



# Appropriate Drug Use in Food Animals

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## Disclaimer

The opinions expressed in this program do not necessarily represent those of the FDA and should not be used as part your defense in a court of law or public opinion.



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## Concerned Parties

- FDA
- USDA
- EPA
- Veterinarians
- Producers
- Public



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## Why?

- Responsibility to ensure safe and wholesome food supply
- Responsible use necessary to maintain availability of therapeutic options



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## Definitions

- Food animal – “food producing animal”
- From the ‘compliance folks’ at FDA:  
*“I am not aware of a definition per se. The correct term is “food producing animals,” which pretty much seems to mean animals that produce food. Is any more of a definition needed?”*

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## Definitions

- Food animal species are food producing animals in the eyes of the FDA
- When use drugs in pet food animal species, *veterinarian* is responsible for ensuring that the animal does not enter the food chain



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## Definitions

- **Extralabel** - use of any approved drug (prescription or over the counter) in a manner that is not in accordance with the approved label or the package insert. [This may include use in a different species, route of administration, dosage or dosing frequency.]
- **Minor species** - species other than cattle, horses, swine, chickens, turkeys, dogs and cats (sheep were a major species until 2000)
- **Drug** - any compound for which the diagnosis, cure, treatment, mitigation, or prevention of a disease is claimed
- **Withdrawal time** - the time at which 99% of animals would be expected to reach the tolerance level for drug residue [95% confidence]

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## Acts and Programs

- AMDUCA (1994)
- MUMS (2004)
- National Research Support Project #7
- PMO



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# AMDUCA

- Collection of requirements which allow veterinarians to use some FDA-approved drugs in an extralabel fashion based upon several criteria



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# Extralabel Drug Use

- Only on the order or supervision of a veterinarian
- Only FDA approved human and animal drugs
- Valid VCPR
- Therapeutic purposes only. Use of extralabel drugs for production purposes, manipulation of reproduction or growth promotion is not allowed.
- Applies to dosage form and drugs in water. ELDU in feed is prohibited.
- Not permitted if violative residue if results in violative residue or residue may present a risk to public health.
- Prohibited drugs are precluded from use under ELDU.

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- Animal health is threatened or suffering or death may result from failure to treat
- There is a written or oral order of a licensed veterinarian in the context of a valid VCPR
  - The veterinarian has assumed responsibility for making clinical judgements regarding the health of the animal(s) and the need for medical treatment, and the client has agreed to follow the veterinarian's instructions.
  - The veterinarian has sufficient knowledge of the animal(s) to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s). This means that the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of an examination of the animal(s), or by medically appropriate and timely visits to the premises where the animal(s) are kept.
  - The veterinarian is readily available, or has arranged for emergency coverage, for follow-up evaluation in the event of adverse reactions or the failure of the treatment regimen.
- There is no approved product or the approved product is clinically ineffective as determined within a valid VCPR
- After establishing a careful medical diagnosis and an extended withdrawal time, assuring the identity of treated animals is maintained, and assuring that the withdrawal time is observed and that no illegal residues occur.

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## Prohibited Drugs in "FPA" [21 CFR 530.41]

- Extralabel use is prohibited
  - Chloramphenicol
  - Nitroimidazoles
  - Sulfonamides in dairy cattle >20m age
  - Clenbuterol
  - Dipyrone
  - Flouroquinolones
  - Glycopeptides (\$8000/cow for vancomycin)
  - Nitrofurans
  - Phenylbutazone in adult dairy cattle
  - Genetian violet

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## Pasteurized Milk Ordinance

- Item 15R
- FDA letters of warning
  - Colloidal silver
  - DMSO – non-medical grade
  - Dipyrone
  - ECP
  - Flunixin – ROI
  - Genetian violet



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## MUMS

The Minor Use and Minor Species Animal Health Act of 2004 (MUMS act) amended the Federal Food, Drug, and Cosmetic Act (the act) to authorize the U.S. Food and Drug Administration (FDA, the agency) to establish new regulatory procedures that provide incentives intended to make more drugs legally available to veterinarians and animal owners for the treatment of minor animal species and uncommon diseases in major animal species.

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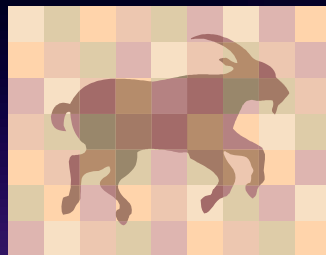
# MUMS

- “Minor use” drugs are for intended uses in major species (horses, dogs, cats, cattle, pigs, turkeys, and chickens) for diseases that occur infrequently or in limited geographic areas and in only a small number of animals annually.
- “Minor species” are all animals other than humans that are not one of the major species. They include animals such as zoo animals, ornamental fish, parrots, ferrets, and guinea pigs. Some animals of agricultural importance are also minor species. These include sheep, goats, catfish, game birds, and honey bees among others.

