# Animal Health Industry Supports FDA Antibiotic Judicious Use Guidelines

**President's Council of Advisors on Science and Technology**

**April 4, 2014**

Thank you to the Council for allowing me to make some very brief remarks today regarding antibiotics used in food producing animals. I am Dr. Richard Carnevale, a veterinarian with the Animal Health Institute. AHI is the national trade association representing manufacturers of animal health products – the pharmaceuticals, vaccines and feed additives used in modern food production, and the medicines that keep livestock and pets healthy.

The FDA recently issued Guidance for Industry 213 in December requesting holders of approved antibiotic applications for food producing animals to voluntarily phase out label indications for increasing weight gain or improving feed efficiency, commonly referred to as growth promotion, on medically important antibiotics. FDA defined medically important as those belonging to seven classes, specific entities of which are also used in human medicine. Furthermore, they requested that sponsors restrict the use of these antimicrobial feed and water medications to use by or on the order of a licensed veterinarian by relabeling them as Veterinary Feed Directive or prescription only drugs.

When FDA published the final guidance late last year they asked for sponsors to notify them, by March 2014, of their intentions to engage the agency in effecting the changes to label claims and market status. I am pleased to report that all AHI member companies as well as those belonging to the Generic Animal Drug Association (GADA) and virtually all affected independent sponsors have agreed in writing to cooperate with the agency. FDA released a notice just last week specifically naming those sponsors.

So the first major step has been taken and with everyone's cooperation we hope to finalize these changes within the next three years. There will be challenges to meeting this goal as these changes will have significant impacts on animal agriculture and the veterinary community. But, when complete all medically important antibiotics administered in feed will be used only for therapeutic purposes under the control of licensed veterinarians.

My message to the Council as you work toward recommendations to deal with antibiotic resistance challenges is that the FDA voluntary process should be allowed to work. We have heard calls for making what FDA is doing mandatory but if the agency is to achieve their stated objectives in an effective and timely manner a cooperative approach with industry is the only way to get this done. I have a great deal of experience in the regulation of animal drugs. Prior to my joining AHI nearly 19 years ago I served 13 years in new animal drug evaluation at the FDA Center for Veterinary Medicine and 7 years at the USDA FSIS. I can tell you that if FDA has to enforce a mandatory regulatory approach it will only delay this process for many more years in order to accommodate the administrative procedures the agency must follow in taking regulatory action against legally approved products, and is likely to have a very uncertain outcome.

I again thank the Council for its time today. I trust my comments will be helpful to you in completing this important work.

1325 G Street, NW ■ Suite 700 ■ Washington, D.C. 20005-3104
Telephone (202) 637-2440 ■ Fax (202) 393-1667
www.ahi.org