

FORM OTM-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 OTM-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 Bozeman NIO.
4. **Note:** Both Investigator and Study Monitor should sign and date Form OTM-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	Pennox 343	INAD Number	9033
Proposed Use of Drug	To apply a mark in a variety of fish species for use as a fishery management tool.		
Date of CVM Authorization Letter	April 23, 2010		
Date of Drug Receipt		Amount of Drug Received	
Drug Lot Number		Study Worksheet Number	
Name of Investigator			
Address of Investigator			
Location of Trial			
Pivotal Study (yes/no)		Non-pivotal Study (yes/no)	
Approximate Number of Treated Animals		Approximate Number of Control Animals	
Number of Animals Used Previously ¹			
Study Protocol Number	9033		
Approximate dates of trial (start/end)			
Species, Size, and Type of Animals			
Maximum daily dose and duration	200-700 mg/L for 2-6 hours		
Methods(s) of Administration	Immersion (single static bath treatment)		
Withdrawal Period	zero days		
¹ To be filled out by the NIO			

Date Prepared:

Investigator:

Date Reviewed:

Study Monitor:

Date Reviewed:

Sponsor:
