

# DAIRY VETERINARY NEWSLETTER

November 2015

## Is Medicated Feed for Livestock Going to be Less Common? What about the Regulatory Burden? How Will Dairy/Food Animal Veterinarians be affected?

I would not be surprised if most dairy veterinarians have had similar experience to mine with new federal regulatory requirements that affect the industry. It often seems to take many years, usually longer than first stated, for any change - if there is any at all - to be implemented. There are lengthy comment periods and resistance to the proposed change. It is certain that much federal money, and often state and industry money, is spent on trying to implement change. Whether any substantial modification of behavior, improved food safety, etc. results is often hard to tell. There is usually an increased paperwork burden, including for practicing veterinarians or other members of the industry. Enforcement is variable, depending on many factors. Many of these characteristics are already evident in some pending new regulations regarding antibiotics in livestock feed.

### New FDA guidances, the changing VFD, and dairy/food animal veterinarians

The time for implementation is just over a year away for FDA Guidance 213, FDA Guidance 209, and their effects on Veterinary Feed Directives (VFD). A VFD is described as “like a prescription but not the same as a prescription” written by a veterinarian to show “approval - - for antibiotics used in animal feed.” VFD’s are now “currently applied to only a small number of products”. The new guidances are intended to apply VFD’s to “a large number of products” according to FDA. Several colleagues and I attended the second-to-last of the 12 regional meetings around the U.S. regarding the new changes, put on by Farm Foundation in Twin Falls, Idaho last month. Speakers from the FDA, USDA, the beef cattle industry, and a major livestock feed company provided the latest updates on the coming changes. The meeting was called, “**Stewardship of medically-important antimicrobial drug use in food animals: Understanding the new FDA Guidances and Veterinary Feed Directive.**”

Many specific questions regarding the practical implementation of the new policies, or what the true regulatory response to violations would be, could not be answered. However, a number of key points were covered:

- FDA Guidance 213 was described as, “for implementing 209”. 213 is the process by which a “sponsor”, which apparently means a pharmaceutical 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.”
- It was stated that a prevention (of disease) claim was the same as a therapeutic claim; it just means that it is not a claim of increased growth from feeding the antibiotic, but rather an effect against a disease.

- December 2016 (what date within that month is not stated in any document I can find) is listed as the “target” time by which all antibiotic labels stating that the product results in “increased gain” or “improved efficiency” must be withdrawn; after 12/16 they will “no longer be legal” under 213.
- What is a “medically important” antibiotic? No list was shown at the meeting, but it can be seen at: <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm052519.pdf>  
The list is long, described in confusing terms, and said to be “reassessed periodically”. This probably means that more drugs can be added to it in the future, which does seem logical for “medically important” drugs. The list includes many penicillins, cephalosporins, fluoroquinolones, aminoglycosides, and tetracyclines as well as many other antibiotics. All of the examples of feed antimicrobials that were given during the meeting were penicillins or tetracyclines, the most common antibiotics in medicated livestock feed.
- Examples of not medically important antibiotics, not covered under the new regulations, were given:
  - Ionophores
  - Bacitracin
  - Bambermycins
  - Carbadox
- The statement was made numerous times that in order to clarify the position of a government agency, “just go on our website”. One of my colleagues was doing this as fast as he could attempt to navigate the maze of the government websites, and repeatedly discovered that the website did not address the question. He commented that the website was of no help in trying to understand the details.
- It was stated that “most drugs have not transitioned” to VFD status yet, meaning that their growth claim labels are not changed yet, but that all were expected to by 12/16.
- In answer to the question of what happens with any antibiotic product that has not transitioned by 12/16, will it be completely disallowed in animal feed, the answer was that FDA does not know. The speaker was sure that someone was working on that. They also stated that all companies were expected to comply by 12/16. (Companies were told in December 2013 that this must be completed within 3 years; the allotted time is nearly two-thirds expired.) A clear answer regarding those antibiotics for livestock feed that have not “transitioned” and still have the old labeling will be needed beginning 1/1/17.
- VFD’s must have an expiration date (not the same as the expiration date on the drugs they authorize, which presumably must be a later date than the VFD expiration date). Tells how long the VFD is valid.
- VFD’s must have a duration of use; how long the medicated feed is to be fed once any animal or group of animals begins consuming it.
- VFD’s are “expected” to have no refills. Currently, VFD’s are not allowed to have refills.
- FDA Center for Veterinary Medicine (CVM) has a Blue Bird Label website. Just search for “CVM Blue Bird label”. It was stated that there are approximately 250 product labels for antibiotics to be fed to livestock, poultry, fish and bees; there are certainly a lot of them. There is a typical government disclaimer in this document. It seems that these are meant to be the most current list of approved labels for antibiotics in feed. I noticed that nearly all of them contained the old language about “increased gain” or “improved efficiency”. A small proportion of the labels said, “for treatment of”, or “for control of”, or “for treatment and control of” a disease or disease complex (e.g. “bacterial enteritis caused by *Escherichia coli*” or “bacterial enteritis...and bacterial pneumonia”). This latter format where control of a disease is the indication on the label, with nothing about weight gain, meets the new requirements as far as I can tell.

