Medicated feeds

Overview of the use of medicated feeds in production animal agriculture

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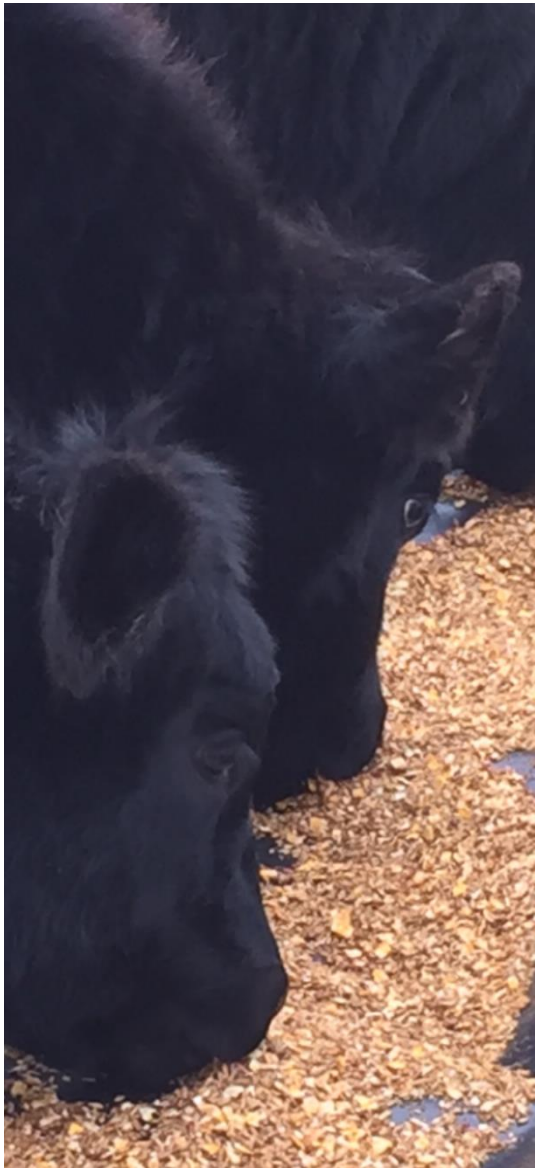


Over the next 30 minutes…

- What are medicated feeds?
- How are they regulated?
- What constitutes their legal use?
- What changes are on the horizon?

What is a medicated feed?

- Any animal feed that contains a “new animal drug”
  - A “new animal drug” is any drug that has been approved for use in animals by the U.S. Food and Drug Administration

- Drugs are substances (other than food) that are intended to affect the structure or function of the body
  - Antimicrobials
    - Antibiotics
    - Antiparasitics
  - Others such as hormone analogues, non-hormone and non-antibiotic growth promotants, etc.

Different uses of drugs to medicated feed

- Therapeutic – high level
  - Treatment of disease or a condition
  - Prevention of disease or a condition
  - Control of disease or a condition

- Sub-therapeutic – low level
  - Growth promotion
  - Feed efficiency

What feeds can be medicated?

- Any nutrient source for animals (with the exception of drinking water) that contains a drug is considered a medicated feed
  - Complete feeds
  - Free-choice supplements
  - Top dresses
  - Milk replacers
  - Premixes

How are medicated feeds regulated?

- Regulated at both the federal and state levels
  - U.S. Food and Drug Administration (FDA)
    - Oversee new animal drug evaluation and approval
    - Regulate use of new animal drugs to medicated animal feed
    - Responsible for feed mill licensing
    - Serve as “advisors” to state regulators
  - State department of agriculture
    - Use federal regulations to establish more state-specific regulations
    - Work collaboratively with FDA and USDA to provide surveillance and compliance

New animal drug evaluation and approval

- FDA uses a team approach to evaluate drugs and determine safety and efficacy for their labeled use
  - Safe to animals and humans who consume animal products
  - Effective at achieving its label claim in the animal
- Teams include animal scientists, veterinarians, chemists, microbiologists, pharmacologists, toxicologists and biostatisticians

Where can medicated feed regulations be found?

