# Algorithm for Extra-Label Drug Use

## Flowchart



## Description

Title: “You made a care diagnosis in the presence of a valid veterinarian/client/patient relationship. You are contemplating extra-label drug use. You must ask yourself …”

Top of chart begins Q: "Are the animals to be treated as food animals?"

1. If “No” to treating as food animals, then Q: “There a few restrictions on extra-label use in non-food animals. Does an animal drug exist which fulfills all of the following: 1) contains the needed ingredient, 2) in the proper dosage form, 3) labeled for the indication, and 4) is clinically effective?”
	1. Note: In either case, in non-food animals you may use a human drug extra-labelly, even when an animal drug exists. Economic reasons are valid. Maintain required records. Label drug appropriately.
	2. If “Yes” to non-food animal drug meeting restrictions, then “Use this drug per label, as extra-label drug use is unnecessary.”
	3. If “No” to non-food animal drug meeting restrictions, then “Proceed with extra-label use of an animal drug, if available. Maintain required records. Label drug appropriately.”
2. If “Yes” to treating as food animals, then Q: “Does a drug labelled for food animals exist which fulfills all of the following: 1) contains the needed ingredient, 2) in the proper dosage form, 3) labeled for the indication, and 4) is clinical effective?”
	1. If “Yes” to food animal drug meeting restrictions, then “You must use this drug per label, as extra-label drug use is unnecessary. Observe label directions and withdrawal time.”
	2. If “No” to food animal drug meeting restrictions, then Q: “Is there a drug approved for food animals which could be used extra-labelly?”
		1. If “Yes”, then “Proceed with extra-label use of food animal drug. Establish extended withdrawal time. Establish food safety. Maintain required records. Label drug appropriately”.
		2. If “No”, then Q: “Is there a human drug or drug approved for non-food animal which could be used extra-labelly?”
			1. If “No”, then “If compounding of approved drugs will prevent animal pain and suffering, refer to FDA compliance policy guide for compounding guidance.”
			2. If “Yes”, then Q: “Is there adequate scientific information available to determine a withdrawal time?”
				1. If “Yes”, then “Proceed with extra-label use of human or non-food animal drug. Establish extended withdrawal time. Ensure food safety. Maintain required records. Label drug appropriately.”
				2. If “No”, then “Drug must not be used, or treated animal must not enter food supply.”