


THE 411 ON FOOD ANIMAL PHARMACEUTICALS

KELLY STILL BROOKS DVM, MPH, DACVPM, DABVP-FOOD ANIMAL

ASSISTANT PROFESSOR, DAIRY AND LIVESTOCK PRODUCTION MEDICINE
KMSTILL@COLOSTATE.EDU

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 JAMES L. VOSS
VETERINARY TEACHING HOSPITAL
COLORADO STATE UNIVERSITY

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I HAVE NO CONFLICTS OF INTEREST OR OTHER APPLICABLE DISCLOSURES FOR THIS PRESENTATION

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OBJECTIVES - PHARMACIST

<p>01</p> <p>Explain in lay terms what a "VCPR" consists of and why it is needed for food animal prescribing.</p>	<p>02</p> <p>Identify key differences in use and legality of over-the-counter, prescription individual dose medications, medicated feeds, and medicated water pharmaceuticals for food animals.</p>	<p>03</p> <p>Describe when compounding is legally permissible for food animal prescribing.</p>
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OBJECTIVES – PHARMACY TECHNICIAN




- IDENTIFY COMMON SPECIES AS FOOD ANIMAL OR NOT AND LIST THE FOUR MAJOR FOOD ANIMAL SPECIES.
- IDENTIFY WHERE MILK AND SLAUGHTER (MEAT) DRUG WITHHOLDING INFORMATION CAN BE FOUND ON A PRESCRIPTION LABEL.
- RECOGNIZE WHEN INTENDED USE OF A MEDICATION IS INCONSISTENT WITH THE PHARMACEUTICAL LABEL FOR FOOD ANIMAL PRESCRIBING.


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COLLECTIVELY:

- ID FOOD ANIMAL SPECIES
- EXPLAIN LEGAL CONSTRAINTS
 - Pharmaceutical Type
 - Pharmaceutical Use
- LOCATE "LABEL USE" INFORMATION
- PREVENT VIOLATIVE DRUG RESIDUES



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LEGAL? RATIONAL? PRACTICAL?

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LEGAL? RATIONAL? PRACTICAL?

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WHAT IS A FOOD ANIMAL?



9CFR301 - "Livestock" Mandatory Inspection

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FOUR MAJOR FOOD ANIMAL SPECIES

21CFR516.3(b)
Major Species:
Cattle, Horses, Swine, Chickens, Turkeys, Dogs, Cats

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	<p>MINOR SPECIES (21CFR516.3(B)) AND FOOD ANIMAL "EXOTICS" (9CFR352)</p> <hr/> <p>Elk, Deer, Antelope, Water Buffalo, Bison, Yak</p>	

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What about pets?

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POLICY STATEMENT:

SMALL RUMINANTS AS FOOD ANIMALS

*"Small ruminant practitioners should consider **sheep, goats and farmed or hunted cervids** to be food animals when making drug treatment decisions, and the *intended use of the animal as a non-food or companion animal* has no bearing on this designation.*

Camelids are *sometimes harvested for human consumption*, and veterinarians treating camelids should carefully consider the *likelihood of animals entering the food supply* to ensure that residues do not occur."

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PHARMACEUTICAL CLASSIFICATIONS



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- ***OVER-THE-COUNTER**
- **PRESCRIPTION**
 - Oral
 - Parenteral
 - Topical
 - Implants & Intra-Vaginal Hormones
 - *Compounded Drugs
 - *Medicated Water
- ***VETERINARY FEED-DIRECTIVE (VFD) DRUGS**
- ***EPA-REGULATED INSECTICIDES & FLY TAGS**

Examples?



* = extra-label use prohibited

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GFI #263 –
JUNE 11, 2023

[GFI #263: Frequently Asked Questions for Farmers and Ranchers | FDA](https://www.fda.gov/animal-veterinary/judicious-use-antimicrobials/gfi-263-frequently-asked-questions-farmers-and-ranchers)
<https://www.fda.gov/animal-veterinary/judicious-use-antimicrobials/gfi-263-frequently-asked-questions-farmers-and-ranchers>

FDA Finalizes Guidance to Bring Remaining Approved Over-The-Counter Medically Important Antimicrobial Drugs Used for Animals Under Veterinary Oversight

[List of Approved New Animal Drug Applications Affected by GFI #263 | FDA](#)
Penicillin, Oxytetracycline, Sulfas, Cephapirin, Spectinomycin, Gentamicin, Tylosin, Lincomycin

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ANIMAL DRUG COMPOUNDING

- **FDA GFI #256 (2022) COMPOUNDING ANIMAL DRUGS FROM BULK SUBSTANCES**
- **LIST OF BULK DRUG SUBSTANCES FOR COMPOUNDING DRUGS FOR USE IN FOOD-PRODUCING ANIMALS OR FREE-RANGE WILDLIFE SPECIES**
- **REQUIRES VCPR**

- **FOOD PRODUCING ANIMALS (ANTIDOTES)**
 - Copper Glycinate (200 mg/m)
- **FREE-RANGE WILDLIFE (SEDATIVES AND ANESTHETICS)**
 - Azaperone tartrate (40 mg/ml)
 - Diprenorphine (2 mg/ml)
 - Etorphine hydrochloride (10 mg/ml)
 - Ketamine hydrochloride (200 mg/ml)
 - Medetomidine hydrochloride (10, 20, 40 mg/ml)

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VETERINARY FEED DIRECTIVES REQUIREMENTS

- GFI #213 - AS OF JAN 1, 2017, ALL MEDICALLY IMPORTANT ANTIBIOTICS FOR USE IN:
 - Water requires Rx
 - Feed requires VFD
- VET MUST BE LICENSED IN STATE WHERE ANIMALS ARE HOUSED AND BEING FED AND VCPR IS REQUIRED
- NO ELDU, DRUG MUST BE USED IN ACCORDANCE WITH LABEL
 - However, FDA released CPG 615.115 in Dec 2016 to allow flexibility in use in minor species
 - Farmed or confined (not wildlife)
 - Similar species

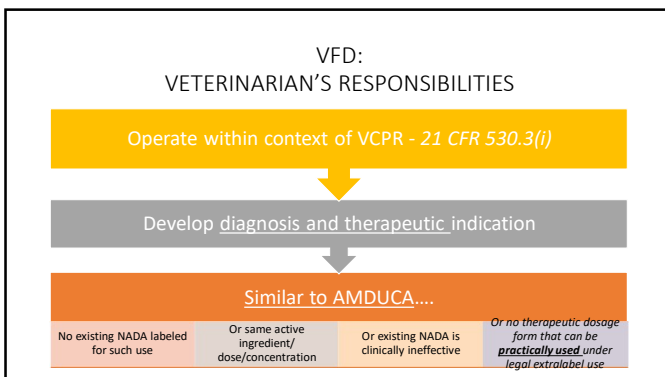
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FDA CPG 615.115 (2017)

"Under the CPG, when there are no approved treatment options available, the health of animals is threatened, and failure to treat affected animals would result in suffering or death, the extralabel use of medicated feeds may be considered for treatment of minor species as long as the conditions and procedures described in the CPG are followed"

"In general, the agency will not recommend or initiate enforcement action against the veterinarians, animal producer, feed mill, or other distributor when extralabel use is consistent with this document."

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PHARMACEUTICAL USE PRACTICES

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- **LABEL USE**
 - Species
 - Indication
 - Dose
 - Route
 - Frequency
 - Duration
- **MILK/SLAUGHTER WITHHOLD**
 - Label




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EXTRA-LABEL DRUG USE (ELDU)

Anything that deviates from label

Requires a Veterinary-Client-Patient Relationship (VCPR)

Significant caveats for legally permissible use
AMDUCA Guidelines
FDA ELDU Prohibited/Restricted Lists



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VCPR – FEDERAL 21 CFR 530.3(I)

COLORADO: CRS SEC 12-315-104(19); 4 CCR 727-1, RULE 1.18(7)1.21(9)

1. A **veterinarian has assumed the responsibility for making medical judgments** regarding the health of (an) animal(s) and the need for medical treatment, and the **client (the owner of the animal or animals or other caretaker) has agreed to follow the instructions** of the veterinarian;
2. There is **sufficient knowledge of the animal(s) by the veterinarian** to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s); and
3. The **practicing veterinarian is readily available for followup** in case of adverse reactions or failure of the regimen of therapy. Such a relationship can exist only when 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.

