RESPONSIBILITIES OF THE CLINICAL INVESTIGATOR IN TESTING INVESTIGATIONAL NEW ANIMAL DRUGS

The development and approval of new drugs for animals is important to the continued well-being of the nation's animal population. If the drug is to be used in food-producing animals, the use of the meat, milk and eggs for human consumption from treated animals must be considered.

As a participant in the development process of a new animal drug, the investigator must be:

1. Qualified by scientific training or experience to evaluate the safety and effectiveness of the Investigational New Animal Drug.
2. Able to conduct investigations (trials) exactly as described in the Investigational New Animal Drug (INAD) file. Before the sponsor of the INAD can ship or deliver an investigational drug, he or she is required to submit to the Food and Drug Administration (FDA) all pertinent information to be supplied to the investigator.

There are several requirements specified in INAD regulations with which the investigator must comply:

1. The investigator cannot use the drug in any other way than described in the investigational and in the animal use protocol.
2. The investigator is required to maintain complete records of the investigation. These records must include the receipt and disposition of each shipment or delivery of the drug under investigation. Copies of all records of the investigation must be retained by the investigator for 2 years after the termination of the investigation of approval of a New Animal Drug Application. The sponsor is obligated to report any adverse effects associated with the drug usage to FDA. If the investigator fails or refuses to report his findings to the sponsor, he or she is no longer qualified as an investigator. Such omissions will reflect on the final outcome of the New Animal Drug Application.
3. Authorization for disposal of investigational animals for food purposes must be obtained by the sponsor of the INAD. This authorization does not exempt investigational animals from compliance with other applicable inspection requirements. A request for authorization must be supported by evidence to show that food derived from treated food-producing animals will be consistent with public health, or that the food product does not contain residues or metabolites of the drug. When an investigator plans to ship animals to a processing plant, he or she must notify the sponsor when and where he or she plans to ship the animals. The sponsor should notify FDA and U.S. Department of Agriculture (USDA) at least 10 days prior to shipment. FDA works in liaison with the USDA inspectors at processing plants to assure that animals offered for slaughter are properly inspected.

4. If an investigational drug is also subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970, records concerning shipment, delivery, receipt and disposition of the drug, which are required to be kept under Section 511.1(a) and (b), Title 21, Code of Federal Regulations, shall, upon request of a properly authorized employee of the Bureau of Narcotics and Dangerous Drugs of the U.S. Department of Justice, be made available by the investigator or sponsor to whom the request is made, for inspection and copying.
5. Unlicensed experimental veterinary biological products are regulated by the USDA.