

# National INAD Program Overview

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USFWS - AADAP

**Northwest Fish Culture Conference**

December 11 - 13, 2012



# Investigational New Animal Drug Exemptions (INAD)

- What are they and why are they important?
  - An FDA process that authorizes and controls the transport, possession, and use of certain unapproved drugs
  - Used under FDA approved study protocols to maintain the health and fitness of aquatic species and to meet management needs
  - Contribute drug effectiveness and safety data that may be used to support future drug approvals



## What they are not?

- A “use permit”!!!

# Key Personnel Involved

- Study Investigator
  - Designated by the facility
  - Responsible for conducting the INAD study



## Study Monitor

- Designated by the facility
  - Responsible for supervision of the study
- Field Trial Coordinator (a.k.a. me)
  - USFWS Employee with the AADAP Office
  - Responsible for administering the NIP

# Benefits of Participating in the National INAD Program (NIP)

- Access to needed drugs
  - Facility is enrolled under the INAD Program
  - Notify FDA and drug manufacturers of your facility's participation



Submit study data to Field Trial Coordinator

- Quarterly Drug Receipt Reports and Annual Reports
- Establishes a centralized database
  - Actual data under each INAD on efficacy and safety

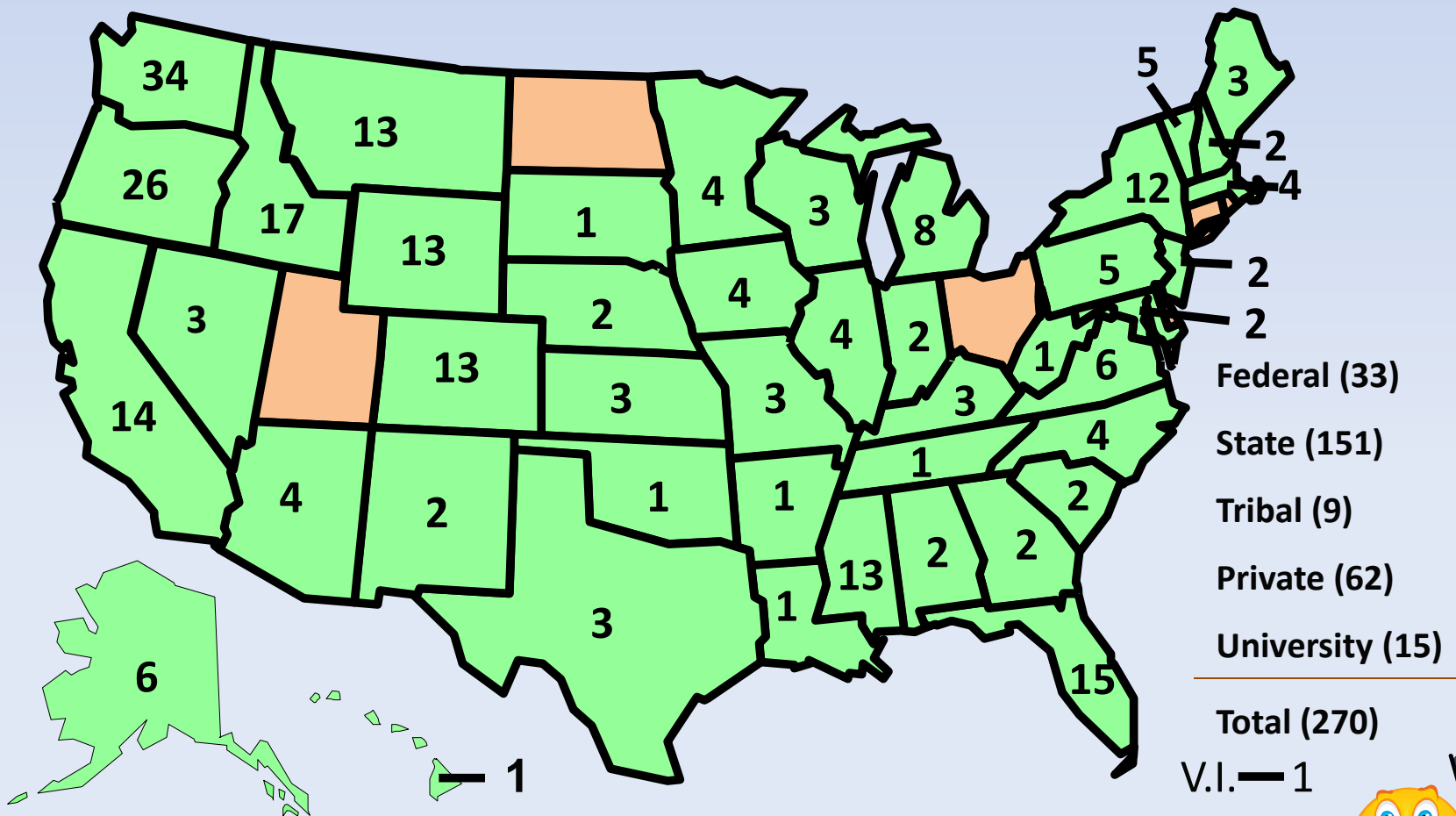
# INADs Administered by NIP

- Florfenicol  
(Fish & Lobster)
- OTC Med. Feed  
(Fish & Shrimp)
- Chloramine – T
- Diquat
- OTIMM
