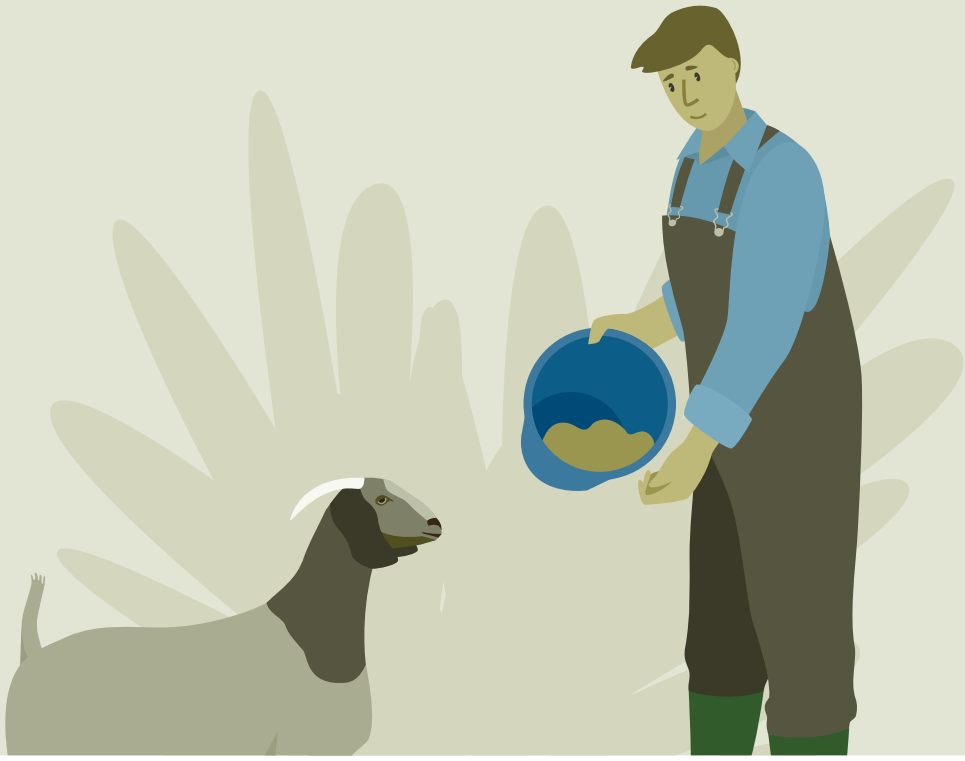
Creating Partnerships

Partnership Pathways

Utilize the Veterinary Feed Directive and Additional Guidelines in Establishing a VCPR

MODULE 4 STUDY GUIDE

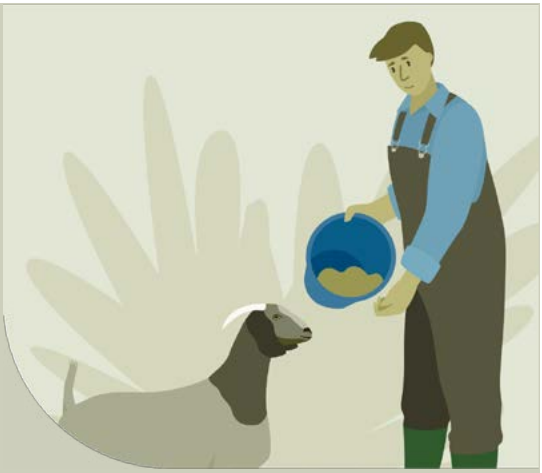


USDA United States Department of Agriculture

TEXAS A&M UNIVERSITY

PRAIRIE VIEW A&M UNIVERSITY

Utilize the Veterinary Feed Directive and Additional Guidelines in Establishing a VCPR



History of Medicated Feed

1940s — 1950s

Antibiotics started being added to feeds
(*Journal of Applied Animal Nutrition, Vol. 4; e3)*

1962

Kefauver Harris Amendment

- Required drug manufacturers to provide proof of effectiveness

1968

Animal Drug Amendments

- Ensure that animal drugs are safe and effective for their intended use
- Do not result in unsafe residues
- Clearance for use of a drug in a medicated feed

1996

Animal Drug Availability Act

- Provide new flexibility to get new animal drugs and medicated feed to market
  (https://www.fda.gov/about-fda/fda-history/milestones-us-food-and-drug-law)

History of Medicated Feed

FDA instituted current Good Manufacturing Practices (cGMPs) for feed in 1965
(JF Scheid in Animal Feed Contamination, 2012)

Second Generation of Medicated Feed Rules

- **Category I** – no withdrawal time
- **Category II**
  - Withdrawal time- the time required after the administration of a drug needed to assure that drug is eliminated from the body.
  - Zero tolerance for residues
- **Type A** medicated article– Regulate as new animal drug
- **Type B or C** medicated feed – Regulate as animal feed containing drug
- **Category II Type A** products must be licensed (Medicated Feed Application)

cGMP Guidelines

FDA licensed feeds

- Minimum requirements
- Not precise instructions
- Flexibility for various types of feeds, equipment, facilities.
- Handling and proofreading labels

Non-FDA licensed feeds

'Labels shall be received, handled, and stored in a manner that prevents label mixups and [ensures] that the correct labels are used for the medicated feed. All deliveries of medicated feeds, whether bagged or in bulk, shall be adequately labeled to [ensure] that the feed can be properly used.'

