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

August 10, 2021

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 FDA's Animal Drug User Fee Act (ADUFA) reauthorization draft recommendations.

Congress has consistently required that the FDA consult with consumer advocacy groups when developing recommendations to present to Congress on ADUFA goals. KAW asks that the FDA take this requirement seriously and sufficiently acknowledge the views of stakeholders outside of the regulated industry when making its recommendations to Congress. The failure to include input by stakeholders outside of the regulated industry will inevitably erode public support for the program.

This is the fourth time that KAW has participated in ADUFA reauthorization. While KAW has consistently provided input on reauthorization, the FDA has repeatedly disregarded that input. The FDA's recommendations to Congress on re-authorization have consistently included the wishes of the regulated industry but have not included public health measures such as directing ADUFA funds to post-marketing surveillance as requested by other stakeholders. This must change.

The Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) have long deemed antibiotic resistance as one of the world's leading health threats. Antibiotic resistance contributes to at least 35,000, perhaps up to 162,000, U.S. deaths per year; and experts project a global toll of 10 million annual deaths by 2050.[2] Stopping the overuse and misuse of antibiotics in animal agriculture is an essential part of controlling this urgent public health threat.

[1] Keep Antibiotics Working is a coalition of twenty 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.

3525 W. Peterson Avenue, Suite #213 • Chicago, IL 60659-3314 • PHONE: 773-525-4952

We recommend that the FDA include both goals and funding related to post-marketing surveillance as part of its recommendations to Congress. These should include the following:

1. Collecting antibiotic use data on farms.

The FDA should ask Congress to authorize the use of funds collected under ADUFA to close the data gap in on-farm antibiotic use. While ADUFA Section 105 provides very useful data on the overall sales of antibiotics for use in food animals, this is not the equivalent of antibiotic use data. The 105 data do not provide important details on species of use or indication. The FDA has funded several efforts through universities to collect data on farms, however there is no indication that these initiatives will be ongoing or that a national surveillance system will be established.

The FDA has 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,"[3] therefore, using ADUFA funds for this purpose would be consistent with the ADUFA goals in support of the drug approval process. The FDA has also pointed to a lack of resources as a reason for not collecting data on farms. Directing a portion of ADUFA funds to this purpose would help address the resource shortage and help close a critical data gap that hinders the FDA's ability to ensure the safety of animal drugs.

2. The FDA should set targets for antibiotic use reductions.

The FDA should include within its recommendations to Congress a commitment to set antibiotic use reduction targets. KAW asks that the FDA set ambitious national targets for reducing antibiotic use both in agriculture and human settings in order to maintain the effectiveness of the drugs that the FDA has approved. Targets allow federal agencies to maintain accountability to their public health mission and adequately track progress over time. Setting of targets for antibiotic use reductions does not preclude setting other targets or goals related to antibiotic stewardship.

3. Post marketing safety surveillance.

KAW asks that a portion of the funds collected under ADUFA be directed to post-marketing safety surveillance related to the public health risk of antibiotic resistance. ADUFA funds are designated for the review process of animal drug applications. The FDA has consistently described both surveillance efforts of enteric bacteria through the National Antimicrobial Resistance Monitoring System (NARMS) and data collection on sales and distribution as supporting the safety of drugs both pre- and post-approval. KAW believes that both the NARMS

[3] Federal Register 77(145):44178 July 27, 2012.

program and the efforts to collect antimicrobial sales and antibiotic use data fall under the activities included in the process for the review of animal drug applications and therefore should receive funding through ADUFA.

4. Accelerating timelines for taking action on antibiotic resistance.

We also ask for expedited timelines on the FDA's proposal to set duration limits for medically important antimicrobials that lack a defined duration of use.[4] The proposed timeline delays placing duration limits on product labels until 2030 or even later.[5] Fourteen years will have elapsed from the year that the FDA identified duration limits as a priority (2016)[6] to the year when these modest rules may go into effect (2030). Without further action, the overuse of medically important antibiotics in livestock production will continue, largely unchanged. This continues to put public health at risk. ADUFA consistently sets goals for how quickly the FDA acts on drug approvals. The agency should also commit to timely action on protecting public health.

