505(j)(5)(F),”; and

16 (B) by striking “drug approved under sec-  
17 tion 505(j)” and inserting “drug approved pur-  
18 suant to an application submitted under sub-  
19 section (b)(2) or (j) of section 505”; and

20 (4) by amending paragraph (3) to read as fol-  
21 lows:

22 “(3) PRESERVATION OF PEDIATRIC EXCLU-  
23 SIVITY AND OTHER PROVISIONS.—This subsection  
24 does not affect—

1           “(A) the availability or scope of exclusivity  
2           under—

3                   “(i) this section;

4                   “(ii) section 505 for pediatric formu-  
5           lations; or

6                   “(iii) section 527;

7           “(B) the question of the eligibility for ap-  
8           proval of any application under subsection  
9           (b)(2) or (j) of section 505 that omits any other  
10          conditions of approval entitled to exclusivity  
11          under—

12                   “(i) clause (iii) or (iv) of section  
13           505(j)(5)(F);

14                   “(ii) clause (iii) or (iv) of section  
15           505(e)(3)(E); or

16                   “(iii) section 527; or

17           “(C) except as expressly provided in para-  
18           graphs (1) and (2), the operation of section 505  
19           or section 527.”.

○