

FORM CCP-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 CCP-1 **immediately** upon receipt of CCP.
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 CCP-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	CCP	INAD Number	8391
Proposed Use of Drug	To induce gamete maturation in a variety of fish species.		
Date of CVM Authorization Letter	July 7, 2006		
Date of Drug Receipt	3/11/08	Amount of Drug	1 gm
Drug Lot Number	111222	Study Worksheet Number	08-XXX
Name of Investigator	John Doe		
Address of Investigator	123 Hatchery Rd; Somewhere, USA 55555		
Location of Trial	Fish Hatchery B		
Pivotal Study (yes/no)	no	Non-pivotal Study (yes/no)	yes
Approximate Number of Treated Animals	18	Approximate Number of Control Animals	0
Number of Animals Used Previously ¹			
Study Protocol Number	8391		
Approximate dates of trial (start/end)	March 2008		
Species, Size, and Type of Animals	Adult Musky		
Maximum daily dose and duration	25 mg/Kg body weight		
Methods(s) of Administration	Injection		
Withdrawal Period	72 hrs for wild stock; 30 days for domestic (non-wild) broodstock.		

¹ To be filled out by the NIO

Date Prepared: 3/11/08

Investigator: Sign here

Date Reviewed: 3/11/08

Study Monitor: Sign here

Date Reviewed: _____

Sponsor: _____