- H<sub>2</sub>O<sub>2</sub>
- SLICE
- Aqui-S 20E
- Benzoak
- sGnRH<sub>a</sub>  
(implant and injection)
- CCP
- CP
- LHRH<sub>a</sub>
- Calcein
- MT Med. Feed



# USFWS's National INAD Program

*Federal, State, Tribal and Private Aquaculture Partners Piggybackin' on FWS INADS – October 2012*



# INAD Field Data for Years 2004 - 2010

- 119 Fish Species Treated
  - 30 Salmonid
  - 75 non-Salmonid
  - 18 Marine
  - 10 Other
- Total number of fish treated
  - 574.9 M
- Total of  $\approx 5,000$  Studies Conducted
  - 83% successful
  - 4% unsuccessful
  - 13% inconclusive
- Virtually no adverse effects from INAD use



# INAD Forms

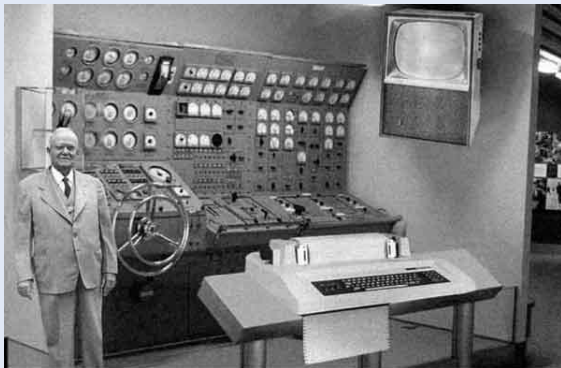
- Drug Receipt Form – Form 1
  - Filled out each time INAD drug is received
- Study Worksheet – Form W
  - Filled out prior to the start of a study
- Inventory Form – Form 2
  - Filled out each time an INAD drug is used
- Results Report – Form 3
  - Filled out after the completion of the study





# INAD Program Management System (Online Data Reporting)

- Allow INAD participants to enter data directly into the NIP online database
  - Accurate and complete data
    - Less transcription errors
    - Prompts for all required data to be filled out
- Built in system of “crosschecks”
  - Set criteria for each INAD to ensure Study Protocol is followed
    - Fish species; dosage, duration; purpose of drug



Launched February 2012

- Over 425 INAD participants
- Over 650 studies in various stages


# INAD Program Management System (Online Data Reporting)

Login page:

