

December 23, 2019

Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

RE: Docket No. FDA-2019-D-3614 for comment on draft guidance for industry (GFI) #263 "Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue To Be Available Over-the-Counter."

We the undersigned organizations ask that the U.S. Food and Drug Administration (FDA) move forward expeditiously to finalize and implement [GFI#263](#), which directs the makers of medically important antibiotics for use in animals to require veterinary prescriptions before these products can be used. We also ask FDA to expedite implementation of the rest of the actions described in its five year action plan for "[Supporting Antimicrobial Stewardship in Veterinary Settings](#)." Both are important steps to help mitigate an evolving crisis of antibiotic resistance that puts at risk millions of American lives as well as the practice of modern medicine.

Humans and animals suffer in rising numbers from bacterial infection that no longer respond to antibiotic treatment. Recently, the Centers for Disease Control and Prevention (CDC) [estimated](#) there now are more than 2.8 million antibiotic-resistant infections in people in the U.S. each year and these infections currently lead to more than 35,000 deaths. Experts at Washington University of St. Louis recently [estimated](#) the likely number of deaths may be nearly five times as high.

Whatever the number, too many resistant infections are causing too many deaths. Lowering these numbers requires a broad range of actions including making sure that the correct antibiotics are used correctly and only when needed. The oversight of trained professionals is essential.

The value of mandatory professional oversight became clear in 2017, when [overall sales of medically important antibiotics for use in food-producing animals](#) dropped significantly after FDA [completed implementation](#) of the agency's plan to require a veterinarian's order for the use of these drugs in feed and water. Given that this large sales reduction was made without reports of significant impacts on animal health or productivity, it is likely that FDA requiring veterinary oversight eliminated a fairly high level of unnecessary use of antibiotics in food-producing animals. Now that the FDA is considering moving forward with GFI #263, which covers the remaining medically important antibiotics used in animals that do not currently require a prescription, we hope for continued drops in unnecessary uses of these important medicines.

The two-year timeline already included within draft GFI #263 is quite sufficient for drug sponsors to take action, and for food animal producers to make appropriate adjustments in their practices; we reject any longer timeline as providing unnecessary delay.

Moreover, we urge the FDA to promptly implement the additional steps laid out in its five year stewardship plan, including:

- Acting quickly (for the first time in almost 17 years) to revise its list of medically important antibiotics in Appendix A of [FDA Guidance for Industry #152](#) (GFI#152). The current 2003 version of that list has been rendered out-of-date by many new animal and human drug approvals, and the appearance of significant new information on the risk of antibiotic resistance. We therefore call on FDA to update this list while the agency implements GFI #263.
- Acting without delay to impose limits on the duration of use for *ALL* medically important antibiotics used in food-producing animals. We urge that these duration limits should be sufficiently short so as to protect public health.
- Improving how data on the sales of antibiotics intended for food animal production are reported. In particular, we urge the FDA to begin reporting such data corrected by animal biomass, as is already done by Public Health Canada, and equivalent food safety agencies in the United Kingdom and the European Medicines Agency. Correcting the data by animal biomass is needed to improve transparency and to harmonize with international data collection efforts.
- Creating a comprehensive and sustainable program for collecting antibiotic use data.

The spread of antibiotic resistant infections is a challenging and complicated threat to human and animal health. Controlling this threat requires action on a wide range of fronts. Requiring medical professional oversight of antibiotic use is an important part of this control, so we strongly support FDA finalizing and implementing GFI#263 as part of a broader response to the antimicrobial resistance.

Sincerely,

Antibiotic Resistance Action Center at the Milken Institute School of Public Health, George
Washington University
Center for Biological Diversity
Center for Science in the Public Interest
Consumer Reports
Food Animal Concerns Trust
Health Care Without Harm
Natural Resources Defense Council
U.S. PIRG