

May 9, 2016

The Honorable Robert M. Califf, M.D., Commissioner of Food and Drugs  
The Honorable Michael R. Taylor, Deputy Commissioner for Foods and Veterinary Medicine  
Tracey H. Forfa, Acting Director, Center for Veterinary Medicine  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

**Re: Monitoring the Sale and Use of Agricultural Antibiotics**

Dear Commissioner Califf, Deputy Commissioner Taylor, and Acting Director Forfa:

We, the undersigned organizations, write to request that the Food and Drug Administration (FDA) address misunderstandings related to the sales and distribution data collected and publically reported by FDA under Section 105 of the Animal Drug User Fee Amendments of 2008 (ADUFA).

This request is prompted by questions recently raised during a panel discussion at the Consumer Federation of America's (CFA's) National Food Policy Conference.<sup>1</sup> Many of our organizations have previously expressed concern about the limitations of the ADUFA data and the resulting inability of the federal data collection system to address critical questions regarding antibiotic use in food animals. Nonetheless, we consider - and have consistently cited - the ADUFA data as an indicator of trends in the use of specific antimicrobial drug classes. These data play a critical role in the public policy debate around antibiotic use in food-producing animals, and all sides of the debate must clearly understand the data to engage in productive dialog. Therefore, we urge FDA to act immediately to clear up misunderstandings about these data.

Regarding the specific issues raised during CFA's meeting, we are most concerned with the question regarding the extent to which ADUFA data, which are collected at the drug manufacturer level, account for antibiotics that may be exported after they are sold or distributed by a drug manufacturer. We understand that ADUFA data in fact do not account for exports by entities downstream of the manufacturer, but believe that this practice does not represent a significant portion of sales. However, if the proportion of these sales is significant, it is important for the public and policymakers to know the extent of such exports. Therefore, we ask that FDA respond to this question and, if needed, collect and report additional data to answer it.

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<sup>1</sup> At a public panel discussion on April 6, Dr. James MacDonald, chief of the U.S. Department of Agriculture (USDA) Economic Research Service's Structure, Technology and Productivity Branch, questioned the accuracy of FDA reports that show an over 20% increase in antibiotic sales from 2009 to 2014. MacDonald suggested instead that antibiotic use in food animals may have actually declined. He identified two ambiguities in FDA data collection that could have accounted for reported increase. First, he noted that part of the reported sales increase could reflect sales of antibiotics for use in companion animals. Second, he indicated that FDA fails to account for antibiotics that may be exported after they are distributed by a manufacturer. See for instance: <http://www.agri-pulse.com/Panel-calls-for-clarity-in-antibiotic-use-data-04062016.asp>

The second question raised at the CFA conference concerns the amount of animal antibiotics being used for companion animals. The ADUFA reports do not support a claim that antibiotic use trends in companion animals are a significant factor in animal antimicrobial sales. The most recent ADUFA report states that “product sales volume for [drug] applications [which are approved for both livestock and companion animals] is very small compared to product sales volume for other applications with the same active ingredients that are approved for use solely in food-producing animals.”<sup>2</sup> While ADUFA data do capture some companion animal uses, such uses are likely to be a minor contributor to overall sales, and their impact on trends over time is negligible.

Please note that our interpretation is additionally based on the fact that the vast majority of medically-important antibiotic drug sales are for use in feed or water – according to 2014 ADUFA data, 74% of medically important drugs were sold for use in feed and 22% for use in water – administration routes that are uncommon for most companion animal species. In fact, we were unable to identify a single feed antibiotic for any of the major companion animal species (i.e. dogs, cats, and horses)<sup>3</sup>. For minor companion animal species, the only feed drugs we could identify are chlortetracycline for pet birds. According to the 2014 ADUFA sales and distribution report, antibiotics reported for use in water did not include any that could have been sold or distributed for use in companion animals. The dosage forms more typically administered to companion animals (i.e. oral or topical treatments and injection uses) make up less than 1% and 2% of sales according to 2014 ADUFA data, respectively.

In light of the questions raised, we ask that FDA reaffirm that companion animal use accounts for only a very small portion of reported animal antibiotic sales in the U.S. and thus could not account for the large rise in sales between 2009 and 2014.

In addition to responding directly to this letter, we ask that FDA address these specific concerns in future ADUFA Section 105 reports and on the FDA website on the page titled “Questions and Answers: Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals” at the following address:  
<http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/ucm236149.htm>. We also ask that FDA finalize the proposed rule on species-specific sales data, which will allow estimated sales for companion animals to be more clearly identified.

Finally, we urge FDA without further delay to start collecting antibiotic distribution data from feed mills. These data will serve as an additional way of capturing information on the vast majority of medically important antibiotics that are administered in feed. Collection of these data is especially important in light of the limitations of the ADUFA data currently being discussed, and also is in line with the discussion at the CFA conference about current data collection being concentrated only at a single point in the antibiotic distribution chain.

We and other public health and consumer advocates have long asked for FDA to collect these data from feed mills. In addition to the aforementioned benefits, such data also would be valuable tools to gauge FDA’s success in implementing its new Veterinary Feed Directive Rule.

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<sup>2</sup> ADUFA 2014 Summary Report, at 10, available at:

<http://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM476258.pdf>

<sup>3</sup> 21 CFR 558 Subpart B.

Similarly, data from livestock integrators could provide additional information about antibiotics used in water.

In short, FDA, in collaboration with other food, disease and environmental agencies, must move forward with a more robust data collection system that can be used to address fundamental questions about antibiotic use, including trends in use over time, differences by species and production class (e.g. laying hens verses broiler chickens raised for meat or dairy versus beef cattle), and specific reasons for use (e.g., specific indication of use). Such data are central to understanding the underlying drivers of the trends in antibiotic use over time.

We look forward to your responses to our request and we would appreciate the opportunity to meet with you to discuss this issue and FDA's efforts to combat antimicrobial resistance more broadly. Please contact Steven Roach by email at [sroach@foodanimalconcerns.org](mailto:sroach@foodanimalconcerns.org) to respond or if you have any questions.

Sincerely,

Keep Antibiotics Working  
American College of Preventive Medicine  
Antibiotic Resistance Action Center, Milken Institute School of Public Health at the George Washington University  
Center for Food Safety  
Center for Foodborne Illness Research & Prevention  
Center for Science in the Public Interest  
Consumer Federation of America  
Consumers Union  
Environmental Working Group  
Food and Water Watch  
Food Animal Concerns Trust  
Humane Society of the U.S.  
Health Care Without Harm  
Infectious Disease Society of America  
The Johns Hopkins Center for a Livable Future  
National Center for Health Research  
Natural Resources Defense Council  
School Food Focus  
STOP Foodborne Illness  
US PIRG  
Waterkeeper Alliance