

FORM DQT-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 DQT-1 **immediately** upon receipt of Reward[®].
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 DQT-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	Reward[®]	INAD Number	10-969
Proposed Use of Drug	Control mortality caused by bacterial gill disease and external flavobacteriosis in a variety of fish species		
Date of CVM Authorization Letter	October 31, 2007		
Date of Drug Receipt	3/30/08	Amount of Drug Received	30 gal
Drug Lot Number	TBR0001110	Study Worksheet Number	08-XXX
Name of Investigator	John Doe		
Address of Investigator	123 Hatchery Rd; Anywhere, USA 555		
Location of Trial	Fish Hatchery A		
Pivotal Study (yes/no)	no	Non-pivotal Study (yes/no)	yes
Approximate Number of Treated Animals	700,000	Approximate Number of Control Animals	0
Number of Animals Used Previously¹			
Study Protocol Number	10-969		
Approximate dates of trial (start/end)	4/1 – 11/30/08		
Species, Size, and Type of Animals	CCF 1-7"; WAE 1-8"; Musky 10"		
Maximum daily dose and duration	2-18 mg/L = 4 hr 19-28 mg/L = 1 hr		
Methods(s) of Administration	Immersion (static bath or flow-through treatment)		
Withdrawal Period	5 days for channel catfish, muskellunge, tiger muskellunge, and northern pike; 30 days for all other fish species		

¹ To be filled out by the NIO

Date Prepared: 4/1/08

Investigator: Sign here

Date Reviewed: 4/1/08

Study Monitor: Sign here

Date Reviewed: _____

Sponsor: _____