115TH CONGRESS
1ST SESSION

S. _____

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.

IN THE SENATE OF THE UNITED STATES

Mr. HATCH (for himself and Mr. MENENDEZ) introduced the following bill; which was read twice and referred to the Committee on _____

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.

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 "Orphan Products Extension Now Accelerating Cures and Treatments Act of 2017".

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

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

"SEC. 505G. EXTENSION OF EXCLUSIVITY PERIODS FOR A DRUG APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION.

''(a) DESIGNATION.—

''(1) IN GENERAL.—The Secretary shall designate a drug as a drug approved for a new indication to prevent, diagnose, or treat a rare disease or condition for purposes of granting the extensions under subsection (b) if—

''(A) prior to approval of an application or supplemental application for the new indication, the drug was approved or licensed under section 505(c) of this Act or section 351(a) of the Public Health Service Act but was not so approved or licensed for the new indication;

''(B)(i) the sponsor of the approved or licensed drug files an application or a supplemental application for approval of the new indication for use of the drug to prevent, diagnose, or treat the rare disease or condition; and

"(ii) the Secretary approves the application or supplemental application; and

"(C) the application or supplemental application for the new indication contains the consent of the applicant to public notice under paragraph (3) with respect to the designation of the drug.

"(2) REVOCATION OF DESIGNATION.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), a designation under paragraph (1) shall not be revoked for any reason.

"(B) EXCEPTION.—The Secretary may revoke a designation of a drug under paragraph (1) if the Secretary finds that the application or supplemental application resulting in such designation contained an untrue statement of material fact.

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

"(b) EXTENSION.—

"(1) IN GENERAL.—If the Secretary designates a drug as a drug approved for a new indication for a rare disease or condition, as described in subsection (a)(1)—

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

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

"(B)(i) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 or a listed patent for which a certification has been submitted under subsections (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of 6 months after the date the patent expires (including any patent extensions); or

"(ii) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of 6 months after the date the patent expires (including any patent extensions).

"(2) RELATION TO PEDIATRIC AND QUALIFIED INFECTIOUS DISEASE PRODUCT EXCLUSIVITY.—Any extension under paragraph (1) of a period shall be in addition to any extension of the periods under sections 505A and 505E of this Act and section 351(m) of the Public Health Service Act, as applicable, with respect to the drug.

"(c) LIMITATIONS.—Any extension described in subsection (b)(1) shall not apply if the drug designated under subsection (a)(1) has previously received an extension by operation of subsection (b)(1).

"(d) DEFINITION.—In this section, the term 'rare disease or condition' has the meaning given to such term in section 526(a)(2).".

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

(c) CONFORMING AMENDMENTS.—

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

(A) in subsection (b), 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 paragraph (1) to the lengths of the exclusivity periods after application of pediatric exclusivity, the 6-month extensions described in paragraph (1) shall be in addition to any extensions under section 505G."; 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 paragraph (1) to the lengths of the exclusivity periods after application of pediatric exclusivity, the 6-month extensions described in paragraph (1) shall be in addition to any extensions under section 505G.''.

(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

(B) by striking ''any extension of the period under section 505A'' and inserting ''any extension of the periods under sections 505A and 505G, as applicable,''.

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

''(5) RELATION TO EXCLUSIVITY FOR A BIOLOGICAL PRODUCT APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION.—Notwithstanding the references in paragraphs (2)(A), (2)(B), (3)(A), and (3)(B) to the lengths of the exclusivity periods after application of pediatric exclusivity, the 6-month extensions described in such paragraphs shall be in addition to any extensions under section 505G.''.

SEC. 3. ORPHAN DRUGS.

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

(1) in subsection (a), in the matter following paragraph (2), by striking ''such drug for such disease or condition'' and inserting ''the same drug for the same disease or condition'';

(2) in subsection (b)—

(A) in the matter preceding paragraph (1), by striking ''If an application'' and all that follows through ''such license if'' and inserting ''During the 7-year period described in sub-

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

(B) in paragraph (1), by striking ''notice'' and all that follows through ''assure'' and inserting ''of exclusive approval or licensure notice and opportunity for the submission of views, that during such period the holder of the exclusive approval or licensure cannot ensure''; and

(C) in paragraph (2), by striking ''such holder provides'' and inserting ''the holder provides''; and

(3) by adding at the end the following:

''(c) CONDITION OF CLINICAL SUPERIORITY.—

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

ready approved drug, the Secretary shall require such sponsor, as a condition of such exclusive approval or licensure, to demonstrate that such drug is clinically superior to any already approved or licensed drug that is the same drug.

''(2) DEFINITION.—For purposes of paragraph (1), the term 'clinically superior' with respect to a drug means that the drug provides a significant therapeutic advantage over and above an already approved or licensed drug in terms of greater efficacy, greater safety, or by providing a major contribution to patient care.

''(d) REGULATIONS.—The Secretary may promulgate regulations for the implementation of subsection (c). Beginning on the date of enactment of the Orphan Products Extension Now Accelerating Cures and Treatments Act of 2017, until such time as the Secretary promulgates regulations in accordance with this subsection, the Secretary may apply any definitions set forth in regulations that were promulgated prior to such date of enactment, to the extent such definitions are not inconsistent with the terms of this section, as amended by such Act.

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

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

''(2) upon granting exclusive approval or licensure under subsection (a) on the basis of a demonstration of clinical superiority as described in subsection (c), shall publish a summary of the clinical superiority findings.''.

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

SEC. 4. PEDIATRIC INFORMATION ADDED TO LABELING.

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

(1) in the section heading, by striking ''**UNDER SECTION 505(j)**'';

(2) in paragraph (1)—

(A) by striking ''under section 505(j)'' and inserting ''under subsection (b)(2) or (j) of section 505''; and

(B) by striking ''or by exclusivity under clause (iii) or (iv) of section 505(j)(5)(F)'' and inserting '', or by exclusivity under clause (iii) or (iv) of section 505(j)(5)(F), clauses (iii) and (iv) of section 505(c)(3)(E), or section 527(a), or by an extension of such exclusivity under this section or section 505E'';

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

(A) by inserting ''clauses (iii) and (iv) of section 505(c)(3)(E), or section 527,'' after ''section 505(j)(5)(F),''; and

(B) by striking ''drug approved under section 505(j)'' and inserting ''drug approved pursuant to an application submitted under subsection (b)(2) or (j) of section 505''; and

(4) by amending paragraph (3) to read as follows:

''(3) PRESERVATION OF PEDIATRIC EXCLUSIVITY AND OTHER PROVISIONS.—This subsection does not affect—

"(A) the availability or scope of exclusivity under—

"(i) this section;

"(ii) section 505 for pediatric formulations; or

"(iii) section 527;

"(B) the question of the eligibility for approval of any application under subsection (b)(2) or (j) of section 505 that omits any other conditions of approval entitled to exclusivity under—

"(i) clause (iii) or (iv) of section 505(j)(5)(F);

"(ii) clauses (iii) or (iv) of section 505(c)(3)(E); or

"(iii) section 527; or

"(C) except as expressly provided in paragraphs (1) and (2), the operation of section 505 or section 527.".