

FORM LHRHa-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 LHRHa-1 **immediately** upon receipt of LHRHa.
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 LHRHa-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	LHRHa	INAD Number	8061
Proposed Use of Drug	To induce gamete maturation in a variety of fish species.		
Date of CVM Authorization Letter	8/15/03		
Date of Drug Receipt	4/12/08	Amount of Drug Received	30 mg
Drug Lot Number	1111	Study Worksheet Number	08-XXX
Name of Investigator	John Doe		
Address of Investigator	123 Hatchery Rd; Anywhere, USA 55555		
Location of Trial	Fish Hatchery A		
Pivotal Study (yes/no)	no	Non-pivotal Study (yes/no)	yes
Approximate Number of Treated Animals	20	Approximate Number of Control Animals	
Number of Animals Used Previously¹			
Study Protocol Number	8061		
Approximate dates of trial (start/end)	March 2008		
Species, Size, and Type of Animals	Adult paddlefish		
Maximum daily dose and duration	100 ug/Kg body weight		
Methods(s) of Administration	Injection		
Withdrawal Period	14 days		

¹ To be filled out by the NIO

Date Prepared: 4/12/08

Investigator: Sign here

Date Reviewed: 4/12/08

Study Monitor: Sign here

Date Reviewed: _____

Sponsor: _____