

November 18, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rockville, Maryland 20852

Re: Docket No. 98-D-0969 Antibiotic Resistance in Food-Producing
Animals Public Workshops

The Coalition for Animal Health is comprised of the major national trade associations representing the animal production, animal feed and animal health industries, as well as the veterinary profession. We are pleased to respond to the agency's request for comments on its proposed workshops on "Antibiotic Resistance in Food-Producing Animals."

The Coalition commends the Center for Veterinary Medicine for providing the opportunity to comment on the scope and format of public workshops that seek to develop a risk-based regulatory structure for antibiotics used in food animals. We strongly believe that a scientific assessment of the actual risk from the use of antibiotics in food animals will identify the appropriate safeguards to protect human health and allow the continued approval of these products in food animals.

The Coalition has been actively involved in the antibiotic resistance issue and provided comments to CVM at the Veterinary Medical Advisory Committee meeting in January 1999. Those comments highlighted the need for the completion of risk assessments **prior** to any changes in the current regulatory structure. The workshops planned for December 1999 and January 2000 should allow the thoughtful review of the CVM risk assessment model to guarantee that it incorporates the available science and clearly articulates the risk actually faced by the public.

To allow the workshops to realize their full potential, CVM should ensure that participants have all the necessary information about the workshops' structure, scope and format in a timely fashion. CVM also should ensure that participants have all relevant information necessary to review the CVM risk assessment model and all other relevant agency activities that may fall within the scope of the workshops in a timely matter.

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In determining the scope of the workshops and any breakout sessions occurring within them, we believe that CVM should clearly establish the goals and procedures by which the participants should operate. Every effort should be made to ensure that participants' comments address these goals in a meaningful way and are supported by science. A thorough examination of the technical aspects of the CVM risk assessment and accompanying risk management plan is critical to the development of a regulatory approach that is balanced and effective. As a part of defining the scope of the workshops, subsequent activities and time frames should be identified.

We believe the format of the workshop should allow for experts in risk assessment, microbiology and foodborne pathogens to provide background information to all participants to help focus the discussion at topic-specific breakout sessions. In addition, CVM should provide all participants with a clear understanding of the requirements (both ad hoc and established through regulation) currently in place to evaluate the safety of antibiotics for use in food animals. The breakout sessions should have facilitators capable of ensuring a focused discussion that can contribute to a meaningful review of the model put forward by CVM and not just a restatement of previously determined positions.

In regards to the Workshop on Risk Assessment and the Establishment of Resistance Thresholds, the Coalition, for Animal Health encourages CVM to clearly separate and discuss the various components of the risk assessment/risk management model. We believe that risk assessment, risk management and risk communication are related but separate activities and the successful application of these concepts requires that the differences be clearly understood. At the outset of this session, CVM should provide an in-depth discussion of the risk assessment/risk management model that is currently being developed. The risk assessment component of this model must quantify the probability estimates associated with the risks to humans from the use of antibiotics in food animals. In addition, the Coalition is interested in the mitigation activities contemplated in conjunction with the establishment of thresholds.

The Coalition encourages CVM to include opportunities during the workshop to discuss a process that will make the risk assessment/risk management model responsive to changes in the conditions encountered over time. For example, according to USDA the foodborne pathogen reduction activities currently in place are significantly reducing the risk of human illness. The participants in the workshop should have the opportunity to evaluate the model in terms of its ability to incorporate necessary changes and modifications.

Finally, the Coalition for Animal Health encourages CVM to allow participants to thoroughly evaluate monitoring and resistance thresholds and the scientific concepts upon which they are based. There is concern that the time between the release of the CVM risk assessment and the first workshop will not be adequate to sufficiently evaluate the risk assessment and form a considered response. It is imperative that the process allows for

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thoughtful input from all stakeholders. If the risk assessment is not ready for release with adequate time for this to occur, the workshop should be postponed.

The Coalition appreciates the opportunity to provide comments on the upcoming workshops. We expect to provide additional comments on the pre-approval workshop at a later date.

Sincerely,

American Farm Bureau Federation
American Farm Industry Association
American Sheep Industry Association
Animal Health Institute
National Cattlemen's Beef Association
National Chicken Council
National Pork Producers Council
National Turkey Federation



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