Rules and Regulations:
The Pasteurized Milk Ordinance
and
The Animal Medicinal Drug Use Clarification Act

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Pasteurized Milk Ordinance
300+ pages

1) A regulation developed through the cooperative efforts of state, federal and private organizations.

2) Regulates all Grade A milk entering interstate commerce. (~70% of milk produced)

3) Covers virtually all grade A producers.
Standards

- The PMO sets the standards for the production of milk and milk products from cow to processing plant.
- The PMO sets standards for dairy farm inspections.
- The PMO outlines in detail the requirements for dairies to be in compliance.
Enforcement

- The state departments of agriculture are responsible for enforcement of the PMO.
- State inspectors visit grade A dairy farms to ensure compliance with the PMO.
- Federal inspectors visit each milkshed (grade A dairy farms in a geographic area) in the US to ensure nationwide compliance with a 90% rating.
Penalties

- A milkshed must have a weighted average score of 90% or risk being delisted.
- A milkshed that is delisted cannot market milk in interstate commerce.
- This has a huge economic impact on all producers in the milkshed.
A significant part of the PMO is regulation to ensure that proper labeling, storage and residue avoidance procedures are used.

- The PMO sets requirements for drug labeling and storage.
- The PMO specifies penalties for shipping milk containing violative drug residues.
The result of these regulations is:

- Direct regulation of the dairy farm.
- Direct regulation of the producers and veterinarians in regard to storage, labeling and residue prevention.
Drug Storage

- Separate storage is required for lactating cow drugs and nonlactating cow drugs.
  - Separate shelves in a cabinet, refrigerator, etc will be adequate.
  - Some items such as antiseptics, wound dressings, vaccines, vitamins and minerals need only be stored where they will not contaminate milk or milk contacting equipment or surfaces and are exempt from labeling requirements.
Also Exempt

- Water, Saline and Ringers solution
- Sugar solutions
- Propylene Glycol
- Prostaglandins (Estrumate, Lutalyse…)
- Pituitary hormones (Oxytocin, PLH, PH, Gonadotropin, Corticotropin, and FSH)
Drug Labeling Requirements

Manufacturers’ OTC (over the counter) Drug Label

- Name of drug
- Active ingredients
- Directions for use
- Withholding times (meat and milk)
- Name of distributor or manufacturer.
What is Over the Counter?

- These drugs can be purchased over the counter by a non-veterinarian.
- The label contains enough information to guide safe and effective use of this drug.
Any drug with the following statement is a prescription drug.

- “Caution, Federal law restricts this drug to use by or on the order of a licensed veterinarian”

- Other statements such as:
  - For veterinary use only
  - restricted drug

Do not confer prescription status.

THE NAME AND ADDRESS OF THE DISPENSING VET MUST BE AFFIXED
Label Requirements

» Manufacturers Prescription Drug Label

➢ Name of drug
➢ Active ingredients
➢ Directions for use
➢ Prescription legend
➢ Withholding time (meat and milk)
➢ Name of distributor or manufacturer

(also added is the dispensing vets name and address)
Extra label drug use is:

- Giving an animal a drug no matter if the drug is Over The Counter (OTC) or Prescription (Rx) or compounded, in a manner different *in any way* from what is written on the label.
  - Exm. Tetracycline given at a greater dose or used in a foot bath.
  - Banamine used in lactating cattle.
  - Penicillin used in the uterus rather than IM.
  - Human drug used in an animal.
Label Requirements

 Veterinarians label ADDED TO the manufacturers label on any product OTC or Rx dispensed or prescribed for an “Extra Label Use”
 1) Name and address of veterinarian
 2) Animal ID
 3) Active ingredients
 4) Animal class and health problem
 5) Directions for use
 6) Withholding time
 7) Cautionary statements (residue test, dangers)
What is required to use drugs in an extra label manner?

- ELDU is allowed only by or on the order of a veterinarian.
- Drugs must be FDA approved for animals or people.
- There must be a valid veterinarian/client/patient relationship.
- Drugs must be used for a therapeutic purpose, not for production enhancement.
What else??

- Drugs are to be given as a dose or in water not as a feed additive.
- ELDU is not allowed if it results in a violative food residue or any residue that may be a risk to public health.
- If the FDA prohibits use of a drug it cannot be used Extra Label contrary to that prohibition.
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 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?

NO

THERE ARE FEW RESTRICTIONS ON EXTRALABEL USE IN NON-FOOD ANIMALS.
DOES 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

HUMAN DRUG

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

YES

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

NO

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

†Drugs Prohibited for Extralabel Use in Food Animals
(Current as of January 1998)

Chloramphenicol
Clenbuterol
Diethylstilbestrol (DES)
Dimetridazole
Iproniazide
Other Nitroimidazoles
Furazolidone (except for approved topical use)
Nitrofurazone (except for approved topical use)
Sulfonamide drugs in lactating dairy cows
(except approved use of sulfadimethoxine, sulfadimethazine, and sulfathiaxopyridazine)
Fluoroquinolones
Glycopeptides (example: vancomycin)

* and ** - See reverse side for record and label requirements.
*** - Compounding of bulk drugs is generally illegal.
Drugs Prohibited for Extralabel Use in Food Animals (as of 1/98)

- Chloramphenicol
- Clenbuterol
- Diethylstilbestrol (DES)
- Dimetridazole
- Ipronidazole
- Other Nitroimidazoles
- Furazolidone (except for approved tropical use)
- Nitrofurazone (except for approved tropical use)
- Sulfonamide drugs in lactating dairy cows (except approved use of sulfadimethoxine, sulfabromomethazine and sulfathoxypyridazine)
- Fluoroquinolones
- Glycopeptides (example: vancomycin)
What’s the point.

- The purpose of all this regulation is to protect the consumer from consumption of products containing drugs or chemicals that may injure them.

- Also to protect the image of your products as safe and wholesome and free of adulterating substances.
How do I avoid a residue in my products?

- Employ preventive herd health management (NYSCHAP).
- Establish a valid vet/client/patient relationship.
- Use only FDA approved OTC or Rx drugs.
- Make sure all drugs are properly labeled.
- Store drugs properly.
Administer all drugs according to label directions.

Identification of treated animals.

Keep good treatment records on all treated animals.

Use drug residue screening tests.

All farm workers must be aware of the importance of not shipping adulterated products.
Trust

When ever a consumer purchases milk or meat to feed their families they are expressing confidence in you the producer and the marketing system that brings these products to there table.