

Form OTC-W: Worksheet for Designing Individual Field Trials under INAD 9332

INSTRUCTIONS

1. Investigator must fill out Form OTC-W for each trial conducted under this INAD **before** actual use of Oxytetracycline Medicated Feed. The Investigator is responsible that Form OTC-W is completed accurately.
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 OTC-W.

SITE INFORMATION

Facility			
Address			
Investigator			
Reporting Individual (if not Investigator)			
Phone		Fax	

FISH CULTURE AND DRUG TREATMENT INFORMATION

Fish species to be treated		Disease to be treated	
Average fish weight (gm)		Average fish length (in)	
Number of fish per unit (e.g. 10,000 fish/raceway)			
Number of treated units		Number of treated fish	
Number of untreated control units		Number of control fish	
Estimated total weight of fish to be treated (lbs)		Projected % body weight to be fed	
Planned % TM pre-mix (e.g. 2, 4, 6%) in feed (see feed company order sheet)		Intended OTC dosage (gm/100 lbs fish/day)	
Planned duration of drug treatment (days)		Estimated total amount of medicated feed needed for proposed treatment (lbs)	
Anticipated date treatment will be initiated			
OTC-Feed manufacturer		OTC-Feed lot number	

STUDY DESIGN: Describe in detail the purpose of the clinical trial. For example you might compare OTC dosage, number of fish per unit, or disease to be treated. 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.

Study designed by _____

DISPOSITION OF TREATED FISH (Human Food Safety Considerations):

Check applicable box(es):

Study Objective A - Current label: salmonids; 21 day withdrawal period

Study Objective B - 10 gram dosage: all freshwater and marine species; 70 day withdrawal period

Study Objective C - Current label: non-salmonid freshwater and marine species; 40 day withdrawal period

Study Objective D - 6.0 gram dosage: abalone 35 day withdrawal period

Study Objective E - Mark skeletal tissue in a variety of fish species; 21 days for standard dose (salmonids); 40 days for standard dose (non-salmonids); 70 days for high dose (all species)

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

WORKER SAFETY CONSIDERATIONS:

Investigator should initial here to indicate that all personnel handling drug have read Material Safety Data Sheet for Terramycin[®] 200 for Fish and have been provided protective equipment, in good working condition, as described in the MSDS.

Date Prepared: _____

Investigator: _____

Date Reviewed: _____

Study Monitor: _____