



Overview of NIP Forms

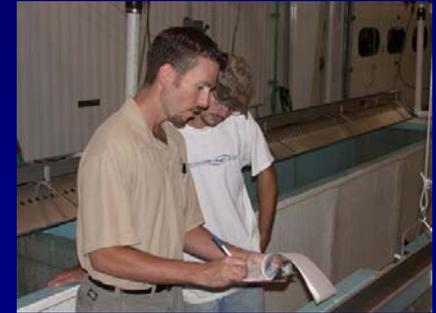
Jim Bowker
(filling in poorly, again, for)

Bonnie Johnson
National INAD Program Coordinator
USFWS - AADAP



INAD Forms - Data Reporting

- Form "AQS"– W: Worksheet for Designing Individual Field Trials
- Form AQS– 1: Report on Receipt of Drug
- Form AQS– 2: Drug Inventory Form
- Form AQS– 3: Results Report Form
- Addendum 2 - Discharge Worksheet



Study Worksheet - Page 1

SITE INFORMATION

Facility	Ennis NFH		
Address	180 Fish Hatchery Rd		
	Ennis, MT 59729		
Investigator	Tom Pruitt		
Reporting Individual (if not Investigator)	Bernie Schrable, Assist. Hatchery Manager		
Phone	406-682-4847	Fax	406-682-7635

FISH CULTURE AND DRUG TREATMENT INFORMATION

Fish species		rainbow trout	
Number of treated fish		200	
Average fish weight (gm)	616.9	Average fish length (in)	15.0
Estimated total weight of fish treated (lbs)		272	
Intended level of anesthesia (Handleable - H; Anesthetized - AN; Euthanized - E)			H
Intended Aqwi-S dosage (mg/L)	20 & 40	Planned duration of Aqwi-S treatment (minutes)	2.5 - 5.0
Estimated total amount of Aqwi-S needed for proposed treatment (ml)		130	
Anticipated date treatment will be initiated		Feb. 10, 2006	
Aqwi-S manufacturer	Aqwi-S LTD	Aqwi-S lot number	B200122

Study Worksheet - Page 2

STUDY DESIGN: Describe in detail the purpose of the clinical trial, the number of experimental animals, Aqwi-S dosage, anticipated treatment duration, and primary response variable(s) (e.g. time to anesthesia, level of anesthesia, time to recovery, etc.). 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 test the efficacy of Aqwi-S on rainbow trout at 20 and 40 ppm for spawning operations.

Study designed by Bernie Schrable

DISPOSITION OF TREATED FISH (Human Food Safety Considerations):

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

BS 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.

WORKER SAFETY CONSIDERATIONS:

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

Drug Receipt Form

Name of Drug	Aqui-S	INAD Number	10-541
Proposed Use of Drug	Use an anesthetic for use in a variety of fish species.		
Date of CVM Authorization Letter	June 27, 2002		
Date of Drug Receipt	1/13/06	Amount of Drug Received	1000 ml
Drug Lot Number	B200122	Study Worksheet Number	10-541-06-12
Name of Investigator	Tom Pruitt		
Address of Investigator	180 Fish Hatchery Rd; Ennis, MT 59729		
Location of Trial	Ennis NFH; Ennis, MT 59729		
Pivotal Study (yes/no)	no	Non-pivotal Study (yes/no)	yes
Approximate Number of Treated Animals	200	Approximate Number of Control Animals	0
Number of Animals Used Previously ¹	2,551		
Study Protocol Number	10-541		
Approximate dates of trial (start/end)	Feb 7, 2006		
Species, Size, and Type of Animals	RBT, Adults		
Maximum daily dose and duration	60 mg/L AQUI-S for up to 60 minutes		
Methods(s) of Administration	Static bath		
Withdrawal Period	21 days for all fish species		

¹ To be filled out by the NIO

Results Report Form - Page 1

SITE INFORMATION

Facility	Ennis NFH
Reporting Individual	Bernie Schrable

FISH CULTURE AND DRUG TREATMENT INFORMATION

Aquis-S lot number	B200122	Total amount of drug used (ml)	125.4
Fish species treated	Rainbow Trout	Aqui-S dosage used (mg/L)	20 & 40
Average fish weight (gm)	616.9	Average fish length (in)	15.0
Total number of treated fish	177	Approximate fish age (fingerling/juvenile/adult)	Adult
Treatment bath vol. (gal)	50	Number of fish/bath	8
Treatment duration (minutes)	2.5 - 4.0	Treatment date	2/10/06