<http://www.aadapinad.com/>

INAD PROGRAM MANAGEMENT SYSTEM  
(ONLINE DATA REPORTING)

Returning Investigators & Study Monitors



USER NAME

PASSWORD

[Forgot Password?](#)

LOGIN

Establishing New User Accounts

Participation in the INAD PROGRAM MANAGEMENT SYSTEM requires that each facility (i.e., Investigator), as well as each facility's designated Study Monitor, create individual user accounts. Study monitor accounts should be created **before** facility accounts. During the establishment of a new facility account the facility's designated Study Monitor may then be selected from a drop-down menu, thereby effectively "linking" the facility with the appropriate Study Monitor. Pending review by the AADAP Office, each facility and Study Monitor will receive email notification with respect to the successful establishment of new user accounts.

[CHECK TO SEE IF YOUR FACILITY IS ALREADY ENROLLED](#)

USER ROLE

☒ Study Monitor ☐ Facility / Investigator

CREATE ACCOUNT

# Enrollment Form – Who you are

## GENERAL FACILITY INFORMATION \*Indicates Required Field

INVESTIGATOR FIRST NAME\*:

INVESTIGATOR LAST NAME\*:

PHONE NUMBER\*:

FAX NUMBER:

CURRENT NPDES PERMIT # (ENTER N/A IF UNAVAILABLE)\*:

TYPE OF FACILITY\*:

Federal Agency



AGENCY NAME\*:

My Agency/Company not listed please list below



IF OTHER:

FACILITY NAME\*:

FACILITY ADDRESS\*:

CITY\*:

STATE\*:

AL



ZIP CODE\*:

# Enrollment Form – and what you need to use

## SELECT STUDY MONITOR FOR THIS FACILITY

Tony Amandi (Corvallis, OR)

## INAD SIGN-UP: DRUGS THAT THIS FACILITY IS INTERESTED IN USING UNDER INAD AUTHORIZATION DURING THE CURRENT CALENDAR YEAR

**Instructions:** 1) select the current calendar year; 2) select the DRUG/INAD that will be used; 3) select the fish species to be treated; 4) enter the estimated number of fish to be treated; and 5) click on the ADD DRUG/INAD button. If more than one fish species is to be treated under a specific DRUG/INAD repeat the process (i.e., steps 1-5) for each species. Repeat the entire process for each DRUG/INAD that will be used. When all sign-up information has been entered, click on the SUBMIT DATA button.

**Note:** FDA and appropriate drug sponsors will be notified of each facility's DRUG/INAD participation.

| YEAR | DRUG/INAD                              | SPECIES  | NUMBER OF FISH TO BE TREATED |
|------|--|--|------------------------------|
| 2012 | Aquaflor (florfenicol) #10-697         | Rainbow Trout ( <i>Oncorhynchus mykiss</i> )           | 500000                       |
| 2012 | Aquaflor (florfenicol) #10-697         | Chinook Salmon ( <i>Oncorhynchus tshawytscha</i> )     | 100000                       |
| 2012 | Channel Catfish Pituitary (CP) #11-468 | Fish species not listed (contact AADAP to add species) |                              |

+ ADD DRUG / INAD

- Fish species not listed (contact AADAP to add species)
- Blue Catfish (*Ictalurus furcatus*)
- Blue/Channel Catfish Hybrid (*Ictalurus furcatus* x *I. punctatus*)
- Channel Catfish (*Ictalurus punctatus*)
- Flathead Catfish (*Pylodictis olivaris*)
- White Catfish (*Ameiurus catus*)
- Yaqui Catfish (*Ictalurus pricei*)

**Billing Information:** By submitting this form for approval I verify that the above-described facility would like to sign-up to participate in the National INAD Program. Further by submitting this form, I understand that if this is a non-federal facility, then a sign-up charge of \$400 per INAD will be invoiced for this facility. Note: if 17-Methyltestosterone Medicated Feed is selected, then the sign-up charge is \$600 for this INAD. If a facility has not previously participated in the National INAD Program, a one-time start-up charge of \$100 will be included. Invoices will be mailed out upon completion and approval of this form.