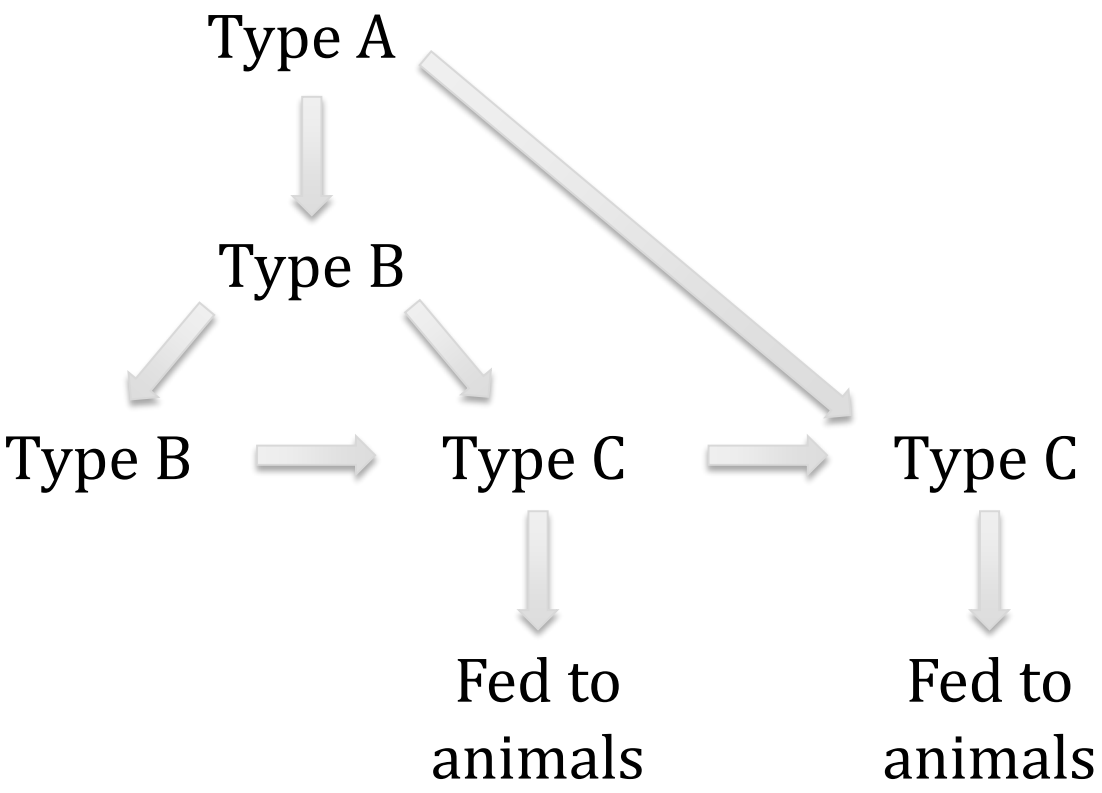
- Code of federal regulations (CFR)
  - eCFR can be accessed online at http://www.ecfr.gov/cgi-bin/text-idx?SID=e81bdc7d926392de2a02e4c9b3882a36&mc=true&tpl=/ecfrbrowse/Title21/21cfr558_main_02.tpl

- Feed additive compendium
  - Summary of regulations and pertinent information for most drugs that can be used to manufacture medicated feed
  - Can be ordered through http://www.feedcompendium.com/
  - Not verified by the FDA for accuracy

Types of medicated feeds

- Type A medicated article
  - Most concentrated form of drug
  - Used to make Type B or Type C medicated feeds
  - Never fed directly to animals
- Type B medicated feed
  - Less concentrated than Type A, more concentrated than Type C
  - Used to make other Type B or Type C medicated feeds
  - Never fed directly to animals
- Type C medicated feed
  - Less concentrated than Type B
  - Used to make other Type C medicated feeds or fed directly to animals

Going from a Type A medicated article to a Type C medicated feed



Feed mill licensing

- Category I drug
  - Type A medicated article can be used by anyone to produce a Type B or C medicated feed
- Category II drug
  - Requires a medicated feed mill license in order for a Type A medicated article to be used to produce a Type B or C medicated feed
  - Does not require a license for a Type B or C medicated feed to be used to produce another Type B or C medicated feed
  - Requires a medicated feed mill license in order to produce any type of liquid medicated feed
- Drug category listings can be found at: http://www.ecfr.gov/cgi-bin/text-idx?SID=49b35282f10bacb63b262e65f572d7c6&mc=true&node=se21.6.558_14&rgn=div8

What constitutes legal use of a medicated feed?

- Medicated feeds must be manufactured and used in accordance with their approval
- Indications for use are required to be outlined on the feed tag
- It is unlawful to mix or feed in a manner that is not approved
- Veterinarians are not permitted to prescribe off-label use of a medicated feed
- Use of one drug in combination with another requires the two drugs to be approved for use in that specific combination

Where to find specific approved uses for medicated feeds?

