

AMENDMENT NO. 1

Calendar No. _____

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

IN THE SENATE OF THE UNITED STATES—118th Cong., 1st Sess.

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**
3 **SUBSTANCES.**

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

7 “(tt)(1) The term ‘zootechnical animal food sub-
8 stance’ means a substance that—

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

11 “(B) is intended to—

1 “(i) affect the byproducts of the digestive
2 process of an animal;

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

6 “(iii) affect the structure or function of the
7 body of the animal, other than by providing nu-
8 tritive value, by altering the animal’s gastro-
9 intestinal microbiome; and

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

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

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

16 “(B) is a hormone;

17 “(C) is an active moiety in an animal drug,
18 which, prior to the filing of a petition under section
19 409 was approved under section 512, conditionally
20 approved under section 571, or indexed under sec-
21 tion 572, or for which substantial clinical investiga-
22 tions have been instituted and for which the exist-
23 ence of such investigations has been made public;

24 “(D) is an ionophore; or

1 “(E) is otherwise excluded from the definition
2 based on criteria established by the Secretary
3 through notice and comment rulemaking.

4 “(3) A zootechnical animal food substance shall be
5 deemed to be a food additive within the meaning of para-
6 graph (s) and its introduction into interstate commerce
7 shall be in accordance with a regulation issued under sec-
8 tion 409. A zootechnical animal food substance shall not
9 be considered a drug under paragraph (g)(1)(C) solely be-
10 cause the substance has an intended effect described in
11 subparagraph (1).”.

12 (b) FOOD ADDITIVES.—Section 409 of the Federal
13 Food, Drug, and Cosmetic Act (21 U.S.C. 348) is amend-
14 ed—

15 (1) in subsection (b)—

16 (A) by redesignating paragraphs (3)
17 through (5) as paragraphs (4) through (6), re-
18 spectively; and

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

21 “(3) In the case of a zootechnical animal food
22 substance, such petition shall, in addition to any ex-
23 planatory or supporting data, contain—

24 “(A) all relevant data bearing on the effect
25 the zootechnical animal food substance is in-

1 tended to have and the quantity of such sub-
2 stance required to produce the intended effect;
3 and

4 “(B) full reports of investigations made
5 with respect to the intended use of such sub-
6 stance, including full information as to the
7 methods and controls used in conducting such
8 investigations.”;

9 (2) in subsection (c)—

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

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

15 “(I) with respect to one or more proposed
16 uses of the food additive involved, the condi-
17 tions under which such additive may be safely
18 used (including specifications as to the par-
19 ticular food or classes of food in or on which
20 such additive may be used, the maximum quan-
21 tity which may be used or permitted to remain
22 in or on such food, the manner in which such
23 additive may be added to or used in or on such
24 food, and any directions or other labeling or
25 packaging requirements for such additive as the

1 Secretary determines necessary to assure the
2 safety of such use); and

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

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

9 (B) in paragraph (3)—

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

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

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

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

21 (3) by adding at the end the following:

22 “(1) ZOOTECHNICAL ANIMAL FOOD SUBSTANCES.—

23 The labeling of a zootechnical animal food substance—

1 “(1) shall include the statement: ‘Not for use in
2 the diagnosis, cure, mitigation, treatment, or preven-
3 tion of disease in animals.’; and

4 “(2) may include statements regarding the in-
5 tended effect of the substance on the structure or
6 function of the body of animals, as set forth in sec-
7 tion 201(tt)(1).”.

8 (c) MISBRANDED FOOD.—Section 403 of the Federal
9 Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amend-
10 ed by adding at the end the following:

11 “(z) If it is a zootechnical animal food substance and
12 the labeling of the food does not include the statement
13 required by section 409(l)(1).”.

14 (d) RULE OF CONSTRUCTION.—Nothing in this sec-
15 tion, or the amendments made by this section, shall be
16 construed to authorize the Secretary of Health and
17 Human Services to require the use of any zootechnical
18 food substance or food additive (as those terms are defined
19 in section 201 of the Federal Food, Drug, and Cosmetic
20 Act, as amended by subsection (a)).