SUBMIT FOR APPROVAL >>

# Investigator Homepage

[INVESTIGATOR HOMEPAGE](#)[NEW STUDY REQUEST](#)[MANAGE/VIEW DRUG INVENTORY](#)[ACCOUNT INFO](#)[DOUG CURTIS](#)[\(SIGN OUT\)](#)

## INVESTIGATOR HOMEPAGE

[USEFUL LINKS](#)[GLOSSARY](#)[FAQ](#)[CONTACT](#)[MANUAL](#)

The new upgrade to the IPMS database was successfully uploaded! Please review your inventories and make the necessary changes.

### 4 STUDIES REQUIRING ACTION

#### ACTIVE STUDIES

FILTER

|  | START DATE | INAD NAME                     | STUDY NUMBER  | STATUS                  | STAGE  | TREATMENT INITIATED |  |
|--|------------|-------------------------------|---------------|-------------------------|--------|---------------------|--|
|  | 08/24/2012 | AQUAFLO (FLORFENICOL) #10-697 | 10-697-12-069 | IN-LIFE PHASE OF STUDY  | 4 OF 7 | YES                 |  |
|  | 08/12/2012 | AQUAFLO (FLORFENICOL) #10-697 | 10-697-12-064 | IN-LIFE PHASE OF STUDY  | 4 OF 7 | YES                 |  |
|  | 07/25/2012 | AQUAFLO (FLORFENICOL) #10-697 | 10-697-12-048 | IN-LIFE PHASE OF STUDY  | 4 OF 7 | YES                 |  |
|  | 02/06/2012 | AQUAFLO (FLORFENICOL) #10-697 | 10-697-12-004 | IN-LIFE PHASE OF STUDY  | 4 OF 7 | YES                 |  |
|  | 07/22/2012 | AQUAFLO (FLORFENICOL) #10-697 | 10-697-12-047 | AWAITING AADAP APPROVAL | 6 OF 7 | YES                 |  |
|  | 04/22/2012 | AQUAFLO (FLORFENICOL) #10-697 | 10-697-12-008 | AWAITING AADAP APPROVAL | 6 OF 7 | YES                 |  |

#### STUDY STAGES:

Stage 1: New study initiated by investigator (*Form W*)  
Stage 2: Study awaiting review and approval by Study Monitor  
Stage 3: Study awaiting review and study number assignment by AADAP  
Stage 4: In-life phase of study; treatment, data collection and Results Report (*Form 3*)  
Stage 5: Results Report (*Form 3*) awaiting review and approval by Study Monitor  
Stage 6: Results Report (*Form 3*) awaiting review and approval by AADAP  
Stage 7: Study complete

[VIEW/UPDATE STUDY >>](#)

#### COMPLETED STUDIES

FILTER

|  | START DATE | INAD NAME                     | STUDY NUMBER  | STATUS   | STAGE  | TREATMENT INITIATED |  |
|--|------------|-------------------------------|---------------|----------|--------|---------------------|--|
|  | 06/14/2012 | AQUAFLO (FLORFENICOL) #10-697 | 10-697-12-025 | COMPLETE | 7 OF 7 | YES                 |  |
|  | 06/14/2012 | AQUAFLO (FLORFENICOL) #10-697 | 10-697-12-024 | COMPLETE | 7 OF 7 | YES                 |  |
|  | 03/05/2012 | AQUAFLO (FLORFENICOL) #10-697 | 10-697-12-014 | COMPLETE | 7 OF 7 | YES                 |  |
|  | 01/20/2012 | AQUAFLO (FLORFENICOL) #10-697 | 10-697-12-003 | COMPLETE | 7 OF 7 | YES                 |  |

