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David Horowitz, Assistant Commissioner for Policy  
Division of Dockets Management  
United States Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
Rockville, MD 20852

Dear Assistant Commissioner Horowitz,

December 14, 2009

We are writing on behalf of the Alliance for the Prudent Use of Antibiotics (APUA) due to our concerns about the misuse of antibiotics in food animal production and its negative impact on the treatment of human infections. APUA is a science-based public health organization established in 1981 to preserve the power of antibiotics. Towards this end, we urge you to strengthen regulations to improve surveillance of antimicrobial use in agriculture to help curtail widespread antimicrobial resistance that has devastating effects on human health. Therefore, we strongly support Docket No. FDA-2009-N-0512 (Section 105 of the Animal Drug User Fee Amendments of 2008.)

Current regulations in agriculture are woefully inadequate for obtaining the kind of basic information that is readily available to control antimicrobial use in human medicine. These data are necessary to guide public policy and identify and decrease unnecessary antibiotic uses in agriculture and minimize the heavy selective pressure that fosters emergence of drug-resistant bacteria in agricultural settings.

An APUA report, *Antibiotics in Animals and the Impact on Resistance (FAAIR) Project*, published in June 2002 in *Clinical Infectious Diseases*,\* presented evidence from national experts and six overarching policy recommendations to improve the safety of antimicrobial practice in food animal production. The most fundamental need identified was for reported quantitative data on specific antimicrobial usage. The panel determined that manufacturers should be required to report agent, formulation, intended animal species and route of administration for all antimicrobials in order to inform public policy decisions to minimize antimicrobial overuse and misuse in agriculture.

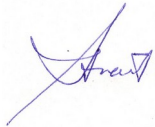
In February 2006, these recommendations were corroborated by a separate APUA-convened expert group involving diverse industry, academic and government stakeholders. The group determined that timely information from manufacturers would be more useful for surveillance purposes if all manufacturers were required to report annual data on a single date. Individual stakeholders, in their comments on the need for increased monitoring of antimicrobial use in agriculture, stressed that better data would make risk assessments and models more accurate and provide some of the evidence necessary for effective antimicrobial regulations to be put in place to protect human health from the effects of resistance.\*\*

While the proposed measures in Section 105 would be important steps in surveillance, the practical utility of this data will be immensely broadened in conjunction with a larger federal monitoring effort that would require manufacturers to report antimicrobial use in all food animal products and involve veterinarians and animal owners, who can best track end-user data on antimicrobial use. Such data, when linked with trends of antimicrobial resistance in food

animals, would allow for informed policy decisions that would most effectively limit the impact of agricultural use of antimicrobials on resistance in human populations.

Thank you for your attention and proactive stance on this pressing public health threat. We remain available and interested in assisting furtherance of surveillance and regulatory measures to provide data to help assess and evaluate the amount of antibiotics used in food animal production and guide policy interventions to preserve the power of antibiotics for when they are needed most.

Sincerely,



Stuart B. Levy, MD, President, APUA



Kathleen T. Young, Executive Director, APUA

## References

\*Barza, M. and S. L. Gorbach, guest eds. The Need to Improve Antimicrobial Use in Agriculture: Ecological and Human Health Consequences. *Clin Infect Dis* 2002;34(Suppl 3): S71-144.

\*\*McEwen, S. A. and P. J. Fedorka-Cray, eds. Animal Antimicrobial Use Data Collection in the United States: Methodological Options. *Prev Vet Med* 2006;73(2-3): 105-228.

CC:

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