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Enabled by:	Ag Guide, AVMA, USDA, FDA
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Title: Quality Assurance - Drug Residues and Labeling of Drugs Used in Food Animals

I. **Purpose**:

The purpose of this policy is establish a safety standard and procedure with regard to drug use in food animals used for agricultural and biomedical research or teaching. *The 4th edition of the Guide for the Care and Use of Agricultural Animals in Research and Teaching* (Ag Guide) includes guidance on residue avoidance (pp.13-15).

II. **Policy**:

All units using food animals must meet or exceed the requirements in the Ag Guide, and all local, state and federal regulations pertaining to food animals. This pertains to any animals or animal products that are destined to enter the food chain).

III. **Procedure**:

Residue Avoidance: Before an animal may be slaughtered for human or animal food purposes, time must be allowed for medications, drugs approved by the Food and Drug Administration (FDA), or substances allowed by the FDA for experimental testing under the Investigational New Animal Drug (INAD) exemption to be depleted from the tissues. A record of the product used, dose, route of administration, duration of treatment, and period of withdrawal must be maintained. Adherence to proper withdrawal times must be ensured before animals are transported to the auction, market, or abattoir.

Residues of 3 groups of chemicals must be prevented from occurring in research animals if these animals or their products are to enter the human food chain. These are:

1. approved drugs used according to directions on the label
2. drugs used in an extra-label fashion
3. other chemicals such as herbicides, pesticides, and wood preservatives

The FARAD Compendium of FDA Approved Drugs provides information about drugs that are available for treating animal diseases, the withholding times for milk and eggs, and pre-slaughter withdrawal times for meat. Information about the drugs approved for use in food animals in the United States is included in this online database (http://www.farad.org/). In the event that animals are given an investigational drug, no meat, eggs, or milk from those animals may be processed for human consumption unless authorization has been granted by the FDA or the US Department of Agriculture and an appropriate INAD exemption from the FDA has been obtained for use of the

investigational drug. In such cases, the investigator must follow specifications outlined in the INAD.

Drug Storage and Control

Storage should be in an area that is clean and dry and that offers protection from changes in temperature, sunlight, dust, moisture, and vermin. The manufacturer's labeling should be consulted for specific information regarding appropriate storage conditions and product shelf life. Product containers should be periodically evaluated to assess for potential leakage or contamination of the stored product. Products in damaged containers or with missing or illegible labels should be disposed of properly.

In addition to dating the first use of the product, and to minimize the potential for treatment errors, products should be physically segregated according to indicated use (e.g., lactating, non-lactating, pregnant, or neonatal)

Labeling of Containers of Drugs Prescribed for Food Animals:

The following are the minimum labeling standards for veterinary prescribed drugs per AVMA policy:

- Name of the prescribing veterinarian
- Identification of animal(s) treated, species and numbers of animals treated (when possible)
- Date of treatment, prescribing, or dispensing of drug
- Name, active ingredient, quantity of the drug (or drug preparation) to be prescribed or dispensed
- Drug strength (if more than once strength is available)
- Dosage and duration
- Route of administration
- Number of refills (if applicable)
- Cautionary statement (if applicable)
- Expiration date (if applicable)
- Slaughter withdrawal and/or milk withholding times (see "Drug Residues" section below)

The actual container must have the veterinarian's name and contact information, name of the drug, identification of the animal to be treated, adequate directions for proper use, and cautions/precautions including milk and meat withdrawal times. This information may be part of the manufacturers label or as a label attached by the prescribing veterinarian.

If there is inadequate space on the label for any of the other required information, the veterinarian must provide the additional information on a separate sheet that accompanies the drug dispensed or prescribed.

For over the counter (OTC) compounds, the drugs must be administered according to the manufacturer's label. Labeled milk and meat withdrawal times must be followed.

Drug Residues:
University-owned animals receiving pharmaceuticals may not be shipped directly for slaughter for human consumption until after drug withdrawal times have been met.

With approval from the Attending Veterinarian (AV), agricultural animals that have not cleared their withdrawal times for drugs may be shipped to buyers (*not for immediate slaughter*) with adequate identification and with written notification to the buyer. Use the Department of Food and Agriculture form 513-037 "Notification of Drug Treated Livestock".

For drugs that do not have established withdrawal/withholding times, consult with the AV. With thorough review of pharmacokinetic data and consultation with sources such as FARAD, safe withholding/withdrawal times may be determined for many drugs. However, certain drugs may never be approved for use in animals intended for human consumption. See Extra Label Drug Use below.
The FARAD website is: http://www.farad.org/

Extra Label Drug Use:
The campus will comply with the Extra Label Drug Use (ELDU) guidelines from the Animal Medicinal Drug Use Clarification Act (AMDUCA) of 1994, Public Law 103-396 (US Food and Drug Administration, 1994). Information including drugs prohibited for extra label use in food animals can be found at the following website:
https://www.avma.org/KB/Resources/Reference/Pages/AMDUCA.aspx

Containers for extra label use of drugs prescribed for food animals must be labeled with the following information:

- Name of prescribing veterinarian
- Established name of the drug
- Any specific directions for use including the class/species or identification of the animal or group
- The dosage frequency, route of administration and duration of therapy
- Specific withdrawal, withholding, or discard time for meat, milk, eggs, or any other food
- Any cautionary statements.

Hazardous Chemicals:
Hazardous chemicals that could potentially contaminate meat, milk, or eggs must be stored, used, and disposed of in a manner that prevents contamination of animals and residues in milk, meat, or eggs. Containers must be properly labeled and stored, and expiration dates should be kept. Personnel must be informed of their potential hazard and wear appropriate protective clothing.