

114TH CONGRESS
1ST SESSION

S. 2388

To amend the Federal Food, Drug, and Cosmetic Act to provide for reciprocal marketing approval of certain drugs, biological products, and devices that are authorized to be lawfully marketed abroad, and for other purposes.

IN THE SENATE OF THE UNITED STATES

DECEMBER 10, 2015

Mr. CRUZ (for himself and Mr. LEE) 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 provide for reciprocal marketing approval of certain drugs, biological products, and devices that are authorized to be lawfully marketed abroad, 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 “Reciprocity Ensures
5 Streamlined Use of Lifesaving Treatments Act of 2015”.

1 **SEC. 2. RECIPROCAL MARKETING APPROVAL FOR CERTAIN**
2 **DRUGS, BIOLOGICAL PRODUCTS, AND DE-**
3 **VICES.**

4 The Federal Food, Drug, and Cosmetic Act is amend-
5 ed by inserting after section 524A of such Act (21 U.S.C.
6 360n-1) the following:

7 **“SEC. 524B. RECIPROCAL MARKETING APPROVAL.**

8 “(a) IN GENERAL.—A covered product with recip-
9 rocal marketing approval in effect under this section is
10 deemed to be subject to an application or premarket notifi-
11 cation for which an approval or clearance is in effect under
12 section 505(c), 510(k), or 515 of this Act or section
13 351(a) of the Public Health Service Act, as applicable.

14 “(b) ELIGIBILITY.—The Secretary shall, with respect
15 to a covered product, grant reciprocal marketing approval
16 if—

17 “(1) the sponsor of the covered product submits
18 a request for reciprocal marketing approval; and

19 “(2) the request demonstrates to the Sec-
20 retary’s satisfaction that—

21 “(A) the covered product is authorized to
22 be lawfully marketed in one or more of the
23 countries included in the list under section
24 802(b)(1);

1 “(B) absent reciprocal marketing approval,
2 the covered product is not approved or cleared
3 for marketing, as described in subsection (a);

4 “(C) the Secretary has not, because of any
5 concern relating to the safety or effectiveness of
6 the covered product, rescinded or withdrawn
7 any such approval or clearance;

8 “(D) the authorization to market the cov-
9 ered product in one or more of the countries in-
10 cluded in the list under section 802(b)(1) has
11 not, because of any concern relating to the safe-
12 ty or effectiveness of the covered product, been
13 rescinded or withdrawn;

14 “(E) the covered product is not a banned
15 device under section 516; and

16 “(F) there is a public health or unmet
17 medical need for the covered product in the
18 United States.

19 “(c) SAFETY AND EFFECTIVENESS.—

20 “(1) IN GENERAL.—The Secretary—

21 “(A) may decline to grant reciprocal mar-
22 keting approval under this section with respect
23 to a covered product if the Secretary affirma-
24 tively determines that the covered product—

1 “(i) is a drug that is not safe and ef-
2 fective; or

3 “(ii) is a device for which there is no
4 reasonable assurance of safety and effec-
5 tiveness; and

6 “(B) may condition reciprocal marketing
7 approval under this section on the conduct of
8 specified postmarket studies, which may include
9 such studies pursuant to a risk evaluation and
10 mitigation strategy under section 505-1.

11 “(2) REPORT TO CONGRESS.—Upon declining
12 to grant reciprocal marketing approval under this
13 section with respect to a covered product, the Sec-
14 retary shall—

15 “(A) include the denial in a list of such de-
16 nials for each month; and

17 “(B) not later than the end of the respec-
18 tive month, submit the list to the Committee on
19 Energy and Commerce of the House of Rep-
20 resentatives and the Committee on Health,
21 Education, Labor and Pensions of the Senate.

