115TH CONGRESS
2D SESSION

S. _____

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

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 _____

A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Strengthening Antibiotic Oversight Act''.

SEC. 2. REVIEW OF ANTIBIOTIC DURATION OF USE.

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

retary'') shall review the durations of use of approved indications of medically-important antibiotics labeled for use in animals. After such review, the Secretary shall require the sponsor of any such medically-important antibiotic drug with an approved indication with a duration of use in animals that exceeds 21 days to submit data, within one year of such review, to support such duration over 21 days. If, after review of the data submitted, the Secretary determines that the duration is not scientifically justified or the disease can be prevented or treated through other reasonable means after 21 days of treatment with such antibiotic drug, the Secretary shall withdraw the approval of the indication with a duration of use over 21 days, and issue an approval of a new indication with a scientifically-justified duration of use that is 21 days or shorter.

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

''(I) Review of approved durations of use of medically-important antibiotics in accordance with section 2(a) of the Strengthening Antibiotic Oversight Act.''.

SEC. 3. USE OF ANIMAL DRUG USER FEES.

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

"(J) Inspection of veterinary feed directives and feed distribution reports maintained under section 558.6(c) of title 21, Code of Federal Regulations (or any successor regulations) to identify amounts of antibiotics used in such feed, the purposes for the use of such antibiotics, and the species and production classes receiving such feed, which may be done in collaboration with the Department of Agriculture, and reporting of such information to Congress.".