

DAIRY VETERINARY NEWSLETTER

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FDA's New Guidance #213 - What Impact Will It Have?

A new initiative from the FDA, Guidance #213, may have far reaching implications for food animal and mixed practice veterinarians serving owners of food animals. Below is information from the FDA website that can be viewed at:

<http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/ucm390738.htm>

“On December 11, 2013, the FDA announced the implementation of its plan to help phase out the use of medically important antimicrobials in food animals for food production purposes. As part of this plan, FDA asked the animal pharmaceutical industry to seek withdrawal of animal drug approvals relating to any production uses and transfer the remaining therapeutic uses of these drugs under the oversight of a veterinarian.”

The FDA also asked that 26 “affected sponsors”, pharmaceutical companies manufacturing agricultural animal antimicrobials, notify the agency by March 12, 2014 regarding their intent to “engage with FDA” regarding the new plan. 25 of the 26 sponsors, accounting for 99.6% of the products and 99.95% of the product sales of affected antibacterial compounds according to 2011 FDA data, did so. This is stated by FDA to include allowance of the publication of the sponsors’ names, which FDA has done:

ADM Alliance Nutrition, Inc.
Agri Laboratories, Ltd.
Bayer Healthcare LLC, Animal Health Division
Boehringer Ingelheim Vetmedica, Inc.
Contemporary Products, Inc.
Cross Vetpharm Group Ltd.
Elanco Animal Health, A Division of Eli Lilly & Co.
First Priority, Inc.

G.C. Hanford Manufacturing Co.
Huvepharma AD
Intervet, Inc.
Med-Pharmex, Inc.
Merial Ltd.
Micro Beef Technologies LTD
Novartis Animal Health US, Inc.
Pennfield Oil Co.
Phibro Animal Health Corp.
Quo Vademus, LLC
Ridley USA Inc.
Sparhawk Laboratories, Inc.
Strategic Veterinary Pharmaceuticals, Inc.
Veterinary Services, Inc.
Vetoquinol N.-A., Inc.
Virbac AH, Inc.
Zoetis Inc.

The FDA has also published an updated list of affected products so far. It is a long list, but can be viewed at:

<http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/ucm390429.htm>

The list includes many antibiotics alone, in combination, or combined with other products such as anthelmintics and coccidiostats. A large number of the products contain sulfonamides, tetracyclines, macrolides, or aminoglycosides.

Some parts of Guidance #213 include:

Therapeutic Uses that Help Assure the Health of Animals

“FDA believes that, in light of the risk that antimicrobial resistance poses to public health, the use of medically important antimicrobial drugs for production purposes in food-producing animals does not represent a judicious use of these drugs. Such uses are typically administered through the feed or water on a herd- or flock-wide basis and are currently approved for such uses as increasing rate of weight gain or improving feed efficiency. - -

FDA believes that production use indications such as ‘increased rate of weight gain’ or ‘improved feed efficiency’ are no longer appropriate for the approved conditions of use for medically important antimicrobial drugs. In contrast, FDA considers uses that are associated with the treatment, control, and prevention of specific diseases to be therapeutic uses that are necessary for assuring the health of food-producing animals.”

Medically Important Antimicrobial Drugs

There is some discussion regarding Appendix A and what constitutes a “medically important” drug, i.e. its “human medical importance”. The FDA then states, “At this time, FDA considers all antimicrobial drugs listed in Appendix A - - to be ‘medically important’ in the context of implementing the recommendations - -

FDA recognizes that - - Appendix A is not static and should be periodically reassessed and updated as necessary. However, - - FDA believes the existing Appendix A provides adequate clarity for purposes of moving forward - - Therefore, the current list of medically important antimicrobial drug classes that are the subject of this (new) guidance includes: aminoglycosides, lincosamides, macrolides, penicillins, streptogramins, sulfonamides, and

tetracyclines.”

