

Animal Health - A Core Business

Sinclair Provides Capabilities and Services for Animal Health Clients Submitting Master Files Supporting INADAs, NADAs, ANADAs to the FDA's Center for Veterinary Medicine

Special Capabilities

- ☛ Felines
- ☛ Canines
- ☛ Large in-house colonies of non-naïve animals of dogs and cats, plus Class A suppliers of naïve animals.
- ☛ Miniature Swine – Breeding Colony (Sinclair, Yucatan, Hanford)
- ☛ Housing and SOPs for the following species:
 - Goats
 - Sheep
 - Rodents (Mouse, Rat, Hamster)
 - Horses
 - Rabbits
 - Poultry
 - Ferrets
- ☛ High Capacity for Small and Large Animals

NADA Technical Sections – Requirements, In Part:

- ☛ Effectiveness
- ☛ Target animal safety
- ☛ Human food safety (Tissue Residue Depletion)

Sinclair can Demonstrate Effectiveness by well-controlled studies...

- ☛ Efficacy studies in a target species
- ☛ Laboratory animal studies
- ☛ Bioequivalence studies (Efficacy vs Blood Level)

Sinclair has a long history of evaluating the efficacy of test articles for human and animal health in a number of therapeutic areas, including nutrition, obesity, diabetes, cardiovascular, wound healing, osteoporosis, ocular, dermal, antibiotics, vaccines, and parasite control.

Target Animal Safety and Human Safety (Food Animal Drug Residues)

Sinclair Capabilities:

- ☛ Pilot dose escalation studies
- ☛ MTD studies
- ☛ Tolerance studies
 - 10X dose at max duration (acute administration)
 - 21 days (long-term administration)
- ☛ Toxicity/margin of safety studies
 - Toxicity studies in the target animal species under conditions of use
 - Maximum dose with no adverse effect
 - Margin of safety in the target animal
- ☛ Special Studies
 - Reproductive safety studies (neonatal swine capability)
 - Injection site irritation (injectables)
 - Animal class safety studies (e.g., pediatric, geriatric)
- ☛ Toxicology for Human Safety
 - 90-day feeding studies
 - One-year (chronic) feeding studies
- ☛ Drug Residues
 - Total residue and metabolism Study
 - Determine the marker residue
 - Determine the target tissue
 - Tissue residue depletion (muscle, kidney, liver, fat, milk, eggs)
 - Objective: Run a residue depletion study under field conditions to determine how long it takes marker residues to deplete to below the tolerance.
 - User safety – e.g., residue determination after topical applications