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ANIMAL MEDICINAL DRUG USE CLARIFICATION ACT (AMDUCA, 1994)

- **FDA-APPROVED DRUGS**
- **INJECTABLE, INDIVIDUAL-DOSE ORAL, AND WATER MEDICATIONS**
- **ANY DEVIATION FROM LABEL**
 - Species and/or Indication
 - Dose, Route, and/or Frequency
- **HEALTH, BUT NOT PRODUCTION**
- **VCPR AND EXTENDED WITHHOLD INTERVAL REQUIRED**


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Labeled?	<ul style="list-style-type: none"> • Must Use Approved Labeled Drug if Available for: <ul style="list-style-type: none"> • Species & Use (Indication) • and same Active Ingredient, Dosage Form, Concentration • May use ELDU if approved drug is clinically ineffective
Other Food Animal Label?	<ul style="list-style-type: none"> • Prohibited from using approved human drug if ELDU of an animal drug approved for food animal species is possible
Human Drug / Non-Food Animal Drug	<ul style="list-style-type: none"> • Animal prohibited from entering the food supply if scientific information on the human food safety aspect is not available

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PROHIBITED FROM ELDU
21CFR530.41 & AMDUCA (1994)

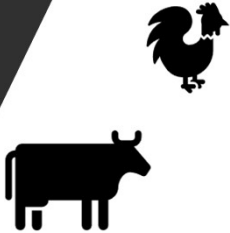
- **GROUP 1: NO LABEL FOR FOOD ANIMAL SPECIES**
 - Chloramphenicol, clenbuterol, diethylstilbestrol (DES), Nitroimidazoles (e.g. metronidazole), Nitrofurans (including topical), glycopeptides (e.g. vancomycin), dipyron, gentian violet
- **GROUP 2: LABEL FOR FOOD ANIMAL SPECIES**
 - Fluoroquinolones (enrofloxacin)
- **NO COMPOUNDING**
- **VFDS**
 - Exception: SR VFDs (CPG 615.115)



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RESTRICTED FROM ELDU
21CFR530.41 & AMDUCA (1994)

- **ANTIVIRAL MEDICATIONS**
 - Poultry
- **SULFAS**
 - Lactating Dairy Cattle
- **PHENYLBUTAZONE**
 - Lactating Dairy Cattle
- **CEPHALOSPORINS**
 - Exceptions:
 - Indication
 - 1st generation (cephapirin)
 - Minor species



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VOLUNTARY RESTRICTION

- **AABP & AASRP POLICY STATEMENT: AMINOGLYCOSIDE USE IN RUMINANTS**
- **VETERINARIANS SHOULD NOT USE OR PRESCRIBE EXTRALABEL AMINOGLYCOSIDES IN RUMINANTS**
- **SUBSTANTIAL RISK FOR VIOLATIVE RESIDUES IN FOOD PRODUCTS ASSOCIATED WITH THE PROLONGED ELIMINATION OF AMINOGLYCOSIDES.**





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VETERINARY FEED DIRECTIVE (VFD) CPG 615.115

LIMITS TO EXTRALABEL USE

ACCEPTABLE DEVIATIONS FROM LABEL:

1. MINOR SPECIES NOT ON LABEL
2. INDICATIONS NOT ON LABEL
3. EXTENSION OF LABELED WITHDRAWAL TIME

- CANNOT "PROMOTE" USE
- APPROVED MEDICATED ANIMAL FEEDS ONLY
 - No NADAs not approved for use in feed
 - Not drugs prohibited from extralabel use
- THERAPEUTIC USE ONLY
 - Prevent/Control/treat Disease (Therapeutic)

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ADDITIONAL RESOURCES

- **AMERICAN ASSOCIATION OF BOVINE PRACTITIONERS**
 - Position Statement Concerning Aminoglycoside Use in Cattle (2016)
 - Position Statement Concerning Antimicrobial Resistance (2019)
 - Establishing and Maintaining the VCPR in Bovine Practice Guidelines (2020)
 - Drug Use Guidelines for Bovine Practice (2015)
 - Key Elements for Implementing Antimicrobial Stewardship Plans in Bovine Veterinary Practices Working with Beef and Dairy Operations (2022)
 - Joint AABP-AVC Judicious Therapeutic Use of Antimicrobials in Cattle Guidelines (2019)
- **AMERICAN ASSOCIATION OF SMALL RUMINANT PRACTITIONERS**
 - Position Statement Concerning Small Ruminants as Food Animals (2020)
 - Position Statement Concerning Aminoglycoside Use in Small Ruminants (2020)
 - Position Statement Concerning Prudent Drug Use Guidelines (2020)
 - VCPR in Small Ruminant Practice Guidelines (2020)
 - Antimicrobial Stewardship Guidelines (2020)
 - Therapeutic Drug Use Guidelines for Small Ruminant Practitioners (2020)

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ADDITIONAL RESOURCES

- **FDA CENTER FOR VETERINARY MEDICINE**
 - Unapproved Drugs
 - Drugs Prohibited for Extralabel Use in Animals
 - Judicious Use of Antimicrobials
 - AMDUCA
- **AVMA**
 - AVMA/AABP Prudent Use Guidelines
 - Extralabel Drug Use Algorithm
- **FOOD ANIMAL RESIDUE AVOIDANCE DATABANK (FARAD)**

