Bill Cassidy, M.D.

TAM17982 S.L.C.

AMENDMENT NO. 1 Calendar No._____

Purpose: To direct the Secretary to issue guidance regarding the demonstration of bioequivalence.

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. CASSIDY

Viz:

At the appropriate place, insert the following:

SEC. _____. GUIDANCE REGARDING BIOEQUIVALENCE.

(a) IN GENERAL.—In accordance with subsection (b), the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue product-specific guidance, that—

(1) applies to complex non-biologic drugs; and

(2) outlines how to demonstrate bioequivalence to the reference drug in order to facilitate generic development for such drugs.

(b) DEADLINE FOR ISSUING GUIDANCE.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall publish a guidance for each complex non-biologic drug that is approved under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)). Such guidance shall be published not less than 2 years prior to the earliest date on which an abbreviated new drug application may be submitted pursuant to section 505(j) of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) that refcrences such drug.

(c) APPLICABILITY.—This section applies to guidances whose deadline would be on or after October 1, 2017, based on subsection (b).