



Drug Residue Avoidance

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Kansas Department of Agriculture

Serving the State's Largest Industry

- Agency devoted to supporting agriculture
- Protect both animal and human health
- Ensure a safe food-supply
- Regulate compliance of state laws
- Serves as an accurate and reputable source of information





Goals

KDA received an FDA-funded grant to help fund this outreach and education initiative.

- Promote the prevention of illegal drug residues in animal-derived foods through educational outreach and training.
- Improve communication and promote effective management practices for drug residue prevention.
- Increase knowledge of proper drug use in food-producing animals.

- Project Overview
- History of Antibiotics
- Residues
- Withdrawal Time
- Human Health Hazards
- Residue Testing
- US Food Safety & Security
- Veterinary Feed Directive
- Veterinary-Client-Patient Relationship
- Extra-Label Drug Use
- Prevention Practices
- Conclusion





Outreach & Educational Materials:

- Species-specific brochures
- PowerPoint slide sets
- Video training modules



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Drug Residue Avoidance *Beef*



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Drug Residue Avoidance *Dairy*



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Drug Residue Avoidance *Swine*



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Drug Residue Avoidance *Poultry*



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Drug Residue Avoidance *Small Ruminants*



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INTRODUCTION

The dairy industry is committed to producing safe and wholesome products to fulfill the world's expanding appetite for high-quality milk and dairy products.

It is through continuous evaluation of quality management practices and disease prevention protocols that producers keep animals healthy and comfortable.

Dairy producers make the judicious use of antibiotics a top priority. Many precautions are taken so that sick animals requiring treatment do not have contaminated milk or meat enter the food supply chain.

DRUG RESIDUE

Drug residue refers to the presence of veterinary drugs or pesticides in milk.

In the dairy industry, sick or lame cattle are often treated. The risk of violative drug residues can be minimized if treatment protocols are carefully followed and approved drugs are used for the class of animal being treated.

Well-maintained treatment records, proper doses and administration, all contribute to successful management practices, reducing the risk of drug residues in the milk.



ILLEGAL DRUG RESIDUE

An "illegal drug residue" is any drug found above the allowable range in milk or an animal sent to slaughter.

IMPORTANCE OF DRUG RESIDUE

Contaminated milk is a major concern for human health. Any adulterated product may result in **drug residue allergies** and/or the development of **antibiotic resistant bacteria**.

Producers found guilty for illegal drug residue may face the following:

- financial penalties,
- criminal penalties,
- refusal at sale barns and packing facilities, or
- negative public perception.

RESIDUE TESTING & MONITORING

The Grade A Pasteurized Milk Ordinance requires all bulk milk tankers be sampled and analyzed for beta-lactam drug residues before the milk is processed. Additional screening of other drug residues is performed through a random sampling program. Positive test results lead to the mandatory testing of raw milk samples from each farm that supplied raw milk for that truckload.

Residues in fresh meat products are monitored by the Food Safety Inspection Service through the National Residue Program (NRP). The NRP helps prevent the entry of animals containing violative residues of pesticides, drugs or potentially hazardous chemicals into the food chain through monitoring and enforcement. Random samples are tested for monitoring the national residue incidence.

PREVENTION PRACTICES

Veterinary Client Patient Relationship

It is important for a producer to have an ongoing relationship with an accredited veterinarian. This helps to ensure the veterinarian has assumed responsibility for making medical judgments regarding the health of the animal and need for medical treatment.

Keep Good Records

Record keeping is simply a good business practice. Thorough records will inspire consumer confidence and demonstrate control over risk factors that have residue potential. Should your operation get cited for a residue violation and you believe it is a case of mistaken identity, good records are your best evidence that the animal in question does not belong to you.

Avoid Extra-Label Drug Use (ELDU)

ELDU is the use of an animal drug in a manner that is different from label instructions in regard to the disease being treated, route of administration of the drug, dosage of the drug or recommended treatment regimen. It is important to follow all labeled directions and withdrawal dates. All extra label drug usage must be under the supervision of a licensed veterinarian.

