Institutional Animal Care and Use Committee
Clemson University

POLICY #21: INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC) POLICY FOR USE OF NON-PHARMACEUTICAL-GRADE AGENTS OR MIXTURES OF PHARMACEUTICALS IN RESEARCH WITH VERTEBRATE ANIMALS

Background: USDA Policy 3 states the following regarding the use of non-pharmaceutical grade drugs in animal research:

Investigators are expected to use pharmaceutical-grade medications whenever they are available, even in acute procedures. Non-pharmaceutical grade chemical compounds should only be used in regulated animals after specific review and approval by the IACUC for reasons such as scientific necessity or non-availability of an acceptable veterinary or human pharmaceutical-grade product. Cost savings alone are not an adequate justification for using non-pharmaceutical grade compounds on regulated animals.

The Guide for the Care and Use of Laboratory Animals (The Guide, 8th ed.) states the following regarding the use of non-pharmaceutical grade drugs in animal research:

The use of non-pharmaceutical grade chemical compounds may be necessary to meet the scientific goals of a project or when a veterinary or human pharmaceutical-grade product is unavailable. In such instances, consideration should be given to the grade, purity, sterility, pH, pyrogenicity, osmolality, stability, site and route of administrations, formulation, compatibility, and pharmacokinetics of the chemical or substance to be administered, as well as animal welfare and scientific issues relating to its use.

IACUC Considerations: Specific issues to consider include: a) safety; b) efficacy; and c) the inadvertent introduction of research-complicating variables. Although the potential animal welfare consequences of complications are less evident in non-survival studies, the scientific issues remain the same, and the principles and need for professional judgment outlined above still apply. In any case, the use of non-pharmaceutical grade chemicals or substances must be described and justified in the animal use protocol (AUP) and be approved by the CU-IACUC.

Any non-pharmaceutical chemical agents administered in survival studies must be sterile, maintained in a sterile container, and labeled to provide the name and concentration of the compound as well as its expiration date. The investigator, in consultation with the Attending Veterinarian, is responsible for determining the “shelf life” for the compound after being dissolved in solvent. If the shelf life is not obtainable, it is recommended that the drug solution be re-prepared each day it is used. Any untoward effects/negative outcomes should be reported to the Attending Veterinarian and the IACUC. The use of non-pharmaceutical grade substances in food animals precludes the use of the animal for food.