College of Veterinary Medicine Policies and Procedures

Subject: Adverse Drug Event Reporting Protocol

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ADVERSE DRUG EVENT REPORTING PROTOCOL

Purpose:

1. To monitor adverse events associated with the use of drugs, biologics and pesticides in animals that are patients of the Animal Health Center and to provide this information to the appropriate agencies in an effort to help prevent future adverse reactions.

2. To monitor adverse events associated with drugs, biologics and pesticides experienced by a client, animal handler, veterinarian, technician, student, or anyone involved with the treatment of Animal Health Center patients.

Procedures: The Animal Health Center shall review and report all suspected adverse medication and biological events to manufacturers and appropriate regulatory agencies such as the United States Department of Agriculture (USDA) for biologics, the Food and Drug Administration (FDA) for drugs, and the Environmental Protection Agency (EPA) for topically applied external parasiticides in the following manner:

1. Upon observation of a suspected adverse event in a patient as defined below, the veterinarian assigned to the case will complete the Animal Health Center Adverse Drug Reaction Reporting Form and submit it to the Pharmacist for completion of the pharmacy review section of the form.

2. The Pharmacist will return the completed form to the veterinarian along with the reporting information for submission to the appropriate agencies.

3. It is the responsibility of the veterinarian on the case to obtain client consent prior to submission of reports to the manufacturer and regulatory agency and to make sure that the completed forms are then submitted to the proper agencies.

4. A copy of the completed forms shall be retained in the Pharmacy and in the patient's medical record.

5. If the adverse event affects a human, the event will be reported to the manufacturer and the appropriate agency. In addition, the person's physician will be contacted and provided with all pertinent information regarding the incident, including the veterinarian's knowledge of the adverse reaction, information regarding the manufacturer, and place of acquisition, as well as the veterinarian's reporting procedure and feedback received as a result of the report.

Definitions:

a) Adverse Drug Event – The Center for Veterinary Medicine (CVM) defines and ADE as "any side effect, injury, toxicity, or sensitivity reaction (or failure to perform as expected) associated with use of an animal drug, whether or not determined to be attributable to the drug". The Adverse Event Reporting Protocol also applies to human-approved drugs when administered to veterinary patients. Refer to the FDA website: www.fda.gov/cvm/

b) Vaccine or biological reaction – The USDA defines an adverse event as any undesirable occurrence after the use of an immunobiological product, including illness or reaction, whether or not the event was caused by the product. For products intended to diagnose disease, adverse events refer to anything that hinders discovery of the correct diagnosis. Refer to the USDA website: www.usda.gov/

c) Insecticide reaction – The Environmental Protection Agency (EPA) has jurisdiction over topically applied insecticides. Any suspected reaction should be reported to the EPA Office of Pesticide Programs at (800) 858-PEST. Refer to the EPA website: www.epa.gov/

d) Reports – Completed reports should include all information pertinent to the patient including name, breed, age, reaction and treatment as well as the overall health status and previous history.

Approved: Gary J. Burt 9-26-12

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