

114TH CONGRESS
1ST SESSION

S. 621

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 and control of animal diseases, in order to minimize the development of antibiotic-resistant bacteria.

IN THE SENATE OF THE UNITED STATES

MARCH 2, 2015

Mrs. FEINSTEIN (for herself, Ms. COLLINS, Mrs. GILLIBRAND, and Ms. WARREN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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 and control 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 2015”.

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 and control of animal dis-
 5 eases, in order to minimize the development of antibiotic-
 6 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 (q)), the
 22 applicant has failed to demonstrate that a New
 23 Animal Drug Application for an antimicrobial
 24 labeled for disease prevention or control fails to
 25 meet the criteria in subsection (q)(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 “(q) 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 Food and Drug Admin-
18 istration has initiated or completed withdrawal
19 or modification of an approved label for growth
20 promotion, feed efficiency, or other production
21 use or over-the-counter use, in accordance with
22 the Guidance for Industry entitled, ‘New Ani-
23 mal Drugs and New Animal Drug Combination
24 Products, Administered in or on Medicated
25 Feed or Drinking Water of Food-Producing

1 Animals: Recommendations for Drug Sponsors
2 for Voluntarily Aligning Product Use Condi-
3 tions with GFI #209’, published in December
4 2013; and

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

7 “(i) for disease control or prevention
8 at the same or similar dosage level as ap-
9 plicable for the approved production use
10 described in subparagraph (B);

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

13 “(iii) specifying a dosage that is not
14 expected to treat a specific bacterial patho-
15 gen.

16 “(2) REVIEW OF DISEASE PREVENTION AND
17 CONTROL APPROVALS.—

18 “(A) IN GENERAL.—Not later than Janu-
19 ary 1, 2017, the Secretary shall initiate a proc-
20 ess whereby—

21 “(i) not later than January 1, 2018,
22 a sponsor of an antimicrobial drug de-
23 scribed in paragraph (1) shall submit to
24 the Secretary evidence demonstrating that,
25 with respect 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 is linked
8 to a specific etiologic agent;

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 reasonable cer-
16 tainty of no harm to human health
17 due to the development of anti-
18 microbial resistance; and

19 “(ii)(I) if the Secretary determines
20 that the evidence submitted under clause
21 (i) is sufficient to demonstrate that the
22 drug meets the requirements described in
23 subclauses (I) through (VI) of such clause,
24 not later than December 31, 2018, the
25 Secretary shall issue a revised label ap-

1 proval for the antimicrobial drug, as nec-
2 essary; or

3 “(II) if the Secretary determines that
4 the evidence submitted under clause (i) is
5 insufficient to demonstrate that the drug
6 meets the requirements described in sub-
7 clauses (I) through (VI) of such clause, not
8 later than December 31, 2018, the Sec-
9 retary shall withdraw approval of any indi-
10 cation claims described in paragraph
11 (1)(C) for which the Secretary determines
12 the evidence is insufficient and, as nec-
13 essary, issue a revised label approval.

14 “(B) WITHDRAWAL OF CLAIMS.—On or
15 before January 1, 2018, the sponsor of a drug
16 described in paragraph (1) may request the ap-
17 proval of the Secretary to remove any label
18 claim described in paragraph (1)(C), and the
19 Secretary shall approve any such request and,
20 as necessary, issue a revised label. The sponsor
21 shall not be required to submit the evidence re-
22 quired under subparagraph (A)(i) with respect
23 to any claim so withdrawn.

24 “(3) EXEMPTIONS.—In the case of a drug that
25 is a medically important antimicrobial for which the

1 Secretary grants an exemption under section 505(i),
2 the withdrawal of indication claims in a food-pro-
3 ducing animal in accordance with paragraph (2)(B)
4 shall be effective on the date that is 2 years after
5 the date on which the Secretary grants the exemp-
6 tion, unless, not later than 2 years after the date on
7 which the Secretary grants the exemption, the Sec-
8 retary provides a written determination of intent to
9 extend the exemption.

10 “(4) DEFINITION.—In this subsection, the term
11 ‘medically important antimicrobial’ means a drug
12 that—

13 “(A) is intended for use in food-producing
14 animals; and

15 “(B) is composed wholly or partly of—

16 “(i) any kind of penicillin, tetracy-
17 cline, macrolide, lincosamide, streptogram-
18 in, aminoglycoside, sulfonamide, cephalo-
19 sporin, or fluoroquinolone; or

20 “(ii) a drug from an antimicrobial
21 class that is listed as ‘highly important’,
22 ‘critically important’, or ‘important’ by the
23 World Health Organization in the latest
24 edition of its publication entitled ‘Critically

1 Important Antimicrobials for Human Med-
2 icine’ (or a successor publication).”.

3 **SEC. 4. SENSE OF THE SENATE REGARDING VETERINARY**
4 **OVERSIGHT OF USE OF MEDICALLY IMPOR-**
5 **TANT ANTIMICROBIALS.**

6 (a) IN GENERAL.—It is the sense of the Senate that
7 a valid veterinarian-client-patient relationship should exist
8 to ensure that medically important antimicrobials are used
9 in food-producing animals in a manner that is consistent
10 with professionally accepted best practices.

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

15 (1) The veterinarian has assumed the responsi-
16 bility for making medical judgments regarding the
17 health of the patient and the client has agreed to
18 follow the veterinarian’s instructions.

19 (2) The veterinarian has sufficient knowledge of
20 the patient to initiate at least a general or prelimi-
21 nary diagnosis of the medical condition of the pa-
22 tient. This means that the veterinarian is personally
23 acquainted with the keeping and care of the patient
24 by virtue of—

1 (A) a timely examination of the patient by
2 the veterinarian; or

3 (B) medically appropriate and timely visits
4 by the veterinarian to the premises where the
5 animal or animals are kept.

6 (3) The veterinarian is readily available for fol-
7 low-up evaluation or has arranged for veterinary
8 emergency coverage and continuing care and treat-
9 ment.

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

12 (5) Patient records are maintained.

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