

## Form CALC-W: Worksheet for Designing Individual Field Under SE-MARK® INAD 10-987

### **INSTRUCTIONS**

1. Investigator must fill out Form CALC-W for each trial conducted under this INAD **before** actual use of SE-MARK® for marking. The Investigator is responsible that Form CALC-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 CALC-W.

### **SITE INFORMATION**

Facility	Fish Hatchery A		
Address	123 Fish 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	Sockeye	Number of fish to be treated	97,000
Average fish weight (gm)	1.5	Average fish length (in)	2.0
Volume of treatment tank/ container (gal)	6.3	Number of fish per treatment tank/container	25,000
Planned duration of drug treatment (e.g. min or hr)	4 min	Intended drug dosage (mg/L)	5.0 g/L
Salt pre-treatment (yes or no)	yes	% salt solution and duration of treatment (min)	5%; 4 min
Anticipated date treatment will be initiated		May 1, 2008	
Estimated total weight of fish treated (lbs)	120	Estimated total amount of drug needed for proposed treatment (ml)	1,200
Drug manufacturer	Western Chemical	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 create an external mark on sockeye fed fry that will be detectable for smolt and 4 yr old return Identification. Fish will be checked for a mark one day post-treatment.

Study designed by John Doe

**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.

**DISPOSITION OF MARKING SOLUTION (Environmental Safety Considerations):**

jd Marking solution will be stored on-site in a secure, leak-proof container that clearly identifies container contents (Investigator should initial).

Marking solution will be disposed of by shipment to Emerald Services, Inc., 1825 Alexander Avenue, Tacoma, WA 98451 according to procedures detailed in general Waste-stream Profile #216200B (Investigator should initial).

**WORKER SAFETY CONSIDERATIONS:**

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

Date Prepared: 4/25/08 Investigator: Signature here

Date Reviewed: 4/25/08 Study Monitor: Signature here