

**AMENDMENT**

**OFFERED BY MS. SCHAKOWSKY OF ILLINOIS**

At the end of title II, add the following (and make such technical and conforming amendments as may be necessary):

1 **SEC. \_\_\_\_ . PROOF OF SAFETY OF CRITICAL ANTIMICROBIAL**  
2 **ANIMAL DRUGS.**

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

6 “(rr) **CRITICAL ANTIMICROBIAL ANIMAL DRUG.**—  
7 The term ‘critical antimicrobial animal drug’ means a  
8 drug that—

9 “(1) is intended for use in food-producing ani-  
10 mals; and

11 “(2) is composed wholly or partly of—

12 “(A) any kind of penicillin, tetracycline,  
13 macrolide, lincosamide, streptogramin, amino-  
14 glycoside, or sulfonamide; or

15 “(B) any other drug or derivative of a  
16 drug that is used in humans or intended for use  
17 in humans to treat or prevent disease or infec-  
18 tion caused by microorganisms.

1           “(ss) NONTHERAPEUTIC USE.—The term ‘nonthera-  
2 peutic use’, with respect to a critical antimicrobial animal  
3 drug, means any use of the drug as a feed or water addi-  
4 tive for an animal in the absence of any clinical sign of  
5 disease in the animal for growth promotion, feed effi-  
6 ciency, weight gain, routine disease prevention, or other  
7 routine purpose.”.

8           (b) APPLICATIONS PENDING OR SUBMITTED AFTER  
9 ENACTMENT.—Section 512(d)(1) of the Federal Food,  
10 Drug, and Cosmetic Act (21 U.S.C. 360b(d)(1)) is amend-  
11 ed—

12           (1) in the first sentence—

13                   (A) in subparagraph (H), by striking “or”  
14 at the end;

15                   (B) by redesignating subparagraph (I) as  
16 subparagraph (J); and

17                   (C) by inserting after subparagraph (H)  
18 the following:

19                   “(I) with respect to a critical antimicrobial  
20 animal drug or a drug of the same chemical  
21 class as a critical antimicrobial animal drug,  
22 the applicant has failed to demonstrate that  
23 there is a reasonable certainty of no harm to  
24 human health due to the development of anti-  
25 microbial resistance that is attributable, in

1 whole or in part, to the nontherapeutic use of  
2 the drug; or”; and

3 (2) in the second sentence, by striking “(A)  
4 through (I)” and inserting “(A) through (J)”.

5 (c) PHASED ELIMINATION OF NONTHERAPEUTIC  
6 USE IN ANIMALS OF CRITICAL ANTIMICROBIAL ANIMAL  
7 DRUGS IMPORTANT FOR HUMAN HEALTH.—Section 512  
8 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
9 360b) is amended by adding at the end the following:

10 “(q) PHASED ELIMINATION OF NONTHERAPEUTIC  
11 USE IN ANIMALS OF CRITICAL ANTIMICROBIAL ANIMAL  
12 DRUGS IMPORTANT FOR HUMAN HEALTH.—

13 “(1) APPLICABILITY.—This subsection applies  
14 to the nontherapeutic use in a food-producing ani-  
15 mal of a drug—

16 “(A)(i) that is a critical antimicrobial ani-  
17 mal drug; or

18 “(ii) that is of the same chemical class as  
19 a critical antimicrobial animal drug; and

20 “(B)(i) for which there is in effect an ap-  
21 proval of an application or an exemption under  
22 subsection (b), (i), or (j) of section 505; or

23 “(ii) that is otherwise marketed for use.

24 “(2) WITHDRAWAL.—The Secretary shall with-  
25 draw the approval of a nontherapeutic use in food-

1 producing animals described in paragraph (1) on the  
2 date that is 2 years after the date of enactment of  
3 this subsection unless—

4 “(A) before the date that is 2 years after  
5 the date of the enactment of this subsection,  
6 the Secretary makes a final written determina-  
7 tion that the holder of the approved application  
8 has demonstrated that there is a reasonable  
9 certainty of no harm to human health due to  
10 the development of antimicrobial resistance that  
11 is attributable in whole or in part to the non-  
12 therapeutic use of the drug; or

13 “(B) before the date specified in subpara-  
14 graph (A), the Secretary makes a final written  
15 determination under this subsection, with re-  
16 spect to a risk analysis of the drug conducted  
17 by the Secretary and other relevant informa-  
18 tion, that there is a reasonable certainty of no  
19 harm to human health due to the development  
20 of antimicrobial resistance that is attributable  
21 in whole or in part to the nontherapeutic use of  
22 the drug.

23 “(3) EXEMPTIONS.—Except as provided in  
24 paragraph (5), if the Secretary grants an exemption  
25 under section 505(i) for a drug that is a critical

1 antimicrobial animal drug, the Secretary shall re-  
2 scind each approval of a nontherapeutic use in a  
3 food-producing animal of the critical antimicrobial  
4 animal drug, or of a drug in the same chemical class  
5 as the critical antimicrobial animal drug, as of the  
6 date that is 2 years after the date on which the Sec-  
7 retary grants the exemption.

8 “(4) APPROVALS.—Except as provided in para-  
9 graph (5), if an application for a drug that is a crit-  
10 ical antimicrobial animal drug is submitted to the  
11 Secretary under section 505(b), the Secretary shall  
12 rescind each approval of a nontherapeutic use in a  
13 food-producing animal of the critical antimicrobial  
14 animal drug, or of a drug in the same chemical class  
15 as the critical antimicrobial animal drug, as of the  
16 date that is 2 years after the date on which the ap-  
17 plication is submitted to the Secretary.

18 “(5) EXCEPTION.—Paragraph (3) or (4), as the  
19 case may be, shall not apply if—

20 “(A) before the date on which approval  
21 would be rescinded under that paragraph, the  
22 Secretary makes a final written determination  
23 that the holder of the application for the ap-  
24 proved nontherapeutic use has demonstrated  
25 that there is a reasonable certainty of no harm

1 to human health due to the development of  
2 antimicrobial resistance that is attributable in  
3 whole or in part to the nontherapeutic use in  
4 the food-producing animal of the critical anti-  
5 microbial animal drug; or

6 “(B) before the date specified in subpara-  
7 graph (A), the Secretary makes a final written  
8 determination under this subsection, with re-  
9 spect to a risk analysis of the critical anti-  
10 microbial animal drug conducted by the Sec-  
11 retary and any other relevant information, that  
12 there is a reasonable certainty of no harm to  
13 human health due to the development of anti-  
14 microbial resistance that is attributable in  
15 whole or in part to the nontherapeutic use of  
16 the drug.”.