Injection Technique

Administer the shot in the neck area. Inject subcutaneously when possible. Inject in a clean area. Take into account route of administration, size of animal, location of injection, volume of injection and thickness of fluid when selecting a needle size. Use disposable syringes and do not use bent needles.

Drug Residue Avoidance in Poultry



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Poultry Industry

The poultry industry is a dynamic and highly specialized industry.

This large commercial industry is heavily influenced by the slightest of changes in economic factors such as feed, availability and cost. Each year billions of chickens are raised in both commercial and backyard settings as a source of food, for both meat and eggs.

Drug Residue Avoidance in Feedlot Cattle



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Feedlot Segment

The beef industry is committed to producing a safe, wholesome and affordable beef product of the highest quality.

It is through the dedication and commitment of all who participate in the food supply chain to ensure animals are healthy and free from disease.

Antibiotics should be used appropriately to prevent residues from occurring in cattle sent to market.

Commercial vs. Backyard

Backyard:

- Less than 100 birds per household
- Increased space per chicken
- Specialized production
- Allows birds to scratch, forage, peck and have outdoor exercise
- Low productivity
- High mortality rates (due to lack of technical know-how and access to key inputs)
- Require large amount of land
- Can be weather dependent

Commercial:

- More than 100 birds per operation
- Meets the demand of both meat and eggs
- Increases production
- Highly efficient system which saves land, feed, labor and other resources
- Continuous production year round
- Creates potential health risks, animal abuse and harmful to the environment
- Faces global competition and is largely dependent on access to cheap inputs and improvements in production and marketing efficiency

Both commercial and backyard operations have to use nationally approved medications (antibiotics) regularly to keep the poultry birds free from diseases.

Animal Drug Residue Concerns

- Consumer health risk
- Consumer preference
- Production loss for the producer (lost milk product, lost animal)
- Legal action against the producer (violation of illegal residues)

Drug Residue vs. Illegal Drug Residue

"Drug residue" refers to the presence of veterinary drugs or pesticides in meat.

"Illegal drug residue" is any drug found above the allowable range in an animal sent to slaughter



Drug Residue vs. Illegal Drug Residue

"Drug residue" refers to the presence of veterinary drugs or pesticides in meat or eggs.

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Reasons for antibiotic use:

- Increased feed efficiency
- Increased growth promotion
- Treat and prevent disease
- Overcome parasite infections
- Alleviate pain from an injured bird



Drug Residue

Residues found in beef above the tolerable levels most often occur due to the following:

- uninformed drug use by small segments of the animal industry
- failure to adhere to proper withdrawal regulations
- extra-label use of drugs
- lack of animal identification or traceability

There are regulations to ensure that no residues beyond the prescribed tolerance levels enter the food supply chain.

What are the consequences of Illegal Drug Residue?

Producers who are found guilty of illegal drug residue may face the following:

- financial penalties
- criminal penalties
- refusal at the sale barn and packing facilities
- negative public perception





