AMENDMENT TO H.R. _____

OFFERED BY M__. _____

[Page and line numbers refer to A(G)DUFA reauthorization draft, INTRO__07, dated April 17]

Page 10, line 14, strike ''described'' and insert ''provided''.

Page 22, line 7, strike ''described'' and insert ''provided''.

At the end of the bill add the following new sections (and conform the table of contents accordingly):

SEC. 304. ISSUANCE OF RECOMMENDATIONS.

Not later than September 30, 2019, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall issue recommendations that the Secretary, in the letters described in section 101(b) of the Animal Drug User Fee Amendments of 2013 (Public Law 113–14), agreed to develop regarding the feasibility of pursuing statutory revisions that may expand the use of conditional approval of new animal drugs under section 571 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ccc) to appropriate categories of new animal drugs.

SEC. 305. 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 sections 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.

SEC. 306. FOOD ADDITIVES INTENDED FOR USE IN ANIMAL FOOD.

(a) FOOD ADDITIVE PETITIONS FOR ANIMAL FOOD.—Section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348) is amended by adding at the end the following:

''(k) FOOD ADDITIVES INTENDED FOR USE IN ANIMAL FOOD.—(1) In taking action on a petition under subsection (c) for, or for recognition of, a food additive intended for use in animal food, the Secretary shall review reports of investigations conducted in foreign countries, provided by the petitioner.

''(2) Not later than 12 months after the date of enactment of the Animal Drug and Animal Generic Drug Use Fee Amendments of 2018, the Secretary shall post on the internet website of the Food and Drug Administration—

''(A) the number of petitions for food additives intended for use in animal food filed under subsection (b) that are pending;

''(B) how long each such petition submitted under subsection (b) has been pending, including such petitions the Secretary has extended under subsection (c)(2); and

''(C) the number of study protocols that have been pending review for over 50 days, and the number that have received an extension.

''(3) In the case of a food additive petition intended for use in animal food, the Secretary shall provide information to the petitioner on the required contents of such petition. If the Secretary requires additional studies beyond what the petitioner proposed, the Secretary shall provide the scientific rationale for such requirement.''.

(b) ENSURING THE SAFETY OF PET FOOD.—Section 1002(a) of the Food and Drug Administration Amendments Act of 2007 (21 U.S.C. 2102(a)) is amended—

(1) by striking paragraph (1); and

(2) by redesignating paragraphs (2) and (3) as paragraphs (1) and (2), respectively.

(c) GUIDANCE ON PRE-PETITION CONSULTATION PROCESS FOR ANIMAL FOOD ADDITIVES.—

(1) IN GENERAL.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this subsection as the ''Secretary'') shall publish draft guidance relating to the voluntary pre-petition consultation process for food additives intended for use in animal food.

(2) CONTENTS.—The guidance under paragraph (1) shall include—

(A) the recommended format to submit to the Food and Drug Administration existing data, including any applicable foreign data, for assessment prior to submission of a food additive petition for animal food under section 409(b) of the Federal Food, Drug, and Cosmetic Act;

(B) the manner and the number of days by which the Food and Drug Administration intends to review and respond to such existing data, including with respect to providing a scientific rationale for any additional data request;

(C) circumstances under which the submission of study protocols is recommended prior to submission of a food additive petition under such section 409(b);

(D) the manner in which the Secretary intends to inform the person submitting a study protocol for a food additive if the review of such study protocol will take longer than 50 days; and

(E) best practices for communication between the Food and Drug Administration and industry on the development of pre-petition submissions of study protocols and existing data for food additives.

(3) FINAL GUIDANCE.—The guidance under paragraph (1) shall be finalized, withdrawn, or reissued not later than 1 year after the close of the comment period on the draft guidance.