Trust for America's Health
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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

August 10, 2015

RE: Comment Docket No. FDA-2012-N-0447; Antimicrobial Animal Drug Sales and Distribution Reporting

To Whom It May Concern:

On behalf of Trust for America's Health (TFAH), a nonprofit, nonpartisan public health organization dedicated to improving the health of all Americans, I am pleased to submit comments in support of the U.S. Food and Drug Administration's (FDA) draft rule to improve data collection efforts regarding antibiotic use in food animals.

According to the Centers for Disease Control and Prevention (CDC), each year more than two million Americans develop antibiotic-resistant infections and at least 23,000 people die as a result. The CDC and World Health Organization warn that we are nearing a "post-antibiotic era" where existing drugs are ineffective against even the most common bacterial threats. The CDC cautions that much of the antibiotic use in food animals may be unnecessary and inadvertently contribute to the development of resistance. This proposed rule is crucial to our nation's efforts to overcome the threat of antibiotic resistance.

In 2012, the FDA published its advanced notice of proposed rulemaking "Antimicrobial Animal Drug Sales and Distribution Reporting" (Docket No. FDA-2012-N-0447). This rule would make changes to the data reporting requirements of drug sponsors made by amendments made to the Animal Drug User Fee Act (ADUFA) in 2008. Currently, these reports include information on the class of antibiotics sold, their importance to human medicine, and their marketing status. Although these data have been useful in understanding the general ways that medically-important antibiotics are used in animals, more nuanced and detailed numbers are necessary to understand what consequences, if any, they may have for human health.

In the three years since the announcement of this proposed rule, the FDA published Guidance for Industry (GFI) #213, which allows industry to change the claims and marketing status of antibiotics – without submitting additional data unless a new claim is made – to comply with newly-defined appropriate therapeutic uses. Moreover, the FDA also issued the Veterinary Feed Directive (VFD) final rule in 2015 to bring antimicrobial use in food-producing animals under veterinary supervision. GFI #213 and the VFD rule make important changes to how we steward antibiotics. In so doing, however, they also highlight the parallel need for good baseline data to evaluate the impact of these regulatory changes and give new urgency to this proposed data collection rule.

Consequently, TFAH strongly supports requirements for the collection of species-specific sales data. As stated in the proposed rule, the FDA believes that drug sponsors already have access to this information. Since pigs, cows, chickens, and turkeys are raised differently, data that are more granular can help us understand what relationship agricultural antibiotic use may have with the development of resistance. We encourage the FDA to make as much of this data publicly available while also protecting business confidentiality.

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Furthermore, we also support requirements for the publication of annual summary data by December 31 of the following year. Regular, consistent reporting can help us understand the potential public health risks associated with antibiotic use and how these may change with time.

Collecting data on how food animals use antibiotics is an important first step to understanding their potential association with resistance trends. We appreciate the FDA's commitment, as well as its collaboration with the U.S. Department of Agriculture and CDC, to tackling this growing threat to the nation's health. TFAH urges the finalization of this rule as soon as possible.

Thank you for your consideration of these comments. We look forward to a final rule that will make a significant improvement in our nation's health. If you have any questions, please feel free to contact Dara Lieberman, TFAH's Senior Government Relations Manager, at dlieberman@tfah.org.

Sincerely,

Jeffrey Levi, PhD
Executive Director