

March 3, 2019

ANIMAL CARE AND USE PROGRAM
Non-Pharmaceutical Grade Chemical or Other Substances Use

1. **PURPOSE:** To consolidate APHIS/USDA, OLAW/NIH and AAALAC International policies, guidance and regulations related to the use of non-pharmaceutical grade (NPG) chemicals and other substances (i.e., compounds) in research with animals. As such, this document explains how the VA meets the expectations of all three organizations.
2. **POLICY:** Research Service implements the guidance provided in the Guide for the Care and Use of Laboratory Animals, Eighth Edition concerning the use of non-pharmaceutical drugs and or components.
3. **RESPONSIBILITY:** Investigators are responsible for insuring their research protocol and any affected amendments clearly define the use of non-pharmaceutical grade compound use in animal research and the impact of its use on animal health and the experimental data. Institutional Animal Care and Use Committee (IACUC) is responsible for evaluating the data provided by principal investigator and approving research.
4. **ACTION:**
 - a. **PHARMACEUTICAL-GRADE CHEMICALS OR OTHER SUBSTANCES:** The use of these chemicals or other substances ensures toxic or unwanted side effects are not introduced into studies conducted with experimental animals. Pharmaceutical-grade chemicals or other substances must be used when available for all animal related procedures.
 - b. **NON-PHARMACEUTICAL GRADE COMPOUNDS:** Investigators may use these compounds when the pharmaceutical-grade is unavailable or when there is a scientific justification which has been reviewed and approved by the IACUC. For example, the use may be necessary to meet the scientific goals of a project or when a veterinary or human pharmaceutical-grade product is unavailable. Principal investigators will include the following information in their Animal Component for Research Protocol (ACORP) or modification to protocol: safeguards used to ensure quality control/sterility during compound preparation plus site and route of administration of the chemical or substance to be administered, as well as animal welfare and scientific issues related to its use.
 - c. **RECOMMEND GUIDELINES:** Principal investigator and the IACUC should use the following as a guide in the submission and evaluation of an ACORP that intends to use non-pharmaceutical chemicals or compounds:
 - (1) The compound is required to generate data that are part of the study or that are comparable to previous work.
 - (2) The chemical properties of the compound are appropriate for the study and the route of administration.
 - (3) The method of preparation, labeling, administration and storage of formulations should be appropriately considered with the aim of maintaining their stability and quality.
 - d. **JUSTIFICATION:** The following are examples of scientific justification that would be acceptable for IACUC approval of NPG use in animal research studies:

RESEARCH SERVICE POLICY MEMORANDUM 19-72

- (1) An equivalent veterinary or human drug is available for experimental use, the chemical-grade reagent is required to replicate methods from previous studies because results are directly compared to those of replicated studies.
- (2) An equivalent veterinary or human drug is available, dilution or change in formulation is required
- (3) The available human or veterinary drug is not concentrated enough to meet experimental requirements.
- (4) The available human or veterinary drug does not meet the non-toxic vehicle requirements for the specified route of administration.
- (5) The available human or veterinary drug recent exorbitant cost increases due to unavailability or shortages have placed it logistically into the unavailable category
- (6) Cost savings alone is not a justification for using non-pharmaceutical-grade compounds in regulated animals.

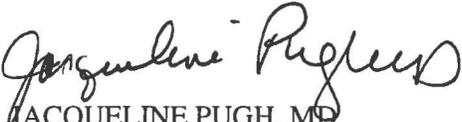
e. NPG COMPOUNDS: must be prepared according to industry standards or to established laboratory practices. Compounds must be labeled and include a date of preparation. A safety data sheet is the final requirement to provide information to the researcher in case of an accident in the use of the NPG.

5. **REFERENCES:** Guide for the Care and Use of Laboratory Animals, Eighth Edition; USDA Policy # 3, Veterinary Care; and OLAW/NIH Guidelines for the Use of Non-Pharmaceutical Grade Compounds in Laboratory Animals.

6. **RESPONSIBILITY:** ACOS for Research (151)

7. **RECISSION:** Research Service Policy Memorandum 13-72, dated March 2013

8. **RECERTIFICATION:** March 2024


JACQUELINE PUGH, MD
ACOS Research and Development