

115TH CONGRESS
2D SESSION

S. 3099

To require the review of durations of use of approved indications of medically-important antibiotics labeled for use in animals.

IN THE SENATE OF THE UNITED STATES

JUNE 20, 2018

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

A BILL

To require the review of durations of use of approved indications of medically-important antibiotics labeled for use in animals.

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 “Strengthening Anti-
5 biotic Oversight Act”.

6 **SEC. 2. REVIEW OF ANTIBIOTIC DURATION OF USE.**

7 (a) IN GENERAL.—Not later than 6 months after the
8 date of enactment of this Act, the Secretary of Health and
9 Human Services (referred to in this section as the “Sec-

1 retary”) shall review the durations of use of approved indi-
 2 cations of medically-important antibiotics labeled for use
 3 in animals. After such review, the Secretary shall require
 4 the sponsor of any such medically-important antibiotic
 5 drug with an approved indication with a duration of use
 6 in animals that exceeds 21 days to submit data, within
 7 one year of such review, to support such duration over
 8 21 days. If, after review of the data submitted, the Sec-
 9 retary determines that the duration is not scientifically
 10 justified or the disease can be prevented or treated
 11 through other reasonable means after 21 days of treat-
 12 ment with such antibiotic drug, the Secretary shall with-
 13 draw the approval of the indication with a duration of use
 14 over 21 days, and issue an approval of a new indication
 15 with a scientifically-justified duration of use that is 21
 16 days or shorter.

17 (b) PROCESS FOR THE REVIEW OF ANIMAL DRUG
 18 APPLICATIONS.—Section 739(8) (21 U.S.C. 379j–11(8))
 19 is amended by adding at the end the following:

20 “(I) Review of approved durations of use
 21 of medically-important antibiotics in accordance
 22 with section 2(a) of the Strengthening Anti-
 23 biotic Oversight Act.”.

1 **SEC. 3. USE OF ANIMAL DRUG USER FEES.**

2 Section 739(8) (21 U.S.C. 379j–11(8)), as amended
3 by section 2, is further amended by adding at the end the
4 following:

5 “(J) Inspection of veterinary feed direc-
6 tives and feed distribution reports maintained
7 under section 558.6(c) of title 21, Code of Fed-
8 eral Regulations (or any successor regulations)
9 to identify amounts of antibiotics used in such
10 feed, the purposes for the use of such anti-
11 biotics, and the species and production classes
12 receiving such feed, which may be done in col-
13 laboration with the Department of Agriculture,
14 and reporting of such information to Con-
15 gress.”.

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