

How Producers Can Prepare for FDA Guidance #263

Julia Herman, DVM, MS, DACVPM Beef Cattle Specialist Veterinarian, NCBA, a contractor to the Beef Checkoff

Cattle producers prioritize animal health and welfare daily. Part of responsible cattle care is utilizing the tools we have judiciously and at the appropriate times. The Beef Checkoff-funded Beef Quality Assurance (BQA) program has produced guidelines on the judicious use of antimicrobials that the cattle industry has been following for many years. The threat of antimicrobial resistance is very real, and the agricultural industry is working towards minimizing its risks. Using antibiotics judiciously can help slow the rate of potential antimicrobial resistance development and keep these products working longer. Efforts to combat antimicrobial resistance are present in both human and animal health realms.

As mentioned in December's issue of *National Cattlemen*, the Food and Drug Administration (FDA) Center for Veterinary Medicine (CVM) will implement their Guidance for Industry (GFI) #263 which instructs animal drug companies to voluntarily change labels so that antibiotics, which are medically important for human medicine and currently available over-the-counter (OTC) for animals, will require a prescription from a licensed veterinarian for legal use. These product labels will be transitioned from OTC to "prescription only" over the next few months. In practical terms, this means that livestock producers will need an established veterinarian-client-patient relationship (VCPR) before purchasing prescription antibiotics.

A VCPR is legally defined by state and federal statutes as well as by the American Veterinary Medical Association. An established VCPR allows the veterinarian to diagnose and treat animals, prescribe medications, and issue Certificates of Veterinary Inspection (CVIs) or health certificates. Because the VCPR is required to be renewed annually, a yearly consultation with your veterinarian is recommended where multiple facets of the operation are evaluated, goals for the next year are set, and potential interventions are considered. This meeting and farm visit can provide in-depth understanding of the operation's capabilities and limitations which can help shape future recommendations. For those producers who already have an established VCPR, they will likely not see much change after the guidance is enacted.

FDA Guidance #263 will be fully enacted in June of 2023, and the first preparation step that producers can do is establish a VCPR. BQA has an example VCPR on their website (*bqa.org*) for producers to use. Cattle producers who do not regularly consult with a veterinarian or have an existing VCPR will need to work on establishing one prior to the deadline. The benefits of a VCPR go well beyond prescription writing, as veterinarians can be a valued partner on the cattle operation. Developing annual vaccination, feed sampling, nutrition consults, biosecurity or preconditioning programs are many ways to incorporate a veterinarian's expertise to your operation. Veterinarians are trained to evaluate individual animals within a herd system and provide integrative management plans to prevent diseases or problems from occurring in the future. This would be a good time to sit down with your herd veterinarian and discuss common treatment protocols for your individual herd. Having a protocol acts as

a training tool for anyone caring for the cattle, and it also plans ahead for what medications you may need.

When seeking veterinary care, the availability of a veterinarian may be a challenge for some rural areas. Some ideas to find available large animal veterinarians in your area include:

- Speaking with your community or other ranchers
- Getting involved with local or state cattlemen's associations
- Reaching out to extension agents or universities (including veterinary schools)
- Discussing opportunities with state Veterinary Medical Associations

It is important to note that these products are not being removed from the marketplace. Rather, they are being transitioned from OTC to veterinary oversight to help combat overuse/misuse. While these affected products will not be abruptly removed this summer, the products may start to become hard to find as local feed or farm supply stores choose not to restock. **Do not** go out and stock up on these products. Having an excess amount of product will risk having too much product that expires before it can be used. As discussed in the BQA guidelines, expired product is less effective and risks higher treatment failure. Responsible antimicrobial use involves receiving veterinary input and only purchasing products when needed. Some businesses may decide to not stock these products after June 2023 because they are not legally considered a "pharmacy", which requires the ability to review veterinary authorizations and track veterinary prescriptions. As such, discuss with your veterinarian about how to best access these products.

Each operation is unique, and finding a veterinary practice that supports the needs of your operation is essential. Veterinarians are one branch of your operation's resource team and can help with short-term and long-term goals towards profit and sustainability. Building a comprehensive management plan for your herd with your veterinarian will help you and your operation adapt to unforeseen obstacles, improving animal welfare, antimicrobial stewardship, and cattle care factors in the future.

Originally published in the February 2023 National Cattlemen.