November 22, 2017

Division of Dockets Management (HFA-305)
Food and Drug Administration (FDA)
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket No. FDA-2011-N-0656 for "Animal Drug User Fee Act; Recommendations; Request for Comments; Extension of Comment Period

The undersigned Keep Antibiotics Working (KAW)[1] member groups, appreciate this opportunity to comment on the FDA's Animal Drug User Fee Act (ADUFA) reauthorization draft recommendations.

These are the third ADUFA draft recommendations upon which KAW member organizations have commented. KAW and member organizations commented on FDA recommendations for ADUFA reauthorization in 2008 and in 2013. Like the previous two times, we are disappointed that FDA has once again failed to include input provided by consumer and patient advocates in its draft recommendations, even though Congress has consistently required that FDA consult with stakeholders other than the regulated industry in developing its recommendations. Despite this, in 2008 Congress included in its reauthorization Section 105, which directed the FDA to collect and report data on sales of antibiotics for use in food animals. This was a major recommendation of the consumer advocacy organizations including KAW.

Section 105 closed a clear gap in FDA's oversight of veterinary drugs by addressing a major threat to public health – the rise of antibiotic resistant bacteria. The data collected and reported under Section 105 have provided useful information on the extent of antibiotic use on farm, and created a baseline from which to measure the impact of efforts to reduce antibiotic overuse. Since 2008, the threat of antibiotic resistance has only grown. With this growth, attention to the threat by both the public and policy-makers has risen. What is unclear is whether we are willing to take action to make certain that the direst predictions of a future where antibiotics no longer work do not become reality.

Keeping that in mind, we once again ask FDA to include in its recommendations to Congress on ADUFA reauthorization, actions aimed at addressing the threat of antibiotic resistance. The inclusion of Section 105 in the 2008 ADUFA reauthorization clearly indicates that post-marketing safety related responses to antibiotic resistance is within the scope of ADUFA.

[1] Keep Antibiotics Working, a coalition of health, consumer, agricultural, environmental, humane, and other advocacy groups with more than 10 million supporters, is dedicated to eliminating the inappropriate use of antibiotics in farm animals, a significant contributor to the rise in antibiotic resistant disease.

We have two main asks for FDA's recommendations to Congress:

1. First, FDA should ask Congress to authorize the use of funds collected under ADUFA to close the gap in data on antibiotic use on farm. While Section 105 provides very useful data on the overall sales of antibiotics for use in food animals, it is not the same as use data and lacks important details. The 105 data do not provide needed information on species and indication. Starting in 2016, FDA does require drug makers to estimate sales by species, but it will be difficult to judge the accuracy of these estimates without the collection of actual on-farm data. The estimates also will provide no information on the reason for use or the production class – dairy or beef cattle and layer or broiler chickens. FDA has funded several efforts through universities to collect data on farm, but there is no indication that these initiatives will be ongoing and no data have yet been reported.

   FDA has consistently argued that better data on antibiotic use is important for "science-based decision making in the approval and monitoring of safe and effective antimicrobial drugs[2]," and so using ADUFA funds for this purpose would be consistent with the ADUFA goals in support of the drug approval process. FDA has also consistently pointed to a lack of resources as a reason for not collecting data on farm. Directing a portion of ADUFA funds to this purpose would help address the resource shortage and help close a critical data gap that hinders FDA's ability to ensure the safety of animal drugs.

   We ask that FDA include within its ADUFA reauthorization recommendations, the authority to use a portion of the collected funds to support the collection of data on antibiotic use on farm.

2. Second, FDA should ask Congress to streamline the process for requiring drug sponsors to make changes to existing labels that put public health at risk and are at odds with FDA policy. FDA has taken important steps to improve the stewardship of antibiotics used in food animals through the implementation of Guidances #209 and #213, but FDA has also indicated that more needs to be done. Specifically, FDA has recognized the need to address those medically important antibiotics for which there are no defined durations. FDA in 2016 sought comment[3] on how it could move forward with setting duration limits on the 32% of products covered by Guidance #213, for which there are indications without any defined durations. We support this effort, because using antibiotics for long durations increases the risk of the selection and dissemination of antibiotic resistance.

   FDA already has the authority to set duration limits based on its safety and efficacy assessment of new animal drug applications. At the same time, FDA has described its

[2] Federal Register 77(145):44178 July 27, 2012.
[3] 81 Fed Reg. 63187 (September 14, 2016)

process for requiring drug sponsors to make changes to existing labels as cumbersome and resource intensive even when existing labels put public health at risk and are at odds with FDA policy. This has made it difficult for FDA to implement necessary changes. FDA must be able to require label changes for products that do not align with existing policy in a timely manner.

Both of these requests are consistent with FDA CVM's "Key Initiatives for Antimicrobial Stewardship." Including them in ADUFA could provide needed resources and streamline FDA's authority to move these initiatives forward. In addition, we also supports other actions under ADUFA to address the public health threat from antibiotic resistance.

We have previously asked FDA to consider addressing the overuse of antibiotics more broadly than just looking at duration limits and instead address any use of antibiotics in animals that are not sick. This is consistent with the recently released World Health Organization guidelines on use of medically important antimicrobials in food-producing animals.[4] We have also previously asked that FDA set targets for reductions in antibiotic use as an important tool for improving stewardship and for monitoring the impact of efforts aimed at promoting stewardship. We support FDA including actions related to these in FDA's ADUFA reauthorization recommendations.

Finally, we call upon FDA to heed Congress's direction to take into consideration stakeholders other than the regulated industry when making its recommendations to Congress. Antibiotic resistance is a growing public health threat with dire consequences for human and animal health. We ask that you use the opportunity of the ADUFA reauthorization to strengthen the FDA response.

Sincerely,

Food Animal Concerns Trust
Natural Resources Defense Council
Center for Foodborne Illness Research & Prevention
Antibiotic Resistance Action Center, the George Washington University
Consumer Federation of America
The Humane Society of the United States
Humane Society Legislative Fund
Johns Hopkins Center for a Livable Future
U.S. PIRG
Center for Food Safety

[4] WHO. 2017. WHO guidelines on use of medically important antimicrobials in food-producing animals.