PetMedicus Laboratories Receives MUMS Designation for Ondansetron (VML-028) in Cisplatin-Induced Emesis

PetMedicus Laboratories, a client of ACI, was officially granted Minor Use and Minor Species (MUMS) status for their generic version of ondansetron (VML-028) for use in prevention of cisplatin-induced emesis on August 24, 2007 (http://www.fda.gov/cvm/MumsDesigList.htm). ACI played an important role in helping PetMedicus obtain this designation, representing only the second approved application for minor use in a major species of a Center for Veterinary Medicine (CVM) drug candidate. The designation was, in part, due to the completion of epidemiologic surveys by the ACI oncology network sites. These surveys provided essential population data that enabled the CVM to determine that the PetMedicus application fulfilled the requirements for minor use of a potential drug candidate.

Overview of MUMS

The US Food and Drug Administration (FDA) created the Minor Use and Minor Species Animal Health Act of 2004 (MUMS act) http://www.fda.gov/cvm/MUMSDrugDesg.htm. The MUMS act amended the Federal Food, Drug, and Cosmetic Act by, among other things, establishing section 573 to create new regulatory procedures that provide incentives intended to make more drugs legally available to veterinarians and animal owners for the treatment of minor animal species and uncommon diseases in major animal species. This Act parallels similar legislation passed under the Orphan Drug Act http://www.fda.gov/orphan/oda.htm for humans. The final rule implements section 573 of the MUMS act and describes the procedure for designating a new animal drug as a minor use or minor species drug. MUMS designation of a new animal drug grants drug sponsors seven years of exclusive marketing rights for these limited-demand drugs to encourage the commercial development of drugs for minor uses or in minor animal species.

Thanks to all of our ACI network sites for their participation and assistance in completing these invaluable surveys!