OFFICE OF ANIMAL CARE AND USE (OACU)
INFORMATIONAL MEMO
August 2011

In order to provide better service to our Principal Investigators (PI), research staff, and administrative managers, the Office of Animal Care and Use (OACU) has compiled this informational memo. Please feel free to call the OACU staff if you have any questions about any items in this memo.

Use of Non-Pharmaceutical-Grade Compounds in Animals

All agents used for anesthesia, analgesia, euthanasia and acute intervention are required to be pharmaceutical or veterinary grade, unless the use of a research grade agent has been approved by the Institutional Animal Care and Use Committee (IACUC).

New Animal Care Application (ACAP) Addendum – Treatment of Live Animals with Non-Pharmaceutical-Grade Compounds (this includes all experimental compounds, anesthetics, analgesics and agents used for euthanasia and acute intervention)

ACAP contains a new addendum (Addendum 11.2) to be completed when investigators submit new or continuing applications or amendments proposing the use of non-pharmaceutical grade compounds in live animals. Pharmaceutical-grade refers to a product that: a) is at least 99% pure with no unknown substances, b) is produced in a government approved facility with appropriate documentation, and c) meets consistent specifications for each batch of product produced.

The Guide for the Care and Use of Lab Animals (8th Edition) states that “pharmaceutical-grade chemicals should be used, when available, for all animal-related procedures. The use of non-pharmaceutical-grade chemicals or substances should be described and justified in the animal use protocol and be approved by the IACUC. Consideration should be given to the grade, purity, sterility, pH, pyrogenicity and pharmacokinetics of the chemical or substance to be administered, as well as animal welfare and scientific issues relating to its use”. The Office of Laboratory Animal Welfare (OLAW), United States Department of Agriculture (USDA) and National Institutes of Health (NIH) (Wolff et al., 2003; USDA 1997; NIH 2008) consider that the use of non-pharmaceutical grade compounds in animals “should be based on: (1) scientific necessity, (2) no availability of an acceptable veterinary or human pharmaceutical-grade compound, and (3) specific review and approval by the IACUC.
Obtaining Pharmaceutical and Veterinary Agents for Use in Animals

Investigators are increasingly having a difficult time ordering the necessary agents to be used in research experiments, irrespective of whether the agent is a controlled or non-controlled substance. Vendors readily sell veterinary agents to individuals with a veterinary license. Some are willing to accept a DEA Researcher License if a veterinary license is not available. However, in order to purchase a controlled substance, each individual must have a DEA Researcher License. OACU personnel spoke with a Program Manager at the Department of Human Health and Services (DHHS) -NC in order to inquire about the possibility of an Institutional DEA License. The Program Manager indicated that this is no longer a viable option as the updated federal policy requires knowledge of where and how the individual controlled substances are stored.

To apply for a DEA Researcher License, contact the DHHS-NC Controller at (919) 733-1765 to request a NC Controlled Substances Registration Certificate. This certificate must be approved prior to applying for the federal license. Information about obtaining a license can be found in http://www.deadiversion.usdoj.gov/drugreg/index.html

The following companies may provide veterinary grade agents to researchers who are able to supply a DEA Researcher License in lieu of a veterinary license. The IACUC cannot endorse these pharmaceutical firms, nor can it guarantee that these firms will continue to supply these pharmaceuticals in forms suitable for animal studies.

- **MedVet International** (800-544-7521) [http://www.shopmedvet.com/]
  Has an in-house veterinarian who reviews all veterinary product orders. The veterinarian may permit the purchase of these veterinary products (controlled or non-controlled) with a DEA Researcher License, particularly if the recipient is a research institution.

- **Southern Anesthesia** ([http://sasvet.com/]), ask for Cooper (800-456-0757 ext 265)
  Currently, researchers holding a DEA Researcher License may purchase veterinary drugs.

- **TW Medical** (888-787-4483) [http://www.twmedical.com/]
  Has recently merged with a new company, and the inventory is reduced. This company will sell items in stock to researchers who hold a DEA Researcher License.

- **Purchase of Isoflurane from North Carolina Hospitals**
  - Place an order through Pharmacy Support, located on the ground floor of the Memorial Hospital, (919) 966-1368 or 966-1366
    - Fill out and submit an order sheet located outside the entrance
    - The following information must be provided
      - Grant number
      - 6-digit stock number (a reference book is located with the order sheets)
      - Product name
      - Quantity required
    - Ensure you have valid UNC identification

- As an alternative to the veterinary product suppliers, it may prove beneficial to contact a pharmacy compounding facility for the pharmaceutical manufacture of agents required in...
Currently, pharmaceutical grade powdered Sodium Pentobarbital can be ordered from PCCA (Professional Compounding Centers of America). Contact at www.pccarx.com or 1-800-331-2498. A copy of the DEA-222 license will need to be mailed to PCCA for regulatory purposes.

Pharmaceutical Grade Tricaine Methanesulfonate (MS222)
- Finquel: http://www.argent-labs.com/argentwebsite/ms-222.htm

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