

Changes Concerning Over the Counter Medications

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On January 1, 2017, changes were enacted concerning medically important over the counter (OTC) feed additive antibiotics to bring them under the oversight of veterinarians (currently known as VFD). As this change was enacted, future guidance documents were being prepared for medically important OTC injection antibiotics. These documents were part of FDA's 5-year plan to support the judicious use of antimicrobials. The goal is to only use medically important antimicrobials when necessary for treatment, control and prevention of specific diseases.

The Food and Drug Administration (FDA) has now published a report that starting June 11, 2023, medically important OTC injection antibiotics will become prescription items as well. With this announcement, your veterinarian will become

increasingly important in developing prevention protocols, diagnosing and treating disease in your herd. Selecting the proper treatment depends on accurately diagnosing the problem, so work with your veterinarian to develop a health care program designed to fit your specific needs. If you have not established a veterinary client patient relationship (VCPR), I strongly recommend that you consider establishing this relationship as soon as possible.

An appropriate veterinarian client patient relationship will exist when:

- The veterinarian has assumed the responsibilities for making clinical judgements on your farm.
- The veterinarian has examined your animals within the past 12 months or made annual visits to the premises where the animals are kept.
- The veterinarian is readily available or has arranged for emergency follow up evaluation in the event of an adverse reaction to the medication.

Extra-Label Drug Use

Currently, using any FDA-approved medication in a manner other than listed on the label is considered extra-label drug use. This will still be applicable under the new regulations. Always make sure to use any medication prescribed by a veterinarian in the manner in which instructed. Extra-label drug use can only be prescribed by a veterinarian, and these requirements must be met:

- A VCPR must exist between the veterinarian and producer.
 - The veterinarian and producer must make sure the animal is properly identified, assign meat and milk withdrawal times, and abide by these withdrawal times to ensure no illegal residues occur.
- A cattle producer cannot use drugs (including OTC drugs) in an extra-label manner without a veterinarian's prescription. This is OFF-LABEL and ILLEGAL.
- Administering products according to label directions includes dosage, route of administration, reason for administration, adhering to proper withdrawal times, etc.
- Veterinarians are even prohibited from using some antibiotics/medications in an extra-label manner.
- Extra-label use of feed medications is prohibited.
- Use of any estrogenic compound in a food animal is prohibited.



Source: Image courtesy of U.S. Food and Drug Administration

OFF-LABEL use of vaccines is not illegal but such use will reduce the efficacy of the vaccine, as well as release the manufacturer from any product liability. In other words, if a vaccine is stored and administered according to all label directions and supported by proper documentation, then in the case of an adverse event related to the product, the manufacturer might be liable. If you choose to use a vaccine in an off-label manner, then the manufacturers are released from all product liability. So, to maintain maximum product efficacy and product liability it is strongly recommended to use all vaccines according to label directions.

Treatment Decisions

The new regulations do not require you to call your veterinarian just to give an injection of antibiotics. When you are visited by your veterinarian to establish a VCPR, you should be instructed on how and when to treat. It will be up to you and your veterinarian how much antibiotics and refills will be given to you to treat in the future if needed. If you are not certain about the most effective treatment options at the time of administering medications, consult with your veterinarian.

The decision to treat should be based on certain criteria:

- Will the animal return to a healthy, productive state without treatment?
- Will treatment return the animal to a healthy, productive state?
- What treatment best fits the disease and herd management?
- What are the withdrawal times once the animal is treated?
- Should the animal be sold?
- Would euthanasia be a better option?

Storing Drugs on your Operation

Stocking up on medications prior to the regulations starting is a plan with several problem areas. Medications require certain guidelines for storage, and drug performance declines if the expiration date has passed. Improper temperature and exposure to air or light will affect drug efficacy. Additionally, it is considered extra label use if the product is administered past the expiration date. All the information you need to properly store any animal health product should be on the label of the drug container.

1. Always check the expiration date/lot number on the label at purchase.
2. Do your homework when purchasing vaccines. Only purchase the amount needed to work the cattle you have available. Especially when using modified live vaccines. Once mixed, they need to be used and not stored for later use.
3. Some drugs, and all vaccines, need to be refrigerated at 40 to 50 degrees F and must not be frozen. Keep an accurate thermometer in your refrigerator to monitor the temperature.
4. When vaccinating, mark syringes to identify which syringe is for which vaccine. Never mix killed vaccines with modified live. This will render the vaccines useless. Use disposable syringes for medications, and properly dispose of when finished. Use clean needles to draw contents from multi-dose bottles. Change needles for every animal to minimize disease spread and drug contamination. Do not store medication in syringes.
5. Avoid exposing vaccines and other medicines to direct sunlight. This may degrade the product. Use an insulated cooler for storing syringes and drugs while working on cattle to avoid sunlight and maintain the proper temperature.
6. Collect used needles in a rigid plastic container. Dispose of them by returning them to your veterinarian. Destroy disposable syringes so they cannot be reused or misused. **Read labels.** Some drugs and vaccine containers require incineration before disposal. Used needles, scalpels, etc. are considered medical waste and must be handled and disposed of in accordance with laws which govern them. Visit www.safeneedledisposal.org for more information on safe needle disposal.
7. Consult your local veterinarian regarding any questions on proper use of medications.



Source: Image courtesy of U.S. Food and Drug Administration



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Proper handling and administration of medications is critical in the efficacy of that medication. If you have any questions concerning the new regulations or administration of medications, please contact your local veterinarian, Extension agent, or Lew Strickland, Extension veterinarian, at lstrick5@utk.edu or 865-974-3538.



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