Q&A: Final Guidance 213 and VFD

Q. WHY ARE PHARMACEUTICAL COMPANIES SUPPORTING THIS PROCESS?

A: We believe there's a great deal of consumer misunderstanding about how antibiotics are used in animal agriculture. Many consumers seem to believe all antibiotics are used just to promote growth. We hope that by eliminating that use we can have a clearer conversation with consumers about the important therapeutic uses to keep food animals healthy.

Q. WON'T FARMERS SIMPLY USE ANTIBIOTICS THE SAME WAY AND CALL IT SOMETHING DIFFERENT? ISN'T PREVENTION THE SAME THING AS GROWTH UNDER A DIFFERENT NAME?

A: Absolutely not. These are very different claims. To get FDA to approve a prevention claim, sponsors must submit data showing the drug at a given dose acts against a specific disease or a specific bacterium. Growth claims require data showing increased average daily weight gain or increased feed efficiency. That’s why FDA calls prevention a therapeutic, or targeted use. Under the new FDA guidance only veterinarians will be authorized to order medically important antibiotics to be used in feed and as a reminder, farmers must use the antibiotic according to the label directions – off-label use is strictly prohibited for feed uses.

Q. WILL THIS REDUCE ANTIBIOTIC USE IN FARM ANIMALS?

A: We don’t know. Use is driven by many factors, including the number of animals as well as factors like weather and disease outbreaks. Growth uses of medically important antibiotics represent only a small percentage of overall use, so even if all other factors are static it’s unlikely overall use would be greatly affected.

Q. HOW WILL THIS IMPACT PUBLIC HEALTH?

A: If experience in other countries is an indication, we don’t expect measureable impacts. The removal of antibiotics for growth promotion in Denmark resulted in some reductions in resistance rates in animals but no observable impact in humans. That’s because the vast majority of important bacterial infections in humans are unrelated to animals and are resistant to antibiotics that are not used in animals.

Q. WHAT IS THE INDUSTRY’S TIMETABLE FOR STOPPING THE USE OF MEDICALLY IMPORTANT ANTIBIOTICS FOR GROWTH PROMOTION?

A. FDA has outlined a timeline of three years. It is important that all of these pieces, including the revised VFD, be final before label changes can be implemented.
Q. WHAT IMPACT WILL THE NEW GUIDANCE DOCUMENTS HAVE ON PRODUCERS, FARMERS AND LIVESTOCK FEEDERS?

A. These changes, when implemented, may restrict the availability of the number of medically-important compounds labeled for feed efficiency or growth promotion. It is possible all these products will be eliminated if companies who market them voluntarily withdraw these label claims. In addition, all medically important products approved for use in feed under a therapeutic claim (treatment, control or prevention) will require the involvement of a veterinarian.

Q. THE DRAFT RECOMMENDATIONS BY FDA ARE NOT BINDING AS THE AGENCY IS ASKING DRUG MANUFACTURERS TO VOLUNTARILY IMPLEMENT THE PROPOSED CHANGES. WHAT IS YOUR REACTION THAT ENFORCEMENT SHOULD HAVE BEEN MORE BINDING?

A. The collaborative, stakeholder approach being used by FDA is the right approach to ensure the changes can be implemented in a way that avoids unintended consequences. More sudden bans in Europe resulted in increased animal death and disease. We believe the collaborative approach, allowing a phase-in time, can avoid these pitfalls. Guidance documents are used by the agency to force action by sponsors. This guidance document will result in the elimination of subtherapeutic uses of medically-important compounds.

Q. HOW DO YOU ANTICIPATE GREATER VETERINARY OVERSIGHT WILL BE IMPLEMENTED ON THE FARM?

A. Most producers/farmers already consult with a veterinarian on animal health issues, including the use of medicines. All producers who wish to administer the antibiotics subject to the FDA action in feed for the therapeutic purposes of treating, controlling or preventing disease will need to consult with a veterinarian and comply with the requirements of the VFD.

