



# THE Agri-Vator

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## 2023 Antibiotic Label Changes

What you need to know regarding upcoming changes to antibiotic labels

By Hayley R. Springer, MS, DVM, PhD; Assistant Clinical Professor, PennState Extension

**Why is this change happening?** The upcoming changes to antibiotic labels are part of a coordinated effort to improve antibiotic stewardship practices. These practices are put in place to minimize the development of antibiotic resistance, which can lead to untreatable infections in both humans and animals. By reducing our need for antibiotics through disease prevention and improving how we use antibiotics, we can help assure that we can continue to use these vital medications to treat human and animal disease for generations to come.

One important aspect of antibiotic stewardship is judicious use of antibiotics, which means that for each disease being treated, the best antibiotic at the best dosage is used to improve the likelihood of recovery while minimizing the risk of resistance. In both human and animal medicine, practitioner oversight of antibiotic use is considered critical to judicious use. Food animal veterinary medicine has long had many prescription antibiotic products under veterinary oversight. In January 2017, several over the counter (OTC) products were shifted from OTC to veterinary feed directive (VFD) status to bring these products under veterinary oversight. This change targeted “medically important” antibiotics because these are the products related to antibiotics vital to human health and in-feed antibiotics because this route of administration most directly puts antibiotics in contact with potential food-borne pathogens, which largely reside in the gut. This change did decrease the amount of antibiotics being purchased for use in animal agriculture with many veterinarians reporting no ill effects to animal health and wellbeing.

**What is the change?** To further improve antibiotic stewardship, the remaining OTC “medically important” antibiotics will transition to prescription status in 2023. This means these products will no longer be able to be sold as OTC products. They will only be available with a veterinary prescription and will need to be purchased from a veterinarian or a pharmacy.

**When will this change occur?** Expect the change to occur around June, 2023. The Food and Drug Administration (FDA) has asked manufacturers to stop shipping OTC products and provide only products labeled for prescription use by June 11, 2023. The change on the store shelves may occur earlier or later than this depending on several factors. Some manufacturers have already shipped the last of their OTC products, some of which may run out before June 11, 2023. Other products have plenty in retail and distribution channels. These products may be on the shelves beyond June 11, 2023. The FDA will honor these remaining products as OTC until their expiration date.

**What products are impacted?** The changes are targeted at products that are both OTC and “medically important” antibiotics. The OTC products are those that are available at retail locations, whether locally or on-line, without a veterinary prescription or veterinary feed directive. Medically important antibiotics belong to classes of antibiotics that are shared between human and veterinary medicine. These classes are targeted because resistance to these types of antibiotics pose the most risk to both human and animal health.

More details and a full list of products, including manufacturer information, is available on the FDA website.

**OTC Antibiotic Active Ingredients Impacted by the June 2023 Changes:** **Injectable Products:** Penicillins, Tetracyclines, Sulfa Antibiotics, Erythromycin, Tylosin, Lincomycin, Spectinomycin, Gentamicin **Intramammary Products (Mastitis Tubes):** Erythromycin, Penicillins, Dihydrostreptomycin, Novobiocin, Cephapirin, Cephapirin Benzathine **Oral Liquids and Boluses:** Dihydrostreptomycin, Sulfa Antibiotics, Tetracyclines, Spectinomycin, Gentamicin **Eye Ointments:** Gentamicin, Tetracyclines

**What products are not impacted?** The upcoming changes will not alter access to products that are already under veterinary

oversight, including all VFD and prescription products. There are also a wide range of non-antibiotic and non-medically important antibiotic products that will remain available over the counter.

**How will farms have access to medications?** Access to these medications will be no different than current requirements for prescription products. To obtain a veterinary prescription, you will need to establish a veterinary-client-patient relationship (VCPR) with a veterinarian. If your farm does not already have a VCPR, it is important to reach out to local veterinarians to determine what is needed to establish a VCPR.

Once a VCPR is established, the veterinarian can provide a prescription for products they deem appropriate for the operation. The product itself may be purchased directly from the veterinarian, via a mail order service through the veterinarian, or from a pharmacy, often on-line, that carries livestock medications. Do not expect your local farm store to carry these products, as they are likely not a pharmacy, which typically requires a pharmacy license and a pharmacist on staff.

