

**FORM FFC-1a. Report on Receipt of Drug - Guide For Reproting Investigational New Animal Drug Shipments For Poikilothermic Food Animals**  
(For Feed Manufacturers)

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: 10-697  
Name of Drug: Aquaflor®  
Trial Number: NA  
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: Aquaflor® (florfenicol)

Proposed Use of Drug: Treatment of certain bacterial diseases that occur in a variety of cultured fish species

Date of CVM Authorization Letter: July 31, 2009

Date Drug Received: \_\_\_\_\_

Amount of Drug Received: \_\_\_\_\_

Name of Feed Manufacturer: \_\_\_\_\_  
(typed or printed)

Address of Feed Manufacturer: \_\_\_\_\_  
\_\_\_\_\_

Pivotal (intended for support of NADA) X and/or nonpivotal X study

For Study Information and Details Refer to Study Number: \_\_\_\_\_

Protocol (*pivotal studies only*): Date submitted to CVM and/or number: FLOR-01-EFF

Maximum dose and duration: 15 mg florfenicol/kg fish per day for 10 consecutive days

Method(s) of Administration: Medicated-feed

Withdrawal Period: Salmonids = 21 days; non-Salmonids = 28 days

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

Feed Manufacturer (Authorized Representative): \_\_\_\_\_  
Signature and Date