WATER QUALITY PARAMETERS

Ave treatment temp (°F)	50	Dissolved Oxygen (mg/L)	9.1
pH	7.2	Hardness - CaCO ₃ (mg/L)	120

Results Report Form - Page 2

Date	Treatment Number	Species	Fish per Treatment	Level of Anesthesia (H; AN; or E)	Aqui-S Dose (mg/L)	Time to Anesthesia (min)	Time to Recovery (min)	Observer Initials
2/10/06	1	RBT	9	H	20	5.0	5.0	BS
2/10/06	2	RBT	10	H	20	4.5	7.0	BS
2/10/06	3	RBT	7	H	20	5.0	6.5	BS
2/10/06	4	RBT	8	H	20	6.0	4.0	BS
2/10/06	5	RBT	7	H	20	5.5	3.0	BS
2/10/06	6	RBT	11	H	20	4.5	5.5	BS
2/10/06	7	RBT	9	H	20	6.5	7.5	BS
2/10/06	8	RBT	10	H	40	4.0	8.0	BS
2/10/06	9	RBT	8	H	40	4.0	4.5	BS
2/10/06	10	RBT	8	H	40	2.5	5.0	BS
2/10/06	11	RBT	7	H	40	3.5	7.0	BS
2/10/06	12	RBT	11	H	40	2.5	6.5	BS
2/10/06	13	RBT	9	H	40	3.0	4.0	BS
2/10/06	14	RBT	10	H	40	3.5	3.0	BS
2/10/06	15	RBT	11	H	40	4.0	5.5	BS
2/10/06	16	RBT	8	H	40	2.5	7.5	BS
2/10/06	17	RBT	7	H	40	3.0	8.0	BS
2/10/06	18	RBT	10	H	40	2.5	4.5	BS

Results Report Form - Page 3

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? Attach any supplemental reports.

Treatment appeared to be successful. All fish became anaesthetized within 7.0 minutes and recovered within 8.0 minutes. No deviations to the protocol occurred.

TOXICITY OBSERVATIONS: Report any apparent drug toxicity including a description of unusual fish behavior.

Fish recovered from the treatment and resumed normal behavior (i.e. eating, swimming, schooling).

DRUG DISCHARGE RESULTING FROM THIS TREATMENT: Calculate actual AQUI-S drug level in hatchery discharge resulting from treatments. Use Addendum 2: Discharge Worksheet for calculations and attach completed Discharge Worksheet to this form. Also indicate method of disposal of AQUI-S.

2.6 ppm & 0.7 ppm (if poured into raceways). However, all AQUI-S treated water was discharged onto the asphalt.

OBSERVED WITHDRAWAL PERIOD OF TREATED FISH:

Observed withdrawal period: X 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).

 60 days

Discharge Worksheet

Calculations: **For the 20 ppm dose**

Step 1 - Calculate the total flow of treated and untreated water during treatment period:

1a Volume of bath treatment: _____ **50 gal** _____

1b Number of bath treatments used: _____ **7** _____ (gal.) or (cuft.)

1c Total hatchery discharge: _____ **10,000 gal** _____ (gal.) or (cuft.) of flow during treatment period.

Step 2 - Calculate the amount of Aqwi-S needed:

$$2a \quad \underset{\text{Amount}}{\underline{26.6}} \text{ mL} = \underset{\substack{\text{Bath Vol. from} \\ \text{line 1a}}}{\underline{50}} * \underset{\substack{\text{number of baths from} \\ \text{line 1b} * \text{Conv. factor}}}{\underline{7(0.0038)}} * \underset{\text{Desired dosage}}{\underline{20}} \text{ ppm}$$

Step 3 - Calculate Aqwi-S level in hatchery discharge during treatment period:

$$3a \quad \underset{\text{Disch. level}}{\underline{0.7}} \text{ ppm} = \underset{\text{Amt. from line 2a}}{\underline{26.6}} / \left(\underset{\text{Total vol. (line 1c)}}{\underline{10,000}} * \underset{\substack{\text{Conver. factor}^* \\ \text{If in gallons use 0.0038} \\ \text{If in cubic ft use 0.0283}}}{\underline{0.0038}} \right)$$

Questions??