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. <u>Note:</u> Both Investigator and Study Monitor should sign and date Form CCP-1.

The sponsor, <u>U.S. Fish and Wildlife Service</u>, 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 Drive	005		0004
Name of Drug	ССР	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		Amount of Drug	
Drug Lot Number		Study Worksheet Number	
Name of Investigator			
Address of Investigator			
Location of Trial			
Pivotal Study (yes/no)		Non-pivotal Study (yes/no)	
Approximate Number of Treated Animals		Approximate Number of Control Animals	
Number of Animals Used Previously ¹			
Study Protocol Number	8391		
Approximate dates of trial (start/end)			
Species, Size, and Type of Animals			
Maximum total dose	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:	Investiga	tor:	
Date Reviewed:	Study Moni		
Date Reviewed:	Spons	sor:	