

Mike Braun

AMENDMENT NO. 1 Calendar No. _____

Purpose: 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—116th Cong., 1st Sess.

S. 1895

To lower health care costs.

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. BRAUN

Viz:

1 At the appropriate place in title II, insert the fol-
2 lowing:

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

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

1 “(D) all relevant United States patents or
2 legal exclusivities are expired;

3 “(E) absent reciprocal marketing approval,
4 the drug is not approved for marketing in the
5 United States;

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8 scinded or withdrawn any such approval; and

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

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

15 “(A) The sponsor conduct appropriate
16 postapproval studies to verify and describe the
17 predicted effect on irreversible morbidity or
18 mortality or other clinical benefit of the drug.

19 “(B) The sponsor submit copies of all pro-
20 motional materials related to the product dur-
21 ing the preapproval review period and, following
22 approval and for such period thereafter as the
23 Secretary determines to be appropriate, at least
24 30 days prior to dissemination of the materials.

1 “(c) **TIMELINE.**—The Secretary shall make a deter-
2 mination on an application described in subsection (a) not
3 later than 180 days after the date of submission of such
4 application.”.