Update on new FDA antimicrobial policy

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The use of antimicrobials in food animals is heavily scrutinized, in part, because of the concern that such usage may facilitate development of antimicrobial resistance to drugs that are important for treating human disease. In response to such concerns, the U.S. Food and Drug Administration (FDA) recently issued guidance related to the use and availability of over-the-counter antimicrobial drugs administered to food animals in feed and water.

The overall goals behind the FDA’s new antimicrobial policies are:

1. Limit the use of “medically important” antimicrobials (i.e., important for treating human disease).
2. Increase veterinary involvement in decisions regarding antimicrobial use in animals.

What are antimicrobial drugs and what is antimicrobial resistance?
Antimicrobial drugs treat infections from a variety of microorganisms (bacteria, viruses, fungi, parasites). An antibiotic is a specific type of antimicrobial that is effective against bacteria. All antibiotics are antimicrobials, but not all antimicrobials are antibiotics.

Antimicrobial resistance occurs when bacteria or other microorganisms become resistant to the effects of a drug. This means that the drug, and similar drugs, will no longer be effective against those microorganisms. Antimicrobial resistance is a complex phenomenon with many causes. Antimicrobial usage, whether in humans or animals, can likely facilitate the development of resistance, but resistance can also occur spontaneously.

What is the FDA doing?
In December 2013, the FDA began taking action to further promote the judicious use of medically important antimicrobial drugs in food animals. The new FDA guidance was proposed to improve upon existing guidelines regarding veterinary feed directive (prescription) drugs. The FDA’s goal is to work with animal agriculture in an effort to protect public health by phasing out the use of medically important antimicrobials in food animals for production purposes (e.g., to enhance growth or improve feed efficiency) and to bring the therapeutic uses of such drugs (to treat, control, or prevent specific diseases) under the oversight of licensed veterinarians.
The FDA is requesting that animal drug companies voluntarily revise product labeled uses for medications administered via feed and/or water by (a) removing the use of antimicrobial drugs for production purposes (e.g., to enhance growth or improve feed efficiency); (b) add, where appropriate, scientifically-supported disease treatment, control or prevention uses; and (c) change the marketing status from over-the-counter to prescription for drugs administered through feed or water which will then require veterinary oversight or consultation.

The FDA is focusing on antimicrobial drugs that are:

- “Medically important” drugs (i.e., important for treating human disease);
- Currently FDA-approved to be used for production purposes, such as to enhance growth or improve feed efficiency;
- Currently available over-the-counter; and
- Used in feed or drinking water of food-producing animals.

The new FDA guidance does NOT affect ionophores such as lasalocid and monensin (e.g. Bovatec®, Rumensin®, Pro-Bac-C). Ionophores are feed additives used primarily in beef and dairy cattle diets to increase feed efficiency by altering rumen fermentation patterns. They are often included in dry or liquid manufactured feeds, or in mineral mixtures. Ionophores function by selecting against or negatively affecting the metabolism of certain rumen microbes that decrease digestion efficiency of feedstuffs. Because ionophores have an effect on bacteria, they are technically classified as an antibiotic. However, they are not used therapeutically and have a different mode of action than therapeutic antibiotics. There is also no use of ionophores as antimicrobials for humans, and thus they are not likely to be considered “medically important” by the FDA.

How will these changes impact food animal producers?
Currently, most antimicrobial drugs approved for use in food-producing animals through their feed or water are available over-the-counter. This is about to change. Once animal drug manufacturers voluntarily revise FDA-approved labels, there will be no more antimicrobials used for production purposes (such as growth enhancement or feed efficiency) and the remaining therapeutic uses will require veterinary oversight. Any other use will be a violation of the Federal Food, Drug, and Cosmetic Act.

Are animal drug manufacturers going to comply with this voluntary guidance?
Yes, all 26 of the affected animal drug manufacturers have already committed to comply with the voluntary guidance by phasing out the use of medically important antimicrobials in food-producing animals for food production purposes and phasing in the oversight of a veterinarian for the remaining therapeutic uses of such drugs. While the FDA specified a three-year timeframe (until December 2016) for drug sponsors to complete the recommended changes to their antimicrobial products, some manufacturers have already begun to implement them.

How can you prepare for these changes?
Either initiate or maintain a working relationship with a veterinarian so that when antimicrobials need to be administered through feed or water you have access to a veterinarian that can prescribe the proper treatment.