Animal Medicinal Drug Use Clarification Act (AMDUCA)

2017 NIAA – Antibiotics Council

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D-ABVP-Dairy Practice
AMDUCA

• Animal Medicinal Drug Use Clarification Act.
• Legalized extra-label use of approved drugs by licensed veterinarians.
• 1994
AMDUCA Requirements

- Permitted only by or under the supervision of a licensed veterinarian.
- Valid veterinarian/client/patient relationship must be in place.
  - Careful diagnosis must be made
- Only FDA approved animal and human drugs.
- Therapeutic purposes only – animal’s health is suffering or threatened.
- Specific Record Requirements.
AMDUCA Requirements

- Only in drugs administered parentally or in water. EL use of feed grade drugs is prohibited.
  - Exception: Minor Use Species
    - CPG 615.115
- Cannot result in a violative food residue or a residue that may affect public health.
“Tolerance” vs. “Target Test Level”

- Tolerance = Maximum **legally allowable** level or concentration of a drug or chemical in a food product at the time milk is marketed or the animal is slaughtered.

- Target Test Level (For Milk) = Guide for deciding whether or not to prosecute. They are not and cannot be transformed into tolerances. They are not binding, do not dictate any result, do not limit the FDA’s discretion in any way, and do not protect milk producers from court enforcement action.
US Prohibited Drug Use-Food Animals

Certain drugs PROHIBITED from use:

• Chloramphenicol
• Clenbuterol
• Diethylstilbesterol
• Dimetridazole
• Ipronidazole
• Other Nitroimidazoles
• Furazolidone, nitrofurazone, other nitrofurans.
Prohibited for Extra-Label Use

• Sulfonamide drugs in lactating dairy cows (except approved use of sulfadimethoxine, sulfabromomethazine, & sulfaethoxypyrindazine.)
  – Pneumonia
  – Foot rot
• Fluoroquinolones
• Glycopeptides (vancomycin)
• Phenylbutazone in female dairy cattle 20 months of age or older.
Prohibited for Extra-Label Use

- Cephalosporins (not including cephapirin) in cattle, swine, chickens, or turkeys:
  - (i) For disease prevention purposes;
  - (ii) At unapproved doses, frequencies, durations, or routes of administration; or
  - (iii) If the drug is not approved for that species and production class.
- Cephalosporin drugs approved for humans or small animals
WELCOME TO FARAD

FARAD is a congressionally-mandated risk-management program that is supported by the United States Department of Agriculture (USDA). In view of limited resources, FARAD's focus is limited to food animal species exclusively. The program is maintained by a consortium of universities, including University of California-Davis (UCD), University of Florida (UF), Kansas State University (KSU) and North Carolina State University (NCSU). FARAD's primary mission is to prevent or mitigate illegal or harmful residues of drugs, pesticides, biotoxins and other chemical agents that may contaminate foods of animal origin.

CLICK HERE to view details and download instructions with regard to our new Android App, available now, in the Google play store.

CLICK HERE to submit a question or receive advice regarding residue avoidance or mitigation.

CLICK HERE to search VetGRAM for FDA approved food animal drugs or to access our mobile-friendly VetGRAM, optimized for the iPad and other handheld devices.

CLICK HERE to search FARAD-recommended withdrawal intervals (WDI) for extra-label use of approved food animal drugs.

www.farad.org
Inspections, Compliance, Enforcement, and Criminal Investigations

Farms [REDACTED] 13

Department of Health and Human Services

Public Health Service
Food and Drug Administration
San Francisco District
Pacific Region
1431 Harbor Bay Parkway
Alameda, CA 94502-7070

Telephone: 510-337-6700
FAX: 510-337-6701

UNITED PARCEL SERVICE
DELIVERY SIGNATURE REQUESTED

CMS: 411729
ISU Veterinary Field Services Unit – Client agreement affirming a **Valid** Veterinarian Client Patient Relationship (VCPR)

In order for prescription drugs to be used by lay farm personnel, several requirements must be in place to assure compliance with federal and state regulatory requirements. One such requirement is the

I understand the requirements of the Iowa VCPR and agree that my farm operation has a VCPR with ______________________, DVM, ISU Veterinary Field Services for the following animal classes and areas of my farm. This document does not preclude farms from having other VCPR’s with other veterinarians.

