As of January 1, 2017, producers will need a prescription or a Veterinary Feed Directive (VFD) order to use many of the previously available Over-the-Counter (OTC) antimicrobials. All antimicrobials that are administered in water will require a prescription from a veterinarian. Antimicrobials that are mixed in or on feed will require a Veterinary Feed Directive order from a veterinarian. Hopefully, producers consulted with their veterinarian prior to January 1, 2017, and the transition to these requirements has been smooth.

One of the major differences between prescription drugs and VFD drugs is extralabel use. When congress passed the Animal Medicinal Drug Availability Act (AMDUCA) in 1994, it allowed for veterinarians to use drugs in an extralabel manner provided certain conditions were met. Extralabel use is defined by the Food and Drug Administration (FDA) as: "Actual use or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling. This includes, but is not limited to, use in species not listed in the labeling, use for indications (disease and other conditions) not listed in the labeling, use at dosage levels, frequencies, or routes of administration other than those stated in the labeling, and deviation from labeled withdrawal time based on these different uses." (21 CFR 530.3(a))

Veterinarians and producers took liberties by using many of OTC antimicrobials in feed in an extralabel manner. This practice was never legal. AMUDUCA expressly prohibited the extralabel use of drugs in feed. With many of the OTC antimicrobials becoming VFD drugs, this practice has stopped.

Since many VFD drugs only have label uses for “major” species, veterinarians have had very few options for producers who raise “minor” species. The FDA defines “major” species as “cattle, horses, swine, chickens, turkeys, dogs, and cats.” The FDA defines “minor” species as “all other animals except ‘major’ species.” However, the FDA has provided some guidance for extralabel use of VFD drugs in minor species. The FDA recognizes that very few drugs are approved for use in minor species. Also, some minor species cannot be treated except through medicated feed. In order to prevent suffering and death in minor species, the FDA developed the Compliance Policy Guide (CPG) Section 615.115. In the CPG the FDA has provided guidance on the terms and conditions when a veterinarian may use OTC and/or VFD drugs in feed in an extralabel manner for minor species.

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When a veterinarian recommends the use of a medicated feed in a minor species, certain conditions must be met:

- A proper Veterinary-Client-Patient-Relationship must exist.
- Extralabel use of a medicated feed is for minor species only. The extralabel use of VFD drugs in major species is prohibited.
- The drug used must be a VFD drug or an OTC drug approved to be used in or on feed.
- The major species for which the medicated feed is approved must be similar to the minor species. Example a VFD drug for cattle could be used in sheep and goats but not in birds.
- Medicated feeds may only be used in farmed or confined minor species. Producers may not treat animals in the wild.
- The use of the medicated feed is for therapeutic treatment and not for weight gain, improved feed efficiency, or production purposes.
- A veterinarian, producer, or feed store may not promote a medicated feed for an extralabel use.

The CPG does not give veterinarians permission to use drugs that are expressly prohibited for extralabel use or to use drugs that are not FDA approved.

Any veterinarian that would recommend the extralabel use of a medicated feed in a minor species should make sure that no other treatment option is feasible. He/she must have a close working relationship with the producer. He/she must be confident in the producer’s ability to identify and confine their animals to prevent any marketing of products (milk, eggs, meat, or other edible products) before the withdrawal period was completed.

The producer needs to maintain up-to-date and accurate records. If the FDA request, these records must be made available. A VFD order must be kept for two years. A copy of the recommendations including the diagnosis of the disease, drug choice, dose and duration of drug treatment, and the extended withdrawal for the drug used should be kept. Other records that are important to maintain are feed labels and invoices. Producers also need to keep tract of starting and ending dates of treatment.

Extralabel use of medicated feeds in minor species is great news for producers. However, the responsibility of using these products in a judicious and safe manner by the producers will be essential in order for the FDA to continue to allow the practice in the future. Producers should take these responsibility seriously. If a producer desires to know more about extralabel drug use in minor species, they should read CPG Section 615.115 at [http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-ice/documents/webcontent/ucm074659.pdf](http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-ice/documents/webcontent/ucm074659.pdf) or visit with their veterinarian.