 Pat Roberts

AMENDMENT NO. 1 Calendar No._____

Purpose: To amend the process for conditional approval of new animal drugs and to provide for a process for conditional approval of new indications of an animal drug.

**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 Mr. Roberts, Mr. Burr

Viz:

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

**SEC. 3_____. CONDITIONAL APPROVAL OF NEW ANIMAL DRUGS OR NEW INDICATIONS OF AN ANIMAL DRUG.**

Section 571 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ccc) is amended—

(1) in the section heading, by striking "**FOR MINOR USE AND MINOR SPECIES**" and inserting "**OR NEW INDICATIONS OF AN ANIMAL DRUG**";

(2) in subsection (a)—

(A) in paragraph (1)—

(i) by striking "intended for a minor use or a minor species" and inserting "or a new indication of an animal drug for which an application for approval under section 512 or conditional approval under this section is in effect"; and

(ii) by striking "Such an application may not be a supplement to an application approved under section 512."; and

(B) in paragraph (2)—

(i) in the matter preceding subparagraph (A), by inserting "or new indication for an animal drug for which an approved application under section 512 or conditional approval under this section is in effect" after "drug";

(ii) in subparagraph (B), by inserting "or new indication" after "such drug";

(iii) by amending subparagraph (D) to read as follows:

"(D) data and information to support the–

"(i) intended use of the new animal drug to treat a serious or life-threatening

disease or condition, or for which limited therapeutic alternatives exist; or

"(ii) need for an extended period of time to establish substantial evidence of effectiveness;"; and

(iv) in subparagraph (E), by inserting ", as the Secretary determines appropriate" after "expected need";

(3) by amending subsection (f) to read as follows:

"(f)(1) The label and labeling of a new animal drug with a conditional approval under this section shall—

"(A) bear the statement, 'conditionally approved by FDA pending a full demonstration of effectiveness under application number'; and

"(B) contain such other information as prescribed by the Secretary.

"(2) Notwithstanding any labeling requirements pursuant to the prior approval of an application under section 512, the label and labeling of an animal drug approved under section 512 for which a new indication has conditional approval under this section shall—

"(A) bear the statement, 'this indication has been conditionally approved by FDA pending a full

demonstration of effectiveness under application number'; and

"(B) contain such other information as prescribed by the Secretary.";

(4) by striking subsection (g); and

(5) by redesignating subsection (h) through (j) as subsections (g) through (i), respectively.