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QUESTION 1 - PHARMACIST

• **WHICH OF THE FOLLOWING SITUATIONS BEST REPRESENTS A VALID VETERINARY-CLIENT-PATIENT-RELATIONSHIP (VCPR)? CHOOSE THE BEST ANSWER.**

- A. An on-call veterinarian makes an over-the-phone recommendation to a non-client for use of an OTC antibiotic at 3x the label dose for treatment of his goat's pneumonia.
- B. A regular (weekly) veterinarian for a commercial dairy prescribes a prescription antibiotic for treatment of pneumonia.
- C. A pharmaceutical technical services veterinarian is visiting an out of state swine facility and prescribes a prescription antibiotic for treatment of pneumonia.

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QUESTION 2 - PHARMACIST

• EXTRA-LABEL DRUG USE MAY BE PERMITTED FOR WHICH OF THE FOLLOWING DRUGS? CHOOSE THE BEST ANSWER.

- A. Injectable prescription oxytetracycline (antibiotic) for an extralabel indication in cattle.
- B. Veterinary Feed Directive (VFD) chlortetracycline (antibiotic) for an extralabel indication in cattle.
- C. Injectable prescription enrofloxacin (antibiotic) for an extralabel indication in cattle.

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QUESTION 3 - PHARMACIST

• A CLIENT REQUESTS COMPOUNDED PONAZURIL FOR TREATMENT OF COCCIDIA IN HIS PET GOATS, IS THIS LEGAL? CHOOSE THE BEST ANSWER.

- A. Yes
- B. No

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QUESTION 4 - PHARMACIST

• WHICH OF THE FOLLOWING IS AN EXAMPLE OF LEGAL FOOD ANIMAL PRESCRIBING? CHOOSE THE BEST ANSWER.

- A licensed veterinarian prescribes compounded 200 mg/ml ketamine to an active (VCPR) client to capture a white-tailed deer for examination and treatment.
- A licensed veterinarian prescribes enrofloxacin (Baytril ®) to an active (VCPR) client to treat his goat's pneumonia.
- A producer uses VFD chlortetracycline from his cattle herd to treat his sheep flock pneumonia without veterinary oversight.

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QUESTION 1 – PHARMACY TECHNICIAN

• WHICH OF THE FOLLOWING IS LEGALLY NOT CONSIDERED A FOOD ANIMAL SPECIES? CHOOSE THE BEST ANSWER.

- A. Dairy Cow
- B. Pet Pig
- C. Llama
- D. Yak

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QUESTION 2 – PHARMACY TECHNICIAN

• WHERE CAN YOU FIND THE SLAUGHTER AND MILK WITHHOLDING INTERVAL FOR A DRUG, ASSUMING IT IS USED ACCORDING TO LABEL? CHOOSE THE BEST ANSWER.

- A. From the supplier's website
- B. Calculated by $10 \times t_{1/2}$
- C. In a reference text
- D. On the label

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QUESTION 3 – PHARMACY TECHNICIAN

• FLUNIXIN MEGLUMINE INJECTION (50 MG/ML) IS LABELED FOR USE IN CATTLE AT 1.1-2.2 MG/KG IV ONCE DAILY AS EITHER A SINGLE DOSE OR DIVIDED INTO TWO DOSES ADMINISTERED AT 12-HOUR INTERVALS, FOR UP TO THREE DAYS. YOUR PRESCRIPTION REQUEST FOR A 500 KG COW IS FOR 15 ML ADMINISTERED IM ONCE DAILY FOR THREE DAYS. IS THIS EXTRALABEL USE? CHOOSE THE BEST ANSWER.

- A. Yes
- B. No

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QUESTION 4- PHARMACY TECHNICIAN

• WHICH OF THE FOLLOWING IS INCONSISTENT WITH LEGAL FOOD ANIMAL PRESCRIBING PRACTICES? CHOOSE THE BEST ANSWER.

- A. A veterinarian prescribes an antibiotic to be used in an alpaca and does not specify a slaughter withdrawal interval.
- B. A veterinarian prescribes an antibiotic to be used extralabel in a pet goat and specifies an extended slaughter withdrawal interval.
- C. A veterinarian prescribes metronidazole to be used in a pet pig.

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QUESTIONS?

• KMSTILL@COLOSTATE.EDU

Photo Credit: Kelly Still Brooks

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