

Business Overview

- Feedlot Health (founded in 1983) is a value based professional services company providing a full suite of production consulting services to commercial feedlots and calf grower operations in:
 - " Canada
 - " United States
 - " Mexico

with ongoing business development projects in:

- South Africa
- " China
- " Russia
- Currently provides professional services to beef feedlots and calf grower operations with an annual throughput of approximately 3 million beef cattle.



Mission

To provide a broad range of world-class consulting and research services, along with management and execution tools, to improve the net profitability of our feedlot and calf grower clients.







Overview

- Our Feedlot Health Team includes
 - . 29 member professional services team with expertise in feedlot and calf grower animal health, epidemiology, pathology, animal welfare, animal production, nutrition, meat science, applied research, statistical analysis, economic modeling, process optimization, and quality assurance
 - 40 member support team that includes animal health technologists, project managers, research assistants, administrative personnel, technical assistants, field assistants and technology support personnel





















Business Principles

Alignment

- Philosophy of creating win/win relationships between Feedlot Health and its clients and Feedlot Health and its business partners
- Focus on data collection, analysis, commercial feed trial research, economic modelling and integrated interaction of Feedlot Health team with clients.

Focus on Sustainability

- Expertise extending beyond animal health to include all aspects of procurement, production, and marketing
- Daily veterinary and production oversight of commercial production





















"The Feedlot Health ACC will be responsible for ensuring ethical animal research and associated activities based on provincial and federal legislation and CCAC guidelines, policies and documents, and will oversee the care and welfare aspects of all proposed animal research at Feedlot Health"

Feedlot Health Animal Care Committee

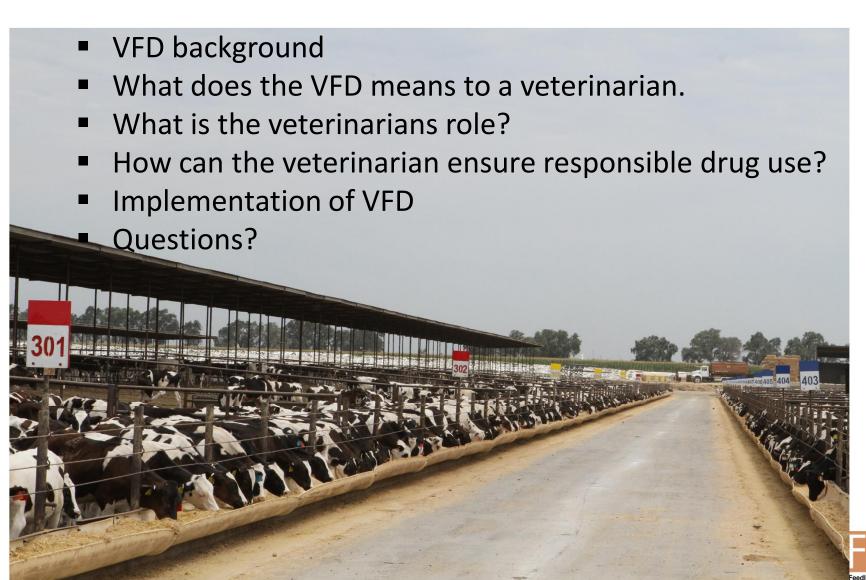
Eric Behlke · Sherry Hannon · Calvin Booker · R Kent Fenton · Tracey Greer Kirsh Berndt · Ashley Gaudet · Kelly Roger · Barb Richardet

Commercial Feedlot and Calf Grower Services

- Feedlot Health provides the following service modules to its customers:
 - . Animal Health Management (AH)
 - Feeds and Feeding Programs (FF)
 - . Performance Enhancement Product Protocols (PEP)
 - . Individual Animal Management (IAM)
 - . Cattle Procurement and Marketing Strategies (PM)
 - . Animal and Facility Certification (AFC)



Why am I here Today??



Background for VFD

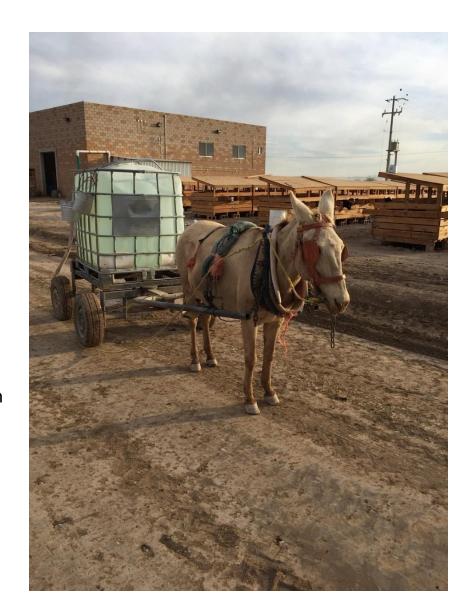
Two FDA guidance's paved the way for framework of VFD:

Guidance #209:

- Limit medically important antimicrobial drugs to therapeutic purposes (i.e., those uses considered necessary for ensuring animal health)
- . Require veterinary oversight or consultation for such therapeutic uses in food producing animals

Guidance #213:

- Set a target for drug sponsors to implement changes to use conditions of medically important antibiotics in food and water to:
 - Withdraw approved production uses such as "increased rate of weight gain" or "improved feed efficiency". Such production uses will no longer be legal
 - Therapeutic uses are to be retained
 - Treatment, control, and prevention indications
- Key principle is to <u>include veterinarian in</u> <u>decision making process</u>



What is a VFD?

