KEEP ANTIBIOTICS WORKING
The Campaign to End Antibiotic Overuse
www.KeepAntibioticsWorking.org

December 19, 2022

RE: Docket No. FDA-2011-N-0656 for "Animal Drug User Fee Act; Public Meeting; Request for Comments"

Comments on "Animal Drug User Fee Act; Public Meeting; Request for Comments"

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

Congress passed the Animal Drug User Fee Act (ADUFA) in 2003 and reauthorizes it every five years. In order to ensure public accountability, Congress has consistently required the FDA to consult with representatives of consumer advocacy groups, appropriate scientific and academic experts, and veterinary professionals - not only the regulated industry - when developing its recommendations to Congress. Keep Antibiotics Working has participated throughout the reauthorization process starting with the initial meeting in May 2021. Despite our best efforts to provide public accountability, the FFA has consistently ignored our input as is reflected in the draft recommendations. The failure to include input from stakeholders outside of the regulated industry will inevitably erode public support for the program.

Antibiotic resistance kills people every day in the U.S. and around the world. Infections that once were easily treatable no longer respond to existing antibiotics. The end result is almost three million infections and up to 162,000 deaths in the U.S. each year.[2] Antibiotic resistance is driven by the overuse of antibiotics both in human medicine and in animal agriculture. Since 2019, the Centers for Medicare & Medicaid Services (CMS) has required acute-care hospitals participating in Medicare and Medicaid to implement antibiotic stewardship programs, but no such accountability exists in agriculture. With two-thirds of medically important antibiotics sold for use in food animals, addressing resistance requires addressing overuse in animals. In 2008, Congress included section 105 of the Animal Drug User Fee Amendments, which directed the FDA to begin collecting and reporting antibiotic sales data.[3] This is a clear indication that antibiotic resistance and post-marketing surveillance are within the scope of ADUFA.

[1] Keep Antibiotics Working is a coalition of nineteen health, consumer, patient, agricultural, environmental, animal protection, veterinary, and other advocacy groups dedicated to eliminating a major cause of antibiotic resistance: the inappropriate use of antibiotics in food animals.
[2] CDC. Antibiotic Resistance Threats in the United States, 2019. Atlanta, GA: U.S. Department of Health and Human Services, CDC; 2019.
[3] ADUFA Section 105. https://www.fda.gov/industry/animal-drug-user-fee-act-adufa/questions-and-answers-summary-report-antimicrobials-sold-or-distributed-use-food-producing-animals

In reading through the proposed recommendations for the reauthorization of the Animal Drug User Fee Act (ADUFA) there is a stark contrast between the FDA's accountability to the regulated industry versus its accountability to the public to protect public health with respect to antibiotic resistance. The proposed recommendations give the FDA strict deadlines to complete review steps for new drugs within days and include metrics and requirements for reporting. The FDA has to act within 30 days in some cases. When considering the FDA's actions to protect the public from antibiotic resistance, the timelines are in years and even decades, never in days. It took from 1977 to 2017, 40 years, to withdraw growth promotion uses for penicillins and tetracyclines. During those 40 years, resistance developed, rendering these drugs ineffective in the treatment of serious foodborne infections. Presently, over twenty years after the FDA identified the collection of antibiotic use data from farms and feedlots as a high priority, there is still no system in place to collect this data. The FDA has not updated its list of medically important antibiotics since it was released in 2003. In 2016, the FDA began working on setting duration limits on medically important antibiotics used in food animals, yet the FDA has released neither a final guidance nor regulation, nor even a draft guidance. The FDA took five years to withdraw the use of fluoroquinolones in poultry after determining it was putting public health at risk from resistant foodborne infections.

At the same time, much of the FDA's day-to-day activity, in part sped up by the ADUFA fees and deadlines, likely increases antibiotic use by adding new indications, new combinations, and new manufacturers for antibiotic drugs. ADUFA has consistently been used by the regulated industry as a way to get its priorities moved forward as evidenced by the expansion of conditional approvals and the exploratory options in the current proposed recommendations to Congress.

All the while, antibiotic-resistant infections continue to sicken and kill people each day. The FDA uses the fees it collects only to approve new antibiotic uses, and not to track ongoing use of already-approved antibiotics to assess how they are used, and make sure that the level of their use remains consistent with public health. That is especially important since public health experts remind us more urgently than ever before that misuse and avoidable uses of these precious medicines are a critical driver of the spread of antibiotic-resistant bacteria.

The FDA can and must use these fees to conduct so-called "post-market" surveillance of antibiotics long on the market.

We ask the FDA in its recommendations to Congress to:

1. **Strengthen U.S. tracking and reporting of antibiotics sold and distributed for use in food-producing animals.**

   We recommend that the FDA include the collection, analysis, and reporting of veterinary feed distribution records and associated veterinary feed directives (VFDs) from firms that

distribute feed directly to livestock feeding operations. Together, these data will provide information on the amount of feed antibiotics delivered to farms, along with the reason for their use. At present time, feed antibiotics represent 64% of all medically important antibiotics sold for use in livestock production. Both feed distribution records and VFDs are of critical public health importance, yet neither is being supplied by current data collection systems. Under existing rules, feed distributors are already required to maintain these records, and to make them available to the FDA, but the FDA is not collecting them.

2. **Include support for its current five-year plan as part of the ADUFA reauthorization and commit to developing a second five-year plan that the FDA will report on in conjunction with the 2028 ADUFA reauthorization.**

   In 2023, the FDA's Center for Veterinary Medicine will complete its existing five-year plan on Supporting Antimicrobial Stewardship In Veterinary Settings. In its discussion of the Plan, the FDA asserts that it is a One-Health-based approach "to combat antimicrobial resistance and preserve the effectiveness of antimicrobial drugs"

   This second five-year plan should address actions not completed during the first plan, include steps to curb antibiotic use in animals that are not sick, and indicate expected outcomes in terms of antibiotic use and antibiotic resistance.

During the last five years, very little action has been taken by the FDA to address the critical public health crisis of antibiotic resistance. There have been numerous meetings and activities but very little action leading to actual changes in how antibiotics are used. We hope the FDA will accept this and future ADUFA reauthorizations as a way to speed up needed action.

Food Animal Concerns Trust

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