



## U.S. Fish & Wildlife Service

### The Aquatic Animal Drug Approval Partnership Program

# Fact Sheet: Florfenicol INAD 10-697

<b>INAD objective/purpose:</b>	Collect supportive and/or pivotal data needed to establish the effectiveness of florfenicol to control mortality caused by certain bacterial diseases.
<b>Drug name:</b>	Florfenicol (Aquaflor <sup>®</sup> )
<b>Source of drug:</b>	Merck Animal Health
<b>Address:</b>	35500 W. 91 <sup>st</sup> Street De Soto, KS 66018
<b>Contact:</b>	Kasha M. Cox Phone: 662-907-0692; email: <a href="mailto:kasha.cox@merck.com">kasha.cox@merck.com</a>
<b>Target pathogen(s):</b>	Bacterial pathogens susceptible to florfenicol, exclusive of already approved claims.
<b>Method of administration:</b>	Medicated feed treatment
<b>Treatment dosage:</b>	10 or 15 milligrams (mg) florfenicol per kilogram (kg) fish body weight per day
<b>Treatment regimen:</b>	10 consecutive days
<b>Withdrawal period:</b>	21 days all salmonids 15 days for freshwater-reared warmwater finfish 28 days all other non-salmonids  No withdrawal period is required for fish that are not susceptible to legal harvest for a period post-treatment equal to the withdrawal periods noted above or are illegal for harvest during those same periods.
<b>Required test parameters:</b>	Investigator must collect mortality data throughout the 5 day pre-treatment, treatment, and 10-day post-treatment period. Investigator should also report general fish behavior and any adverse effects relating to treatment.
<b>Limitations or restrictions on use of drug:</b>	Not for use for existing FDA-approved claims for florfenicol.  Investigator must follow all instructions in the Study Protocol for INAD 10-697 regarding drug acquisition and handling, fish treatment and disposition, and data reporting requirements.  Drug discharge must be in compliance with local NPDES permitting requirements.
<b>Required INAD fee:</b>	\$700/facility/year
<b>AADAP Contact Information:</b>	Ms. Bonnie Johnson, FWS-AADAP Phone: 406-994-9905 Fax: 406-582-0242 email: <a href="mailto:bonnie_johnson@fws.gov">bonnie_johnson@fws.gov</a>