

Non-Pharmaceutical Grade Substance Policy

Adopted by UCAR October 17, 2012

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“OLAW and USDA agree that pharmaceutical-grade¹ chemicals and other substances, when available, must be used to avoid toxicity or side effects that may threaten the health and welfare of vertebrate animals and/or interfere with the interpretation of research results². However, it is frequently necessary to use investigational compounds, veterinarian- or pharmacy-compounded³ drugs and/or Schedule I⁴ controlled substances to meet scientific and research goals.” [OLAW FAQ F4](#): May investigators use non-pharmaceutical-grade compounds in animals?

Definition – pharmaceutical-grade compound is a drug, biologic, or reagent that is approved by the Food and Drug Administration (FDA) or for which a chemical purity standard has been established by the [United States Pharmacopeia-National Formulary](#) (USP-NF), or [British Pharmacopeia](#) (BP).

Procedures that may cause more than momentary or slight pain or distress to animals must be performed using veterinary or human pharmaceutical grade compounds unless the use of the investigational chemical or formulation is scientifically necessary, appropriately justified and approved by UCAR. Examples of commonly used drugs are: Analgesics (e.g. buprenorphine), anesthetics (e.g. ketamine), euthanasia agents (e.g. Euthasol™, Sleep Away™) and paralytics (e.g. Vecuronium).

When a non-pharmaceutical grade substance is proposed for experimental use, the investigator and UCAR must consider animal welfare and scientific issues related to the use of substances in all survival and non survival studies. For all non-pharmaceutical grade substances **used in laboratory animals, the Investigator and UCAR shall consider the following factors: grade/purity being proposed, the formulation of the final product, and issues such as sterility, pyrogenicity, stability, pH, osmolality, site/route of administration, pharmacokinetics, physiological compatibility, side effects and adverse reactions, storage and quality control.** Cost savings alone is not an adequate justification for the use of non-pharmaceutical-grade or compounded drugs in animals. If you adhere to the provisions in this policy then you are adhering to UCAR guidelines. If you have any questions regarding this policy, please contact the UCAR office at X5-1693.

OLAW's guidance on the use of non-pharmaceutical-grade substances was first published in 2003 (Lab Animal. 2003;32(9):33-36) and posted on the OLAW website on September 11, 2006. The USDA's position on non-pharmaceutical-grade substances may be found in the Animal Care Manual Policy 3. On March 1, 2012, OLAW, with USDA and AAALAC, offered additional guidance through a webinar on the "Use of Non-Pharmaceutical-Grade Chemicals and Other Compounds in Research with Animals."

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2 A listing of pharmaceutical-grade drugs and biologics is available through the FDA database. The Orange Book is the reference for FDA-approved human drugs. The Green Book is the reference for FDA-approved veterinary drugs.

3 Veterinary compounding is the customized manipulation of an approved drug by a veterinarian, or by a pharmacist upon the prescription of a veterinarian, to meet the needs of a research study. IACUCs considering the use of veterinary compounding for research purposes are advised to consult Veterinary Compounding for more information about federal regulations.

4 United States Department of Justice Drug Enforcement Agency controlled substances Schedule I and II-IV drugs may be used in biomedical research according to the standards of the Code of Federal Regulations 1301.13.