Animal Classes: (circle all that apply)  
Beef Cattle  
Dairy Cattle  
Swine  
Goats  
Sheep  
Other: ______________________

Management Areas: (circle all that apply):  
Reproduction  
Milk Quality  
Youngstock  
Replacements  
Feedlot  
Cow-calf  
Individual animal medicine  
Veterinary Feed Directive  
Other: ______________________

Farm name address:  
Signature and Date:
LIVESTOCK OWNER CERTIFICATE

The undersigned certifies that, to the best of his/her/its knowledge, while under my ownership, possession or direct control, none of the livestock described herein are adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act, i.e., none of the cattle or other ruminants have been fed any feed containing ruminant derived meat and bone meal as required in 21 CFR 589.2000.

All feed additives and over the counter medications have been used in accordance with label directions and requirements. I am aware of the requirements of the Veterinary Feed Directive Final Rule and prescription medications, including antimicrobials, have been used within the confines of a valid veterinarian-client-patient relationship. Minimum withdrawal times for any medication, as indicated on the label or by approval of the veterinarian, have been reached prior to sale or shipment of the animal for slaughter.

To the best of my knowledge, the cattle presented for slaughter are acceptable for human consumption. This means that biological, chemical, and physical hazards are identified, and to the extent possible, controlled at the farm level. Hazards that need to be managed at the slaughter establishment must be identified to Cargill.

The cattle presented to Cargill for slaughter, have been handled, while under my ownership or control, in compliance with Health of Animals Regulations. I am also aware that Cargill will not accept unfit to transport or non-ambulatory animals.

For more information concerning the handling and loading of cattle, please reference the Beef Quality Assurance Program’s Master Cattle Transportation Guide. This program is a satisfactory representation of industry approved practices for the humane handling of cattle while loading, during transportation, and at unloading.

We agree to allow Cargill inspections of our feed ingredient records and facilities.

Do you have a current BQA certification? 
YES or No

Have you had a BQA assessment in the last 12 months? 
YES or No

Seller:

Name (please print)

And/or:

Business/Farm/Ranch Names (if applicable)

By:

Date:

Street Address

City/Zip

Business telephone #

Cell phone #

Signature/Title

E-mail address

Revised 11/2016
AMDUCA Examples
Small Animal Practitioner

– Adult doe with a non-healing brisket wound
– rDVM (SA) started enrofloxacin 125mg PO q24
AMDUCA Examples

• Your classmate calls with about a Shorthorn cow with chronic mastitis.
  – Milk is only used to feed a few calves.
  – Organism isolated from milk only sensitive to enrofloxacin.

1. Would systemic administration be a good choice from a pharmacologic standpoint?
2. Is this legal?
AMDUCA Examples

1. Changing the dose, such as giving more penicillin than is listed on the label?
2. Changing the dose of oxytocin, giving more than is listed on the label for milk letdown?
OXYTOCIN INJECTION

Rx
Vet Tek
Purified Oxytocic Principle (20 USP Units per mL)
Sterile Aqueous Solution
FOR ANIMAL USE ONLY
HAZARDOUS
KEEP OUT OF REACH OF CHILDREN

DESCRIPTION: Oxytocin injection is a sterile aqueous solution of highly purified oxytocic principle derived by synthesis or obtained from the posterior lobe of the pituitary gland of healthy domestic animals used for food by humans. Oxytocin injection contains 20 USP Units of oxytocin and less than 0.4 units of presser activity per mL. Each mL of sterile solution also contains 0.9% w/v sodium chloride, 0.5% w/v chlorobutanol (as a preservative), with water for injection q.s. and pH adjusted to 3.0 to 5.0 with acetic acid.

