Use of Pharmaceutical Grade Compounds in Vertebrate Animals

Pharmaceutical grade compounds are to be used for all vertebrate species based on the Public Health Service Policy (PHS Policy), the United States Department of Agriculture (USDA) regulations, and The Guide for the Care and Use of Laboratory Animals (current edition). The use of non-pharmaceutical grade chemical compounds in experimental animals (including rats, mice, birds) under certain circumstances has been, and will continue to be, a necessary and acceptable component of biomedical research.

Their use should be based on:
- Scientific necessity
- Non-availability of an acceptable veterinary or human pharmaceutical grade product
- Specific review and approval by the Institutional Animal Care and Use Committee (IACUC)

In preparing and reviewing proposals to use non-pharmaceutical grade compounds, investigators and IACUCs should consider a number of related animal welfare and scientific factors including safety, efficacy, and the inadvertent introduction of research complicating variables. While issues such as sterility, pyrogenicity, stability, pharmacokinetics and quality control can be assumed to have been addressed during the course of producing pharmaceutical grade compounds, the same cannot always be said for substances produced in the research laboratory using non-pharmaceutical grade chemical compounds (e.g. saline, glucose, etc.). Cost savings alone is not an adequate justification for using non-pharmaceutical compounds in animals (e.g. Halothane, etc.).

In order to obtain IACUC approval for the use of non-pharmaceutical grade products, Addendum B: Use of Non-Pharmaceutical Grade Compounds must be completed. Although the potential animal welfare consequences of complications are less evident in non-survival studies, the scientific issues remain the same. The principles and need for professional judgment outlined above still apply.

The use of non-pharmaceutical grade compounds in vertebrate species must be explicitly detailed in the IACUC protocol and IACUC approval gained prior to use of the drug. Note that all secondary containers must be labeled according to IACUC policy #017.