**What about emergencies?** Proactive planning is an important part of raising livestock. The upcoming changes to antibiotic access do not require a veterinarian to examine each animal personally. By establishing a VCPR and written treatment protocols, some veterinarians may allow specific products to be kept on hand for use as cases of common diseases arise.

**What should be done with impacted products already on the farm?** When the VFD changes came into effect in January 2017, to legally feed any VFD-containing feed already on farm, the operation had to acquire a VFD order from a veterinarian. This type of requirement will not occur with this change. The newly labeled prescription products will carry verbiage similar to “use by or on the order of a veterinarian only” (Rx label). Prior to the change, the product label will not carry this type of a phrase, which allows it to be sold OTC (OTC label). Any product purchased with an OTC label will be honored as OTC until the product’s expiration date. Any product carrying a Rx label will require a veterinary prescription. This is a bit confusing, but the short version is that if the product was purchased as an OTC product, it can be used as an OTC product until it expires, but a veterinary prescription will be needed for future purchases if the product was impacted by the 2023 changes.

**How should farms prepare?** The impact of these changes will vary greatly from farm to farm. For operations that already have an established VCPR and get most of their medications from their veterinarian, the change may be unnoticeable. For operations relying solely on OTC antibiotics, the impact will be much greater. Some important steps to prepare include:

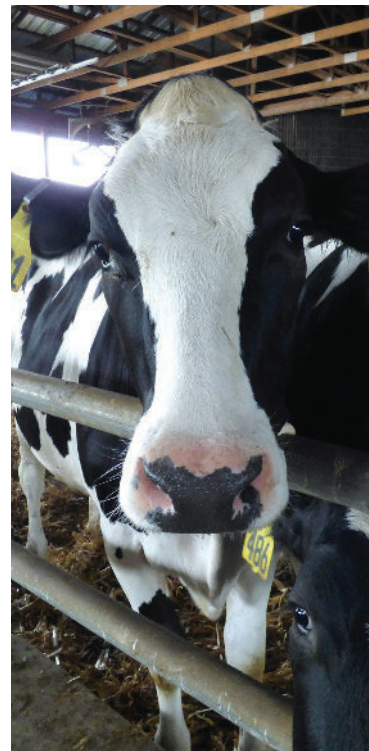
- Assure your operation has a valid VCPR.
- If you do not have a VCPR, establish one by calling local veterinarians to learn what is required to set up and maintain a VCPR and schedule needed appointments.
- If you do have a VCPR, check with your veterinarian to assure your VCPR is up to date and to determine what is needed to maintain your VCPR.
- Acquire necessary veterinary recommendations to assure animal health

Once a VCPR is established, your veterinarian will make the final call on prescription medication use on the operation.

The upcoming antibiotic label changes will hardly be noticed by some and will be a big change for others. Taking proactive steps to assure you will have access to medication by establishing a VCPR and talking about medication use with your veterinarian are a great starting point. Although this transition may be challenging for some, it is an important step towards improving antibiotic stewardship and preserving the medications veterinarians rely on to fight disease.

**How can I learn more?** Check with your local extension office for more information.

**Edited for space.** For the full article please go to: <https://extension.psu.edu/questions-answered-2023-antibiotic-label-changes>



## Nutritionists

**Herbert Bonnice Jr.** Tunkhannock, PA  
570.351.2724  
hbonnice@gmail.com

**Robert Davis** Christiana, PA  
610.470.5226  
davisrobert243@gmail.com

**Homer Eberly** Ephrata, PA  
717.587.2581  
hoeberly@windstream.net

**Wilson Eberly** Ephrata, PA  
717.405.2397  
wilsone@emypeople.net

**Tom Good** Lititz, PA  
717.314.1638  
tcgood5400@gmail.com

**Dan Hillyer** Dover, PA  
717.891.5692  
hillyerdan@comcast.net

**Jim Longenecker** Christiana, PA  
717.278.3121  
jimg.longenecker@gmail.com

**Bob Nichols, DVM** Waynesboro, PA  
717.262.5013  
bndvm300@gmail.com

**Tim Rutledge** Reinholds, PA  
717.371.7667  
cowpatties1@me.com

**Adam Zurin** Manheim, PA  
717.682.5103  
azurin5001@gmail.com