Department of Agriculture

Drug Residue Avoidance



Website

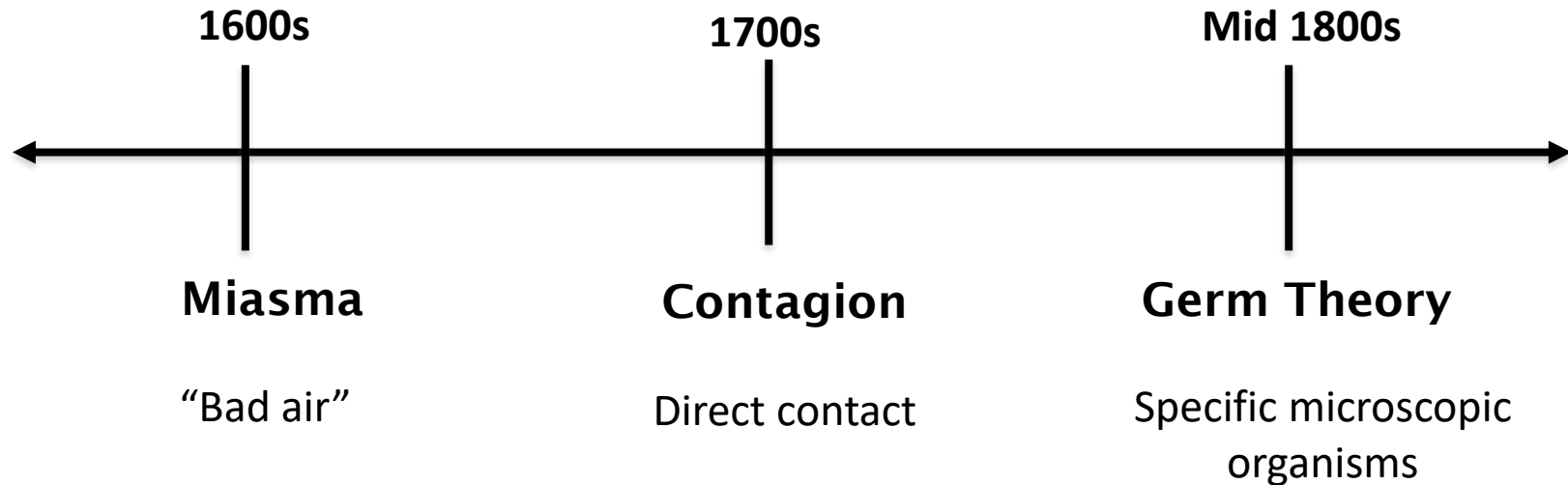
- KDA will create a section on their website devoted to drug residue prevention. This website will be available to the public. Items found on this website include:
 - Beef Cattle, Dairy Cattle, Swine, Poultry and Small Ruminants brochures
 - Cow/calf, Feedlot, Dairy Cattle, Swine and Poultry PowerPoint slide sets
 - Beef Cattle, Dairy Cattle, Swine, Poultry and Small Ruminants online training modules
- Phone numbers and email address of contact individuals
- Other related information and resources



Outcome

- The **success** of this prevention program will be determined by:
 - the number of Kansas citizens who watch the video modules,
 - attend presentations, or
 - contact the organizations involved with questions or concerns.

History of Antibiotics



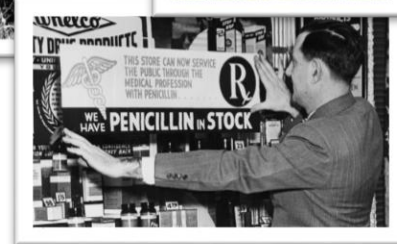
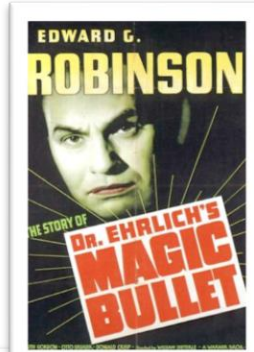
Godfrey's Cordial (Mother's Friend) & Dalby's Carminative



- Most widely used patent medicines given to infants and children in England and the United States during the late 18th and early part of the 19th century.
- Used for colic and diarrhea
- Godfrey's Cordial: Contains one grain of opium in each two ounces
- Dalby's Carminative: three grains of opium in the same amount
- Naturally, infants died due to opium poisoning during this time

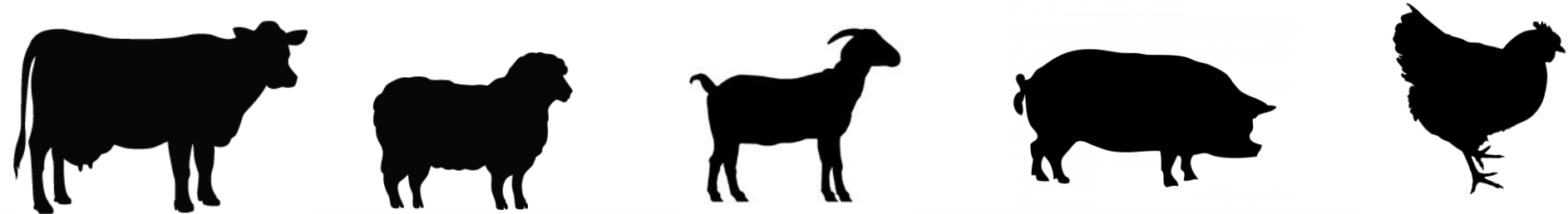
Discoveries

- Dr. Paul Ehrlich: “magic bullet”
 - Compound 606 aka Salvarsan
 - Treated Syphilis
- Alexander Fleming: “wonder drug”
 - Penicillin
 - Treated WWII bacterial infections
 - Antibiotics have reduced the rate of infections in the U.S. by nearly 80%, from 280 to 60 deaths per 100,000.



