



AMENDMENT NO. 1 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:

1 At the appropriate place in title III, insert the following:  
2

3 **SEC. 3 \_\_\_\_ . FOOD ADDITIVES INTENDED FOR USE IN ANI-**  
4 **MAL FOOD.**

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

9 “(k) FOOD ADDITIVES INTENDED FOR USE IN ANI-  
10 MAL FOOD.—(1) In taking action on a petition under sub-  
11 section (c) for, or for recognition of, a food additive in-

1. The first part of the document is a list of names and addresses of the members of the committee. The names are listed in alphabetical order and include the following: [illegible names].

2. The second part of the document is a list of the names and addresses of the members of the committee who have been elected to the office of [illegible]. The names are listed in alphabetical order and include the following: [illegible names].

3. The third part of the document is a list of the names and addresses of the members of the committee who have been elected to the office of [illegible]. The names are listed in alphabetical order and include the following: [illegible names].

4. The fourth part of the document is a list of the names and addresses of the members of the committee who have been elected to the office of [illegible]. The names are listed in alphabetical order and include the following: [illegible names].

5. The fifth part of the document is a list of the names and addresses of the members of the committee who have been elected to the office of [illegible]. The names are listed in alphabetical order and include the following: [illegible names].

6. The sixth part of the document is a list of the names and addresses of the members of the committee who have been elected to the office of [illegible]. The names are listed in alphabetical order and include the following: [illegible names].

7. The seventh part of the document is a list of the names and addresses of the members of the committee who have been elected to the office of [illegible]. The names are listed in alphabetical order and include the following: [illegible names].

8. The eighth part of the document is a list of the names and addresses of the members of the committee who have been elected to the office of [illegible]. The names are listed in alphabetical order and include the following: [illegible names].

9. The ninth part of the document is a list of the names and addresses of the members of the committee who have been elected to the office of [illegible]. The names are listed in alphabetical order and include the following: [illegible names].

10. The tenth part of the document is a list of the names and addresses of the members of the committee who have been elected to the office of [illegible]. The names are listed in alphabetical order and include the following: [illegible names].

Handwritten signature in blue ink, appearing to read "Mary Gray".

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

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

7 “(A) the number of petitions for food additives  
8 intended for use in animal food filed under sub-  
9 section (b) that are pending;

10 “(B) how long each such petition submitted  
11 under subsection (b) has been pending, including  
12 such petitions the Secretary has extended under sub-  
13 section (c)(2); and

14 “(C) the number of study protocols that have  
15 been pending review for over 50 days, and the num-  
16 ber that have received an extension.

17 “(3) In the case of a food additive petition intended  
18 for use in animal food, the Secretary shall provide infor-  
19 mation to the petitioner on the required contents of such  
20 petition. If the Secretary requires additional studies be-  
21 yond what the petitioner proposed, the Secretary shall pro-  
22 vide the scientific rationale for such requirement.”.

23 (b) ENSURING THE SAFETY OF PET FOOD.—

24 (1) IN GENERAL.—Section 1002 of the Food  
25 and Drug Administration Amendments Act of 2007

1 (21 U.S.C. 2102) is amended by adding at the end  
2 the following:

3 “(c) RULE OF CONSTRUCTION.—Nothing in sub-  
4 section (a) shall be construed to affect the memorandum  
5 of understanding between the Food and Drug Administra-  
6 tion and the Association of American Feed Control Offi-  
7 cials (MOU 255-07-7001) as it relates to definitions of  
8 animal feed and animal feed ingredients, including the au-  
9 thority of Food and Drug Administration to renew or  
10 modify to the MOU at its discretion.”.

11 (c) GUIDANCE ON PRE-PETITION PROCESS FOR ANI-  
12 MAL FOOD ADDITIVES.—

13 (1) IN GENERAL.—Not later than 18 months  
14 after the date of enactment of this Act, the Sec-  
15 retary of Health and Human Services (referred to in  
16 this subsection as the “Secretary”) shall publish  
17 draft guidance relating to the voluntary pre-petition  
18 process for food additives intended for use in animal  
19 food.

20 (2) CONTENTS.—The guidance under para-  
21 graph (1) shall include—

22 (A) the recommended format to submit to  
23 the Food and Drug Administration existing  
24 data, including any applicable foreign data, for  
25 assessment prior to submission of a food addi-

1           tive petition for animal food under section  
2           409(b) of the Federal Food, Drug, and Cos-  
3           metic Act;

4           (B) the manner and the number of days by  
5           which the Food and Drug Administration in-  
6           tends to review and respond to such existing  
7           data, including scientific rationale for any addi-  
8           tional data request;

9           (C) circumstances under which the submis-  
10          sion of study protocols is recommended prior to  
11          submission of a food additive petition under  
12          such section 409(b);

13          (D) the manner in which the Secretary in-  
14          tends to inform the person submitting a study  
15          protocol for a food additive if the review of such  
16          study protocol will take longer than 50 days;  
17          and

18          (E) best practices for communication be-  
19          tween the Food and Drug Administration and  
20          industry on the development of pre-petition sub-  
21          missions of study protocols and existing data  
22          for food additives;

23          (3) FINAL GUIDANCE.—The guidance under  
24          paragraph (1) shall be finalized, withdrawn, or re-

- 1 issued not later than 1 year after the close of the
- 2 comment period on the draft guidance.