TAM17972

Paul Amdt #1

S.L.C.

AMENDMENT NO. 1 Calendar No._____

Purpose: To permit the use of clinical investigational data from outside the United States in certain circumstances.

IN THE SENATE OF THE UNITED STATES—115th Cong., 1st Sess.

S. 934

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

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. PAUL

Viz:

At the appropriate place, insert the following:

SEC. _____. USE OF CLINICAL INVESTIGATION DATA FROM OUTSIDE THE UNITED STATES.

Section 569B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–8b) is amended—

(1) in subsection (a)—

(A) by striking "In determining" and inserting "Subject to subsection (c), in determining";

(B) by inserting "or section 351 of the Public Health Service Act" after "this chapter"; and

(C) by striking ", including the European Union, if the applicant demonstrates that such data are" and inserting "unless the Secretary determines the data is not";

(2) in subsection (b), by striking ", including in the European Union,"; and

(3) by adding at the end the following:

"(c) APPLICATIONS FOR A DRUG THAT HAS BEEN APPROVED OUTSIDE THE US.—

"(1) IN GENERAL.—In the case of an application for approval or clearance of a drug, biological product, or device under this chapter or section 351 of the Public Health Service Act where such drug, biological product, or device has been approved in a country described in paragraph (2), within the timelines established in the letters referred to in section 101(b) of the Prescription Drug User Fee Amendments of 2017 in the case of a drug or within the timelines established in the letters referred to in section 201(b) of the Medical Device User Fee Amendments of 2017 in the case of a device, or such

additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall—

"(A) approve the application, if the Secretary finds no grounds for denying approval of the application; or

"(B) provide written notice to the sponsor of the application of a finding that is grounds for denying approval, including the rationale for such finding, and provide the sponsor an opportunity for a hearing.

"(2) APPLICABLE COUNTRIES.—

"(A) IN GENERAL.—Subject to subparagraph (B), the countries described in this paragraph are—

"(i) Australia;

"(ii) Austria;

"(iii) Belgium;

"(iv) Canada;

"(v) Chile;

"(vi) Czech Republic;

"(vii) Denmark;

"(viii) Estonia;

"(ix) Finland;

"(x) France;

"(xi) Germany;

"(xii) Greece;

"(xiii) Hungary;

"(xiv) Iceland;

"(xv) Ireland;

"(xvi) Israel;

"(xvii) Italy;

"(xviii) Japan;

"(xix) Korea;

"(xx) Latvia;

"(xxi) Luxembourg;

"(xxii) Mexico;

"(xxiii) Netherlands;

"(xxiv) New Zealand;

"(xxv) Norway;

"(xxvi) Poland;

"(xxvii) Portugal;

"(xxviii) Slovak Republic;

"(xxix) Slovenia;

"(xxx) Spain;

"(xxxi) Sweden;

"(xxxii) Switzerland;

"(xxxiii) Turkey; and

"(xxxiv) United Kingdom.

"(B) REVISIONS TO LIST.—The Secretary may add countries to, or remove countries from,

the list under subparagraph (A), as the Secretary determines appropriate.".