Rand Paul

PAUL

AMENDMENT NO. 2 Calendar No._____

Purpose: To require the Food and Drug Administration to take into consideration the results of clinical investigations conducted in the European Union when reviewing applications approval of drugs and devices in the United States.

IN THE SENATE OF THE UNITED STATES—112th Cong., 2d Sess.

S._____

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, 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 end of title XI, add the following:

SEC. 11___. USE OF CLINICAL INVESTIGATION DATA FROM THE EUROPEAN UNION.

Subchapter E of chapter V (21 U.S.C. 360bbb et seq.), as amended by this Act, is amended by adding at the end the following:

"SEC. 569B. USE OF CLINICAL INVESTIGATION DATA FROM THE EUROPEAN UNION.

"Notwithstanding any other provision of this Act, in determining whether to approve, license, or clear a drug or device pursuant to an application submitted under this chapter, the Secretary shall take into consideration the results of the clinical investigations conducted with respect to such drug or device in the European Union, if such drug or device has been approved for marketing in the European Union.".