5. Monitoring unethical and illegal marketing of veterinary drugs.

The FDA should recommend that Congress authorize funds from ADUFA fees be used to monitor post-marketing advertising of veterinary drugs. Inappropriate advertising of veterinary drugs can undermine antimicrobial stewardship efforts and contribute to antibiotic overuse and the associated antibiotic resistance. KAW has uncovered unethical marketing by some of the major drug companies for some of the most widely used antibiotics.

For example, in marketing materials, the drug maker Elanco inappropriately recommended "proactively" treating subclinical illness in animals with a drug approved for disease treatment.[7] More recently the drug maker Zoetis has promoted extra-label use of the medically important drug chlortetracycline.[8] Both of the antibiotics promoted by these marketing efforts are some of the most widely used antibiotics in the animal species for which the drugs were promoted. These marketing programs were submitted to the FDA staff at the time of dissemination; however, no

[4] Center for Veterinary Medicine | FDA. "FDA Seeks Public Comment on Potential Approach for Defining Durations of Use for Certain Medically Important Antimicrobial Drugs for Food Animals." *FDA*, February 22, 2021. https://www.fda.gov/animal-veterinary/cvm-updates/fda-seeks-public-comment-potential-approach-defining-durations-use-certain-medically-important.

[5] Center for Veterinary Medicine | FDA. "FDA-TRACK: Progress on FDA's Support of Antimicrobial Stewardship in Veterinary Settings." *FDA*, May 26, 2021. https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-progress-fdas-support-antimicrobial-stewardship-veterinary-settings.

[6] 81 Fed Reg. 63187 (September 14, 2016).

[7] Hakim, Danny, and Matt Richtel. "Warning of 'Pig Zero': One Drugmaker's Push to Sell More Antibiotics." *The New York Times*, June 7, 2019, sec. Health. https://www.nytimes.com/2019/06/07/health/drug-companies-antibiotics-resistance.html.

[8] Zoetis. "Chlortetracycline Pulses Cost-Effective Treatment for BRD." BRD Solutions from Zoetis. Accessed May 4, 2021. https://www.brd-solutions.com/insights/chlortetracycline-pulses-cost-effective-treatment-for-brd.aspx.; Zoetis. "The Value of In-Feed Chlortetracycline in Starting Cattle." zoetisus.com. Revised May, 2016. Accessed May 4, 2021. https://www.zoetisus.com/products/beef/feed-additive-solutions/docs/value-of-in-feeed-chlortetracycline.pdf ; Zoetis. "Cattle Feed Additive Treatments." zoetisus.com. Accessed May 12, 2021. https://www.zoetisus.com/products/beef/feedadditive-solutions/treatments.aspx#.

action was taken by the agency. The FDA has indicated to KAW that resource constraints limit the FDA's ability to look closely at all submitted promotional materials. Therefore, directing a portion of ADUFA funds to this purpose may address these constraints.

Sincerely,

Alliance to Save our Antibiotics
Antibiotic Resistance Action Center, George Washington University
Association for Professionals in Infection Control and Epidemiology
Center for Biological Diversity
Center for Food Safety
Consumer Reports
Earthjustice
Family Farm Defenders
Farm Sanctuary
Food & Water Watch
Food Animal Concerns Trust
Food Tank
Government Accountability Project Food Integrity Campaign
Health Care Without Harm
Humane Society Legislative Fund
Humane Society of the United States
Humane Society Veterinary Medical Association
Illinois Public Health Association
Interfaith Center on Corporate Responsibility
Johns Hopkins Center for a Livable Future
MRSA Survivors Network
Natural Resources Defense Council
Northeast Organic Dairy Producers Alliance
Organic Consumers Association
Prevention Institute
Public Health Institute
Roots of Change
San Francisco Bay Physicians for Social Responsibility
Science and Environmental Health Network
Socially Responsible Agriculture Project
The Alliance for Natural Health USA
World Animal Protection US