[CREATE REPORT >>](#)[VIEW STUDY >>](#)

#### CHEMICAL USE LOG - FORM 2

| DATE RECEIVED | DRUG / INAD                   | DRUG LOT NUMBER | AMOUNT ON-HAND |  |
|---------------|-------------------------------|-----------------|----------------|--|
| 08/24/2012    | AQUAFLO (FLORFENICOL) #10-697 | 035830          | 230.000        |  |
| 08/09/2012    | AQUAFLO (FLORFENICOL) #10-697 | 035830          | 250.000        |  |



4

## STUDIES REQUIRING ACTION

## ACTIVE STUDIES

FILTER

|  | START DATE | INAD NAME                     | STUDY NUMBER  | STATUS                  | STAGE  | TREATMENT INITIATED |
|--|------------|-------------------------------|---------------|-------------------------|--------|---------------------|
|  | 08/24/2012 | AQUAFLO (FLORFENICOL) #10-697 | 10-697-12-069 | IN-LIFE PHASE OF STUDY  | 4 OF 7 | YES                 |
|  | 08/12/2012 | AQUAFLO (FLORFENICOL) #10-697 | 10-697-12-064 | IN-LIFE PHASE OF STUDY  | 4 OF 7 | YES                 |
|  | 07/25/2012 | AQUAFLO (FLORFENICOL) #10-697 | 10-697-12-048 | IN-LIFE PHASE OF STUDY  | 4 OF 7 | YES                 |
|  | 02/06/2012 | AQUAFLO (FLORFENICOL) #10-697 | 10-697-12-004 | IN-LIFE PHASE OF STUDY  | 4 OF 7 | YES                 |
|  | 07/22/2012 | AQUAFLO (FLORFENICOL) #10-697 | 10-697-12-047 | AWAITING AADAP APPROVAL | 6 OF 7 | YES                 |
|  | 04/22/2012 | AQUAFLO (FLORFENICOL) #10-697 | 10-697-12-008 | AWAITING AADAP APPROVAL | 6 OF 7 | YES                 |

## STUDY STAGES:

Stage 1: New study initiated by investigator (Form W)

VIEW/UPDATE STUDY &gt;&gt;

## COMPLETED STUDIES

FILTER

|  | START DATE | INAD NAME                     | STUDY NUMBER  | STATUS   | STAGE  | TREATMENT INITIATED |
|--|------------|-------------------------------|---------------|----------|--------|---------------------|
|  | 06/14/2012 | AQUAFLO (FLORFENICOL) #10-697 | 10-697-12-025 | COMPLETE | 7 OF 7 | YES                 |
|  | 06/14/2012 | AQUAFLO (FLORFENICOL) #10-697 | 10-697-12-024 | COMPLETE | 7 OF 7 | YES                 |
|  | 03/05/2012 | AQUAFLO (FLORFENICOL) #10-697 | 10-697-12-014 | COMPLETE | 7 OF 7 | YES                 |
|  | 01/20/2012 | AQUAFLO (FLORFENICOL) #10-697 | 10-697-12-003 | COMPLETE | 7 OF 7 | YES                 |

CREATE REPORT &gt;&gt;

VIEW STUDY &gt;&gt;

**Study Number 10-697-12-025**  
**Aquaflor (florfenicol) #10-697 Clinical Field Trials**

**Summary of Results and Disposition of Medicated Fish**

**Part 1 - Facility, Investigator and Study Information:**

|  |                                |                              |
|--|--------------------------------|------------------------------|
| - Facility:                                  | <b>Wizard Falls Hatchery</b>   |                              |
| - Investigator:                              | <b>Doug Curtis</b>             | - Monitor:                   |
| - Treatment date(s) covered by this summary: | <b>06/14/2012 - 06/23/2012</b> | <b>Craig Banner</b>          |
| - Drug lot number(s):                        | <b>035830</b>                  | - Pre-mix concentration (%): |
|  |                                | <b>0.000</b>                 |

