

FORM CLT-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 CLT-1 **immediately** upon receipt of chloramine-T.
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 CLT-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	Chloramine-T	INAD Number	9321
Product Name (check one)	____ Halamid® <u> x </u> Actamide		
Proposed Use of Drug	Treatment or control of bacterial gill disease or certain flavobacteriosis that occur in a variety of fish species		
Date of CVM Authorization Letter	December 5, 2007		
Date of Drug Receipt	8/15/08	Amount of Drug Received	10 kg
Drug Lot Number	111222C	Study Worksheet Number	08-XXX
Name of Investigator	John Doe		
Address of Investigator	123 Hatchery Rd; Anywhere, USA 11122		
Location of Trial	Fish Hatchery A		
Pivotal Study (yes/no)	no	Non-pivotal Study (yes/no)	yes
Approximate Number of Treated Animals	150,000	Approximate Number of Control Animals	0
Number of Animals Used Previously¹			
Study Protocol Number	9321		
Approximate dates of trial (start/end)	Aug – Dec 2008		
Species, Size, and Type of Animals	Fingerling - steelhead trout		
Maximum daily dose and duration	20 mg/L for 1hour		
Methods(s) of Administration	Immersion (static bath or flow-through treatment)		
Withdrawal Period	Zero		

¹ To be filled out by the NIO

Date Prepared: 8/15/08

Investigator: Sign here

Date Reviewed: 8/15/08

Study Monitor: Sign here

Date Reviewed: _____

Sponsor: _____