Mike Braun
Amendment #1

AMENDMENT NO._____ Calendar No._____

Purpose: To allow sponsors of certain new drug applications to rely upon investigations conducted in certain foreign countries.

IN THE SENATE OF THE UNITED STATES—117th Cong., 2d Sess.

S. 3799

To prepare for, and respond to, existing viruses, emerging new threats, and pandemics.

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 (for himself and Mr. PAUL)

Viz:

At the appropriate place in subtitle A of title V, insert the following:

SEC. 5____. DRUGS APPROVED IN CERTAIN FOREIGN COUNTRIES.

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

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

"(7) An application described in paragraph (2) may rely upon investigations conducted in a country listed under section 802(b)(1)(A) or designated under section

802(b)(1)(B), including premarket clinical and nonclinical investigations and postmarket surveillance studies, if the drug that is the subject of such application has been approved in such country."; and

(2) in subsection (c)—

(A) in paragraph (1), by striking "Within" and inserting "Except as provided in paragraph (6), within"; and

(B) by adding at the end the following:

"(6)(A) In the case of an application that relies on investigations conducted in a foreign country, as described in subsection (b)(7), within 90 days after the filing of such application under subsection (b), the Secretary shall approve the application if the Secretary determines evidence that—

"(i) at the time of application, the drug is authorized to be marketed in a country listed under section 802(b)(1)(A) or designated under section 802(b)(1)(B);

"(ii) the drug is safe and clinically effective;

"(iii) the manufacturer is capable of manufacturing the drug safely and consistently, and can ensure the safety of the supply chain outside the United States;

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

"(v) absent reciprocal marketing approval, the drug is not approved for marketing in the United States;

"(vi) the Secretary has not, because of any concern relating to safety or effectiveness, rescinded or withdrawn any such approval; and

"(vii) the Secretary finds that none of the grounds for denying approval specified in subsection (d) applies.

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

"(i) The sponsor conduct appropriate post-approval studies to verify and describe the predicted effect of the drug on irreversible morbidity or mortality or another clinical benefit of the drug.

"(ii) The sponsor submit copies of all promotional materials related to the drug during the preapproval review period and, following approval and for such period thereafter as the Secretary determines to be appropriate, at least

30 days prior to the dissemination of the materials.

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

"(D) ADVISORY COMMITTEE.—

"(i) ESTABLISHMENT.—For the purpose of providing expert scientific advice and recommendations to the Secretary regarding the approval of applications described in subsection (b)(7), the Secretary shall establish a standing Foreign Drug Review Advisory Committee.

"(ii) MEMBERSHIP.—The standing Foreign Drug Review Advisory Committee established under clause (i) shall consist of employees of the Food and Drug Administration and individuals appointed by the Secretary, reflecting a balanced composition of sufficient scientific expertise. The Secretary shall appoint members who have diverse interests, education, training, experience, and expertise in biopharmacology, statistics, chemistry, legal issues, ethics, and other appropriate expertise pertaining to the drugs under review, such as expertise in foreign

regulatory and manufacturing practices and drug development, and other individuals, as the Secretary determines appropriate.

"(iii) REVIEW OF APPLICATIONS.—Upon the filing of an application described in subsection (b)(7)—

"(I) the Secretary shall immediately refer the application to the Foreign Drug Review Advisory Committee for review; and

"(II) within 60 days after the receipt by such advisory committee of such application, the advisory committee shall provide the Secretary with recommendations with respect to such application.

"(E) PUBLICATION OF FINAL DECISION.—The Secretary shall make publically available, on the website of the Food and Drug Administration, each final decision on whether to approve an application described in subsection (b)(7), including the rationale for the decision and the recommendations and conclusions of the Foreign Drug Review Advisory Committee under subparagraph (D)(iii).".

(b) TECHNICAL AMENDMENT.—Section 802(b)(1)(A)(i) of the Federal Food, Drug, and Cosmetic

Act (21 U.S.C. 382(b)(1)(A)(i)) is amended by striking "or South Africa" and inserting "South Africa, or the United Kingdom".