

AUBURN UNIVERSITY

Institutional Animal Care and Use Committee (IACUC)

Policy on the Use of Non-Pharmaceutical Grade Compounds

OLAW and USDA state that the use of non-pharmaceutical-grade compounds should be based on:

1. scientific necessity;
2. non-availability of an acceptable veterinary or human pharmaceutical-grade compound; and
3. specific review and approval by the IACUC.

Investigators should consider relevant animal welfare and scientific issues including safety, efficacy, and the inadvertent introduction of new variables. Although one can assume that issues such as sterility, pyrogenicity, stability, pharmacokinetics, and quality control have been addressed during the course of producing pharmaceutical-grade compounds, one cannot say the same for substances produced in the research laboratory using non-pharmaceutical-grade chemical compounds. Cost savings alone do not adequately justify the use of non-pharmaceutical-grade compounds in animals. 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.

The following points should be considered when submitting protocols for IACUC approval:

- 1) When used in animal research, non-pharmaceutical-grade compounds should go through a purification/ sterilization process such as filter sterilization e.g. 0.22 micron filter
- 2) Any expected side effects should be described.
- 3) A rationale for using non-pharmaceutical grade compounds should be included. Cost savings alone do not adequately justify the use of non-pharmaceutical grade compounds in animals.

ADOPTED: December 18, 2012
REAFFIRMED: October 4, 2021