

## Oxytetracycline Bath Marking Clinical Field Trials

### OTM-3: Results Report Form - Version 4

### Oxytetracycline Bath Marking INAD 9033

#### **INSTRUCTIONS**

1. Investigator must fill out Form OTM-3 no later than 10 days after completion of the 20-day post-treatment observation period. Study Number must be recorded on all pages of Form OTM-3. Attach lab reports and other information.
2. If Oxytetracycline Bath Marking was not used under the assigned Study Number, fill out only the Site Information portion on this page, and skip to the end of page 3 and fill out only the "Negative Report" section.
3. Investigator should keep the original on file, and send a copy to the Study Monitor. Within 10 days of receipt, the Study Monitor should send a copy to the Bozeman NIO for inclusion in the permanent file.
4. **Note:** Both Investigator and Study Monitor should sign and date Form OTM-3.

#### **SITE INFORMATION**

Facility	
Reporting Individual	

#### **FISH CULTURE AND DRUG TREATMENT INFORMATION**

Drug lot number		Total amount of drug used (gm)	
Fish species treated		OTM dosage used (mg/L)	
Average fish weight (gm)		Average fish length (in)	
Number of fish per unit (e.g. 10,000 fish / tank)			
Number of treated units		Total number of treated fish	
Number of control units		Total number of control fish	
Treatment duration (hours)		Immersion date	

#### **WATER QUALITY PARAMETERS**

Ave pre-treatment temp (°F)		Dissolved Oxygen (mg/L)	
Ave treatment temp (°F)		pH	
Ave post-treatment temp (°F)		Hardness - CaCO <sub>3</sub> (mg/L)	

### Marking Record - Version 4

**INSTRUCTIONS**

1. Investigator should fill out the Marking Record as completely as possible.
2. Prior to initiation of the trial, fill out Rearing Unit ID, whether a rearing unit is Treated or Control, and the number of fish in each rearing unit.
3. Enter the **“Marking Grade”** for each unit in the proper column to indicate the quality of the mark:  
3 = excellent, 2 = good, 1 = poor, and 0 = no mark.
4. Use additional copies of this form if more than 6 rearing units are involved in the trial.

		Facility:							
		Rearing Unit ID							
		<u>T</u> reated or <u>C</u> ontrol							
		Number of Fish							
Fish Number	Date	Days Post Treatment	Mark	Mark	Mark	Mark	Mark	Mark	Observer Initials
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									
12									
13									
14									
15									
16									
17									
18									
19									
20									

**RESULTS:** Describe in detail treatment results. Was treatment successful? If treatment did not appear to be successful, explain why not? Were there any mitigating environmental conditions that may have impacted treatment results? Were there any deviations from the Study Protocol?

**Pathology Report:** Attach pathology report to this form. Report should include: 1) a description of how the pathogen(s) was identified; 2) disease identification records that confirm the presence of the pathogen; and 3) the name and title of the individual performing the diagnosis.

Pathology Report included:  pre-treatment  post-treatment

**Toxicity observations:** Report any apparent drug toxicity including a description of unusual fish behavior.

**DRUG DISCHARGE RESULTING FROM THIS TREATMENT:** Use Addendum 2: Discharge Worksheet for calculations and attach completed Discharge Worksheet to this form. Enter the value from Addendum 2 step 3 in this space.

**OBSERVED WITHDRAWAL PERIOD OF TREATED FISH:**

Observed withdrawal period: \_\_\_\_\_ 1 year

Estimated number of days between last treatment and first availability of fish for human consumption (ensure this time period meets the withdrawal period). \_\_\_\_\_

\_\_\_\_\_ **NEGATIVE REPORT** Oxytetracycline Bath Marking was not used at this facility under this Study Number during the reporting period. (Investigator should initial for negative reports as soon as the Study Number is known to be no longer needed or valid.)

**Date Prepared:** \_\_\_\_\_ **Investigator:** \_\_\_\_\_

**Date Reviewed:** \_\_\_\_\_ **Study Monitor:** \_\_\_\_\_