

115TH CONGRESS
1ST SESSION

S. _____

To amend the Federal Food, Drug, and Cosmetic Act to ensure the safety and effectiveness of medically important antimicrobials approved for use in the prevention, control, and treatment of animal diseases, in order to minimize the development of antibiotic-resistant bacteria.

IN THE SENATE OF THE UNITED STATES

Mrs. FEINSTEIN (for herself and Ms. COLLINS) introduced the following bill; which was read twice and referred to the Committee on

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to ensure the safety and effectiveness of medically important antimicrobials approved for use in the prevention, control, and treatment of animal diseases, in order to minimize the development of antibiotic-resistant bacteria.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Preventing Antibiotic
5 Resistance Act of 2017”.

1 **SEC. 2. PURPOSE.**

2 The purpose of this Act is to ensure the safety and
3 effectiveness of medically important antimicrobials ap-
4 proved for use in the prevention, control, and treatment
5 of animal diseases, in order to minimize the development
6 of antibiotic-resistant bacteria.

7 **SEC. 3. EVIDENCE OF SAFETY OF MEDICALLY IMPORTANT**
8 **VETERINARY ANTIMICROBIALS.**

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

13 (1) in the first sentence—

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

16 (B) in subparagraph (I), by inserting “or”
17 at the end; and

18 (C) by inserting after subparagraph (I) the
19 following:

20 “(J) with respect to a medically important
21 antimicrobial (as defined in subsection (r)), the
22 applicant has failed to demonstrate that a new
23 animal drug application for an antimicrobial la-
24 beled for disease prevention or control meets
25 the criteria in subsection (r)(2)(A);” and

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

3 (b) ENSURING JUDICIOUS USE IN ANIMALS OF
4 MEDICALLY IMPORTANT ANTIMICROBIALS.—Section 512
5 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
6 360b) is amended by adding at the end the following:

7 “(r) ENSURING JUDICIOUS USE IN ANIMALS OF
8 MEDICALLY IMPORTANT ANTIMICROBIALS.—

9 “(1) APPLICABILITY.—This subsection applies
10 to medically important antimicrobials approved for
11 use in a food-producing animal—

12 “(A)(i) for which there is in effect an ap-
13 proval of an application or an exemption under
14 subsection (b), (i), or (j) of section 505; or

15 “(ii) that is otherwise marketed for human
16 use;

17 “(B) for which the Guidance for Industry
18 entitled, ‘New Animal Drugs and New Animal
19 Drug Combination Products, Administered in
20 or on Medicated Feed or Drinking Water of
21 Food-Producing Animals: Recommendations for
22 Drug Sponsors for Voluntarily Aligning Prod-
23 uct Use Conditions with GFI #209’, published
24 in December 2013 applies; and

1 “(C) for which the Food and Drug Admin-
2 istration has approved a label—

3 “(i) for disease control or prevention
4 at the same or similar dosage level as ap-
5 plicable for the approved production use
6 described in subparagraph (B);

7 “(ii) that does not specify an explicitly
8 defined duration of therapy; or

9 “(iii) specifying a dosage that is not
10 expected to treat a specific bacterial patho-
11 gen.

12 “(2) REVIEW OF DISEASE PREVENTION AND
13 CONTROL APPROVALS.—

14 “(A) IN GENERAL.—Not later than Janu-
15 ary 1, 2019, the Secretary shall initiate a proc-
16 ess of reviewing medically important
17 antimicrobials described in paragraph (1), in
18 accordance with subparagraph (B).

19 “(B) REVIEW OF APPROVAL.—

20 “(i) IN GENERAL.—If, not later than
21 January 1, 2020, a sponsor of an anti-
22 microbial drug described in paragraph (1)
23 submits to the Secretary sufficient evi-
24 dence to demonstrating that, with respect
25 to such drug—

1 “(I) there is evidence of effective-
2 ness in controlling or preventing bac-
3 terial disease;

4 “(II) an approved use is con-
5 sistent with accepted veterinary prac-
6 tice;

7 “(III) an approved use targets a
8 specific bacterial pathogen;

9 “(IV) an approved use is appro-
10 priately targeted to animals at risk of
11 developing a specific bacterial disease;

12 “(V) an approved use has an ex-
13 plicitly defined duration of therapy;
14 and

15 “(VI) there is not a reasonable
16 probability of risk to the public health
17 due to the development of anti-
18 microbial resistance,

19 the Secretary, not later than December 31,
20 2020, shall issue a revised label approval
21 for such antimicrobial drug, as necessary.

