TAM18197 S.L.C.

AMENDMENT NO. 1 Calendar No._____

Purpose: To require guidance on the use of certain elements in clinical investigation protocols and applications for new animal drugs.

IN THE SENATE OF THE UNITED STATES—115th Cong., 2d Sess.

S. 2434

To amend the Federal Food, Drug, and Cosmetic Act to reauthorize user fee programs relating to new animal drugs and generic new animal drugs.

Referred to the Committee on Health, Education, Labor and Pensions and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. Murphy

Viz:

At the end of title III, insert the following:

SEC. 3_____. GUIDANCE ADDRESSING INVESTIGATION DESIGNS.

(a) IN GENERAL.—For purposes of assisting sponsors in incorporating complex adaptive and other novel investigation designs, data from foreign countries, real world evidence (including ongoing surveillance activities, observational studies, and registry data), biomarkers, and surrogate endpoints (referred to in this section as "elements of investigations") into proposed clinical investigation protocols and applications for new animal drugs under sec-

tions 512 and 571 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b; 360ccc), the Secretary of Health and Human Services (referred to in this section as the "Secretary") shall issue guidance addressing the use of such elements of investigations in the development and regulatory review of such new animal drugs.

(b) CONTENTS.—The guidance under subsection (a) shall address how the Secretary will evaluate the elements of investigations proposed or submitted pursuant to section 512(b)(1)(A) of the Federal Food, Drug, and Cosmetic Act or to meet the commitment under section 571(a)(2)(F) of such Act, and how sponsors of such applications may obtain feedback from the Secretary on technical issues related to such investigations prior to the submission of an application to the Secretary.

(c) MEETING.—Prior to issuing the guidance under subsection (a), the Secretary shall consult with stakeholders, including representatives of regulated industry, consumer groups, academia, veterinarians, and food producers, through a public meeting to be held not later than 1 year after the date of enactment of this Act.

(d) TIMING.—The Secretary shall issue a draft guidance under subsection (a) not later than 1 year after the date of the public meeting under subsection (c), and shall finalize such guidance not later than 1 year after the date

on which the public comment period on such draft guidance ends.