AMENDMENT NO._____ Calendar No._____

Purpose: 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—115th Cong., 1st Sess.

H. R. 1628

To provide for reconciliation pursuant to title II of the concurrent resolution on the budget for fiscal year 2017.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. CRUZ to the amendment (No. 267) proposed by Mr. MCCONNELL

Viz:

At the appropriate place, insert the following:

SEC. ___. RECIPROCAL MARKETING APPROVAL FOR CERTAIN DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES.

The Federal Food, Drug, and Cosmetic Act is amended by inserting after section 524A of such Act (21 U.S.C. 360n–1) the following:

"SEC. 524B. RECIPROCAL MARKETING APPROVAL.

''(a) IN GENERAL.—A covered product with reciprocal marketing approval in effect under this section is

deemed to be subject to an application or premarket notification for which an approval or clearance is in effect under section 505(c), 510(k), or 515 of this Act or section 351(a) of the Public Health Service Act, as applicable.

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

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

''(2) the request demonstrates to the Secretary's satisfaction that—

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

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

''(C) the Secretary has not, because of any concern relating to the safety or effectiveness of the covered product, rescinded or withdrawn any such approval or clearance;

''(D) the authorization to market the covered product in one or more of the countries included in the list under section 802(b)(1) has

not, because of any concern relating to the safety or effectiveness of the covered product, been rescinded or withdrawn;

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

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

''(c) SAFETY AND EFFECTIVENESS.—

''(1) IN GENERAL.—The Secretary—

''(A) may decline to grant reciprocal marketing approval under this section with respect to a covered product if the Secretary affirmatively determines that the covered product—

''(i) is a drug that is not safe and effective; or

''(ii) is a device for which there is no reasonable assurance of safety and effectiveness; and

''(B) may condition reciprocal marketing approval under this section on the conduct of specified postmarket studies, which may include such studies pursuant to a risk evaluation and mitigation strategy under section 505–1.

''(2) REPORT TO CONGRESS.—Upon declining to grant reciprocal marketing approval under this section with respect to a covered product, the Secretary shall—

''(A) include the denial in a list of such denials for each month; and

''(B) not later than the end of the respective month, submit the list to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate.

''(d) REQUEST.—A request for reciprocal marketing approval shall—

''(1) be in such form, be submitted in such manner, and contain such information as the Secretary deems necessary to determine whether the criteria listed in subsection (b)(2) are met; and

''(2) include, with respect to each country included in the list under section 802(b)(1) where the covered product is authorized to be lawfully marketed, as described in subsection (b)(2)(A), an English translation of the dossier issued by such country to authorize such marketing.

''(e) TIMING.—The Secretary shall issue an order granting, or declining to grant, reciprocal marketing ap-

proval with respect to a covered product not later than 30 days after the Secretary's receipt of a request under subsection (b)(1) for the product. An order issued under this subsection shall take effect subject to Congressional disapproval under subsection (g).

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

''(1) the Secretary and the sponsor of the covered product shall expeditiously negotiate and finalize the form and content of the labeling for a covered product for which reciprocal marketing approval is to be granted; and

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

''(A) classify the device pursuant to section 513; and

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

''(g) CONGRESSIONAL DISAPPROVAL OF FDA ORDERS.—

"(1) IN GENERAL.—A decision of the Secretary to decline to grant reciprocal marketing approval under this section shall not take effect if a joint resolution of disapproval of the decision is enacted.

"(2) PROCEDURE.—

"(A) IN GENERAL.—Subject to subparagraph (B), the procedures described in subsections (b) through (g) of section 802 of title 5, United States Code, shall apply to the consideration of a joint resolution under this subsection.

"(B) TERMS.—For purposes of this subsection—

"(i) the reference to 'section 801(a)(1)' in section 802(b)(2)(A) of title 5, United States Code, shall be considered to refer to subsection (c)(2); and

"(ii) the reference to 'section 801(a)(1)(A)' in section 802(e)(2) of title 5, United States Code, shall be considered to refer to subsection (c)(2).

"(3) EFFECT OF CONGRESSIONAL DISAPPROVAL.—Reciprocal marketing approval under this section with respect to the applicable covered

product shall take effect upon enactment of a joint resolution of disapproval under this subsection.

''(h) APPLICABILITY OF RELEVANT PROVISIONS.—The provisions of this Act shall apply with respect to a covered product for which reciprocal marketing approval is in effect to the same extent and in the same manner as such provisions apply with respect to a product for which approval or clearance of an application or premarket notification under section 505(c), 510(k), or 515 of this Act or section 351(a) of the Public Health Service Act, as applicable, is in effect.

''(i) FEES FOR REQUEST.—For purposes of imposing fees under chapter VII, a request for reciprocal marketing approval under this section shall be treated as an application or premarket notification for approval or clearance under section 505(c), 510(k), or 515 of this Act or section 351(a) of the Public Health Service Act, as applicable.

''(j) OUTREACH.—The Secretary shall conduct an outreach campaign to encourage the sponsors of covered products that are potentially eligible for reciprocal marketing approval to request such approval.

''(k) COVERED PRODUCT DEFINED.—In this section, the term 'covered product' means a drug, biological product, or device.''.