ACTIONS: Oxytocin acts directly on the smooth musculature of the uterus in all species to induce rhythmic contractions, although in some species the uterine cervix does not respond to oxytocin. The responsiveness of the uterine musculature to oxytocin varies greatly with the stage of the reproductive cycle. During the early phases of pregnancy the uterus is relatively insensitive to the effects of oxytocin, while in the late phases the sensitivity is markedly increased. Most authorities attribute this varying response to the varying levels of estrogen and progesterone during the course of pregnancy. Oxytocin also has been shown to exert a milk ejecting effect, occasionally referred to as the galactogogic effect. The actual mechanism by which oxytocin stimulates the release of milk from the mammary glands is not known with certainty, but oxytocin is presumed to act on certain smooth muscle elements in the gland.

INDICATIONS: Because of the specific action of oxytocin upon the uterine musculature, it is recommended as an aid in the management of the following conditions:
1) To precipitate labor
2) To accelerate normal parturition
3) Postpartum evacuation of uterine debris
4) Postoperative contraction of the uterus following a cesarean section and control of uterine hemorrhage.
Oxytocin will contract the smooth muscle cells of the mammary gland to induce milk let-down if the udder is in a proper physiological state.

Source: Valley Vet website  www.valleyvet.com
DOSAGE AND ADMINISTRATION:

Obstetrical Use: Inject aseptically by the intravenous, intramuscular or subcutaneous route as follows:

<table>
<thead>
<tr>
<th></th>
<th>EWES, SOWS:</th>
<th>COWS, HORSES:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration</td>
<td>1.5 to 2.5 mL</td>
<td>5.0 mL</td>
</tr>
<tr>
<td>Units</td>
<td>30 to 50 USP Units</td>
<td>100 USP Units</td>
</tr>
</tbody>
</table>

These dosages are recommended, and may be repeated as indicated.

Milk Let-down:

Inject aseptically by the intravenous, intramuscular or subcutaneous route.

<table>
<thead>
<tr>
<th></th>
<th>COWS:</th>
<th>SOWS:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration</td>
<td>0.5 to 1.0 mL</td>
<td>0.25 to 1.0 mL</td>
</tr>
<tr>
<td>Units</td>
<td>10 to 20 USP Units</td>
<td>5 to 20 USP Units</td>
</tr>
</tbody>
</table>

These dosages are recommended and may be repeated as necessary.
AMDUCA Examples

1. Changing the dose, such as giving more penicillin than is listed on the label?

2. Changing the dose of oxytocin, giving more than is listed on the label for milk letdown?

3. Changing the frequency of use, such as giving Spectramast™ LC twice a day instead of once a day.
4. Changing the route of administration, such as giving flunixin intramuscularly (IM) or subcutaneously (SQ) instead of intravenously (IV)?

5. Giving a drug for an indication (disease) not listed on the label, such as using Excede® for diarrhea?

6. Changing the withholding times, such as not following milk withholding times for fresh cows after dry treatment administration.

7. Changing the duration of therapy (Polyflex is labeled for up to 7 days, can you give it longer)?
AMDUCA Examples

9. Treatment of a single 4-H calf that has been pre-conditioned and not sick with Excede to prevent it from getting respiratory disease.
Interpretation of FDA prohibition

1. You must use all by label for dose, route, duration, etc
   You cannot use Naxcel IV
   You cannot use more frequent or longer than labeled (??)

2. You can use any of the products exactly as they are labeled
   You cannot use Excede SQ – it must be BOE. +/-MOE

3. You cannot use them in a manner the label says you cannot
   You cannot use Excenel and Excede for veal calves

4. You cannot interchange the labels – Naxcel for Metritis

5. You CAN use them in an extra label fashion for a disease where there is no other indicated product (AMDUCA) and under the direction of a Veterinarian
   You MUST use them by the labeled dose, route, duration, etc
   – cystitis

6. You cannot use them for Prevention
   There is most likely a concern about using for ’Control’ vs ‘Prevention’
   • ‘Control’ (Excede) – treatment of a group of animals where some are already sick. This can also be applied to specific situations that are listed on the label - high risk
     – Post uterine prolapse
     – Pre- C-section
   • ‘Prevention’ – treatment of a group of animals none of which are sick or high risk
     – Buy single 4-H calf that has been preconditioned
“Yes ... I believe there's a question in the back.”

Food Supply Veterinary Medicine
Veterinary Diagnostic and Production Animal Medicine
Iowa State University