Antibiotic Use in Animals

- Penicillin – Bovine Mastitis
- Streptomycin – Improve the growth of chicks
- Chlorotetracycline – Improve weight gains and reduce amount of feed needed to bring broilers to market weight



- Demand
- Technology
- Management
- Production



The goal of an efficient livestock operation is to raise animals or produce a product that will in turn result in a profit.

Residue

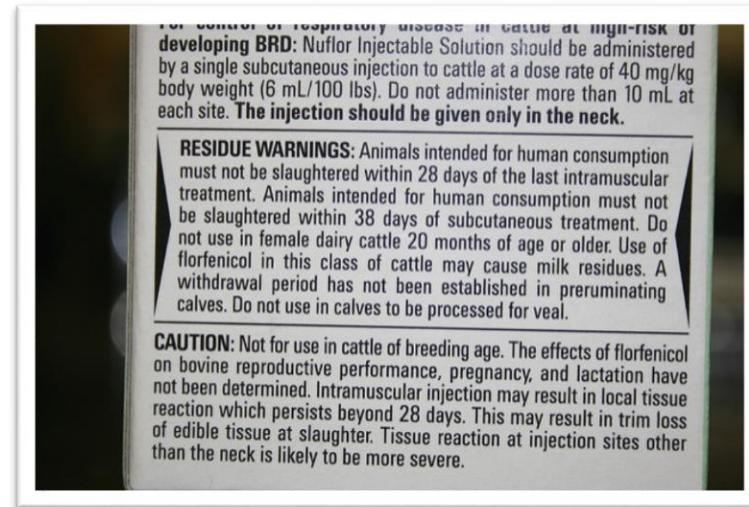
A residue is any compound or metabolite of a compound that is present in edible tissues from food animals because of the use of a compound in or on animals.

- Any animal that receives antibiotic therapy cannot be sent to slaughter until the drug has reached an acceptable level and deemed safe for human consumption. Drug concentrations above this level are illegal causing the food to be adulterated and known as a **violative residue**.



Withdrawal Time

- It is the period of time between when a drug is administered and when drug concentrations are below the tolerance level.





Human Health Hazards

Animal health affects food-safety and food-safety affects public health.

- Toxicity (clenbuterol)
- Allergic or hypersensitivity reactions (beta-lactams)
- Carcinogenic effect (nitrofurans, nitroimidazoles)
- Mutagenic effect (neomycin and gentamicin)
- Teratogenic effect (thalidomide)
- Disruption of normal flora
- Potential for the development and transfer of antibiotic resistant bacteria
- Consumer preference (antibiotic free)

Teratogenic Effects

- Thalidomide incident in Europe
- Presumably a safe sleep-aid used by many following World War II
- Off-label use to alleviate morning sickness
- 3 years - competitive with those of aspirin
- Phocomelia - an interference in the development process causing shortened, absent, or flipper-like limbs
- More than 10,000 birth defects worldwide
- Drug approval and monitoring systems in place today by the FDA





Residue Testing

- USDA FSIS protects public health by ensuring the supply of meat, poultry, and processed egg products are safe, wholesome, and do not contain violative residues
- National Residue Program – monitor, detect, reduce and control violative residues in both domestic and imported food products



