

# FORM MT-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 MT-1 **immediately** upon receipt of 17-alpha methyltestosterone medicated feed.
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 MT-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	17-alpha methyltestosterone medicated feed		
INAD Number	11-236	Study Number	
Proposed Use of Drug	Production of tilapia populations comprised of greater than 90% male fish (i.e. sex reversal)		
Date of CVM Authorization Letter	December 20, 2007		
Date of Medicated Feed (MF) Receipt	7/25/08	Amount MF Received (kg)	320
Medicated Feed (MF) Batch Number	R82A-143-2008	MF Manufacture Date	5/22/2008
Location of Trial (facility name)	Tilapia Farm A		
Name of Investigator	John Doe		
Address of Investigator	123 Fish Hatchery Rd; Anytown, MT 01234		
Pivotal Study (yes/no)	no	Non-pivotal Study (yes/no)	yes
Approximate Number of Treated Animals	640,000	Approximate Number of Control Animals	0
Number of Animals Used Previously <sup>1</sup>			
Study Protocol Number	11-236		
Approximate dates of trial (start/end)	July 2008 - December 2008		
Species, Size, and Type of Animals	California Mossambica Fry		
Maximum daily dose and duration	9 mg/kg body weight for 28 consecutive days		
Methods(s) of Administration	Medicated feed		
Withdrawal Period	Batch culture = 120 days Partial harvest/restock culture = 350 g fish weight		

<sup>1</sup> To be filled out by the NIO

Date Prepared: 7/26/08

Investigator: John Doe

Date Reviewed: 7/26/08

Study Monitor: Joe Brown

Date Reviewed: \_\_\_\_\_

Sponsor: \_\_\_\_\_