22 “(d) REQUEST.—A request for reciprocal marketing
23 approval shall—

24 “(1) be in such form, be submitted in such
25 manner, and contain such information as the Sec-

1 retary deems necessary to determine whether the cri-
2 teria listed in subsection (b)(2) are met; and

3 “(2) include, with respect to each country in-
4 cluded in the list under section 802(b)(1) where the
5 covered product is authorized to be lawfully mar-
6 keted, as described in subsection (b)(2)(A), an
7 English translation of the dossier issued by such
8 country to authorize such marketing.

9 “(e) TIMING.—The Secretary shall issue an order
10 granting, or declining to grant, reciprocal marketing ap-
11 proval with respect to a covered product not later than
12 30 days after the Secretary’s receipt of a request under
13 subsection (b)(1) for the product. An order issued under
14 this subsection shall take effect subject to Congressional
15 disapproval under subsection (g).

16 “(f) LABELING; DEVICE CLASSIFICATION.—During
17 the 30-day period described in subsection (e)—

18 “(1) the Secretary and the sponsor of the cov-
19 ered product shall expeditiously negotiate and final-
20 ize the form and content of the labeling for a cov-
21 ered product for which reciprocal marketing ap-
22 proval is to be granted; and

23 “(2) in the case of a device for which reciprocal
24 marketing approval is to be granted, the Secretary
25 shall—

1 “(A) classify the device pursuant to section
2 513; and

3 “(B) determine whether, absent reciprocal
4 marketing approval, the device would need to be
5 cleared pursuant to section 510(k) or approved
6 pursuant to section 515 to be lawfully marketed
7 under this Act.

8 “(g) CONGRESSIONAL DISAPPROVAL OF FDA OR-
9 DERS.—

10 “(1) IN GENERAL.—A decision of the Secretary
11 to decline to grant reciprocal marketing approval
12 under this section shall not take effect if a joint res-
13 olution of disapproval of the decision is enacted.

14 “(2) PROCEDURE.—

15 “(A) IN GENERAL.—Subject to subpara-
16 graph (B), the procedures described in sub-
17 sections (b) through (g) of section 802 of title
18 5, United States Code, shall apply to the con-
19 sideration of a joint resolution under this sub-
20 section.

21 “(B) TERMS.—For purposes of this sub-
22 section—

23 “(i) the reference to ‘section
24 801(a)(1)’ in section 802(b)(2)(A) of title

1 5, United States Code, shall be considered
2 to refer to subsection (c)(2); and

3 “(ii) the reference to ‘section
4 801(a)(1)(A)’ in section 802(e)(2) of title
5 5, United States Code, shall be considered
6 to refer to subsection (c)(2).

7 “(3) EFFECT OF CONGRESSIONAL DIS-
8 APPROVAL.—Reciprocal marketing approval under
9 this section with respect to the applicable covered
10 product shall take effect upon enactment of a joint
11 resolution of disapproval under this subsection.

12 “(h) APPLICABILITY OF RELEVANT PROVISIONS.—
13 The provisions of this Act shall apply with respect to a
14 covered product for which reciprocal marketing approval
15 is in effect to the same extent and in the same manner
16 as such provisions apply with respect to a product for
17 which approval or clearance of an application or pre-
18 market notification under section 505(c), 510(k), or 515
19 of this Act or section 351(a) of the Public Health Service
20 Act, as applicable, is in effect.

21 “(i) FEES FOR REQUEST.—For purposes of imposing
22 fees under chapter VII, a request for reciprocal marketing
23 approval under this section shall be treated as an applica-
24 tion or premarket notification for approval or clearance

1 under section 505(c), 510(k), or 515 of this Act or section
2 351(a) of the Public Health Service Act, as applicable.

3 “(j) OUTREACH.—The Secretary shall conduct an
4 outreach campaign to encourage the sponsors of covered
5 products that are potentially eligible for reciprocal mar-
6 keting approval to request such approval.

7 “(k) COVERED PRODUCT DEFINED.—In this section,
8 the term ‘covered product’ means a drug, biological prod-
9 uct, or device.”.

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