Extralabel Drug Use (ELDU)

**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 Veterinary/Client/Patient relationship is a prerequisite for all ELDU.
- Rules apply to dosage form drugs and drugs administered in water. ELDU in feed is prohibited.
- ELDU is not permitted if it results in a 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.
- Number of animals treated.
- Condition 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 two years.
- FDA may have access to these records to estimate risk to public health.

**Label Requirements**
- Name and address of prescribing veterinarian.
- Established name of the drug.
- Any specified directions for use including 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.

Information and chart are from *Extralabel Drug Use AMDUCA Guidance Brochure (January 1998)*, which was produced by: The American Veterinary Medical Association, 1931 N. Meacham Rd., Suite 100, Schaumberg, IL 60173-4360.

*If you have questions about the regulations,*

*Call Mr. Dick Arkin at FDA-CVM at (301) 827-0141.*