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?

**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 the 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 approves for non-food animals which could be used extralabelly?

**YES**

Use the drug per label. 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.**

**YES**

Is there adequate scientific information available to determine withdrawal time?

**YES**

Proceed with extralabel drug use of human or non-food animal drug. Establish extended withdrawal time. Ensure food safety. Maintain required records.* Label drug appropriately.**

**NO**

If compounding of approved drugs will prevent pain and suffering, refer to CPG 608.400 for compounding guidance.***

**NO**

Drug must not be used or treated animal must not enter food supply.

and ** See next page for record and label requirements
*** Compounding of bulk drugs is generally illegal