FDA’S POLICY ON ANTIBIOTICS USED IN ANIMAL FEED

On April 11 the Food and Drug Administration (FDA) unveiled three documents that further implement the agency’s policy on antibiotic regulation.

1. **Final Guidance 209:** 209 is the policy document that outlines FDA’s position on phasing out growth promotion claims on medically important antibiotic compounds and phasing in veterinary oversight of these compounds.

   What’s covered? “Medically important” compounds are those listed in the Guidance 152, Appendix A list, and include such compounds as penicillins, tetracyclines, macrolides and streptogramins. Compounds like ionophores, which are not used in human medicine, or bacitracin, which is used for minor human uses, are not covered by this new policy. This policy covers only in-feed and water uses of these medically important compounds.

2. **Draft Guidance 213:** This guidance outlines the process whereby a sponsor, or company, can withdraw growth claims from the label of products containing medically-important antibiotics. It also describes how a sponsor can apply for a prevention claim, or therapeutic claim, on those same compounds. Application for a prevention claim in this case generally follows the process of a supplemental new animal drug application, and requires the sponsor to submit data demonstrating the drug is safe and effective at a specified dose against a targeted pathogen or a targeted disease. The document states FDA would like to achieve elimination of these claims within three years of the final guidance being published. Final guidance will likely not be published until 2013.

3. **Draft codified language on veterinary feed directive (VFD):** The VFD is the mechanism FDA will use to apply veterinary oversight to a broad range of products used in animal feed. The VFD was first created in the late 1990s, and is currently applied to only a small number of products. The draft codified language is FDA’s attempt to describe changes to the VFD in order to modernize it and make it a more practical mechanism for a large number of products. In essence, a VFD is a mechanism requiring a producer to get approval from a veterinarian for antibiotics used in animal feed. FDA intends to move all medically-important antibiotics out of over-the-counter (OTC) status to VFD status. FDA is still required to publish a proposal rule on these VFD changes, likely sometime in 2013, followed by the publication of a final rule, likely sometime in 2014.
The policy also covers a smaller set of products called water soluble powders. These are antibiotics mixed in water medication systems for a specified period of time only to control or treat bacterial infections and are considered dosage form products by the FDA subject to different labeling regulations. Since they are not used in feed VFD would not apply. However, under the FDA policy companies marketing those kinds of products containing medically important antibiotics would be expected to submit a supplemental application to change the labels from over-the-counter to prescription by a veterinarian only.

What does it all mean?

1. FDA and the animal health industry are committed to preserving the important therapeutic claims on products now available to producers. All claims for disease treatment, disease control and disease prevention will remain.
2. There are no immediate changes. All changes are being phased in over the next four years or so and require further action by FDA in the form of additional publication of rules and guidance.
3. For all medically important antibiotics used in feed, these products will be moved to VFD status. This cannot be done until sometime after a VFD final rule is published. For all medically important antibiotics used in water veterinary prescription status would apply. There is no need to change current regulations governing prescription labels for this change to be effected.
4. For all medically important antibiotics used in feed, growth promotion claims will be eliminated. FDA intends this to be done within three years of publication of final Guidance 213. Assuming that guidance will be published in 2013, growth claims would be targeted for elimination by 2016.
5. On compounds where growth claims exist without prevention claims, sponsors could seek new prevention claims but this would require new data to be submitted to FDA.

Once this policy is fully implemented, all medically important antibiotics used in animal feed or water will be used only for the therapeutic purposes of disease treatment, disease control or disease prevention under the supervision of a licensed veterinarian.