

FORM 1. GUIDE FOR REPORTING INVESTIGATIONAL NEW ANIMAL DRUG SHIPMENTS FOR POIKILOTHERMIC FOOD ANIMALS

Department of Health and Human Services
Center for Veterinary Medicine, HFV-199
Food and Drug Administration
7500 Standish Place
Rockville, Maryland 20855

Date: _____
INAD No: 9013
Name of Drug: Formalin
Trial Number: _____
Lot Number: _____

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 Cosmetic Act. The following information is submitted in triplicate (original and two copies):

Name of Drug: Formalin (Formalin-F, Paracide-F, Parasite-S)

Proposed Use of Drug: Treatment of fungal infections on fish and fish eggs

Date of CVM Authorization Letter: October 14, 1994

Date of Drug Order: _____

Amount of Drug Ordered: _____

Name of Investigator: _____
(typed or printed)

Location of Trial: _____

Pivotal (intended for support of NADA) or nonpivotal _____ study

Approximate Number of Animals: Treated _____ Controls _____

Protocol (*pivotal studies only*): Date submitted to CVM and/or number: June 17, 1993

Approximate Date of Trial: Start: _____ End: _____

Species, Size, and Type of Animals: _____

Maximum dose and duration: Fish - 250 mg/L for 120 minutes

Eggs - 2000 mg/L for 30 minutes

Method(s) of Administration: Static bath or constant flow

Withdrawl Period: 5 days

If the investigation is discontinued, the Food and Drug Administration will be notified, giving the reason and disposition of the drug.

Investigator: _____
Signature and Date

Study Monitor: _____
Signature and Date