

ANIMAL SCIENCE UPDATE: FDA Antibiotic Rule
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The United States Food and Drug Administration (FDA) recently enacted the Guidance for Industry Rule – 263 (GFI-263) referred to here as the FDA Antibiotic Rule. This rule regulates the relationship between veterinarians and livestock producers, and the usage of drugs that are medically important for humans.

The FDA Antibiotic Rule describes the use of antibiotics and provides veterinarians and livestock producers with guidelines for prescribing their sub-therapeutic use in feed or water and therapeutic usages for maintaining animal health well-being. This Rule requires all veterinarians to prescribe such uses: provided there is a Veterinarian-Client-Patient-Relationship (VCPR) in place.

What is a VCPR? According to the American Veterinary Medical Association (AVMA) a VCPR “is the basis for interaction among veterinarians, their clients, and their patients, and is critical to the health of animals.” This agreement means that veterinarians assume responsibility for clinical judgements related to animal health, it guarantees that the veterinarian has the knowledge to make such judgements, and that they are available for evaluation, examination, visitation, emergency coverage, and continuing care and treatment. The veterinarian provides oversight of treatment, compliance, outcome, and the maintenance of patient records. The client agrees to follow the veterinarian’s instructions.

What does this mean? In the future, veterinarians will not be able to prescribe drugs for use by livestock producers unless there is a valid VCPR in place. A VCPR is more than a phone call asking for veterinary advice, it is more than a tele-health consult on a farm that the veterinarian does not have a prior, professional relationship. The veterinarian will be familiar with the farm, its management, its livestock, and existing animal health conditions. So, a valid VCPR is key, but this change does *not* mean that every time you have a sick animal that a veterinarian must visit your farm, examine, and treat that animal. But it does require the farmer will regularly seek out veterinary advice and service to maintain animal health. When a proper VCPR is in place, a veterinarian can prescribe animal drugs for usage on livestock farms. Over the Counter (OTC) antibiotics will not be available without a VCPR **and** a veterinary prescription. Prescriptions can only be filled by veterinarians or animal health companies and other farm service companies or vendors (your local feedstore may not be approved).

It is also important to understand this overall change goes back to the instituting of the Veterinary Feed Directive (VFD) requirement, which was approved by the FDA in 2017. The VFD is focused on maintenance of human and animal health. The VFD ensures that drugs medically important for humans can no longer be used sub-therapeutically in animal feed or water for purposes of growth, performance, feed efficiency, etc. This class of drugs can only be used therapeutically in animal feed or water, that’s when animal health or sickness requires it. In such cases the VFD rule requires veterinarians to authorize the use of animal drugs in feed or water only when a VCPR is in place and only when and if animal health requires it. The VFD may allow some off-label use of drugs only when other options are not available and animal health requires it.

What does this mean? There is concern about the development of microbial resistance to many antibiotics. Many believe this is the result of overprescribing drugs, for both humans and animals, and concern that “superbugs” will result from sub-therapeutic levels in the feed and possibly infect humans;

these bugs may not be affected by antibiotics (human or animal). The VFD rule was enacted to strengthen and give more oversight to individual licensed veterinarians for the purpose of using antibiotics in the feed to treat actual disease conditions.

Beginning with the enactment of the FDA Antibiotic Rule (GFI-263) all antibiotics that are OTC will transition to prescription only from a licensed veterinarian and only when a VCPR is in place. Some of the drugs that will be restricted are penicillin, tylosin, tetracyclines, and sulfamethazine (calf boluses), and mastitis and dry-treat tubes (this is just a representative list, for more information go to <https://www.fda.gov/animal-veterinary/antimicrobial-resistance/list-approved-new-animal-drug-applications-affected-gfi-263> or search for GFI-263 – FDA prohibited animal drug list).

Can these drugs still be used? Of course, but they must be used as directed/recommended from your herd/flock veterinarian with a valid VCPR (when animals are sick, and health and well-being is at risk). (Veterinary-Client-Patient-Relationship) as described above.

There are drugs that are not prohibited, because they are used as animal drugs only, and not in human medicine. These can still be used to enhance growth and feed efficiency. Some approved drugs are listed below:

- Ionophores (monensin (rumensin), lasalocid (Bovatec, etc.)

Other drugs that are not antimicrobials, for example:

- Anthelmintics/Dewormers: Fenbendazole/Safeguard, Ivermectin, Prohibit/Levamisol
- Coccidiostats: Amprolium (Corid), Decoquinate, Diclazuril

Drugs covered by the FDA Antibiotic Rule (GFI-263) are those that are used in both animal and human medicine. **They can no longer be used without veterinary oversight.** Only a veterinarian can legally authorize animal drugs for prescription, and then only after appropriate knowledge of the animals/farm in question, with exam if needed, and when a proper relationship with the client (VCPR must be in place).

The FDA Antibiotics Rule should be seen as positive for the animal and food production industries and may have important effects on human health. Additionally, it will allow more targeted antibiotic treatment, so animals that need treatment get it and those that don't need antimicrobial therapy are not treated unnecessarily. American farmers are innovative, and levels of management are always improving. This rule will allow producers to improve management and disease prevention and reduce reliance on antibiotics.

For more information please go to the FDA website <https://www.fda.gov/animal-veterinary/antimicrobial-resistance/gfi-263-frequently-asked-questions-farmers-and-ranchers> and search the Frequently Asked Questions; also please go to <https://dairy.osu.edu/newsletter/buckeye-dairy-news/volume-25-issue-1/over-counter-antibiotics-will-require-veterinary>

for an excellent overview. On livestock VCPR details, please read:

https://www.aabp.org/resources/aabp_guidelines/VCPRGuideline_032020.pdf

Please contact your veterinarian for assistance or the New Jersey Department of Agriculture Division of Animal Health (<http://www.nj.gov/agriculture/divisions/ah/>). See also your local Rutgers Cooperative Extension Service office for information (<https://njaes.rutgers.edu/county/>)