

Form sGnRHa/Ovaplant-W: Worksheet for Designing Clinical Field Trials under sGnRHa INAD 11-375

INSTRUCTIONS

1. Investigator must fill out Form sGnRHa/Ovaplant-W for each trial conducted under this INAD before actual use of salmon Gonadotropin Releasing Hormone analog. The Investigator is responsible that Form sGnRHa/Ovaplant-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 Bozeman NIO for assignment of the Study Number.
4. The Bozeman NIO 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 sGnRHa/Ovaplant-W.

SITE INFORMATION

Facility			
Address			
Investigator			
Reporting Individual (if not Investigator)			
Phone		Fax	

FISH CULTURE AND DRUG TREATMENT INFORMATION

Fish species to be treated					
Average fish size (in)				Average fish weight (gm)	
Number of treated males				Number of treated females	
Number of control males				Number of control females	
Anticipated date of treatment				Estimated total amount of drug for proposed treatments (mg)	
Intended sGnRHa dosage (ug/kg)	Females		Males	Method of administration	Pellet Implant
Pellet size (i.e., ug sGnRHa per pellet)	Females		Males	Number of pellets per fish	
Drug manufacturer	Syndel International, Inc.			Drug lot number	

Worksheet for Designing Clinical Field Trials - Version 1

STUDY DESIGN: Describe in detail the purpose of the clinical trial. For example you might compare dosage, or treated fish compared to untreated fish. 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):

Fish treated with sGnRHa (Ovaplant[®]) may not be stocked, released, or harvested for human consumption. All treated fish must ultimately be destroyed. Investigator should initial here to indicate awareness that fish disposition must be in compliance with FDA-mandated withdrawal times as described in Section XV of the Study Protocol.

WORKER SAFETY CONSIDERATIONS:

Investigator should initial here to indicate that all personnel handling drug have read the Material Safety Data Sheet for salmon gonadotropin releasing hormone analog (Ovaplant[®]) and have been provided protective equipment, in good working condition, as described in the MSDS.

Date Prepared: _____ Investigator: _____

Date Reviewed: _____ Study Monitor: _____

Form sGnRHa/Ovaplant-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 sGnRHa/Ovaplant-1 **immediately** upon receipt of sGnRHa.
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 Bozeman NIO.
4. **Note:** Both Investigator and Study Monitor should sign and date Form sGnRHa/Ovaplant-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. The following information is submitted in triplicate:

Name of Drug	sGnRHa (Ovaplant®)	INAD Number	11-375
Proposed Use of Drug	To induce gamete maturation in a variety of fish species.		
Date of CVM Authorization Letter	December 15, 2005		
Source of Drug	Syndel International, Inc.		
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)	Yes	Non-pivotal Study (yes/no)	-----
Approximate Number of Treated Animals		Approximate Number of Control Animals	
Number of Animals Used Previously¹			
Study Protocol Number	11-375		
Approximate dates of trial (start/end)			
Species, Size, and Type of Animals			
Maximum total dose	150 ug/Kg body weight		
Methods of Administration	Cholesterol-based pellet implant		
Withdrawal Period	No release of fish treated with pellet implant.		

¹ To be filled out by the NIO

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

Form sGnRHa/Ovaplant-3: Results Report Form

For Use in sGnRHa (Ovaplant®) Clinical Field Trials Conducted under sGnRHa INAD 11-375

INSTRUCTIONS

1. Investigator must fill out Form sGnRHa/Ovaplant-3 no later than 10 days after completion of the study period. Study Number must be recorded on all pages of Form sGnRHa/Ovaplant-3. Attach lab reports and other information.
2. If salmon gonadotropin releasing hormone analog 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 sGnRHa/Ovaplant-3.

SITE INFORMATION

Facility	
Reporting Individual	

FISH CULTURE AND DRUG TREATMENT INFORMATION

Drug lot number		Total amount drug used (mg)	
Fish species treated		Water temperature (°F)	
Drug dosage - males (ug/kg body wt)		Drug dosage - females (ug/kg body wt)	
Average fish weight (gm)		Average fish length (in)	
Number of treated males		Number of treated females	
Number of control males		Number of control females	
Treatment date(s)			
Treatment method	Pellet Implant	Pellet size (i.e., ug sGnRHa per pellet)	
Number of pellets per male		Number of pellets per female	
Spawning/evaluation interval (time from treatment until spawning)		Spawning/evaluation date(s)	

sGnRH_a/Ovaplant® Results Record - Females

INSTRUCTIONS

1. "Ripe" females are those fish that have ovulated or released their eggs. "None-ripe" fish are the converse.
2. Use additional copies of Results Record for additional fish treated.

