REQUIREMENTS FOR USE

- ELDU is permitted only by or under the supervision of a veterinarian.
- ELDU is allowed only for FDA approved animal and human drugs.
- A valid Veterinarian/Client/Patient Relationship is a prerequisite for all ELDU.
- ELDU for therapeutic purposes only (animal's health is suffering or threatened). Not drugs for production use.
- Rules apply to dosage form drugs and drugs administered in water. ELDU in feed is prohibited.
- ELDU is not permitted if it results in violative food residue, or any residue which may present a risk to public health.
- FDA prohibition of a specific ELDU precludes such use.†

* RECORD REQUIREMENTS

- 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.

* * LABEL 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.

EXTRALABEL DRUG USE (ELDU)

An Informational Outline of the Animal Medicinal Drug Use Clarification Act (AMDUCA)

If you have questions about the regulations call the Food and Drug Administration, Center for Veterinary Medicine at (240) 276-9200

American Veterinary Medical Association
1931 N. Meacham Rd., Suite 100
Schaumburg, IL 601 73-4360
www.avma.org

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EXTRALABEL DRUG USE ALGORITHM

YOU MADE A CAREFUL DIAGNOSIS IN THE PRESENCE OF A VALID VETERINARIAN/CLIENT/PATIENT RELATIONSHIP.
YOU ARE CONTEMPLATING EXTRALABEL DRUG USE. YOU MUST ASK YOURSELF….
ARE THE ANIMALS TO BE TREATED AS FOOD ANIMALS?

YES

DOES A DRUG LABELED FOR FOOD ANIMALS EXIST WHICH FULFILLS ALL OF THE FOLLOWING:

- CONTAINS THE NEEDED INGREDIENT,
- IN THE PROPER DOSAGE FORM,
- LABELED FOR THE INDICATION,
- AND IS CLINICALLY EFFECTIVE?

YES

YOU MUST USE THIS DRUG PER LABEL, AS EXTRALABEL DRUG USE IS UNNECESSARY. OBSERVE LABEL DIRECTIONS AND WITHDRAWAL TIME.

NO

IS THERE A DRUG APPROVED FOR FOOD ANIMALS WHICH COULD BE USED EXTRALABELLY?

YES

PROCEED WITH EXTRALABEL USE OF FOOD ANIMAL DRUG. ESTABLISH EXTENDED WITHDRAWAL TIME. ENSURE FOOD SAFETY. MAINTAIN REQUIRED RECORDS.* LABEL DRUG APPROPRIATELY.**

NO

IS THERE A HUMAN DRUG OR DRUG APPROVED FOR NON-FOOD ANIMALS WHICH COULD BE USED EXTRALABELLY?

YES

IS THERE ADEQUATE SCIENTIFIC INFORMATION AVAILABLE TO DETERMINE A WITHDRAWAL TIME?

YES

PROCEED WITH EXTRALABEL USE OF HUMAN OR NON-FOOD ANIMAL DRUG. ESTABLISH EXTENDED WITHDRAWAL TIME. ENSURE FOOD SAFETY. MAINTAIN REQUIRED RECORDS.* LABEL DRUG APPROPRIATELY.**

NO

DRUG MUST NOT BE USED, OR TREATED ANIMAL MUST NOT ENTER FOOD SUPPLY.

NO

IF COMPOUNDING OF APPROVED DRUGS WILL PREVENT ANIMAL PAIN AND SUFFERING, REFER TO FDA COMPLIANCE POLICY GUIDE FOR COMPOUNDING GUIDANCE.***

NO

THERE ARE FEW RESTRICTIONS ON EXTRALABEL USE IN NON-FOOD ANIMALS.
DOES AN ANIMAL DRUG EXIST WHICH FULFILLS ALL OF THE FOLLOWING:

- CONTAINS THE NEEDED INGREDIENT,
- IN THE PROPER DOSAGE FORM,
- LABELED FOR THE INDICATION,
- AND IS CLINICALLY EFFECTIVE?

YES

USE THIS DRUG PER LABEL, AS EXTRALABEL DRUG USE IS UNNECESSARY.

NO

PROCEED WITH EXTRALABEL USE OF AN ANIMAL DRUG, IF AVAILABLE. MAINTAIN REQUIRED RECORDS.* LABEL DRUG APPROPRIATELY.**

OR

HUMAN DRUG

IN NON-FOOD ANIMALS YOU MAY USE A HUMAN DRUG EXTRALABELLY, EVEN WHEN AN ANIMAL DRUG EXISTS. ECONOMIC REASONS ARE VALID.
MAINTAIN REQUIRED RECORDS.*
LABEL DRUG APPROPRIATELY.**

OR

* and ** - See record and label requirements. *** - Compounding of bulk drugs is illegal.

†Drugs Prohibited for *Extralabel* Use in Food Animals

(Current as of April 5, 2012. Check for updates on the FDA Web site at www.fda.gov/cvm)

- Chloramphenicol
- Clenbuterol
- Diethylstilbestrol (DES)
- Dimetridazole
- Ipronidazole
- Other Nitroimidazoles
- Furazolidone, Nitrofurazone, other Nitrofurans
- Sulfonamide drugs in lactating dairy cows (except approved use of sulfadimethoxine, sulfabromomethazine, and sulfaethoxypyridazine).
- Fluoroquinolones
- Glycopeptides (example: vancomycin)
- Phenylbutazone in female dairy cattle 20 months of age or older.
- Adamantane and neuraminidase inhibitor classes of drugs that are approved for treating or preventing influenza A are prohibited therapy in chickens, turkeys, and ducks.
- Cephalosporin (excluding cephapirin) in cattle, swine, chickens, or turkeys
  - Using cephalosporin drugs at unapproved dose levels, frequencies, durations or routes of administration is prohibited;
  - Using cephalosporin drugs in cattle, swine, chickens or turkeys that are not approved for use in that species (e.g., cephalosporin drugs intended for humans or companion animals);
  - Using cephalosporin drugs for disease prevention.