National Residue Program

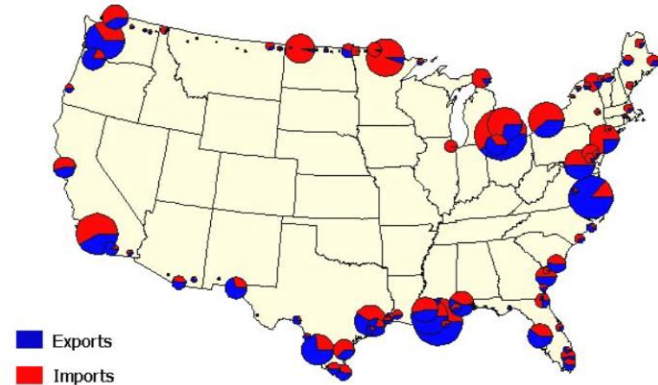
- Tier 1 - collects a set number of samples (carcasses selected at random)
- Tier 2 - samples are taken at the production-level, these are inspector-generated samples of suspect animals
- Tier 3 - targeted sampling at the herd or flock level



National Residue Program

- Products imported from other countries are sampled through the port-of-entry **Import Reinspection Sampling Plan**, where residue monitoring is conducted. This inspection system is in place to confirm that the exporting country is equivalent to U.S. standards.

Top Gateways for International Freight
Exports and imports in tons



Federal Highway Administration
Office of Freight Management and Operations



US Food Safety and Security

- Codex Alimentarius or Food Code is a collection of standards ensure that food is safe and can be traded between countries.
- The objective of the Codex Alimentarius Commission (Codex) is to develop international food safety standards that guarantee consumer health while not impeding trade.

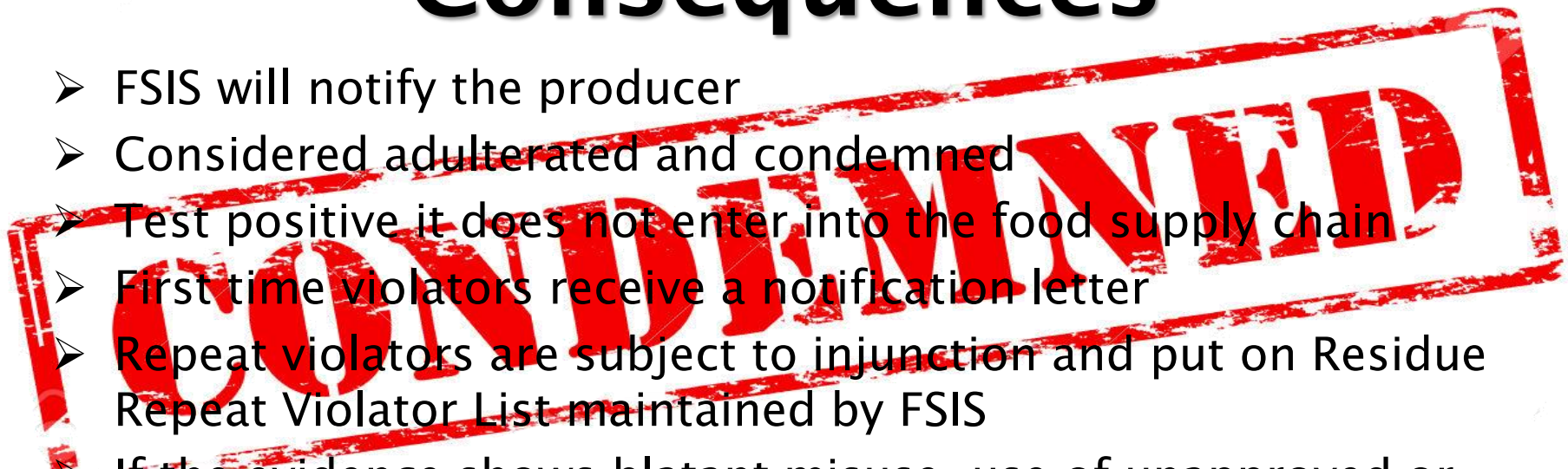
- In-plant inspectors collect and analyze samples at the time of slaughter.
- Samples are selected randomly or based on past violations, questionable practices or any findings/suspicious during ante- or post-mortem inspections.





