

## Form FFC-W. Worksheet for Designing Study Protocols for Aquaflor® INAD #10-697

**INSTRUCTIONS**

1. This Worksheet is an aid for Investigators preparing to use Aquaflor® under INAD #10-697. The information solicited is required to comply with FDA regulations. Before beginning, Investigators should have carefully read through the entire Study Protocol. Fill in this Worksheet as completely as possible.
2. Investigators should keep one copy on file, and send another copy to the Monitor for review and signature. The Monitor should then forward the signed Worksheet to the Study Director. The Study Director will also review the Worksheet, assign the Worksheet a Study Number, and then provide the Investigator and Monitor with the Study Number and approval to proceed with Aquaflor® treatment.

**SITE INFORMATION**

Facility	Fish Hatchery A		
Address	123 Hatchery Rd		
	Anywhere, USA 55555		
Investigator	John Doe		
Reporting individual (if not investigator)			
Phone	555-555-5555	FAX	555-555-5556

**FISH CULTURE AND DRUG TREATMENT INFORMATION**

Fish disease to be treated	columnaris		
Fish species/stock to be treated	Largemouth bass		
Number of fish per unit (indicate tank, raceway or pond)	34,000 raceway		
Number of units to be treated	1	Number of untreated control units	0
Average fish per pound	375	Estimated total weight of fish treated	99 lbs
Intended florfenicol dosage (mg/kg fish/day)	10		
Projected % body weight to be fed ( % BW)	3		
Planned duration of drug treatment (days)	10		
Total medicated feed needed ( lbs or Kg )	29.7		
Planned % Aquaflor® pre-mix in feed	0.066 = 9.0g aquaflor		
Anticipated treatment dates (start/end)	4/28 – 5/7/08		
Feed type (manufacturer/moist vs dry/size) for treatments and controls (identify both if different)	2 mm pellet dry Nelson and sons		

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**STUDY DESIGN:** Variable(s) to be tested: (See Sections VIII - XIII in Study Protocol). Describe in detail the purpose of the clinical trial (hypothesis), the number of experimental units, florfenicol dosage, the number of fish per unit, and the disease to be treated. Study designs must be carefully prepared and lend themselves to rigorous evaluation. If more space is required to describe study design, title additional page(s) "Study Design" and attach to this Worksheet.

**Fish were harvested and placed into raceway. The move stressed the fish and columnaris has been confirmed on the fish. Due to the importance of these fish it is prudent that the infection is eliminated. Will treat with florfenicol for 10 days.**

Study designed by John Doe

### DISPOSITION OF TREATED FISH (Human Food Safety Considerations):

1 yr Estimated time (days, months) from last treatment day to first possible harvest for human consumption

Check applicable box:

Study Objective A. 10 mg florfenicol per kg BW per day for 10 days; 21-day withdrawal period for salmonid species.

Study Objective B 10 mg florfenicol per kg BW per day for 10 days; 28-day withdrawal period for non-salmonid species.

Investigator or alternate shall initial here to indicate awareness that fish disposition must be in compliance with FDA-mandated withdrawal times as described in Section XV. of the Study Protocol.

### WORKER SAFETY CONSIDERATIONS:

Initial here to indicate that all personnel handling drug have read Material Safety Data Sheet for Aquaflor<sup>®</sup> and are aware of SAFETY precautions to be taken when handling medicated feed.

Initials are those of: John Doe  
(Print Name)

Date prepared 4/25/08 Investigator Sign here

Date reviewed 4/25/08 Monitor Sign here