

FORM FFC-1. Report on Receipt of Drug - Guide for Reporting Investigational New Animal Drug Shipments for Poikilothermic Food Animals

INSTRUCTIONS

- Investigator must fill out Form FFC-1 immediately upon receipt of florfenicol-medicated feed.
- Investigator should keep the original on file, and send one copy to the Study Monitor for review.
- Within 10 days of receipt, the Study Monitor should send a copy to the Bozeman NIO.
- Note: Both Investigator and Study Monitor should sign and date Form FFC-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	Aquaflor	INAD Number	10-697
Proposed Use of Drug	Treatment of certain bacterial diseases that occur in a variety of fish species		
Date of CVM Authorization Letter	September 17, 2007		
Date of Drug Receipt	4/28/08	Amount of Drug Received	15 g
Drug Lot Number	028043	Trial Number	08-XXX
Name of Investigator	John Doe		
Address of Investigator	123 Hatchery Dr; Anywhere, USA 55555		
Location of Trial	Fish Hatchery A		
Pivotal Study	no	Non-pivotal Study	yes
Approximate Number of Treated Animals	34,000	Approximate Number of Control Animals	0
Number of Animals Used Previously¹			
Study Protocol Number	10-697		
Approximate dates of trial (start/end)	4/28 – 5/7/08		
Species, Size, and Type of Animals	Largemouth bass; 1.21 g		
Maximum daily dose and duration	10 mg florfenicol/kg fish per day for 10 days		
Methods(s) of Administration	Medicated-feed		
Withdrawal Period	21 days for salmonid species; 28 days for non-salmonid species		

¹ To be filled out by the NIO

Date Prepared: 4/29/08

Investigator: Sign here

Date Reviewed: 4/29/08

Study Monitor: Sign here

Date Reviewed: _____

Sponsor: _____