History of Medicated Feed

1996

Animal Drug Availability Act

- Feed mill licensing
- Veterinary Feed Directive
- Substantial evidence of effectiveness
- Feed use combinations of new animal drugs

2013

FDA Industry Guidance

- Remove all medically important production drugs from feed use in 3 years
- Only use drugs for therapeutic purposes

Veterinary Feed Directive

Animal Drug Availability Act 1996

- Final Rule – December 8, 2000
- Code of Federal Regulation, Title 21, Chapter 1, Subchapter E, Part 558

Veterinary Feed Directive (VFD)

Written (nonverbal) statement issued by a licensed veterinarian in the course of the veterinarian's professional practice that orders the use of a VFD drug (or combination) in or on an animal feed.

Veterinary Feed Directive

VETERINARIAN'S ROLE

§558.6 (b)

- Licensed veterinarian in the course of professional practice and in compliance with all applicable requirements.
- Must be in the context of a veterinarian-client-patient relationship (VCPR) as defined by the State or §530.3(i)
  - Veterinarian assumes responsibility for medical judgements
  - Client agrees to follow the instructions of the veterinarian
  - Sufficient knowledge to initiate at least a general or preliminary diagnosis
  - Veterinarian is readily available for follow-up
  - The veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept.

Veterinary Feed Directive

FEED MILL/PRODUCER ROLE

§558.6(c): The distributor is only permitted to:

- Verify the VFD has all required information
  - Veterinarians will ask for information from producers, and feed mills will verify that the information was obtained.
- Distribute an animal feed containing a VFD drug or combination VFD drug only if it complies with the terms of the VFD and its label
- Must keep VFD feed manufacturing records for 1 year

ALL parties must keep a copy of the VFD for 2 years.

Medicated Feeds

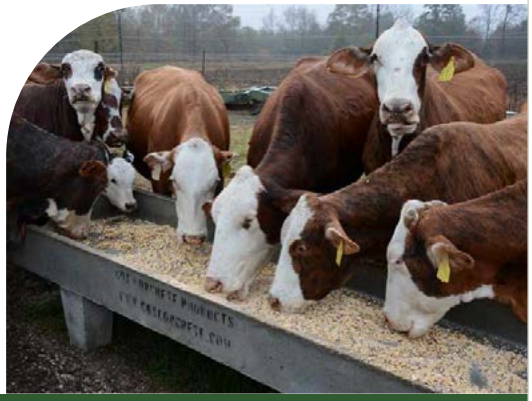
Why are medicated feeds used?

- Prevent diseases
- Treat diseases
- Control diseases
- **Improves growth rate – not allowed for 'medically important'* antibiotics**

VFD and prescriptions for medications in water

- Regulate the use of medically important antibiotics*

** Medically important antibiotics are those that are used in human medicine as well as veterinary medicine.*



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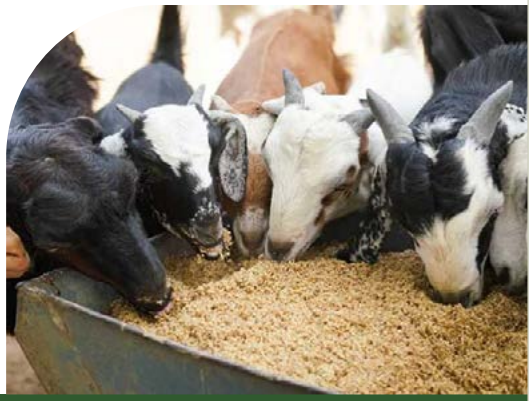
Medicated Feeds

When are medicated feeds used?

- Treatment
  - 10% incidence in one day
  - 25% incidence in 3-5 days
- Prevention
  - Highly infectious disease (i.e. Bovine Respiratory Disease)
  - High incidence of disease (i.e. Bacterial enteritis)
  - Seasonal/climate risk
- Control
  - Low prevalence of disease
  - Pathogen that survives well in the environment (i.e. Anaplasma)



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Medicated Feeds

MEDICATIONS THAT DO NOT REQUIRE A VFD

(not medically important)

- Amprolium
- Bacitracin
- Bambermycin
- Decoquinate
- Fenbendazole
- Laidlomycin
- Lasalocid
- Melengestrol Acetate
- Methoprene
- Monensin
- Morantel
- Poloxalene
- Ractopamine
- Tetraclovinphos

(https://bqa.unl.edu/veterinary-feed-directive)

Medicated Feeds

- Like other pharmaceuticals, withdrawal times still apply to medicated feeds.
- Any medication added to the feed cannot be used in an extra-label manner.
- Requires a VFD if "medically important"
- Requires a prescription if administered through the water

Growth Promotion

- Related to interactions with intestinal microbes
- Improved:
  - Feed efficiency
  - Average daily gain
  - Nutrition
  - Genetics
  - Understanding of the microbiome

