

FORM CALC-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 CALC-1 **immediately** upon receipt of SE-MARK®.
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 CALC-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	SE-MARK®	INAD Number	10-987
Proposed Use of Drug	Marking of calcified structures including otoliths, fin rays, and scales		
Date of CVM Authorization Letter	August 28, 2008		
Date of Drug Receipt	4/27/08	Amount of Drug Received	2 L
Drug Lot Number	111222	Study Worksheet Number	08-XXX
Name of Investigator	John Doe		
Address of Investigator	123 Fish Hatchery Rd; Anywhere, USA 55555		
Location of Trial	Fish Hatchery A		
Pivotal Study (yes/no)	no	Non-pivotal Study (yes/no)	yes
Approximate Number of Treated Animals	97,000	Approximate Number of Control Animals	0
Number of Animals Used Previously¹			
Study Protocol Number	10-987		
Approximate dates of trial (start/end)	May 2008		
Species, Size, and Type of Animals	Sockeye fry – 1.5g		
Maximum daily dose and duration	125-250 mg/L for 1-6 hr 2.5-5.0 g/L for 1-7 min		
Methods(s) of Administration	Immersion (static bath)		
Withdrawal Period	21 days for all fish species		

¹ To be filled out by the NIO

Date Prepared: 5/1/08

Investigator: Sign here

Date Reviewed: 5/1/08

Study Monitor: Sign here

Date Reviewed: _____

Sponsor: _____