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Policy on Use of Pharmaceutical-grade Compounds in Animal Research

Background and Relevance:

The IACUC recognizes that many research protocols involve the administration of chemical compounds to animals. Some of these compounds are experimental, proprietary, or unknown, and may be supplied directly by a company or government agency. Many others are available only in a chemical or reagent grade. In these situations, the researcher should take precautionary measures to ensure purity, sterility, potency, and safety for personnel prior to administering them to live animals.

Compounds that are available in a pharmaceutical grade are preferable because they are already sterilized, pyrogen-free and, if in a soluble form, are already in an appropriate vehicle for use. Pharmaceutical-grade compounds have a known purity, are labeled for safe handling (if applicable) and are typically buffered so as not to cause tissue irritation upon administration. Furthermore, their potency is well characterized and an expiration date indicates its shelf life.

Policy:

Any compound that is used for the purpose of anesthesia, analgesia, anxiolytic effect, or for any other medicinal purpose (anti-microbial, anti-inflammatory, etc.) must be pharmaceutical-grade and within its expiration date. This requirement is in accordance with the USDA's Policy on Veterinary Care (Animal Care Resources Guide, Policy #3, issued 8/16/06). In the event that a compound is classified as an anesthetic, analgesic, sedative, or anxiolytic agent, but is being used for experimental purposes, the investigator is still required to use the pharmaceutical-grade product. Use of a chemical-grade anesthetic, analgesic, or anxiolytic agent is only permissible after specific approval by the IACUC, but only for reasons of scientific necessity or non-availability of an acceptable veterinary or human pharmaceutical-grade product. As per federal policy, cost savings alone is not an adequate justification for using non-pharmaceutical-grade compounds in research animals.

For drugs that are not available except as chemical reagents for use in animals, proper methods to make compounds physiological and sterile are expected when possible. Such compounds should also be within the known lot potency date as provided by the drug company supplier, which can be obtained from technical services.