

Form OTIMM-W: Worksheet for Designing Individual Field Trials under Terramycin 343® INAD 9033

INSTRUCTIONS

1. Investigator must fill out Form OTIMM-W for each trial conducted under this INAD **before** actual use of Oxytetracycline for Immersion. The Investigator is responsible that Form OTIMM-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 OTIMM-W.

SITE INFORMATION

| | | | |
|--|---------------------|-----|--------------|
| Facility | Fish Hatchery A | | |
| Address | 123 Hatchery Rd | | |
| | Anywhere, USA 55555 | | |
| Investigator | John Doe | | |
| Reporting Individual (if not Investigator) | | | |
| Phone | 555-555-5555 | Fax | 555-555-5556 |

FISH CULTURE AND DRUG TREATMENT INFORMATION

| | | | |
|---|----------------|--|--------|
| Fish species to be treated | White sturgeon | Disease to be treated | BGD |
| Average fish weight (gm) | 80.0 | Average fish length (in) | 10.0 |
| No. of fish per unit (e.g. 10,000 fish/raceway) | | | 5,000 |
| Number of treated units | 1 | Number of treated fish | 5,000 |
| Number of untreated control units | 0 | Number of control fish | 0 |
| Anticipated date treatment will be initiated | March 3, 2008 | Anticipated number of treatment | 4 |
| Intended drug target dosage (mg/L) | 20 | Estimated total weight of fish treated (lbs) | 881 |
| Estimated total amount of drug needed for proposed treatment (gm) | 1600 | Planned duration of drug treatment (hours) | 1 |
| Drug manufacturer | pfizer | Drug lot number | 111222 |

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.

To control mortality caused by BGD in white sturgeon.

Study designed by

John Doe

DISPOSITION OF TREATED FISH (Human Food Safety Considerations):

36 months Estimated time (days, months) from last treatment day to first possible harvest for human consumption

Check applicable box(es):

Study Objective A - Withdrawal period of 21 days for variety of salmonid fish.

Study Objective B - Withdrawal period of 21 days for non-salmonid fish.

Study Objective C - Withdrawal period of 60 days for variety of salmonid fish.

Study Objective D - Withdrawal period of 60 days for non-salmonid fish.

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 343[®] and have been provided protective equipment, in good working condition, as described in the MSDS.

Date Prepared: 2/25/08

Investigator: Sign here

Date Reviewed: 2/25/08

Study Monitor: Sign here