22 “(ii) INSUFFICIENT EVIDENCE.—If
23 the sponsor of an antimicrobial drug de-
24 scribed in paragraph (1) does not submit
25 sufficient evidence as described in clause

1 (i) by December 31, 2020, the Secretary
2 shall withdraw approval of any indication
3 claims described in paragraph (1)(B) for
4 which the sponsor does not submit evi-
5 dence or for which the Secretary deter-
6 mines the evidence submitted is insuffi-
7 cient and, as necessary, issue a revised
8 label approval.

9 “(C) WITHDRAWAL OF CLAIMS.—On or be-
10 fore January 1, 2020, the sponsor of a drug de-
11 scribed in paragraph (1) may request the ap-
12 proval of the Secretary to remove any label
13 claim described in paragraph (1)(B), and the
14 Secretary shall approve any such request and,
15 as necessary, issue a revised label. The sponsor
16 shall not be required to submit the evidence re-
17 quired under subparagraph (B)(i) with respect
18 to any claim so withdrawn.

19 “(3) EXEMPTIONS.—In the case of a drug that
20 is a medically important antimicrobial for which the
21 Secretary grants an exemption under section 505(i),
22 the withdrawal of indication claims in a food-pro-
23 ducing animal in accordance with paragraph (2)(B)
24 shall be effective on the date that is 2 years after
25 the date on which the Secretary grants the exemp-

1 tion, unless, not later than 2 years after the date on
2 which the Secretary grants the exemption, the Sec-
3 retary provides a written determination of intent to
4 extend the exemption.

5 “(4) DEFINITION.—

6 “(A) IN GENERAL.—In this subsection, the
7 term ‘medically important antimicrobial’ means
8 a drug that—

9 “(i) is intended for use in food-pro-
10 ducing animals; and

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

12 “(I) any kind of penicillin, tetra-
13 cycline, macrolide, lincosamide,
14 streptogramin, aminoglycoside, sul-
15 fonamide, cephalosporin, or
16 fluoroquinolone, or any drug included
17 in the list pursuant to updates under
18 subparagraph (B); or

19 “(II) a drug from an anti-
20 microbial class that is listed as ‘highly
21 important’, ‘critically important’, or
22 ‘important’ in Appendix A of the
23 Guidance for Industry entitled, ‘Eval-
24 uating the Safety of Antimicrobial
25 New Animal Drugs with Regard to

1 Their Microbiological Effects on Bac-
2 teria of Human Health Concern’ (or
3 any successor guidance).

4 “(B) REVIEW AND UPDATES.—The Sec-
5 retary shall conduct periodic reviews of the
6 drugs included in the list described in subpara-
7 graph (A)(ii)(I), and add to or remove from
8 such list any drugs that the Secretary deter-
9 mines appropriate. A review shall be under-
10 taken at the Secretary’s discretion, but not less
11 than once every five years.”.

12 **SEC. 4. VETERINARY OVERSIGHT OF USE OF MEDICALLY**
13 **IMPORTANT ANTIMICROBIALS.**

14 (a) IN GENERAL.—A valid veterinarian-client-patient
15 relationship should exist to ensure that medically impor-
16 tant antimicrobials are used in food-producing animals in
17 a manner that is consistent with professionally accepted
18 best practices.

19 (b) VETERINARIAN-CLIENT-PATIENT RELATION-
20 SHIP.—In this section, the term “veterinarian-client-pa-
21 tient relationship” means a relationship in which all of the
22 following criteria are met:

23 (1) The veterinarian has assumed the responsi-
24 bility for making medical judgments regarding the

1 health of the patient and the client has agreed to
2 follow the veterinarian's instructions.

3 (2) The veterinarian has sufficient knowledge of
4 the patient to initiate at least a general or prelimi-
5 nary diagnosis of the medical condition of the pa-
6 tient. This means that the veterinarian is personally
7 acquainted with the keeping and care of the patient
8 by virtue of—

9 (A) a timely examination of the patient by
10 the veterinarian; or

11 (B) medically appropriate and timely visits
12 by the veterinarian to the premises where the
13 animal or animals are kept.

14 (3) The veterinarian is readily available for fol-
15 low-up evaluation or has arranged for veterinary
16 emergency coverage and continuing care and treat-
17 ment.

18 (4) The veterinarian provides oversight of treat-
19 ment, compliance, and outcome.

20 (5) Patient records are maintained.