117TH CONGRESS
1ST SESSION

H. R. 1

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 HOUSE OF REPRESENTATIVES

Mr. Roy introduced the following bill; which was referred to the Committee on

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.

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 “Reciprocity Ensures Streamlined Use of Lifesaving Treatments Act of 2021”.
SEC. 2. RECIPROCAL MARKETING APPROVAL FOR CERTAIN

DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES.

The Federal Food, Drug, and Cosmetic Act is amend-
ed 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 recip-
rocal marketing approval in effect under this section is
deemed to be subject to an application or premarket notifi-
cation 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 Sec-
retary’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) or in the United Kingdom;
“(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“(C) the Secretary has not, because of any concern relating to the safety or effectiveness of the covered product, rescinded or withdrawn any such approval or clearance;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) or in the United Kingdom has not, because of any concern relating to the safety or effectiveness of the covered product, been rescinded or withdrawn;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 Sec-
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 approval 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 Dis-
approval.—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 pre-
market 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 applica-
tion or premarket notification for approval or clearance
under section 505(e), 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.”