Policy: Non-Pharmaceutical Compound Use

Definitions:

*Pharmaceutical grade compound:* Drug, biologic, or reagent that is approved by the FDA.

*Veterinary compounding:* Customized manipulation of an approved and prescribed drug by a veterinarian, or pharmacist, per veterinary prescription. For the purposes of the IACUC protocol, pharmaceuticals produced by a licensed compounding pharmacy per veterinary prescription are considered equivalent to pharmaceutical grade compounds and do not require special justification.

OLAW and USDA agree that pharmaceutical-grade medications and other chemical substances, when available, must be used to avoid toxicity or side effects that may threaten the health and welfare of animals and/or interfere with the interpretation of research results.

Principal Investigators are expected to use commercial and pharmaceutical-grade compounds (medications, vehicles, carriers) for all proposed animal activities, whenever possible. The proposed use of non-pharmaceutical-grade compounds should be evaluated for potential adverse consequences, taking into account the potential for side effects, sterility, biocompatibility, stability, compatibility of multiple components, etc. Cost savings alone are not an adequate justification for the use of non-pharmaceutical-grade or compounded drugs in animals.

**Use of non-pharmaceutical grade compounds must be clearly described and justified in a protocol (or related amendment) for IACUC review and approval, prior to any such use.**

Mixing of 2 or more pharmaceutical grade compounds, which is technically a form of compounding, is permissible provided that compatible drugs are mixed immediately before use. Storage of compounded medications, such as medications diluted in saline, should be justified and secondary containers should be labeled with contents, concentration, and expiration date. When mixing or diluting pharmaceutical grade compounds sterility needs to be consistent with intended route of administration. Compounded solutions intended for intravenous (IV) and intraperitoneal (IP) injection should be mixed and stored using strict aseptic technique. Oral medications should be handled in a sanitary fashion, but strict sterility is not required.

Additional information can be found at the OLAW FAQ F.4 here and at the AAALAC, Int’l FAQ here.