There was no distinction made regarding whether labels met the new guidelines or were soon to be outmoded, however.

- A specific question was asked by a sheep producer: They feed a salt which carries oxytetracycline for range ewes during lambing. They plan to get a VFD for 5 tons of feed (presumably with the salt included in that feed), good for 30 days. What if there is a miscalculation and they actually need additional feed before the 30 days is up? Can they get an additional batch of the feed on that same VFD before it expires? The response did not come near answering this question. This is another point that will need to be clearly spelled out by 1/1/17.
- In the past, generic equivalents of the “pioneer” non-generic brand name of a drug could not be used in VFD’s. Generic equivalents of drugs in feed are “expected to be allowed” with the new rules.
- The beef cattle producer gave an interesting talk. He tries to stay away from medicated feed and water, certainly not using them routinely. He is “concerned” that all antibiotic treatment of livestock will be by prescription in the future. He said that it seems clear that the new VFD rules will result in increased paperwork and increased costs for food animal producers.
- A feedlot, cow-calf, and meat packing (including cull dairy cows) consulting veterinarian also gave an interesting presentation. He stated that the Veterinary Client Patient Relationship (VCPR) will be even more important, and that a VCPR includes training of personnel on the farm, not just talking with the owner or a herdsman. A valid VCPR means someone should visit the farm and have familiarity with that farm.
- A question was asked regarding whether in the spirit of attempting to reduce routine antibiotics fed continuously in feed, there would be any clarification or enforcement of what a valid VCPR really is. Will there be any requirement to visit a farm at least once per some unit of time, even at least once per year? What will be done regarding VFD’s being written by veterinarians who have never been in the same state as the farm, let alone ever visited it to be familiar with the disease on that farm? FDA had no answer for this or any knowledge of whether anything was going to change regarding what a VCPR is. There was discussion that many producers, including dairy producers wishing to continuously feed milk replacer or nonlactating dairy animal rations containing antibiotics, will demand VFD’s. If the veterinarian prefers to discuss management, husbandry procedures, etc. or charges hourly for completing the forms, the clients will likely turn to any source they can find to complete the VFD paperwork as inexpensively and rapidly as possible. Whether the amount of medicated feed will be reduced as a result of these new regulations is far from certain.
- The beef veterinarian stated that the FDA forms for the new VFD’s are “inconsistent and unavailable” now. He commented that after 1/1/17 that all antibiotics in water will require a prescription. There is no such thing as a “water feed directive” and they are not covered by VFD.
- The same veterinarian commented that small producers who do not work with a veterinarian and producers in remote areas where no veterinarian is close by will go to the feed store to get medicated feed, and beginning in January 2017 they will now essentially be unable to get it. He mentioned the complexity and time-consuming nature of the forms and paperwork again.
- A representative of IFA feeds also had some good insights. He echoed the concern regarding “a beef producer who has fed oxytet crumbles in his feed since 1979” who will not have heard of a VFD until 2017. The first time that year that he wants the medicated feed he will either not be able to get it or will need to try to find a vet to write a VFD. Whether veterinarians embrace this, and those clients will be good to work with and be able to afford reasonable compensation for veterinary service, time will tell.

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- There was some discussion of measuring the outcomes of the new rules, the main goal of which is to slow or reverse the development of antimicrobial resistance among pathogens causing human disease. There is no evident way to relate any trends in antimicrobial resistance in human pathogens directly with use of antimicrobials on farms. As has been done in Europe, the anticipated outcome to be measured will be whether the total tons of antibiotics sold for use in livestock, poultry, fish and bees is decreased in the next few years after the new guidances take effect.

More remains to be seen regarding the implementation of these changes by the end of 2016. We in extension at Utah State University will certainly update our readers when we learn more, and to whatever extent some of the above issues become clarified. I hope that you enjoy a great holiday season and have a good start to 2016.

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](mailto:David.Wilson@usu.edu).



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