**Client Guidelines**

**Guidelines for all Animals:**

This document is intended to provide a summary of the AMDUCA requirements and does not list all the regulations that may apply. Veterinarians are strongly encouraged to familiarize themselves with the complete regulations. Information is available at www.fda.gov/cvm.

AMDUCA regulations include but are not limited to the following:

1) Extralabel use is only allowed when the health of an animal is threatened, or suffering or death may result from failure to treat.

2) 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(s)
* Dosage prescribed or used
* Duration of treatment

If applicable, specified withdrawal, withholding, or discard time(s) for meat, milk, eggs or animal-derived food.

* Keep records for a minimum of 2 years
* When requested, these records must be made available to FDA

3) Label requirements-

* Name and address of the prescribing veterinarian
* Established name of the drug(s)
* The class/species or identification of the animal or herd, flock, pen, lot or other group of animals being treated
* The dosage, frequency, route of administration and duration of therapy
* Any cautionary statements
* If applicable, veterinarian specified withdrawal, withholding or discard time for meat, milk, eggs or any other food

**Guidelines for extralabel use in food producing animals:**

In addition to the requirements for extralabel use in all animals there are regulations specific for food-producing animals.

Extralabel drug use is only allowed if there is no approved animal drug that is labeled for such use, or that contains the same active ingredient in the required dosage form and concentration. Alternatively, an approved animal drug exists, but a veterinarian finds, within the context of a veterinarian/client/ patient relationship, that the approved drug is clinically ineffective for its intended use.

It is important to note that AMDUCA does not permit extralabel use of drugs in animal feed. AMDUCA also does not permit extralabel drug use for production purposes.

Prior to prescribing or dispensing a food-animal drug for extralabel use the veterinarian must:

* Make a careful diagnosis and evaluation of the conditions for which the drug is to be used.
* Assure that the identity of the treated animal(s) is carefully maintained.
* Use appropriate scientific information to establish a substantially extended withdrawal period prior to marketing milk, meat, eggs or other edible products from the treated animals.
* Take appropriate measures to ensure that the recommended withdrawal times are met and no illegal drug residues occur.
* If there is insufficient scientific information available to determine a withdrawal interval, the veterinarian must not use the drug or the treated animal must not enter the food supply.

Use of a human drug, or an animal drug that is only approved for use in nonfood-producing animals, has further restrictions. These drugs are not permitted if a drug that is labeled for use in a food-producing animal can be used in a labeled or extralabel manner.

The extralabel use of certain drugs is prohibited in food animals. This list may be amended by the Food and Drug Administration. Thus, the following list is accurate as of the publication date of this document.

* Prohibited therapy in food animals: chloramphenicol, clenbuterol, diethylstilbestrol, dimetridazole, ipronidazole, other nitromidazoles, furazolidone, nitrofurazone, glycopeptides, fluoroquinolones.
* Prohibited therapy in lactating dairy cows: any sulfonamide except for approved uses of sulfadimethoxine, sulfabromethazine and sulfaethoxypyridazine.
* Prohibited therapy in female dairy cattle 20 months of age or older: phenylbutazone.
* Prohibited therapy in chickens, turkeys, and ducks: adamantane and neuraminidase inhibitor classes of drugs that are approved for treating or preventing influenza A.
* Prohibited cephalosporin (excluding cephapirin) use in cattle, swine, chickens and turkeys:
	+ Using cephalasporin drugs at unapproved dose levels, frequencies, durations or routes of administration is prohibited.
	+ Using cephalosporin drugs in cattle, swine, chickens or turkeys that are not approved for use in that species (e.g., cephaloporin drugs intended for humans or companion animals):
	+ Using cephalosporin drugs for disease prevention.

**Guidelines for extralabel use in nonfood-producing animals:**

AMDUCA also applies to medical decisions in nonfood producing animals. There is greater latitude for extralabel use in nonfood producing animals. However, the requirements stated above for "all animals" must still be followed. In addition, veterinarians should consider the following when treating nonfood-producing animals:

* Veterinarians may use approved animal and human drugs for therapeutic purposes in an extralabel manner so long as there is no threat to public health.
* An approved human drug may be used for treatment in an extralabel manner even when an identical, approved animal drug exists.
* Extralabel use of a drug labeled for another animal species can be used only if there is no approved, appropriate drug that is labeled for use in the patient's species or if an approved drug exists for the patient's species but is found by the veterinarian to be clinically ineffective.
* Extralabel use without a VCPR is illegal in all animals.

Guidelines for compounding of approved new animal and approved human drugs in all animals:

Compounding from FDA-approved drugs is considered extralabel drug use under FDA rules.

Compounding is the customized manipulation of an approved drug(s) by either a veterinarian, or by a pharmacist upon the prescription of a veterinarian, to meet the needs of a particular patient. For example, mixing two injectable drugs is compounding. Preparing a paste or suspension from crushed tablets is another example of compounding. Likewise, adding flavoring to a drug is compounding.

Compounding is not allowed unless there is no approved new animal or approved new human drug that, when used per label or in an extra label fashion, can appropriately treat the condition diagnosed.

* Compounding must done by or under the order of a veterinarian.
* Compounded drugs must not be used for production or performance purposes.
* A compounded human drug cannot be used in a food-producing animal if a legally compounded animal drug can instead be used.
* Compounded drugs must be prepared from FDA-approved drugs
* The volume of compounded drug must be commensurate with the anticipated need for use in individual patients.
* State laws on compounding must also be followed.
* A veterinarian must be cognizant of the need to maintain a safe food supply. Specifically, veterinarians must not allow entry of a treated animal into the food chain, if there is insufficient scientific evidence indicating a proper withdrawal interval after treatment.