

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			
Address			
Investigator			
Reporting Individual (if not Investigator)			
Phone		Fax	

FISH CULTURE AND DRUG TREATMENT INFORMATION

Fish species to be treated		Number of fish to be treated	
Average fish weight (gm)		Average fish length (in)	
Volume of treatment tank/ container (gal)		Number of fish per treatment tank/container	
Planned duration of drug treatment (e.g. min or hr)		Intended drug dosage (mg/L)	
Salt pre-treatment (yes or no)		% salt solution and duration of treatment (min)	
Anticipated date treatment will be initiated			
Estimated total weight of fish treated (lbs)		Estimated total amount of drug needed for proposed treatment (ml)	
Drug manufacturer	Western Chemical	Drug lot number	

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.

Study designed by _____

DISPOSITION OF TREATED FISH (Human Food Safety Considerations):

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):

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:

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: _____ **Investigator:** _____

Date Reviewed: _____ **Study Monitor:** _____

FORM CALC-1. Report on Receipt of Drug - Guide for Reporting Investigational New Animal Drug Shipments for Poikilothermic Food Animals

INSTRUCTIONS

1. Investigator must fill out Form CALC-1 **immediately** upon receipt of SE-MARK®.
2. Investigator should keep the original on file, and send one copy to the Study Monitor for review.
3. Within 10 days of receipt, the Study Monitor should send a copy to the AADAP Office.
4. **Note:** Both Investigator and Study Monitor should sign and date Form CALC-1.

*The sponsor, **U.S. Fish and Wildlife Service**, submits a notice of claimed investigational exemption for the shipment or delivery of a new animal drug under the provisions of Section 512 of the Federal Food, Drug, and Cosmetics Act.*

Name of Drug	SE-MARK®	INAD Number	10-987
Proposed Use of Drug	Marking of calcified structures including otoliths, fin rays, and scales		
Date of CVM Authorization Letter	August 28, 2008		
Date of Drug Receipt		Amount of Drug Received	
Drug Lot Number		Study Worksheet Number	
Name of Investigator			
Address of Investigator			
Location of Trial			
Pivotal Study (yes/no)		Non-pivotal Study (yes/no)	
Approximate Number of Treated Animals		Approximate Number of Control Animals	
Number of Animals Used Previously ¹			
Study Protocol Number	10-987		
Approximate dates of trial (start/end)			
Species, Size, and Type of Animals			
Maximum daily dose and duration	125-250 mg/L for 1-6 hr 2.5-5.0 g/L for 1-7 min		
Methods(s) of Administration	Immersion (static bath)		
Withdrawal Period	21 days for all fish species		

¹ To be filled out by the NIO

Date Prepared: _____ Investigator: _____
 Date Reviewed: _____ Study Monitor: _____
 Date Reviewed: _____ Sponsor: _____

Form CALC-3: Results Report Form for Use of SE-MARK[®] Under INAD 10-987**INSTRUCTIONS**

- Investigator must fill out Form CALC-3 no later than 30 days after completion of treatment. Study Number must be recorded on all pages of Form CALC-3. Attach lab reports and other information.
- If SE-MARK[®] 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.
- 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 AADAP Office for inclusion in the permanent file.
- Note:** Both Investigator and Study Monitor should sign and date Form CALC-3.

SITE INFORMATION

Facility	
Reporting Individual	

FISH CULTURE AND DRUG TREATMENT INFORMATION

SE-MARK [®] lot number		Amount SE-MARK [®] used (ml)	
Treatment option used (see study circle one)		Option A	Option B
Treatment dosage		Treatment duration	
Pre-treatment with salt solution (circle one)	Yes or No	If yes, salt solution conc. (%) and treatment duration (min)	
Fish species treated		Total number of fish treated	
Ave fish weight (gm or number/pound); circle one used and enter data)		Average fish length (in)	
Treatment bath vol (gal)		Number fish per treatment	
Number of rearing units treated		Treatment 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 ₃ (mg/L)	

Marking Record - Version 1

INSTRUCTIONS

1. Investigator should fill out the Marking Record as completely as possible.
2. Enter the **"Marking Grade"** for each unit in the proper column to indicate the quality of the mark:
3 = readily visible bright green mark; **2** = clearly visible green mark; **1** = dimly visible dull green mark;
and **0** = no mark.
3. Use additional copies of this form if more than 1 rearing unit/lot is involved in the trial.
4. If more that 15 fish are evaluated, append another copy of this form labeled "continuation sheet"

		Facility:								
		Rearing Unit ID								
		Number of Fish								
Fish Number	Date	Days Post Treatment	Pectoral Fin Ray Mark	Pelvic Fin Ray Mark	Opercle Mark	Jaw Mark	Scale Mark	Other Mark (identify)	Observer Initials	
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										
11										
12										
13										
14										
15										

**STUDY
NUMBER** _____

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?

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

OBSERVED WITHDRAWAL PERIOD OF TREATED FISH:

Observed withdrawal period: _____ 21 days

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

DISPOSITION OF MARKING SOLUTION

SE-MARK® solution has been stored on-site in a secure, leak-proof container that clearly identifies container contents (Investigator should initial)

SE-MARK® solution 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)

NEGATIVE REPORT SE-MARK® immersion 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: _____