Overview of NIP Forms

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USFWS - AADAP

AADAP

Aquatic Animal Drug Approval

Partnership Program

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 Aqui-S dosage (mg/L)	20 & 40	Planned duration of Aqui-S treatment (minutes)	2.5 - 5.0
Estimated total amount of Aqui-S needed for proposed treatment (ml)		130	
Anticipated date treatment will be initiated		Feb. 10, 2006	
Aqui-S manufacturer	**Aqui-S LTD**	Aqui-S lot number	B200122

Study Worksheet - Page 2

STUDY DESIGN: Describe in detail the purpose of the clinical trial, the number of experimental animals, Aqui-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 Aqui-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 Aqui-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**

Inventory Form

Qty of Aqui-S from previous page (ml) 0 Facility Ennis NFH Reporting individual Bernie Schrable

Date	Amount of new Aqui-S received (ml)	Lot number of Aqui-S received	Study Number	Amount Aqui-S used in treatment (ml)	Aqui-S transferred (ml)	Aqui-S discarded (ml)	Aqui-S remaining on hand (ml)	Inventory by (initials)
1/13/06	1000	B200122					1000	BS
2/10/06	XXXX	XXXX	10-541-06-12	26.6			973.4	BS
2/10/06	XXXX	XXXX	10-541-06-12	98.8			874.6	BS
	XXXX	XXXX						
	XXXX	XXXX						
	XXXX	XXXX						
	XXXX	XXXX						
	XXXX	XXXX						
	XXXX	XXXX						
	XXXX	XXXX						
	XXXX	XXXX						
	XXXX	XXXX						

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 nuBSer 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 40 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:_____13_____(gal.) or (cuft.)

1c Total hatchery discharge: _____10,000_gal_____(gal.) or (cuft.) of flow during treatment period.

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

2a __98.8____ mL = _____50_____ * __13 (0.0038)_____ * ___40_____ ppm

Amount | Bath Vol. from line 1a | number of baths from line 1b * Conv. factor | Desired dosage

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

3a __2.6____ ppm = ___98.8_____ / (_____10,000_____ * ___0.0038_____)

Disch. level | Amt. from line 2a | Total vol. (line 1c) | Conver. factor*

*If in gallons use 0.0038

If in cubic ft use 0.0283

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 Aqui-S needed:

2a __26.6_ mL = _____50_____ * ____7(0.0038)___ * _____20____ ppm

Amount | Bath Vol. from line 1a | number of baths from line 1b * Conv. factor | Desired dosage

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

3a ___0.7__ ppm = _____26.6_____ / (_____10,000_____ * ___0.0038_____)

Disch. level | Amt. from line 2a | Total vol. (line 1c) | Conver. factor*

*If in gallons use 0.0038

If in cubic ft use 0.0283