

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		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 Previously¹			
Study Protocol Number	10-987		
Approximate dates of trial (start/end)			
Species, Size, and Type of Animals			
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: _____ **Investigator:** _____
Date Reviewed: _____ **Study Monitor:** _____
Date Reviewed: _____ **Sponsor:** _____