Buprenorphine—now a Schedule III Controlled Substance

Buprenorphine, a semisynthetic opioid, has been classified as Schedule V drug since 1985. On 7 October 2002, the Drug Enforcement Administration (DEA) issued its final rule to reschedule buprenorphine from Schedule V to Schedule III under the Controlled Substances Act (CSA). As required by 21 USC 812 (b) for Schedule III control, the DEA determined that (1) buprenorphine has a potential for abuse less than the drugs or other substances in Schedules I and II; (2) buprenorphine has a currently accepted medical use in treatment in the US; and, (3) abuse of buprenorphine may lead to moderate or low physical dependence or high psychological dependence. This change requires users of this drug— one of the most frequently used analgesics for laboratory animals—to update their DEA licenses appropriately.

Investigators may obtain controlled substances permits for research purposes. Both state and federal permits are required. Application forms for the federal license may be obtained on-line at www.deadiversion.usdoj.gov (toll-free telephone 1-800-882-9539). The South Carolina application may be obtained by writing to: SC Dept of Health and Environmental Control, Division of Drug Control, 2600 Bull St., Columbia, SC 29201 (telephone 803-896-0634).

Significant Changes to an AUP

The IACUC wants to stress the importance of timely submission and approval of any significant change or amendment to an approved animal use proposal (AUP). Both the Animal Welfare Act Regulations and Public Health Service Policy require that the IACUC review and approve proposed significant changes to ongoing activities using animals prior to initiation. Some examples of significant changes requiring proposal amendments are changes in: objectives of the study; species or number of animals; degree of invasiveness; switch from nonsurvival to survival surgery; anesthetic or analgesic agents; personnel who treat or handle animals; method of euthanasia; and, other procedures which may change the level of potential pain and discomfort to the animals.

Protocol changes which are very complex or submissions of multiple sequential amendments to an existing protocol are not well suited to the amendment mechanism. Ideally, revisions submitted as amendments should be relatively simple and should not affect the existing documentation. Complex changes to an approved AUP should be documented by the submission of a completely rewritten protocol which must go through the same approval mechanisms as the original protocol before animal experiments can proceed.
The domestic rabbit, *Oryctolagus cuniculus*, has been and continues to be used extensively in research and testing. Rabbits are used in a great variety of biomedical investigations, including studies of hydrocephalus, arteriosclerosis, hyperthermia, malignant lymphoma, teratology, cosmetics, ophthalmology, and reproductive physiology. They are also used frequently as sources of hyperimmune sera and antibody. The most common breed used in research is the albino New Zealand White. An adult male rabbit is called a *buck*, an adult female rabbit is called a *doe*, and an immature rabbit is called a *kit*. Typically, a quarantine period of 14 days is required for rabbits.

The following lists approximate values of life cycle and physiologic data of the rabbit.

**Adult body weight:**
- Male (*buck*) .................. 2-5 kg
- Female (*doe*) .................. 2-6 kg

**Birth weight** .................. 30-80 g

**Weaning age** .................. 4-6 wk

**Life span** .................... 5-6 yr or more

**Cycle length** .................. Induced ovulator

**Gestation period** .......... 29-35 days

**Litter size (no. kits)** ........ 4-10

**Diploid number** ............ 44

**Daily Food intake** .......... 5g/100 g bw

**Daily water intake** ........ 5-10 ml/100 g bw

**GI transit time** ............. 4-5 hr

**Rectal temperature** ........ 38-40 ºC

**Heart rate** .................. 200-300 beats/min

**Respiratory rate** .......... 32-60 breaths/min

**Blood volume** .............. 55-65 ml/kg bw

**Packed cell volume** ........ 34-43 %

**Hemoglobin** ................ 9.8-14.0 g/dl

**Blood pressure** ............ 90-130/80-90 mm Hg

Sources:
The University of South Carolina's animal care and use program first received accreditation by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International in 1984. Since then, USC has maintained Continued Full Accreditation. Program evaluations and site visits are conducted every three years as a requirement for continued accreditation. AAALAC just notified USC of its upcoming triennial accreditation site visit this fall.

Accreditation is voluntary — so why is it that important? It is the gold standard for the humane care and treatment of animals used in teaching and research. At the same time, it enhances the overall quality of science and promotes the validity of research in which animals are used. When a researcher applies for a grant, the funding agency is made aware of USC’s AAALAC accreditation. The funding agency views this as a symbol of quality animal care.

Earlier this year, the US Government introduced a new website—www.regulations.gov—that, according to the site’s homepage, will make it easier for the public “to participate in Federal rulemaking—an essential part of the American democratic process”. This new, easy-to-use website may make it significantly easier for citizens concerned with animal welfare to learn about new regulations on the care and use of laboratory animals, and to respond to them quickly and effectively.

The new website contains descriptions of every proposed and final Federal regulation currently open for comment and published in the Federal Register. Visitors can submit their comments through this website to the participating government agencies, including the Department of Agriculture (USDA) and the Department of Health and Human Services (DHHS).
Animal Care Matters is published four times a year by the Institutional Animal Care and Use Committee (IACUC) and Animal Resource Facilities (ARF) of the University of South Carolina (USC).

The IACUC is an institutional body appointed by the USC President to oversee the program for the humane care and use of all vertebrate animals used for research, teaching, and training. Any investigator who intends to use laboratory animals must submit an Animal Use Proposal (AUP) to the IACUC for its review and approval.

The ARF provides care and maintenance of all animals used by investigators. Preventive care is provided through vendor animal health evaluations, quarantine programs, and sentinel animal diagnostics. Special care and services can be provided upon request.

Comments and submissions for Animal Care Matters are welcome and should be directed to Benilda P. Pooser, Ph.D., IACUC Administrator, at 777-8106 or pooser@gwm.sc.edu.

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