AMENDMENT NO. 1

Purpose: To establish requirements with respect to zootechnical animal food substances.


S. 1844

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. MARSHALL
(for himself and Ms. BALDWIN)

Viz:

1 At the end of title III, add the following:

2 SEC. 304. REGULATION OF ZOOTECHNICAL ANIMAL FOOD SUBSTANCES.

3 (a) DEFINITION.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

4 “(tt)(1) The term ‘zootechnical animal food substance’ means a substance that—

5 “(A) is added to the food or drinking water of animals;

6 “(B) is intended to—
“(i) affect the byproducts of the digestive process of an animal;

“(ii) reduce the presence of foodborne pathogens of human health significance in an animal intended to be used for food; or

“(iii) affect the structure or function of the body of the animal, other than by providing nutritive value, by altering the animal’s gastrointestinal microbiome; and

“(C) achieves its intended effect by acting solely within the gastrointestinal tract of the animal.

“(2) Such term does not include a substance that—

“(A) is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in an animal;

“(B) is a hormone;

“(C) is an active moiety in an animal drug, which, prior to the filing of a petition under section 409 was approved under section 512, conditionally approved under section 571, or indexed under section 572, or for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public;

“(D) is an ionophore; or
“(E) is otherwise excluded from the definition based on criteria established by the Secretary through notice and comment rulemaking.

“(3) A zootechnical animal food substance shall be deemed to be a food additive within the meaning of paragraph (s) and its introduction into interstate commerce shall be in accordance with a regulation issued under section 409. A zootechnical animal food substance shall not be considered a drug under paragraph (g)(1)(C) solely because the substance has an intended effect described in subparagraph (1).”

(b) FOOD ADDITIVES.—Section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348) is amended—

(1) in subsection (b)—

(A) by redesignating paragraphs (3) through (5) as paragraphs (4) through (6), respectively; and

(B) by inserting after paragraph (2) the following:

“(3) In the case of a zootechnical animal food substance, such petition shall, in addition to any explanatory or supporting data, contain—

“(A) all relevant data bearing on the effect the zootechnical animal food substance is in—
tended to have and the quantity of such sub-
stance required to produce the intended effect;
and

"(B) full reports of investigations made
with respect to the intended use of such sub-
stance, including full information as to the
methods and controls used in conducting such
investigations.";

(2) in subsection (e)—

(A) by amending subparagraph (A) of
paragraph (1) to read as follows:

"(A)(i) by order establish a regulation (whether
or not in accord with that proposed by the peti-
tioner) prescribing—

"(I) with respect to one or more proposed
uses of the food additive involved, the condi-
tions under which such additive may be safely
used (including specifications as to the par-
ticular food or classes of food in or on which
such additive may be used, the maximum quan-
tity which may be used or permitted to remain
in or on such food, the manner in which such
additive may be added to or used in or on such
food, and any directions or other labeling or
packaging requirements for such additive as the
Secretary determines necessary to assure the
safety of such use); and

“(II) in the case of a zootchnical animal
food substance, the conditions under which such
substance may be used to achieve the intended
effect; and

“(ii) notify the petitioner of such order and the
reasons for such action; or”; and

(B) in paragraph (3)—

(i) in subparagraph (A), by striking “;
or” and inserting a semicolon;

(ii) in subparagraph (B), by striking
the period and inserting “; or”; and

(iii) by adding at the end the fol-
lowing:

“(C) in the case of a zootchnical animal food
substance, fails to establish that the proposed use of
the substance, under the conditions of use to be
specified in the regulation, will achieve the intended
effect.”; and

(3) by adding at the end the following:

“(I) ZOOTECHNICAL ANIMAL FOOD SUBSTANCES.—

The labeling of a zootchnical animal food substance—
“(1) shall include the statement: ‘Not for use in
the diagnosis, cure, mitigation, treatment, or preven-
tion of disease in animals.’; and
“(2) may include statements regarding the in-
tended effect of the substance on the structure or
function of the body of animals, as set forth in sec-
tion 201(tt)(1).”.
(c) MISBRANDED FOOD.—Section 403 of the Federal
Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amend-
ed by adding at the end the following:
“(z) If it is a zootechnical animal food substance and
the labeling of the food does not include the statement
required by section 409(l)(1).”.
(d) RULE OF CONSTRUCTION.—Nothing in this sec-
tion, or the amendments made by this section, shall be
construed to authorize the Secretary of Health and
Human Services to require the use of any zootechnical
food substance or food additive (as those terms are defined
in section 201 of the Federal Food, Drug, and Cosmetic
Act, as amended by subsection (a)).