

Rand Paul

PAUL
 AMENDMENT NO. 1 Calendar No. _____

Purpose: To require the Food and Drug Administration to base determinations of approval, licensure, and clearance of drugs and devices on the results of clinical investigations conducted in the European Union when reviewing applications of drugs and devices.

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:

- 1 At the end of title XI, add the following:
- 2 **SEC. 11 ____ . USE OF CLINICAL INVESTIGATION DATA FROM**
- 3 **THE EUROPEAN UNION.**
- 4 Subchapter E of chapter V (21 U.S.C. 360bbb et
- 5 seq.), as amended by this Act, is amended by adding at
- 6 the end the following:

1 **“SEC. 569B. USE OF CLINICAL INVESTIGATION DATA FROM**
2 **THE EUROPEAN UNION.**

3 “(a) IN GENERAL.—Notwithstanding any other pro-
4 vision of this Act, in determining whether to approve, li-
5 cense, or clear a drug or device pursuant to an application
6 submitted under this chapter, the Secretary shall base
7 such determination on the results of the clinical investiga-
8 tions conducted with respect to such drug or device in the
9 European Union, if such drug or device has been approved
10 for marketing in the European Union, unless the Sec-
11 retary finds that such investigations are not adequate for
12 such purpose.

13 “(b) NOTICE TO SPONSOR.—If the Secretary finds
14 under subsection (a) that clinical investigations conducted
15 in the European Union are not adequate for the purpose
16 of making a determination on approval, clearance, or li-
17 censure of a drug or device pursuant to an application
18 submitted under this chapter, the Secretary shall provide
19 written notice to the sponsor of the application of such
20 finding and include the rationale for such finding.”