

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:** _____