- http://www.ecfr.gov/cgi-bin/text-idx?SID=e81bdc7d926392de2a02e4c9b3882a36&mc=true&tpl=/ecfrbrowse/Title21/21cfr558_main_02.tpl

Accessibility to medicated feeds

- Most medicated feeds are currently available over-the-counter (OTC)

- Medicated feeds that are not available OTC require a veterinary feed directive (VFD)
  - Aquaflor (florfenicol) for use in swine and fish
  - Pulmotil (tilmicosin) for use in swine and cattle
  - Aivlosin (tylvalosin) for use in swine
  - Kavault (avilamycin) for use in chickens and swine

- There are no prescriptions for medicated feeds

Difference between OTC and VFD

- OTC: Producers can purchase medicated feed directly from a feed mill or distributor without veterinary involvement

- VFD: Medicated feed must be purchased directly from the feed mill or distributor under the direction of the veterinarian
  - Requires…
    - Veterinary oversight under a valid veterinarian-client-patient relationship (VCPR)
    - Submission of a VFD to the feed mill before the feed is manufactured or distributed

Upcoming changes to medicated feeds

- FDA is in the process of amending OTC approvals for feed antimicrobials that are considered medically important
- Any antimicrobial used in both human medicine and to medicate feed will be converted from OTC to VFD status by January 1st, 2017
  - Will not affect antimicrobials that are not used in human medicine
  - Only affects medicated feeds, not injectables
- Removing production claims (i.e. growth promotion and feed efficiency)
  - Affected drugs will only be approved and labelled for treatment, control or prevention of a disease or condition

What is FDA's goal?

- Ensure that antimicrobials in animal feeds…
  - Are used judiciously
  - Aren't used when they don't need to be
- Maintain their efficacy
  - They actually work when they're needed
- Don't contribute to antibiotic resistance in humans
  - Any use of antibiotics contributes to resistance
  - Currently no confirmation of transfer from animal products to humans

What drugs are affected?

Established drug name	Examples of proprietary drug name(s)[$]
chlortetracycline (CTC)	Aureomycin, CLTC, CTC, Chloratet, Chlorachel, ChlorMax, Chlortetracycline, Deracin, Inchlor, Pennchlor, Pfichlor
chlortetracycline/sulfamethazine*	Aureo S, Aureomix S, Pennchlor S
chlortetracycline/sulfamethazine/penicillin*	Aureomix 500, Chlorachel/Pficlor SP, Pennchlor SP, ChlorMax SP
hygromycin B	Hygromix
lincomycin	Lincomix
oxytetracycline (OTC)	TM, OXTC, Oxytetracycline, Pennox, Terramycin
oxytetracycline/neomycin*	Neo-Oxy, Neo-Terramycin
penicillin+	Penicillin, Penicillin G Procaine
sulfadimethoxine/ormetoprim*	Rofenaid, Romet
tylosin	Tylan, Tylosin, Tylovet
tylosin/sulfamethazine*	Tylan Sulfa G, Tylan Plus Sulfa G, Tylosin Plus Sulfamethazine
virginiamycin	Stafac, Virginiamycin, V-Max

http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm482107.htm

Producer responsibilities

- Follow the veterinarian's recommendations and use the VFD medicated feed in accordance with the VFD order
  - Number and location of animals
  - Duration of feeding
  - Withdrawal period
  - Expiration date
  - Maintain VFD records for a minimum of 2 years

Example: Chlortetracycline and stocker cattle

- Producer received a group of "high-risk" stockers from the sale-barn
- A few calves begin to show signs of respiratory disease, and the producer wants to **purchase** a Type C medicated feed with chlortetracycline to control it
  - 1) Producer needs to first consult with their veterinarian
  - 2) Veterinarian writes a VFD for the Type C medicated feed containing chlortetracycline and provides to feed mill or distributor and producer
  - 3) Feed mill or distributor releases Type C medicated feed to the producer
  - 4) Producer feeds Type C medicated feed, adheres to the VFD, and maintains record of that process

Example: Chlortetracycline and stocker cattle

- Producer received a group of "high-risk" stockers from the sale-barn
- A few calves begin to show signs of respiratory disease, and the producer wants to **manufacture** a Type C medicated feed with chlortetracycline to control it
  - 1) Producer needs to first consult with their veterinarian
  - 2) Veterinarian writes a VFD for the Type C medicated feed containing chlortetracycline and provide to the producer
  - 3) Producer manufactures Type C medicated feed
    - Must have submitted a notification of intent to distribute VFD feed to FDA
  - 4) Producer feeds Type C medicated feed, adheres to the VFD, and maintains record of the process

Summary

- Medicated feeds are regulated and can only be fed according to their approval and what is on the label
  - This webinar provides an overview, but is not comprehensive
- Drugs can be used safely and effectively in production animals
  - It is important to adhere to the regulations
- VFD changes will go into effect on January 1st, 2017
  - Encourage producers to begin planning now if they have used medicated feeds in the past that will be affected

Questions?

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