

114TH CONGRESS
1ST SESSION

H. R. 971

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 HOUSE OF REPRESENTATIVES

FEBRUARY 13, 2015

Mr. BILIRAKIS (for himself, Mr. McCAUL, and Mr. BUTTERFIELD) introduced the following bill; which was referred to the Committee on Energy and Commerce

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 of such Act (21 U.S.C. 355f) 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) 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;

3 “(C) the application or supplemental appli-
4 cation for the new indication contains—

5 “(i) a request for designation of the
6 drug under this section;

7 “(ii) the consent of the applicant to
8 notice being given by the Secretary under
9 paragraph (4) respecting the designation
10 of the drug; and

11 “(iii) in the case of a drug for which
12 an extension is sought under subsection
13 (b)(3), a list specifying each patent—

14 “(I) which claims the drug or a
15 method of using the drug; and

16 “(II) with respect to which a
17 claim of patent infringement could
18 reasonably be asserted if a person not
19 licensed by the owner engaged in the
20 manufacture, use, or sale of the drug;
21 and

22 “(D) the Secretary approves the applica-
23 tion or supplemental application.

24 “(2) REVOCATION OF DESIGNATION.—

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

4 “(B) EXCEPTION.—The Secretary may re-
5 voke a designation of a drug under paragraph
6 (1) if the Secretary finds that the application or
7 supplemental application resulting in such des-
8 ignation contained an untrue statement of ma-
9 terial fact.

10 “(3) NOTIFICATION PRIOR TO DISCONTINUANCE
11 OF PRODUCTION FOR SOLELY COMMERCIAL REA-
12 SONS.—A designation of a drug under paragraph (1)
13 shall be subject to the condition that the sponsor of
14 the drug will notify the Secretary of any discontinu-
15 ance of the production of the drug for solely com-
16 mercial reasons at least one year before such dis-
17 continuance.

18 “(4) NOTICE TO PUBLIC.—Notice respecting
19 the designation of a drug under paragraph (1)—

20 “(A) shall be made available to the public;
21 and

22 “(B) shall include any listing of patents
23 under subsection (a)(1)(C)(iii).

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

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

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

15 “(B) the 7-year period described in section 527,
 16 as applicable, shall be extended by 6 months;

17 “(2) if, at the time a drug is designated under
 18 subsection (a)(1)—

19 “(A) the drug is the subject of a listed pat-
 20 ent for which a certification has been submitted
 21 under subsection (b)(2)(A)(ii) or
 22 (j)(2)(A)(vii)(II) of section 505 or a listed pat-
 23 ent for which a certification has been submitted
 24 under subsections (b)(2)(A)(iii) or
 25 (j)(2)(A)(vii)(III) of section 505, the period

1 during which an application may not be ap-
2 proved under section 505(c)(3) or section
3 505(j)(5)(B) shall be extended by a period of 6
4 months after the date the patent expires (in-
5 cluding any patent extensions); or

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

18 “(3) if the drug is a biological product, the Sec-
19 retary shall not grant final effective approval for any
20 application submitted under section 351(k)(1) of the
21 Public Health Service Act for a biosimilar biological
22 product that cites such drug as its reference product
23 until the date that is 6 months after the expiration
24 of every patent that, as of the date on which the
25 drug is designated under subsection (a)(1), is listed

1 for such drug pursuant to subsection (a)(1)(C)(iii),
2 except that, if a court from which no appeal (other
3 than a writ of certiorari) has been or could be taken
4 rules a listed patent invalid or not infringed, then
5 such patent shall no longer be considered for pur-
6 poses of this paragraph.

7 “(c) RELATION TO PEDIATRIC AND QUALIFIED IN-
8 FECTIOUS DISEASE PRODUCT EXCLUSIVITY.—Any exten-
9 sion under subsection (b) of a period shall be in addition
10 to any extension of the periods under sections 505A and
11 505E of this Act and section 351(m) of the Public Health
12 Service Act, as applicable, with respect to the drug.

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

17 “(e) REGULATIONS.—

18 “(1) IN GENERAL.—Not later than 2 years
19 after the date of enactment of this section, the Sec-
20 retary shall adopt final regulations implementing
21 this section.

22 “(2) PROCEDURE.—In promulgating a regula-
23 tion implementing this section, the Secretary shall—

24 “(A) issue a notice of proposed rulemaking
25 that includes the proposed regulation;

1 “(B) provide a period of not less than 60
2 days for comments on the proposed regulation;
3 and

4 “(C) publish the final regulation not less
5 than 30 days before the effective date of the
6 regulation.

7 “(3) RESTRICTIONS.—Notwithstanding any
8 other provision of law, the Secretary shall promul-
9 gate regulations implementing this section only as
10 described in paragraph (2), except that the Sec-
11 retary may issue interim guidance for sponsors seek-
12 ing to submit an application or supplemental appli-
13 cation described in subsection (a) prior to the pro-
14 mulgation of such regulations.

15 “(4) DESIGNATION PRIOR TO REGULATIONS.—
16 The Secretary shall designate drugs under sub-
17 section (a) prior to the promulgation of regulations
18 under this subsection, if such drugs meet the criteria
19 described in subsection (a).

20 “(f) DEFINITION.—In this section:

21 “(1) The terms ‘biological product’, ‘biosimilar’,
22 and ‘reference product’ have the meanings given to
23 such terms in section 351(i) of the Public Health
24 Service Act.

1 “(2) The term ‘rare disease or condition’ has
2 the meaning given to such term in section
3 526(a)(2).”.

4 (b) APPLICATION.—Section 505F 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 subpara-
8 graphs (B) and (C) of subsection (a)(1) of such section
9 505F is first approved under section 505(c) of such Act
10 (21 U.S.C. 355(c)) or section 351(a) of the Public Health
11 Service Act (42 U.S.C. 262(a)) on or after the date of
12 the enactment of this Act.

13 (c) CONFORMING AMENDMENTS.—

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

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

19 “(3) RELATION TO EXCLUSIVITY FOR A DRUG
20 APPROVED FOR A NEW INDICATION FOR A RARE DIS-
21 EASE OR CONDITION.—Notwithstanding the ref-
22 erences in subsection (b)(1) to the lengths of the ex-
23 clusivity periods after application of pediatric exclu-
24 sivity, the 6-month extensions described in sub-

1 section (b)(1) shall be in addition to any extensions
2 under section 505F.”; and

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

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

13 (2) RELATION TO EXCLUSIVITY FOR NEW
14 QUALIFIED INFECTIOUS DISEASE PRODUCTS THAT
15 ARE DRUGS.—Subsection (b) of section 505E of the
16 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
17 355f) is amended—

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

23 (B) by striking “any extension of the pe-
24 riod under section 505A” and inserting “any

1 extension of the periods under sections 505A or
2 505F”.

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

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

○