Rand Paul

AMENDMENT NO. 2 Calendar No._____

Purpose: To clarify the process for filing petitions for food additives intended for use in animal food.

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 _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by _____

Viz:

At the appropriate place in title III, insert the following:

SEC. 3___. 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 in-

tended for use in animal food, the Secretary shall review reports of investigations conducted in foreign countries, provided by the petitioner.

"(2) The Secretary shall post on the internet website of the Food and Drug Administration, no later than March 1 of each year, on—

"(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.