

September 13, 2018

Dr. Scott Gottlieb
Commissioner, Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993
Email: CommissionerFDA@fda.hhs.gov

Dear Dr. Gottlieb:

The undersigned member organizations and allies of the Keep Antibiotics Working Campaign (KAW) write to express our support for further action by the Food and Drug Administration (FDA) to address antibiotic resistance, and to urge the FDA to move forward its plans to publish and apply a method for adjusting antimicrobial sales data by animal biomass. Formed in 2001, KAW is a coalition of advocacy groups that joined to ensure that difficult-to-treat superbugs resulting from the overuse of antibiotics on farms do not reverse the medical advances of the past century.

As you know, antibiotic resistance is a critical threat, and we applaud your recent [statement](#) committing to continue FDA's important work to reduce the overuse of antibiotics in veterinary settings. We look forward to seeing the five-year blueprint you discussed and hope that you will soon release it.

In the meantime, we encourage FDA to move forward expeditiously with publishing a method for adjusting antimicrobial sales data by animal biomass and to apply the adjustment to existing sales data. The FDA Center for Veterinary Method [published and accepted comment](#) on a proposed method last September. When finalized, the biomass adjustment will provide a critical tool to better interpret changes in antimicrobial sales, allowing adjustment for shifts in sales tied to changes in the numbers and weights of animals. However, we would strongly urge that such reporting include side-by-side calculations of biomass using both an improved version of the methodology proposed by the Center (mg/TAB) and a methodology widely in use in Europe and elsewhere (mg/PCU). Addition of the latter to the Center's public calculations would lend greater strength and transparency to the reports, since it would facilitate comparison between reports from the FDA with reports from the European Medicines Agency, Public Health Canada, and the United Kingdom, all of which are now including mg/PCU calculations in their reporting.

Later this year, FDA will publish data on sales of antimicrobials for use in food producing animals in 2017, the first year of implementation for FDA's plan to improve antimicrobial stewardship by removing growth promotion claims and requiring

veterinary oversight of medically important antibiotics in the feed and water of food-producing animals. The 2017 antimicrobial sales data will provide important information on the impacts of the antimicrobial stewardship efforts, and a biomass adjustment method should be ready to apply to this data when it is released. Since no action is required by stakeholders outside the agency, FDA should be able to finalize the method in time for the release of these data. Parallel reporting using both mg/TAB and mg/PCU should begin with adjustments to the 2017 antimicrobial sales data. The parallel reporting should also be applied to the sales data for 2016, the first year for which the data is broken out by animal species allowing the species specific adjustments.

Antibiotic resistance continues to be an urgent health crisis and there is much more that needs to be done. In addition to finalizing and improving the biomass adjustment, FDA should move forward promptly on improving data collection on resistance and antimicrobial use, and take additional steps on stewardship such as updating the list of medically important antibiotics and addressing medically important antimicrobials with unlimited or very long durations. We would be happy to meet with you to discuss these and other ideas for objectives and strategies that the agency might include in its upcoming five-year plan. Until then, we hope you will agree that completing the biomass adjustment discussed above prior to the release of the 2017 sales data is an achievable and worthwhile objective that deserves prioritization.

Sincerely,

Antibiotic Resistance Action Center, the George Washington University
Center for Biological Diversity
Center for Food Safety
Center for Foodborne Illness Research and Prevention
Center for Science in the Public Interest
Clinician Champions in Comprehensive Antibiotic Stewardship collaborative
Consumer Federation of America
Consumers Union
Food Animal Concerns Trust
Government Accountability Project
Health Care Without Harm
Humane Society Legislative Fund
Humane Society of the United States
Humane Society Veterinary Medical Association
Johns Hopkins Center for a Livable Future
National Center for Health Research
U.S. PIRG