

March 13, 2017

The Honorable Stephen Ostroff, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

RE: [Docket No. FDA-2016-D-2635](#); The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals; Establishing Appropriate Durations of Therapeutic Administration

Dear Acting Commissioner Ostroff:

Antibiotic resistance is an urgent and growing public health threat that—[according to the Centers for Disease Control and Prevention](#) (CDC)—costs the U.S. economy up to \$55 billion, results in over 2 million illnesses, and leads to over 23,000 deaths annually. Just last year, the [two resistance threats the CDC is most worried about](#)—carbapenem-resistant enterobacteriaceae (CREs), and colistin-resistant bacteria with the mcr-1 gene—were detected on [U.S. farms](#) and in [U.S. farm animals](#). [CDC estimates](#) that 20% of the serious resistance infections come from food and food animals, and this estimate does not account for emerging threats like CREs and colistin-resistant bacteria.

The undersigned organizations strongly support the Food and Drug Administration (FDA) taking additional needed steps to protect public health from antibiotic resistance threats that originate from the use of antibiotics in food animals. We agree that FDA should establish appropriate durations of administration for medically important antibiotics. That action is critically necessary; however, it is not sufficient.

We note that some of the durations put forward as examples are so long as to constitute almost no limit, e.g. 112 days. Setting that aside, we urge that rather than simply requiring a specified duration of any length (e.g., up to 112 days) as proposed, FDA should instead prohibit any “continuous use” (i.e., 14 days or more as defined in the Code of Federal Regulations see 21 CFR 558.3 (b)(3)) of a medically important antibiotic in feed. If after 14 days the treated animals have not responded to treatment, a veterinarian should re-evaluate and recommend continued treatment only if needed. However, even this precaution would be meaningless if VFDs of 14 days could simply be stacked together for prevention in the absence of evidence of disease or exposure.

This is why we recommend that FDA take the following additional steps:

- Withdraw existing approvals for the use of medically important antibiotics for purposes other than disease treatment or disease control.

- Set time-bound quantitative targets for the reductions both in the overall amount of medically important antibiotics sold for use in food animals and in the amounts for specific critically important antibiotics sold for use in food animals.
- Outline conditions under which it is appropriate to use medically important antibiotics for disease control, including setting requirements for use related to severity of clinical signs in affected animals and observed level of morbidity.
- Ensure that the labels of medically important antibiotics are consistent with all aspects of judicious use, not just duration limits. This should include specifying clear dosages and revising questionable indications such as “maintenance of growth” (which could open the door for growth promotion use) or indications for which an etiologic agent is not specified.

These additional steps are urgently needed if we are to slow and stop the ever-nearer end of the road for antibiotics. Thank you for your consideration and for the Agency’s continued commitment to addressing the threat to public health from antibiotic resistance.

Sincerely,

Keep Antibiotics Working
Food Animal Concerns Trust
Antibiotic Resistance Action Center, Milken Institute School of Public Health, The George Washington University
Food and Water Watch
Alliance for the Prudent Use of Antibiotics
Natural Resources Defense Council
Center for a Livable Future, John Hopkins Bloomberg School of Public Health
U.S. PIRG
Health Care Without Harm
Consumer Federation of America
School Food Focus
Stop Foodborne Illness
Family Farm Defenders
Association for Professionals in Infection Control and Epidemiology
The Humane Society of the United States
The Humane Society Veterinary Medical Association
Cornucopia Institute
Center for Foodborne Illness Research & Prevention
Oregon Tilth
Consumers Union
Center for Food Safety