Be sure the facility name is written here: _____

		sGnRH _a TREATED FISH - Females					CONTROL FISH - Females				
Fish #	Date Treated	Date Evaluated	Ripe	Non-ripe	% Eye-up	% Hatch	Date Evaluated	Ripe	Non-ripe	% Eye-up*	% Hatch*
1											
2											
3											
4											
5											
6											
7											
8											
9											
10											
11											
12											
13											
14											
15											
16											
17											
18											
19											
20											

* If eggs from multiple females have been combined during incubation, indicate data from combined egg lots with a vertical line "connecting" all females contributing to a single egg lot

sGnRHa/Ovaplant® Results Record - Males

INSTRUCTIONS

1. "Ripe" males are those fish that are actively spermiating. "None-ripe" males are the converse.
2. Use additional copies of Results Record for additional fish treated.

Be sure the facility name is written here: _____

		sGnRHa TREATED FISH - Males					CONTROL FISH - Males				
Fish #	Date Treated	Date Evaluated	Ripe	Non-ripe	Milt/fish (ml)	Motility Score	Date Evaluated	Ripe	Non-ripe	Milt/fish (ml)	Motility Score
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? Attach pathology reports; Both Pre-and Post-Treatment.

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

OBSERVED WITHDRAWAL PERIOD OF TREATED FISH:

Observed withdrawal period :

Fish treated with sGnRH_a (Ovaplan[®]) may not be stocked, released, or harvested for human consumption. All treated fish must ultimately be destroyed. Investigator should initial here to indicate compliance with disposition requirements of sGnRH_a (Ovaplan[®]) treated fish

_____ **NEGATIVE REPORT** Salmon gonadotropin releasing hormone analog (Ovaplan[®]) 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:** _____

sGnRH α Treatment Summary Information - Females

(To be completed by the NIO)

Treated Females							
Fish #s	Number of fish	Date Treated	Date Evaluated	Interval between treatment and evaluation (specify hours or days)	% Ripe	% Eye-up	% Hatch

Control Females							
Fish #s	Number of fish	Date Treated	Date Evaluated	Interval between treatment and evaluation (specify hours or days)	% Ripe	% Eye-up	% Hatch
		XXXX		XXXX			
		XXXX		XXXX			
		XXXX		XXXX			
		XXXXX		XXXX			
		XXXX		XXXX			
		XXXX		XXXX			
		XXXX		XXXX			

sGnRHa Treatment Summary Information - Males

(To be completed by the NIO)

Treated males							
Fish #s	Number of fish	Date Treated	Date Evaluated	Interval between treatment and evaluation (specify hours or days)	% Ripe	Milt/fish (ml)	Motility Score

Control Males							
Fish #s	Number of fish	Date Treated	Date Evaluated	Interval between treatment and evaluation (specify hours or days)	% Ripe	Milt/fish (ml)	Motility Score
		XXXX		XXXX			
		XXXX		XXXX			
		XXXX		XXXX			
		XXXXX		XXXX			
		XXXX		XXXX			
		XXXX		XXXX			
		XXXX		XXXX			

Form sGnRHa/Ovaplant-4N: Necropsy Report Form

For Use in sGnRHa/Ovaplant® Clinical Field Trials Conducted under INAD 11-375

INSTRUCTIONS

1. Investigator must fill out Form sGnRHa/Ovaplant-4N for all fish that die or are euthanized during the study period. Use a new copy of Form sGnRHa/Ovaplant-4N for each individual fish.
2. Append and submit all Form sGnRHa/Ovaplant-4Ns with appropriate Form sGnRHa/Ovaplant-3s.

Date _____ Fish Species/ID _____ Fish Length (cm) _____

Evaluator(s): _____

Body surface: normal excess mucus irregular color other _____

Dermal lesion: none hemorrhagic other _____

closed open

Location: dorsal caudal ventral lateral cranial

base of fin - Pectoral (right), Pectoral (left), Adipose, Dorsal, Anal, or Caudal

Gills: normal pale hemorrhagic other _____

Liver: normal pale mottled other _____

Spleen: normal pale enlarged other _____

Kidney: normal pale swollen other _____

Notes and comments of gross pathologies on other organs and tissues.

eyes exophthalmia _____ stomach _____

body cavity _____ gastrointestinal tract _____

gall bladder _____ gas bladder _____

adipose tissue _____ musculature _____

implant site _____

other _____

Investigator: _____ Date: _____