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## Specific Drugs / Classes

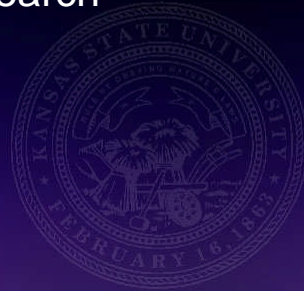
- List of MUMS-approved drugs by species in proceedings, can be searched on <http://www.nrsp-7.org/mumsrx/>



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# FARAD

- One-stop-shop for veterinarians to obtain extended withdrawal times
- Based on available data
- Funding mostly spent on research
  - Ex: melamine in pig feed
- Call first!



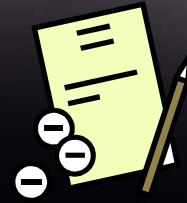
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## VCPR – Principles of Veterinary Medical Ethics (AVMA)

- **THE VETERINARIAN-CLIENT-PATIENT RELATIONSHIP**
  - **The veterinarian-client-patient relationship (VCPR) is the basis for interaction among veterinarians, their clients, and their patients.** A VCPR exists when all of the following conditions have been met:
    - The veterinarian has assumed responsibility for making clinical judgements regarding the health of the animal(s) and the need for medical treatment, and the client has agreed to follow the veterinarians instructions.
    - The veterinarian has sufficient knowledge of the animal(s) to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s). This means that the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of an examination of the animal(s), or by medically appropriate and timely visits to the premises where the animal(s) are kept.
    - The veterinarian is readily available, or has arranged for emergency coverage, for follow-up evaluation in the event of adverse reactions or the failure of the treatment regimen.
  - **When a VCPR exists, veterinarians must maintain medical records**

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# Record Keeping



- Identify the animals, either as individuals or a group.
- Animal species treated.
- Numbers of animals treated.
- Conditions being treated.
- The established name of the drug and active ingredient.
- Dosage prescribed or used.
- Duration of treatment.
- Specified withdrawal, withholding, or discard time(s), if applicable, for meat, milk, eggs, or animal-derived food.
- Keep records for 2 years.
- FDA may have access to these records to estimate risk to public health.

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# Labeling Requirements

- Name and address of the prescribing veterinarian.
- Established name of the drug.
- Any specified directions for use including the class/species or identification of the animal or herd, flock, pen, lot, or other group; the dosage frequency, and route of administration; and the duration of therapy.
- Any cautionary statements.
- Your specified withdrawal, withholding, or discard time for meat, milk, eggs, or any other food.

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## Antimicrobials

- Fluoroquinolone use not allowed
- Penicillin
  - Conflicting data on withdrawal on sheep/goats
  - FARAD cannot recommend with confidence
  - Test milk and urine
- Feed additives



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## Hormones

- Estrus synchronization, embryo transfer
- Non-therapeutic extralabel use not permitted
- You're on your own



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## Example of improper ELDU

- Aloe vera for mastitis on organic dairies
  - Not FDA approved drug



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## Examples of Improper ELDU

- Intramammary Naxcel because Spectramast exists
- Naxcel for metritis because Excenel has label
- Excenel in sheep and goats because Naxcel has MUMS approval

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## Why bother if they're not looking for it?

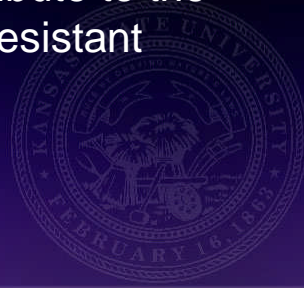
- They can decide to start looking anytime
- Phenylbutazone in dairy cows
  - February 8, 2003



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## Current events in ELDU

- July 2008
- Proposed prohibition on ELDU of cephalosporins in food producing animals
- Believed that they may contribute to the emergence of antimicrobial resistant foodborne pathogens
- Expect amended proposal



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## Take home messages

- Cannot invoke AMDUCA for convenience
- When you invoke ELDU, the veterinarian is responsible for violative residues
- An OTC drug becomes a prescription drug when it is used extralabel
- Need to educate ourselves



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## Take home messages

- If it's used on-label and a violative residue occurs, the liability is with the manufacturer
- If it's used off-label and a violative residue occurs, the liability is with the veterinarian or producer who used it



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