- Multi-class testing method
 - Improved and more sensitive (since 2012)
 - Allows multiple samples to be simultaneously analyzed for different drugs
 - Detection limit 5-500 parts per billion for veterinary drugs and 5-50 ppb for pesticides

Consequences

- 
- FSIS will notify the producer
 - Considered adulterated and condemned
 - Test positive it does not enter into the food supply chain
 - First time violators receive a notification letter
 - Repeat violators are subject to injunction and put on Residue Repeat Violator List maintained by FSIS
 - If the evidence shows blatant misuse, use of unapproved or banned drugs, issuing false guarantees or multiple misdemeanor counts the result will be prosecution.

Milk Residue Screening Detection Tests

DRUG	AMOXICILLIN	AMPICILLIN	CEFTIOFUR	CEPHAPIRIN	CLOXACILLIN	PENICILLIN
TOLERANCE	10 ppb	10 ppb	100 ppb ²	20 ppb	10 ppb	5 ppb
SCREENING TEST						
CHARM SL BETA LACTAM TEST	5.6	8.5	77	13.7	50 ⁷	3.6
CHARM 3 SL3 BETA LACTAM TEST	8.4	8.0	79	20.0	8.6	3.8
DELVOTEST P 5 PACK (VISUAL)	4.6	4.0	ND ³	8.2	NA ¹⁴	2.1
NEW SNAP BETA LACTAM TEST KIT	7.3	5.8	12	11.7	50 ⁷	3.0



Blue Book

Residue Sampling Plan

2014:

- 33 million cattle
- 112 million swine
- 9 billion poultry
- 110 billion pounds of meat

2016:

- 29 million cattle
- 112 million swine
- 9 billion poultry
- 99 billion pounds of meat

2017:

- 30 million cattle
- 117 million swine
- 9 billion poultry
- 98 billion pounds of meat

2015: does not report these numbers



Red Book

Residue Sampling Plan

- 2013 Results: 4,583 residue samples, 19 violations (0.4 percent)
- 2014 Results: 6,066 residue samples, 12 violations (0.2 percent)
- 2015 Results: 6,445 samples, 12 violations (0.2 percent)
- 2016 Results: 7,067 residue samples, 26 violations (0.4 percent)
- 2017 Results: Not published yet

Veterinary Feed Directive

- January 1, 2017
- The purpose of the VFD is enhance responsible antibiotic use via increased veterinary oversight.

Veterinary Feed Directive
Please download/save and use Adobe Acrobat to complete form.

Veterinarian: _____ **Client:** _____
Clinic/Company: _____ **Business/Practice:** _____
Address: _____ **Address:** _____
City: _____ **State:** _____ **ZIP:** _____ **City:** _____ **State:** _____ **ZIP:** _____
Phone: _____ **Fax:** _____ **Phone:** _____ **Cell:** _____
E-mail: _____ **E-mail:** _____

Drug(s) Name: _____ **Drug(s) Level:** _____ **Duration of use:** _____
Species and Production Class: _____ **Number of animals (or lot) authorized:** _____
Indications for use (as approved): _____
Caution (related to this medicated feed, if any): _____

USE OF FEED CONTAINING THIS VETERINARY FEED DIRECTIVE (VFD) DRUG IN A MANNER OTHER THAN AS DIRECTED ON THE LABELING (EXTRALABEL USE) IS NOT PERMITTED.

Approximate Number of Animals: _____ **Other Identification (Age, Weight, Etc.) Optional:** _____
Premises Description: _____
Special Instructions (if any): _____

Affirmation of Intent (for combination VFD Drugs) (check one box)
For VFD drugs for which there are no approved VFD combinations, only the first affirmation statement should be included on the VFD.

☐ This VFD only authorizes the use of the VFD drug(s) cited in this order and is not intended to authorize the use of such drug combination with any other animal drug.

☐ This VFD authorizes the use of the VFD drug(s) cited in this order in the following FDA-approved, conditionally approved or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component:

Drug(s)	Drug Level(s) and any Special Instructions

☐ This VFD authorizes the use of the VFD drug(s) cited in this order in any FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component.

Withdrawal Time (if any): This VFD Feed must be withdrawn _____ days prior to slaughter.

