

Form MT-W: Worksheet for Designing Individual Field Trials Under MT INAD 11-236

INSTRUCTIONS

1. Investigator must fill out Form MT-W for each trial conducted under this INAD **before** actual use of MT medicated feed. The Investigator is responsible for accurate completion of Form MT-W.
2. Investigator should keep the original on file, and fax a copy to the Study Monitor for review.
3. After review, the Study Monitor will fax a copy to the AADAP Office for assignment of the Study Number.
4. The AADAP Office will review the worksheet, and then fax the assigned trial Study Number to both the Investigator and Study Monitor, at which time the trial may be initiated.
5. **Note:** Both Investigator and Study Monitor should sign and date Form MT-W.

SITE INFORMATION

Facility	Tilapia Farm A		
Address	123 Fish Hatchery Rd		
	Anytown, MT 01234		
Investigator	John Doe		
Reporting Individual (if not Investigator)			
Phone	555-555-5555	Fax	555-555-5556

FISH CULTURE AND DRUG TREATMENT INFORMATION

Manufacturer of MT medicated feed		Rangen Inc.	
MT medicated feed batch number	R-79B-354-2007	MT medicated feed manufacture date	1-11-08
Treatment dosage	9 mg/kg bw/day	Treatment duration	28 days
Fish species to be treated	Calif. Mosambica	Number of fish to be treated	500,000
Fish age (days post-hatch)	2	Average fish length (mm)	5
Number of rearing units to be treated	15	Number of fish per treated rearing unit	40,000 - 60,000
Number of control rearing units	0	Number of fish per control rearing unit	0
Feed rate (% body weight fed per day)	15	Estimated total weight of fish treated (kg)	250 kg
Estimated amount of MT medicated feed needed for proposed treatment (kg)			250 kg
Anticipated date treatment will be initiated		August 2008	

Worksheet for Designing Individual Field Trials (cont.)

STUDY DESIGN: Describe in detail the purpose of the clinical trial. Study design must be carefully focused and lend itself to rigorous evaluation. If more space is required to describe study details, title additional page(s) "Study Design" and attach them to this Worksheet.

Eggs will be collected for two weeks consecutively, and the fry will be sex reversed following the study protocol.

Study designed by Joe Brown

DISPOSITION OF TREATED FISH (Human Food Safety Considerations):

JD Investigator should initial here to indicate awareness that fish disposition must be in compliance with FDA-mandated withdrawal times as described in the Study Protocol.

USE AND DISPOSITION OF MT MEDICATED FEED (Environmental Safety Considerations):

JD Investigator should initial here to indicate awareness that MT medicated feed usage and disposition must be in compliance with requirements described in the Study Protocol.

WORKER SAFETY CONSIDERATIONS:

JD Investigator should initial here to indicate that all personnel handling MT medicated feed have read the Material Safety Data Sheet for 17-alpha methyltestosterone and have been provided personal protective equipment, in good working condition, as described in the Study Protocol.

Date Prepared: 8/1/08 Investigator: John Doe

Date Reviewed: 8/1/08 Study Monitor: Joe Brown