**Part 2 - Summary of Study Results:**

**Efficacy of treatment(s):**

|   |   |                                      |             |
|---|---|--------------------------------------|-------------|
| - Disease Treated/Treatment Objective:                                | <b>CWD - Bacterial Coldwater Disease</b>  |                                      |             |
| - Fish Species Treated:   | <b>Rainbow Trout</b>  |                                      |             |
| - Fish weight (fish/lb):  | <b>1000.0</b>   | - Fish length (in):                  | <b>1.3</b>  |
| - Number of treated fish:   | <b>581,972</b>  | - Number of control fish:            | <b>0</b>    |
| - Drug dosage used:   | <b>15.0 mg/Kg fish/day</b>  |                                      |             |
| - Number of treatment days:   | <b>10</b>   |                                      |             |
|   |   | - Number of treatments:              | <b>10</b>   |
| - Environmental and water quality factors affecting efficacy:         |   |                                      |             |
| - Average water temperature (°F):                                     | <b>50.00</b>  | - Dissolved Oxygen (mg/Kg fish/day): | <b>0.00</b> |
| - pH:   | <b>0.00</b>   | - Hardness - CaCo3 (mg/Kg fish/day): | <b>0.00</b> |
| - Evaluation of results and implications for label claim (narrative): |   |                                      |             |
|   | <b>Mortality decreased but not to actual desired numbers. Subsequent studies may very well be needed.</b> |                                      |             |

**Adverse reactions:**

- Evidence of target animal safety: **None**

**Part 3 - Disposition of Medicated Fish:**

- Observed withdrawal period of treated fish met: **Yes**

# Menu Bar



- Investigator Homepage
- New Study Request
- Manage/View Drug Inventory
- Account Info
- Useful Links
- Glossary
- FAQ
- Contact
- Manual



# Manage/View Drug Inventory

MANAGE/VIEW DRUG INVENTORY

USEFUL LINKS

GLOSSARY

FAQ

CONTACT

MANUAL

## DRUG RECEIPT - FORM 1

Click on "Receipt of Drug" button each time a new drug shipment is received.

RECEIPT OF DRUG >>

## CHEMICAL USE LOG - FORM 2

The Chemical Use Log is automatically populated from information entered in Receipt of Drug (Form 1s) and Results Report (Form 3s). Click the "View Drug Receipt" button to review the details of a drug shipment previously received. Click on the "Transfer" button to document the transfer of drug inventory to another authorized facility. Click on the "Discard" button to document the disposal of drug inventory according to guidelines provided in the Study Protocol.

Aquaflor (florfenicol) #10-697

LOT NUMBER: 035830

TRANSFER

DISCARD

DELETE RECEIPT

VIEW/EDIT RECEIPT >>

DATE RECEIVED: 08/24/2012

AMOUNT RECEIVED: 230.000 g

AMOUNT ON-HAND: 230.000 g

DATE OF ACTION

USED IN STUDY

AMOUNT USED

AMOUNT TRANSFERRED

AMOUNT DISCARDED

TOTALS:

0

0

0

LOT NUMBER: 035830

TRANSFER

DISCARD

DELETE RECEIPT

VIEW/EDIT RECEIPT >>

DATE RECEIVED: 08/09/2012



# Drug Receipt - Form 1

## DRUG RECEIPT - FORM 1

[USEFUL LINKS](#)[GLOSSARY](#)[FAQ](#)[CONTACT](#)[MANUAL](#)

Complete this form **immediately** upon receipt of a new drug shipment. Please note that in some situations a new drug shipment may be used for only a single treatment/study, while in other situations it may be used in treatments/studies conducted over the course of several years. Carefully review your information, and then click the "Add to Drug Inventory" button.