VFD Date of Issuance: _____ (Month/Day/Year) **VFD Expiration Date:** _____ (Month/Day/Year)
(As specified in the approval, cannot exceed 6 months after issuance)

Veterinarian's Signature: _____

All parties must retain a copy of this VFD for 2 years after the date of issuance.

Reset Form



Veterinary-Client-Patient Relationship

- Responsible for making medical judgments
- Accepts responsibility for providing the herd's livestock with medical care
- Keeps a written medical record
- Advises the livestock producer about the benefits and risks of different treatment options
- Provides oversight of treatment
- Helps to assure that emergency care can be provided if the need should arise

Extra-Label Drug Use

- The 1994 Animal Medicinal Drug Use Clarification Act (AMDUCA) enacted by Congress provided veterinarians acting within a VCPR the ability to legally prescribe medication in an extra-label manner when the health of an animal is threatened or suffering and/or death may result from failure to treat
- Extra-label drug use or ELDU is the use of an approved drug in a manner that is not in accordance with the approved label directions.





FARAD

Food Animal Residue Avoidance Databank

- Establish extended withdrawal times supported by scientific evidence
- WDI Lookup - searchable database
- Withdrawal Date Calculator (WDC) – calculate future withdrawal dates
- VetGRAM – database containing all regulatory information for all approved drugs in food animals



No Observable Adverse Effect Level



Acceptable Daily Intake



Safe Concentration



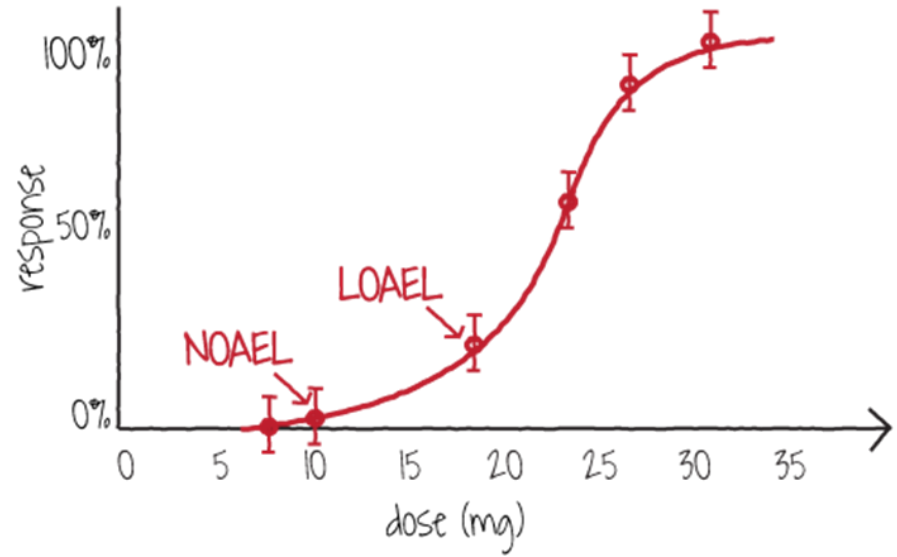
Tolerance



Withdrawal Time

No Observable Adverse Effect Level (NOAEL)

- Dose of a drug that results in no toxic effects
- A safety factor is applied, which may decrease the NOEL by up to a thousand-fold





Acceptable Daily Intake (ADI)

- ADI represents the total dose of a drug that can safely be consumed per day over a human's lifetime without adverse effects.

$$\text{NOAEL} \times \text{Average Human BW} = \text{ADI}$$

$$\text{Safe Concentration} = \frac{\text{ADI} \times \text{Average Human BW}}{\text{Food Consumption}}$$

