

**FORM OTIMM-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 OTIMM-1 **immediately** upon receipt of oxytetracycline.
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 OTIMM-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-343</b>	INAD Number	<b>9033</b>
Proposed Use of Drug	Treatment of certain bacterial diseases that occur in a variety of fish species		
Date of CVM Authorization Letter	October 1, 2007		
<b>Date of Drug Receipt</b>	<u>2/28/08</u>	<b>Amount of Drug Received</b>	<u>5,000 g</u>
<b>Drug Lot Number</b>	<u>111222</u>	<b>Study Worksheet Number</b>	<u>08-XXX</u>
<b>Name of Investigator</b>	<u>John Doe</u>		
<b>Address of Investigator</b>	<u>123 Hatchery Rd; Anywhere, USA 55555</u>		
<b>Location of Trial</b>	<u>Fish Hatchery A</u>		
Pivotal Study (yes/no)	<u>no</u>	Non-pivotal Study (yes/no)	<u>yes</u>
<b>Approximate Number of Treated Animals</b>	<u>15,000</u>	<b>Approximate Number of Control Animals</b>	<u>0</u>
<b>Number of Animals Used Previously<sup>1</sup></b>			
Study Protocol Number	9033		
<b>Approximate dates of trial (start/end)</b>	<u>March – July 2008</u>		
<b>Species, Size, and Type of Animals</b>	<u>White sturgeon; 80 g</u>		
Maximum daily dose and duration	20 mg/L for 1 hour		
Methods(s) of Administration	Immersion (static bath treatment 1 - 4 days)		
Withdrawal Period	21 days for 1 day treatment; 60 days for 2 - 4 day treatment		

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

**Date Prepared:** 2/28/08

**Investigator:** Sign here

**Date Reviewed:** 2/28/08

**Study Monitor:** Sign here

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

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