On April 11 the Food and Drug Administration published three documents providing additional information on implementing its policy on the use of antibiotics in food animals:

1. Final Guidance 209, finalizing its policy to phase-out all growth promotion (subtherapeutic) uses of medically-important antibiotics and phase in veterinary oversight of these products.
2. Proposed Guidance 213, which describes the details of how companies can eliminate the growth claims on the product labels and seek new prevention claims if they so choose.
3. Draft codified language discussing changes the agency proposes to make to the veterinary feed directive (VFD) regulation which is the mechanism the agency is using to extend veterinary oversight to medically important antibiotics used in feed.

Below are answers to several questions that have been asked about this initiative.

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. What does this mean for AHI's member companies and their products? What process will drug companies go through to adjust the labeling of their antibiotics?

A. Companies that market medically important antibiotic products that have a growth promotion claim on the label (meaning increased average daily weight gain or increased feed efficiency) are being asked to remove those claims, or, with those products that have only growth claims, to take those products off the market. At the same time, FDA is establishing a process, similar to the process for any new animal drug, where companies can submit data to seek approval of a disease prevention claim on those compounds.

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 once they have published a final Guidance 213. It is important that all of these pieces, including the revised VFD, be final before label changes can be implemented.

Q. The draft recommendations by FDA are not binding as the agency is asking drug manufacturers to voluntarily put the proposed limits in place. 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.

Q. In lieu of the guidance documents, what happens now with the Federal Court ruling regarding the NRDC?

A. The outcome of the Court decision remains to be seen. Once the case is complete we believe FDA will make a decision about next steps. Notably, this collaborative stakeholder process will address a broader range of products in a shorter time frame than the administrative process required by the court decision.

Q. How do you anticipate greater veterinarian 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 in this topic, and for a full explanation of why antibiotics used in animals 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 is in no way correlated to the potential public health impact.

Q. What are the reasonable metrics for success?

A. This is an effort to align all uses of antibiotics in food animals around therapeutic uses. We are in discussions with FDA on what other metrics may be appropriate.

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 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.

Q. In its statement of April 11, the National Pork Producers said they expect change will harm animal health and put small hog farmers out of business? What evidence is there for this statement or is this just resistance to change?

A. The evidence is the clear data and reporting on the effects of the European ban on antibiotics as growth promoters. Additional animal disease after the ban has led to increased use of antibiotics to treat disease. Also, since the ban the number of pig farms in Denmark has dropped from about 25,000 to about 7,000 despite increased production – meaning small farms have consolidated into large farms. We hope the collaborative process and phased-in approach being pursued by FDA can help minimize these types of consequences.
Q. The U.S. District Court of Southern New York ruled that FDA must complete its NOOH process for tetracyclines and penicillins, why should industry delay for several years removing these antibiotics from food animals?

A. We agree with FDA that the collaborative process they've outlined will lead to changes much more quickly than the administrative process ordered by the judge. The process outlined by FDA will affect more compounds and lead to quicker action than the NOOH process.

Q. What is AHI’s position on the pending litigation in US District Court and Citizen’s Petition?

A. The NOOH process and the Citizen’s Petitions would only be appropriate vehicles if data existed demonstrating these were unsafe uses. They are not. We support the collaborative process undertaken by FDA and believe it will more quickly lead to the alignment of all uses of antibiotics for therapeutic purposes.

Q. FDA’s Mike Taylor commented in USA Today that: “The overuse of medically important antibiotics in food animals should stop”. Do you agree there is significant overuse of AB’s in animals? Why not?

A. No. The term is both subjective and undefined. In fact, producers have an economic incentive to avoid the use of antibiotics. Veterinarians consider the need to use antibiotics a failure because it means other means of protecting the health of animals has failed. And use is closely regulated by the FDA. FDA regulates the directions for use on the label of the product, and producers and veterinarians must follow those directions for use. Off-label or extra-label use of feed antibiotics is illegal.

Q. In 2003, McDonald’s Corporation announced it would only buy chicken from producers who do not use antibiotics for routine disease prevention, and recently four of the nation’s top ten chicken producers (Tyson Foods, Perdue Farms, Foster Farms, and Gold Kist) divulged that they have stopped using antibiotics for growth promotion. Doesn’t this prove that antibiotics for growth and prevention are not needed?

A. Growth promotion and prevention are two different label claims, a key difference being that a prevention claim requires the identification of a disease or bacteria that the antibiotic acts against. So, if those products for prevention are not used, either other means must be used to prevent disease or disease outbreaks will occur. Those disease outbreaks will lead to more antibiotic use for treatment – as has been the case in Europe – or the death loss of animals that will raise the cost of meat production. Research is clear that healthy animals are an important first step in producing the safest meat possible, so the best public health policy is the availability of products that are used judiciously and carefully to protect the health of food animals.