ABOUT THE LABEL

Every drug approved by the FDA must have a label which contains, at a minimum:

- The specific disease or condition to be treated
- The approved species (i.e. cattle, swine, sheep, etc) and class of animal (i.e. lactating, nonlactating, beef)
- Approved dose, route of administration, duration of treatment and frequency of administration
- Slaughter or milk withdrawal time

DEPARTMENT OF AGRICULTURE

Extra-label Drug Use (ELDU)

Extra-label drug use is defined as giving a drug in a different way than is described on the FDA-approved label. This is also sometimes called "off-label".

Why is it important to use a drug as directed on the FDA-approved label?

Approved withdrawal times are based on the label directions, any other use may result in a longer withdrawal time, and a residue violation if the withdrawal time is not properly extended.

When is ELDU allowed?

ELDU is allowed for certain drugs, only with veterinary oversight. With a valid VCPR (veterinary-client-patient relationship), a licensed veterinarian can prescribe the use of a drug that differs from the labeled use.

What drugs are prohibited from ELDU?

For food-producing animals, the extra-label use of certain drugs is prohibited. This includes the fluoroquinolone and cephalosporin antibiotics, which are very important in human medicine.

Drug	ELDU Allowed
Baytril (Enrofloxacin)	PROHIBITED
Advocin (Danofloxacin)	PROHIBITED
Excenel RTU (Ceftiofur HCL)	For a different disease indication only
Excede (Ceftiofur Crystalline Free)	For a different disease indication only
Naxcel/Ceftiflex (Ceftiofur Sodium)	For a different disease indication only

How is ELDU different than a prescription?

A prescription is an instruction written by a veterinarian that authorizes a client (producer) to buy a medicine or treatment or the client to use the drug in a certain way. Most drugs are considered prescription drugs and require a prescription to be dispensed. ELDU is an additional set of instructions given by the veterinarian that differs from the manufacturer's label. These instructions should be included by the veterinarian on a separate label also applied to the medication packaging.

For additional information visit **www.mda.state.mn.us/residue-prevention**

In accordance with the Americans with Disabilities Act, this information is available in alternative forms of communication upon request by calling 651-201-6000. TTY users can call the Minnesota Relay Service at 711. The MDA is an equal opportunity employer and provider.