Judicious Use of Antimicrobials

There is a discussion of the principles of judicious use and the need for veterinary oversight. These examples follow:

“From FDA’s standpoint, the administration of a drug to animals when a veterinarian determines that there is a risk of a specific disease, based on the presence of such risk factors, could be considered judicious prevention use. For example, if a veterinarian determines, based on the client’s production practices and herd health history, that cattle being transported or otherwise stressed are more likely to develop a certain bacterial infection, preventively treating these cattle with an antimicrobial approved for prevention of that bacterial infection would be considered a judicious use. Another example would be the prevention of necrotic enteritis in broiler chickens. In this case, the preventive use of an antimicrobial approved for such use is important to manage this disease in certain flocks in the face of concurrent coccidiosis, a significant parasitic disease in chickens. On the other hand, FDA would not consider the administration of a drug to apparently healthy animals in the absence of any information that such animals were at risk of a specific disease to be judicious. FDA believes that veterinarians are uniquely qualified to determine which specific disease-causing microorganisms are likely to be present in a particular situation and to determine appropriately timed administration to prevent disease based on specific, known risk.

Accordingly, FDA recommends that affected drug sponsors voluntarily revise the conditions of use of their medically important antimicrobial new animal drugs and combination new animal drug products to reflect the need for the professional oversight of a licensed veterinarian. This would mean a change from OTC to VFD [veterinary feed directive] status for medicated feed products and from OTC to Rx status for medicated drinking water products.”

What is a veterinary feed directive? This is the FDA’s description of the VFD: “A ‘veterinary feed directive’ is a written statement issued by a licensed veterinarian in the course of the veterinarian’s professional practice that orders the use of a VFD drug in or on an animal feed. This written statement authorizes the client (the owner of the animal or animals or other caretaker) to obtain and use the VFD drug in or on an animal feed to treat the client’s animals only in accordance with the directions for use approved, conditionally approved, or indexed by the Food and Drug Administration (FDA).”

Timeline for Voluntarily Implementing Changes

FDA says they expect full implementation of the changes by 3 years from the date of publication of the Guidance, which would be by December 2016. As is not uncommon with this kind of change, the FDA includes statements that imply that if progress is not being made, they may institute required changes, but also includes statements that imply that they may extend the voluntary time period. This combination of extended deadlines followed by ultimately making new requirements has been typical of many animal health and food product regulation changes in the past, but it seems clear that implementation will come.

Possible Implications for Food Animal Veterinarians

Obviously the new guidelines represent a big change in how animal drugs are administered in water and feed on livestock and poultry operations. Colleagues of mine have discussed how this may put more economic power and control back into the hands of veterinarians, but will certainly come with more responsibility. There is also the potential for a return to the days of 45 or more years ago, when the ability of veterinarians to charge for important required services such as hog cholera vaccination fueled some resentment by livestock producers toward veterinary medicine. Will there be a practical need in order to provide the most efficient and inexpensive food supply possible to essentially continually medicate feed and water on many farms, with VFD’s and prescriptions

being filled on a routine basis? How would society and the regulatory authorities view this? On the other hand, what if less antibiotic use results in poorer feed efficiency, longer days to market per animal, and some percentage of increased morbidity and mortality in food animals and birds? Can our society and others, with ever increasing demands for food with world population and dietary expectations growing, afford to have less efficiency and greater cost in raising food?

Will antibiotic resistance especially in multi-resistant “super bugs” that do indeed increasingly threaten human lives be decreased or somewhat reversed in association with these changes? Many people on both sides of the argument claim to know, but in reality we really do not know for sure to what extent that may or may not happen if indeed we decrease the total amount and spectrum of antibiotics used in food animals. The widespread usage of antibiotics in humans and animals over the last 60 years or so, and any serious attempt to scale it back, are both unprecedented. Or will an associated need for more expensive treatment of clinical disease outbreaks in food animals actually not only make food more expensive, but result in more pressure on veterinarians by clients to use any and all available antibiotics including vancomycin, commonly identified as the “last line of defense” against nosocomial multi-resistant bacteria such as *Staphylococcus aureus*?

Reading the FDA announcements, it seems clear that whether it is within 3 years or a few more years, the increased regulation of antibiotic use in food and water requiring written direction from a veterinarian is coming. The responsibilities, liabilities, regulatory response to whatever individual veterinarians do regarding herd or flock-wide medication, and the implications for human protection against bacterial infections and the cost of our food remain to be seen.

5600 Old Main Hill
Logan UT 84322-5600

Please let us know your comments and also suggestions for future topics. I can be reached at (435) 760-3731 (Cell), (435) 797-1899 M-Tues, (435) 797-7120 W-F or David.Wilson@usu.edu.



David Wilson, DVM
Extension Veterinarian

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