Policy # SI-10-2013

Policy Title: Determining Expiration Dates

Policy: In order to be in compliance with federal regulations, drugs and medications for use in live animals must be labeled with an expiration date. In addition, in order to ensure sterility of supplies to be used in survival surgeries, autoclaved items must also be labeled. This document provides guidelines for determining the expiration dates of medications and materials intended for use in animal research. Note: Products that do not fall under the category of a “drug” or “medication” do not fall under this policy and individual researchers should use their best judgment when using these products (which frequently are not labeled with an expiration date). The manufacturer’s label should be consulted in these instances.

Definitions: A “drug” is defined by the FDA as: “(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.

General Guidelines

1. When ordering drugs or medications that you don’t use up quickly, it is best to inquire at the time of ordering regarding the expiration date of the lot # the company plans to send you in order to make sure they don’t send products that will be expiring soon.

2. Order small quantities whenever possible and check with other researchers using the same drug to look into the possibility of combining purchases.

3. In order to assure that expired items are identified and discarded, each researcher should inspect their storage areas on a monthly basis.

Dating of Materials

1. Sterile medical supplies: Pre-packaged sterile medical products such as suture material or surgical gloves are distributed with an expiration date. Medical materials marked with an expiration date cannot be used for survival procedures after that date, and should be discarded or, if applicable, re-sterilized.
2. Sterile surgical packs: Sterilized instruments or supplies should be marked with an expiration date based on the date of sterilization. They should be marked with an external “process indicator” such as autoclave tape and should contain a sterilization indicator within the packaging. Cloth-wrapped, paper wrapped, and Dennison® wrapped sterilized equipment have a shelf life of one month. Plastic-wrapped sterilized items (e.g., peel-packs) have a shelf life of 6 months.

Dating of Medications

1. In order to comply with federal regulations, all medications intended for use in live animals must be labeled with an expiration date.

2. Follow the manufacturer’s recommendations as printed on the bottle or package insert of expiration date and storage conditions.

3. Drugs without manufacturer’s expiration dates should be dated upon receipt. The researcher should determine the stability of the drug in order to predict a reasonable shelf life. This is commonly obtained from the manufacturer. If stability is unknown, the drug should not be used beyond one year from purchase.

4. In cases where you reconstitute or aliquot drugs so that they are no longer in their original containers marked with a manufacturer’s expiration date, all containers must be labeled with contents, concentration, date of mixing and expiration date.

Drug Mixtures and Non-manufactured Drugs

1. If refrigerated between uses, multi-dose containers of fluids used for IV or SC administration (e.g. normal saline, lactated Ringers) expire 30 days after opening.

2. If a drug is transferred unchanged into a sealed, sterile container using aseptic technique (e.g. a red-top vacutainer or empty sterile vial), the new label should retain its original expiration date.

3. Unless efficacy beyond 30 days can be demonstrated (i.e. through the use of pharmacokinetic or performance based measures), a drug is diluted or mixed with another compatible drug and transferred to a sealed, sterile container using aseptic technique, expires in 30 days (or at the earliest expiration date of the component drugs, whichever comes first). If a PI wishes to use these types of mixtures beyond the 30 day expiration period, the efficacy data must be provided to support the safe and effective use of those drugs after mixing. In these cases, the expiration date will be the earliest of the original expiration dates of the components of the mixture.