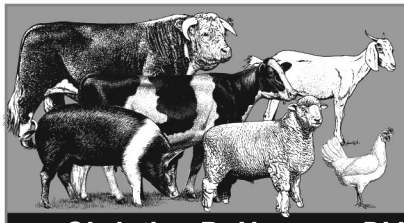

Understanding Drug Use Regulations in Food Producing Animals

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Disclaimer: This is not a complete description of the regulations and is valid as of 5/2020. Please contact your veterinarian for specific drug use recommendations in animals.

Who makes the laws?

Veterinary pharmaceutical use is governed by the Food and Drug Administration (FDA) at the federal level and the Louisiana Board of Veterinary Examiners via the Louisiana Practice Act at the state level. The Environmental Protection Agency (EPA) approves some pesticides for animal use (fly tags, pour-ons for lice, flies, etc).

- FDA approves drugs for either prescription (Rx), over-the-counter (OTC), and veterinary feed directive (VFD) use.
    - Prescription (Rx) and Veterinary Feed Directive (VFD): For use only by or on the order of a licensed veterinarian within the context of a veterinarian-client-patient relationship (VCPR).
        - A VCPR exists when all of the following conditions have been met:
        - The veterinarian has assumed the responsibility for making clinical judgments 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 for follow-up evaluation, or has arranged for emergency coverage, in the event of adverse reactions or failure of the treatment regimen.
        - Over-the-Counter: Products available for purchase by laypersons that do not require a prescription.
- ***Only FDA or EPA approved products are allowed.*** Products from other countries may not be used legally in the U.S.

What is a “food animal”?

FDA considers cattle, swine, sheep, goats, poultry, rabbits and fish food animal species (refer to FDA policy for complete list). While owners may have these species as pets, when it comes to pharmaceutical use, they must be treated as food animals.

What is the difference between “label drug use” and “extra-label drug use” (ELDU)?

Label drug use is exactly what it implies-using a drug exactly as it is labeled including species, indication, dose, route, frequency and duration of administration.

ELDU is defined as any use of a drug in an animal in a manner that is not in accordance with the approved labeling. This includes but is not limited to use in species not listed in the labeling, use for indications (disease and other conditions) not listed in the labeling, use at dosage levels, frequencies, duration or routes of administration other than those stated in the labeling, and deviation from labeled withdrawal times based on these different uses.

When is ELDU acceptable?

- **ELDU is allowed only under the direction of a veterinarian and under a valid veterinary-client-patient-relationship (VCPR) as defined in the federal AMDUCA regulations**
    - Producers cannot make the decision to go to ELDU
    - ELDU of OTC drugs is not permitted unless directed by a veterinarian
- ELDU is only permitted for medical reasons
    - Life of the animal must be threatened
    - Not for production reasons, such as increased milk production
    - ELDU is not permitted for reasons of cost or convenience
- ELDU of medicated feeds is not permitted
- ELDU is not allowed for EPA approved drugs, only for FDA approved drugs
    - This statement will be found on EPA approved products "It is a violation of Federal law to use this product in a manner inconsistent with its labeling"
- ***ELDU is not permitted under any circumstances for some drugs***
    - ***For a complete and up to date list go to www.FARAD.org or the FDA-CVM website***
- **Before ELDU is permitted, a meat and milk withdrawal time must be established**
    - When you deviate in any way from the label (ex. dose, route, species, frequency, duration), the label withdrawal time is no longer valid

What are some examples of prohibited extralabel drug use?

- Use of non-FDA approved products
    - Products such as "Show Calf Calm" that have a pharmacologic effect (ex. calming) but are not FDA approved are illegal
        - **Just because the label says "natural" does not mean it is legal**
- Indication
    - Baytril® is only labeled for respiratory disease in certain species and anaplasmosis in beef cattle
        - ELDU of floroquinolones is not permitted (see list "Drugs Prohibited from Extra-label Drug Use (ELDU) in Food-Producing Animals")
        - ELDU is not permitted for any other condition such as calf diarrhea or joint infection
        - Baytril® is not approved for adult dairy cows
    - Currently, the only sulfonamide available for use in dairy cows older than 20 months of age is sulfadimethoxine (SDM), which must be used according to label instructions. Use of higher doses or sustained-release SDM products is prohibited in adult dairy cows.

- Production purposes
    - Giving oxytocin just to increase milk production in dairy cattle is prohibited (not labeled for this indication)
    - Sedatives such as acepromazine (Ace®) are not approved for food animal species
        - Use of these products will automatically be ELDU
            - Must be under direction of a veterinarian with valid VCPR
            - Must be used only for a medical reason
                - ***Use at livestock shows only for behavior modification is not permitted and considered an illegal use of these drugs under federal law***
- Convenience
    - Flunixin meglumine (ex. Banamine®) labeled for intravenous (IV) use in cattle
        - The only reason for using this product intramuscular (IM) is for convenience. There is not a medical justification for this extralabel use, so it is not permitted. Furthermore, giving cattle flunixin meglumine IM greatly increases the withdrawal time and is very painful and damaging to tissues
        - It is labeled for IM use in swine, so IM use in swine is legal
        - There is now a topical flunixine meglumine product that can be used iin place of the IV product
- Species
    - Baytril® is not approved in sheep and goats
        - ELDU of floroquinolones is not permitted so use of this product in sheep and goats is not permitted
- Few products are approved for sheep and goats. To use products that are permitted for ELDU, one must follow all tenets of AMDUCA
    - Example: an OTC dewormer that is not approved for goats
        - Even though this product can be purchased OTC by producers, it is illegal to use in a species not on the label <u>unless</u> directed by a veterinarian and properly labeled, including withdrawal periods
- Pharmaceutical use in feed
    - Chlortetracycline use for prevention of anaplamsosis in feed or minerals
        - ELDU in feed is not permitted
        - Must select a product that is labeled for anaplasmosis and use exactly according to label directions for dose and administration as directed on a VFD.

Livestock Producer Do's and Don'ts of Prudent Drug Use

- Have a solid herd health program to decrease the need for drugs
- Only use drugs, vaccines, feed medications, etc. according to the label
- Make sure animals have identification
- Keep records of which medications are used on which animals, administration date(s), dose, injection site(s) and outcomes of treatment
- Follow meat and milk withdrawal times
- Avoid inappropriate drug use
    - Using antimicrobials or other drugs when not indicated

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