

116TH CONGRESS
1ST SESSION

S. 658

To provide for an accelerated approval pathway for certain drugs that are authorized to be lawfully marketed in other countries.

IN THE SENATE OF THE UNITED STATES

MARCH 5, 2019

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

A BILL

To provide for an accelerated approval pathway for certain drugs that are authorized to be lawfully marketed in other countries.

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 Act” or the “ADAPT
6 Act”.

1 **SEC. 2. ACCELERATED APPROVAL OF CERTAIN DRUGS**
2 **THAT ARE AUTHORIZED TO BE LAWFULLY**
3 **MARKETED IN OTHER COUNTRIES.**

4 Chapter V of the Federal Food, Drug, and Cosmetic
5 Act (21 U.S.C. 351 et seq.) is amended by inserting after
6 section 506 the following:

7 **“SEC. 506-1. ACCELERATED APPROVAL OF CERTAIN DRUGS**
8 **THAT ARE AUTHORIZED TO BE LAWFULLY**
9 **MARKETED IN OTHER COUNTRIES.**

10 “(a) IN GENERAL.—The Secretary may approve an
11 application for approval for a drug under subsection (c)
12 or (j) of section 505 that is currently authorized to be
13 marketed in one or more of the countries included in the
14 list under section 802(b)(1), upon a determination by the
15 Secretary that the sponsor has submitted evidence suffi-
16 cient to demonstrate all of the criteria under subsection
17 (b)(1).

18 “(b) CRITERIA.—

19 “(1) IN GENERAL.—The Secretary may approve
20 a drug under subsection (a) only if the Secretary de-
21 termines that there is evidence that—

22 “(A) at the time of application, the drug is
23 authorized to be marketed in a country included
24 in the list under section 802(b)(1);

1 “(B) the drug is safe and clinically effec-
2 tive and has a satisfactory history of clinical
3 trials and data;

4 “(C) the manufacturer is capable of manu-
5 facturing the drug safely and consistently, and
6 can assure the safety of the supply chain out-
7 side the United States;

8 “(D) all relevant United States patents or
9 legal exclusivities are expired;

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

13 “(F) the Secretary has not, because of any
14 concern relating to safety or effectiveness, re-
15 scinded or withdrawn any such approval; and

16 “(G) there is a public health or unmet
17 medical need for the drug in the United States.

18 “(2) LIMITATION.—Approval of a drug under
19 this section may, as the Secretary determines appro-
20 priate, be subject to 1 or both of the following re-
21 quirements:

22 “(A) The sponsor conduct appropriate
23 postapproval studies to verify and describe the
24 predicted effect on irreversible morbidity or
25 mortality or other clinical benefit of the drug.

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

7 “(c) TIMELINE.—The Secretary shall make a deter-
8 mination on an application described in subsection (a) not
9 later than 180 days after the date of submission of such
10 application.”.

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