

117TH CONGRESS
2D SESSION

S. 3576

To allow sponsors of certain new drug applications to rely upon investigations conducted in certain foreign countries, and for other purposes.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 3, 2022

Mr. BRAUN (for himself and Mr. PAUL) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To allow sponsors of certain new drug applications to rely upon investigations conducted in certain foreign countries, 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 “Accelerated Drug Ap-
5 proval for Prescription Therapies 2.0 Act” or the
6 “ADAPT 2.0 Act”.

1 **SEC. 2. DRUGS APPROVED IN CERTAIN FOREIGN COUN-**
2 **TRIES.**

3 (a) IN GENERAL.—Section 505 of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 355) is amended—

5 (1) in subsection (b), by adding at the end the
6 following:

7 “(7) An application described in paragraph (2) may
8 rely upon investigations conducted in a country listed
9 under section 802(b)(1)(A) or designated under section
10 802(b)(1)(B), including premarket clinical and nonclinical
11 investigations and postmarket surveillance studies, if the
12 drug that is the subject of such application has been ap-
13 proved in such country.”; and

14 (2) in subsection (c)—

15 (A) in paragraph (1), by striking “Within”
16 and inserting “Except as provided in paragraph
17 (6), within”; and

18 (B) by adding at the end the following:

19 “(6)(A) In the case of an application that relies on
20 investigations conducted in a foreign country, as described
21 in subsection (b)(7), within 90 days after the filing of such
22 application under subsection (b), the Secretary shall ap-
23 prove the application if the Secretary determines evidence
24 that—

25 “(i) at the time of application, the drug is au-
26 thorized to be marketed in a country listed under

1 section 802(b)(1)(A) or designated under section
2 802(b)(1)(B);

3 “(ii) the drug is safe and clinically effective;

4 “(iii) the manufacturer is capable of manufac-
5 turing the drug safely and consistently, and can en-
6 sure the safety of the supply chain outside the
7 United States;

8 “(iv) all relevant United States patents or legal
9 periods of exclusivity are expired;

10 “(v) absent reciprocal marketing approval, the
11 drug is not approved for marketing in the United
12 States;

13 “(vi) the Secretary has not, because of any con-
14 cern relating to safety or effectiveness, rescinded or
15 withdrawn any such approval; and

16 “(vii) the Secretary finds that none of the
17 grounds for denying approval specified in subsection
18 (d) applies.

19 “(B) LIMITATIONS.—Approval of a drug under this
20 section may, as the Secretary determines appropriate, be
21 subject to 1 or both of the following requirements:

22 “(i) The sponsor conduct appropriate post-
23 approval studies to verify and describe the predicted
24 effect of the drug on irreversible morbidity or mor-
25 tality or another clinical benefit of the drug.

1 “(ii) The sponsor submit copies of all pro-
2 motional materials related to the drug during the
3 preapproval review period and, following approval
4 and for such period thereafter as the Secretary de-
5 termines to be appropriate, at least 30 days prior to
6 the dissemination of the materials.

7 “(C) TIMELINE.—If the Secretary does not approve
8 the application or take such other action within such 90-
9 day period, the application shall be considered approved
10 under this subsection.

11 “(D) ADVISORY COMMITTEE.—

12 “(i) ESTABLISHMENT.—For the purpose of pro-
13 viding expert scientific advice and recommendations
14 to the Secretary regarding the approval of applica-
15 tions described in subsection (b)(7), the Secretary
16 shall establish a standing Foreign Drug Review Ad-
17 visory Committee.

18 “(ii) MEMBERSHIP.—The standing Foreign
19 Drug Review Advisory Committee established under
20 clause (i) shall consist of employees of the Food and
21 Drug Administration and individuals appointed by
22 the Secretary, reflecting a balanced composition of
23 sufficient scientific expertise. The Secretary shall ap-
24 point members who have diverse interests, education,
25 training, experience, and expertise in biopharma-

1 cology, statistics, chemistry, legal issues, ethics, and
2 other appropriate expertise pertaining to the drugs
3 under review, such as expertise in foreign regulatory
4 and manufacturing practices and drug development,
5 and other individuals, as the Secretary determines
6 appropriate.

7 “(iii) REVIEW OF APPLICATIONS.—Upon the fil-
8 ing of an application described in subsection
9 (b)(7)—

10 “(I) the Secretary shall immediately refer
11 the application to the Foreign Drug Review Ad-
12 visory Committee for review; and

13 “(II) within 60 days after the receipt by
14 such advisory committee of such application,
15 the advisory committee shall provide the Sec-
16 retary with recommendations with respect to
17 such application.

18 “(E) PUBLICATION OF FINAL DECISION.—The Sec-
19 retary shall make publically available, on the website of
20 the Food and Drug Administration, each final decision on
21 whether to approve an application described in subsection
22 (b)(7), including the rationale for the decision and the rec-
23 ommendations and conclusions of the Foreign Drug Re-
24 view Advisory Committee under subparagraph (D)(iii).”.

1 (b) TECHNICAL AMENDMENT.—Section
2 802(b)(1)(A)(i) of the Federal Food, Drug, and Cosmetic
3 Act (21 U.S.C. 382(b)(1)(A)(i)) is amended by striking
4 “or South Africa” and inserting “South Africa, or the
5 United Kingdom”.

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