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Effects of the VFD – Medically Important Drugs

2021

- 64% of antimicrobials sold were VFD
  - 55% of fed antimicrobials were of the Tetracycline class

2012 – 2021

- Huge increase in prescription and VFD drugs
- Net decrease in overall antibiotic usage by 33%
- 35% decrease in fed tetracyclines
- 72% decrease in fed sulfonamides
- 50% decrease in other fed drugs

(2021 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals)

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Effects of the VFD – Medically Important Drugs

2014 – 2019

- Tissue Residue Study
  - 36% reduction in odds of finding sulfonamide residues
  - 24% reduction in odds of finding tetracycline residues

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Effects of the VFD – Medically Important Drugs

Net 16% decrease in sales

INDICATIONS	% TOTAL
Production Only	3%
Production/Therapeutic	77%
Therapeutic	20%
Total	100%

Production: increased rate of gain or improved feed efficiency
Therapeutic: treatment, control, or prevention of disease

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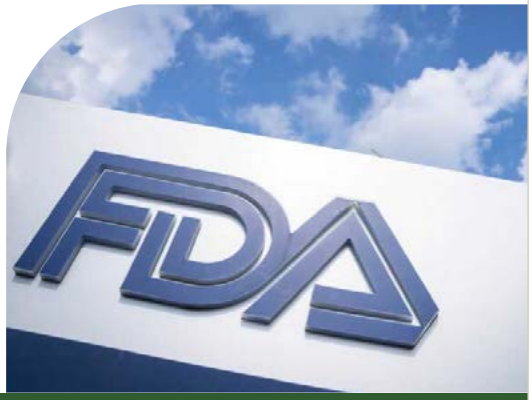
Further Guidelines

FDA Guidance for Industry #263

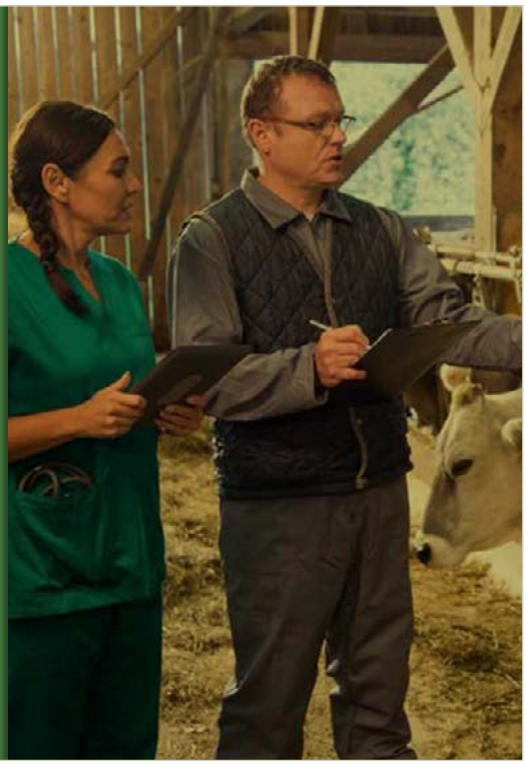
- Facilitate voluntary change for over-the-counter drugs to prescription
- Focus on medically important antimicrobials
- Final implementation June 11, 2023



Creating Partnerships

Takeaways

- The VFD has been successfully accomplished its purpose:
  - Reducing the use of antibiotics
  - Promoting the judicious use of antibiotics
- Guidance #263 seeks to continue to enhance judicious use
- Created an avenue to strengthen the bond between veterinarians and producers



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- FDA Guidance for Industry #263
- 2021 Summary Report On Antimicrobials Sold or Distributed for Use in Food-Producing Animals (fda.gov) https://www.fda.gov/media/163739/download

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AUTHORS
Molly Gonzales, MEd ,EdD
Glennon Mays, DVM
Kevin Washburn, DVM
Brandon Dominguez, DVM
Dee Griffin, DVM, MS
Dan Posey, DVM

CREATIVE TEAM
Bette Bittner, Instructional Designer
Suzanne Kabat, Graphic Design
Vince Chihak, Multimedia Producer
Crystal Schibler, Website Developer
Cory Schibler, Technical Support
Michelle Wiederhold, Project Manager

RESEARCH TEAM
Nicola L. Ritter, MEd, PhD (Principal Investigator)
Milton Daley, PhD
Glennon Mays, DVM
Molly Gonzales, MEd ,EdD
Angelica Frazier
Vanessa Manohar

ADVISORY BOARD MEMBERS
Ms. Kimberly Ratcliff, 100 Ranchers, Inc.
Dr. Dan Posey, West Texas A&M University
Dr. Joe Mask, Texas A&M AgriLife Extension
Ms. Ashley Pellerin, Prairie View A&M University Cooperative Extension Program
Dr. Dee Griffin, West Texas A&M University
Dr. Glennon Mays, Texas A&M University (Ex-officio)
Dr. Milton Daley, Prairie View A&M University (Ex-officio)
Dr. Nicola L. Ritter, Texas A&M University (Ex-officio)