Q. DOES AHI NOW AGREE THAT THE USE OF ANTIBIOTICS IN FOOD ANIMALS CONTRIBUTES TO ANTIBIOTIC RESISTANCE IN BACTERIA THAT CAN INFECT PEOPLE?

A. AHI has always held that antibiotic resistance can result from antibiotic use in animals and humans. However, we also believe there is very little impact to human health from animal use due to the many layers of protection built into the food production and processing systems and the lack of any real connection between animals and most human bacterial resistant diseases. Nor did FDA justify this action on the basis of the safety of these products. There are many published papers on this topic, and for a full explanation of why antibiotics used in animals do not significantly contribute to the burden of antibiotic resistance in humans, please visit www.ahi.org.

Q. WHY DOES AHI NOW SUPPORT THE FDA GUIDANCE AND VFD? AREN’T YOU JUST IN FAVOR OF IT BECAUSE IT IS VOLUNTARY?

A. We are in favor of maintaining the important therapeutic uses of disease treatment, disease control and disease prevention, and believe that phasing-out subtherapeutic uses will increase consumer confidence that antibiotics are being used wisely to protect animal health.
Q. IS IT TRUE, AS ACTIVISTS HAVE ALLEGED, THAT ANIMAL HEALTH COMPANIES ARE WILLING TO GIVE UP GROWTH PROMOTION INDICATIONS BECAUSE THEY CAN TRANSITION TO NEW CONTROL AND PREVENTION INDICATIONS? IS THIS WHY ANIMAL HEALTH COMPANIES ARE BEING SUPPORTIVE?

A. Companies can only transition to those therapeutic claims if they can submit data to FDA demonstrating that a compound at a particular dose will prevent one or more diseases caused by a particular pathogen. Both experience and the progression of science since these growth claims were first introduced strongly indicate that doses lower than treatment doses do prevent disease in animals. However, companies will have to do rigorous testing and submit data to FDA proving this is true in order to get agency approval for new prevention claims.

Q. DO YOU THINK TOTAL ANTIBIOTIC USE WILL DECREASE IN FOOD ANIMALS WITH THIS NEW GUIDANCE?

A. We have no way of knowing how this will affect total use. There are numerous factors that impact the level of antibiotic use necessary, including number of animals, weather, disease threats and management systems. The total volume of use in animals is in no way correlated to the potential public health impact.

Q. WHAT ARE THE CHALLENGES THAT BEEF, DAIRY, HOG, AND POULTRY FARMERS WILL NOW FACE IN MOVING AWAY FROM THE SUBTHERAPEUTIC USE OF MEDICALLY IMPORTANT ANTIBIOTICS?

A. We know from the European experience that antibiotic growth promoters suppress sub-clinical disease. There is a risk of additional animal disease from this action. That risk will be mitigated by the success sponsors have in achieving therapeutic claims, and perhaps by other technologies or management changes available to producers.

Q. WHAT STEPS WILL VETERINARIANS AND ANIMAL HEALTH COMPANIES TAKE TO HELP FARMERS MEET THESE CHALLENGES?

A. In addition to seeking therapeutic claims, animal health companies are always working to develop new tools to help producers deal with disease challenges in their flocks and herds. Veterinarians work with producers to keep their animals healthy and work to prevent the need for using antibiotics. In addition, AVMA has a task force working with the FDA to address the issue of the availability of veterinarians in rural areas.

Q. WILL SOME NEW PRODUCTION TECHNOLOGIES REPLACE ANTIBIOTICS?

A. University and industry researchers are always seeking to identify new technologies to address disease threats in animals and making producers more efficient. It is a long and difficult process. On average, it can take up to 10 years and $100 million to navigate a new animal drug through the FDA approval process. Antibiotics will still maintain a critical role in controlling and treating disease since they have been proven to work.