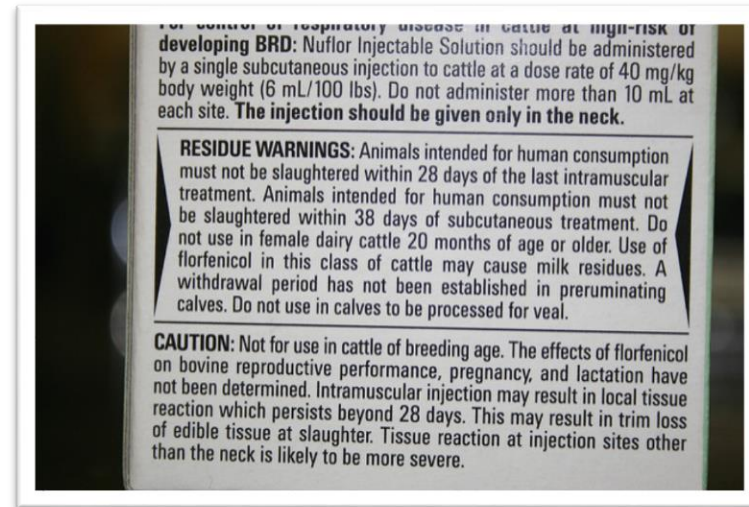


Tolerance Level

- ✓ Established during the drug approval process and listed in the U.S. Code of Federal Regulations
- ✓ The maximum permissible residue level which may be present in tissues or food animal products

Withdrawal Time

- It is the period of time between when a drug is administered and when drug concentrations are **below the tolerance level**.





Prevention Practices

- Establish a valid veterinary-client-patient relationship
- Implement a herd health management plan
- Read and follow all label directions (including withdrawal times and proper drug administration)
- Seek veterinary guidance to establish appropriate extended withdrawal times for extra-label usage of approved drugs
- Identify treated animals
- Keep records that include the identification of the animal (s) treated, treatment date, the product used, dosage and who administered it and withdrawal time
- Train and educate animal caretakers, employees, etc. by providing clear instructions and follow-up
- Practice proper animal handling
- Maintain a clean environment
- Provide proper nutrition
- Implement a biosecurity plan



Core Area Competencies

- **Biostatistics**
 - Data interpretation and analysis
- **Environmental Health**
 - Risk assessment (risks and hazards)
- **Epidemiology**
 - Useful terminology and understanding topics related to disease, food-safety and animal/human health
- **Administration of Health Care Organizations**
 - Importance of health care system, various players involved
- **Social and Behavior Science**
 - Factors that contribute to population health outcomes and how to effectively communicate about the issue to a wide audience



Conclusion

- Our nation has the safest food supply chain in the world.
- Food animal production practices utilize certain compounds that if used incorrectly may pose a public health hazard.
- Residues often result from human management shortfalls.
- One method to address management shortfalls is **effective education**. Drug residue avoidance strategies should be clearly understood by all livestock producers. Residue prevention practices are simple and contribute not only to drug residue avoidance but also to maintaining a healthy and profitable herd.



Dairy

Hildebrand Dairy – Melissa Reed
Kansas Department of Agriculture – George Blush
Kansas Veterinary Diagnostic Laboratory – Dr. Gregg Hanzlieck
Dairy Farmers of America – Peyson Shields, David Darr and Dr. Fabian Bernal
Jim Lauderdale
Food Armor – Dr. Katie MrDutt

Beef

Cattle Empire - Dr. Dave Sjeklocha
Beef Producer - Paige Pratt
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American Angus Association – Ryan Ruppert

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Sabetha Vet Clinic - Dr. Jeff DeMint
Kansas Pork Association - Jodi Oleen

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Nutritionist - Jeff May
Good Shepherd Poultry Ranch, Producer - Frank Reese

Small Ruminants

Goddard Goat Farm, Producer - Noah Goddard
Terabithia Goat Farm, Producer - Becky Thorpe
Veterinarian - Joan Bowen
Veterinarian - Joan Dean Rowe
Extension/Field Veterinarian - Patty Scharko
Kansas State University Sheep & Meat Goat Center
Ebert Sheep Farm – Jeff Ebert

Exhibition

Producer - Dale Lanham
Producer - Brian Creager
Kansas State Fair - Susan Sankey
Kansas Livestock Association – Matt Teagarden
Nebraska State Fair – Bill Angell

Food and Animal Residue Avoidance Databank (FARAD)

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Thank You!!

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Questions?

