S.L.C.
Mike Braun

AM	IENDMENT NO Calendar No	
Pu	rpose: 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		
R	eferred 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	"SEC. 506-1. ACCELERATED APPROVAL OF CERTAIN DRUGS
2	THAT ARE AUTHORIZED TO BE LAWFULLY
3	MARKETED IN OTHER COUNTRIES.
4	"(a) IN GENERAL.—The Secretary may approve an
5	application for approval for a drug under subsection (e)
6	or (j) of section 505 that is currently authorized to be
7	marketed in one or more of the countries included in the
8	list under section 802(b)(1), upon a determination by the
9	Secretary that the sponsor has submitted evidence suffi-
10	cient to demonstrate all of the criteria under subsection
11	(b)(1).
12	"(b) Criteria.—
13	"(1) In General.—The Secretary may approve
14	a drug under subsection (a) only if the Secretary de-
15	termines that there is evidence that—
16	"(A) at the time of application, the drug is
17	authorized to be marketed in a country included
18	in the list under section 802(b)(1);
19	"(B) the drug is safe and clinically effec-
20	tive and has a satisfactory history of clinical
21	trials and data;
22	"(C) the manufacturer is capable of manu-
23	facturing the drug safely and consistently, and
24	can assure the safety of the supply chain out-
25	side the United States;

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8	seinded or withdrawn any such approval; and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.".