

**FORM OTC-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 OTC-1 **immediately** upon receipt of Terramycin® 200 for Fish 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 OTC-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	<b>Terramycin® 200 for Fish</b>	INAD Number	<b>9332</b>
Proposed Use of Drug	Treatment of certain bacterial diseases that occur in a variety of fish species; mark skeletal tissue in a variety of freshwater and marine fish species		
Date of CVM Authorization Letter	June 25, 2007		
<b>Date of Drug Receipt</b>	2/13/08	<b>Amount of Drug Received</b>	300 lbs
<b>Drug Lot Number</b>	Xxx111	<b>Trial Number</b>	08-XXX
<b>Name of Investigator</b>	John Doe		
<b>Address of Investigator</b>	123 Hatchery Rd; Anywhere, USA 55555		
<b>Location of Trial</b>	Fish Hatchery A		
Pivotal Study	<b>no</b>	Non-pivotal Study	<b>yes</b>
<b>Approximate Number of Treated Animals</b>	115,500	<b>Approximate Number of Control Animals</b>	0
<b>Number of Animals Used Previously<sup>1</sup></b>			
Study Protocol Number	9332		
<b>Approximate dates of trial (start/end)</b>	Feb 15 – 28, 2008		
<b>Species, Size, and Type of Animals</b>	RBT; fingerling		
Maximum daily dose and duration	10 g oxytetracycline per 100 lb of fish per day for 14 days		
Methods(s) of Administration	Medicated-feed		
Withdrawal Period	Salmonids = 21-70 days; Non-salmonids = 40-70 days; Abalone = 35 days (see INAD 9332 Study Protocol for specific times based on specific treatment regimen)		

<sup>1</sup> To be filled out by the AADAP Office

**Date Prepared:** 2/13/08

**Investigator:** Sign here

**Date Reviewed:** 2/13/08

**Study Monitor:** Sign here

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

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