- A VFD is a written (nonverbal) statement issued by a licensed veterinarian in the course of the veterinarian's professional practice that authorizes the use of a VFD drug or combination VFD drug in or on an animal feed.
- This written statement authorizes the client (the owner of the animal or animals or other caretaker) to obtain and use animal feed bearing or containing a VFD drug or combination VFD drug to treat the client's animals only in accordance with the conditions for use approved, conditionally approved, or indexed by the FDA. A VFD is also referred to as a VFD order.
 - . A "VFD drug" is a drug intended for use in or on animal feed, which is limited to use under the professional supervision of a licensed veterinarian.
 - . A "combination VFD drug" is an approved combination of new animal drugs intended for use in or on animal feed under the professional supervision of a licensed veterinarian, and at least one of the new animal drugs in the combination is a VFD drug.



What is the Veterinarians Responsibility?

- Must be licensed to practice veterinary medicine.
- Must be operating in the course of the veterinarian's professional practice and in compliance with all applicable veterinary licensing and practice requirements.
- Must write VFD orders in the context of a valid client-patient-relationship (VCPR).
- Must issue a VFD that is in compliance with the conditions for use approved, conditionally approved, or indexed for the VFD drug or combination VFD drug.
- Must prepare and sign a written VFD providing all required information.
- May enter additional discretionary information to more specifically identify the animals to be treated/fed the VFD feed.
- Must include required information when a VFD drug is authorized for use in a drug combination that includes more than one VFD drug.
- Must restrict or allow the use of the VFD drug in combination with one or more OTC drug(s).
- Must provide the feed distributor with a copy of the VFD.
- Must provide the client with a copy of the VFD order.
- Must retain the original VFD for 2 years, and must provide VFD orders for inspection and copying by FDA upon request.



Ensuring Responsible Drug Use

- BIG responsibility but GREAT opportunity to engage with client.
- How can you ensure responsible drug use?

» A VALID VCPR

- A Veterinary Client Patient Relationship (VCPR) is not currently defined in CA but I believe must at least address the following concepts:
 - . Veterinarian has sufficient knowledge (data) of the patient by virtue of patient examination, detailed analysis/monitoring of farm animal health records and/or visits to the facility where patient is managed; and provide for any necessary follow-up evaluation or care.
 - . Veterinarian engages with the client to assume **responsibility for making clinical judgments** about patient health.
 - . Veterinarian **DRIVES THE PROCESS** as **opposed to checking the box approach**
 - . Don't be an additional cost in regulatory compliance
 - Provide meaningful oversight



Ensuring Responsible Drug Use

- What is "Meaningful Oversight?"
- Drive the process
- Have the knowledge
- Use research to identify what is and isn't making a difference on animal health outcomes





Implementation of VFD

- Expected changes:
 - . Minimal:
 - " Education of clients on impending changes
 - "Use of on-site supplementation systems (micromachines) allow combination VFD and feeding of distinct cattle groups easy
- How might relationship with feed and animal health companies evolve?
 - . Team effort from sponsor companies to generate VFD



Expected Challenges

- Managing VFD expirations
- Non-grain feedstuffs: MILK

Milk Replacer:

- . Use of medicated milk replacers convert automatically to VFD?
- Addition of water soluble antimicrobials to milk diets "Rx or VFD?
- . Extra-label water soluble products shown to significantly improve calf welfare... how can we handle these medically important applications?





How will you measure success

- Not cited with a federal offence!!
- Clear animal health protocols and SOPs pertaining to feedstuffs
- Repeatable process that fulfills VFD, Cattle and Clients needs
- EARN the publics trust





Summary

- VFD=written statement to authorize the use of VFD drug or combination VFD in animal feed
- Veterinarian needs to be licensed and maintain a valid VCPR with client
- Provide a written/signed VFD indicating VFD drug use and provide copy to feed mill, client and retain a copy for 2 years



Summary Cont.

- Veterinarians role to ensure responsible drug use
- Big opportunity and responsibility
- Provide <u>meaningful oversight</u>
- Need to understand other medically important products delivered via other feedstuffs such as milk
- Recommend engaging pharmaceutical companies, industry representative and use other available resources:
 - . askcvm@fda.hhs.gov
 - http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm455416.htm