Note: Once this form has been completed and added to drug inventory, **no changes** can be made to it.

|   |  |   |
|---|--|---|
| DRUG*:  | <input type="text" value="Aquaflor (florfenicol) #10-697"/>  |  |
| DATE OF DRUG RECEIPT*:  | <input type="text"/>  |   |
| DRUG LOT NUMBER*:   | <input type="text"/>   |   |
| AMOUNT RECEIVED (g):  | <input type="text"/>   |   |
| DRUG SUPPLIER*:   | <input type="text"/>   |   |
| APPROXIMATE # OF TREATED ANIMALS*:                              | <input type="text"/>   |   |
| APPROXIMATE DATES OF TRIALS (e.g.<br>12/20/2010 - 01/20/2011)*: | <input type="text"/>   |   |
| SPECIES, SIZE AND TYPES OF ANIMALS*:                            | <input type="text"/>   |   |

[ADD TO DRUG INVENTORY >>](#)[VIEW / PRINT RECEIPT REPORT >>](#)

# Drug Receipt Report Sent to FDA

## Report on Receipt of Drug - Guide for Reporting Investigational New Animal Drug Shipments for Poikilothermic Food Animals

*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                           | <b>Aquaflor (florfenicol) #10-697</b>  |
| Proposed Uses of Drug                  | <p>FFC Option A - Determine if 10 mg of florfenicol per kg of fish per day for 10 consecutive days is efficacious when fed as a feed additive for the control of bacterial diseases. Note: for non labeled drug use only.</p> <p>FFC Option B - Determine if 15 mg of florfenicol per kg of fish per day for 10 consecutive days is efficacious when fed as a feed additive for the control of bacterial diseases.</p> |
| Date of CVM Authorization Letter       | August 17, 2011  |
| Date of Drug Receipt                   | August 24, 2012  |
| Drug Lot Number                        | 035830   |
| Amount of Drug Received                | 230.000 g  |
| Name of Investigator                   | Doug Curtis  |
| Address of Investigator                | pob 130<br>Camp Sherman, OR 97730  |
| Location of Trial                      | Wizard Falls Hatchery  |
| Approximate Number of Treated Animals  | 265000   |
| Number of Animals Used Previously      |  |
| Approximate dates of trial (start/end) | 08/25/2012-09/03/12  |
| Species, Size, and Type of Animals     | Rainbow,fingerling,fish  |
| Maximum daily dose and duration        | 15 mg/kg body weight daily for 10 consecutive days   |
| Method(s) of Administration            | Medicated feed   |
| Withdrawal Period                      | 21 days for salmonids; 28 days for nonsalmonids  |

# Chemical use Log – Form 2

LOT NUMBER: 035830

TRANSFER

DISCARD

DELETE RECEIPT

VIEW/EDIT RECEIPT >>

DATE RECEIVED: 07/20/2012

AMOUNT RECEIVED: 92.000 g

AMOUNT ON-HAND: 92.000 g

| DATE OF ACTION | USED IN STUDY | AMOUNT USED | AMOUNT TRANSFERRED | AMOUNT DISCARDED |
|----------------|---------------|-------------|--------------------|------------------|
| TOTALS:        |               | 0           | 0                  | 0                |

LOT NUMBER: 035830

VIEW/EDIT RECEIPT >>

DATE RECEIVED: 07/19/2012

AMOUNT RECEIVED: 50.000 g

AMOUNT ON-HAND: 0.000 g

| DATE OF ACTION | USED IN STUDY        | AMOUNT USED | AMOUNT TRANSFERRED | AMOUNT DISCARDED |      |        |
|----------------|----------------------|-------------|--------------------|------------------|------|--------|
| 07/31/2012     | <u>10-697-12-047</u> | 50 g        |                    |                  | EDIT | REMOVE |
| TOTALS:        |                      | 50 g        | 0 g                | 0 g              |      |        |

LOT NUMBER: 035830

VIEW/EDIT RECEIPT >>

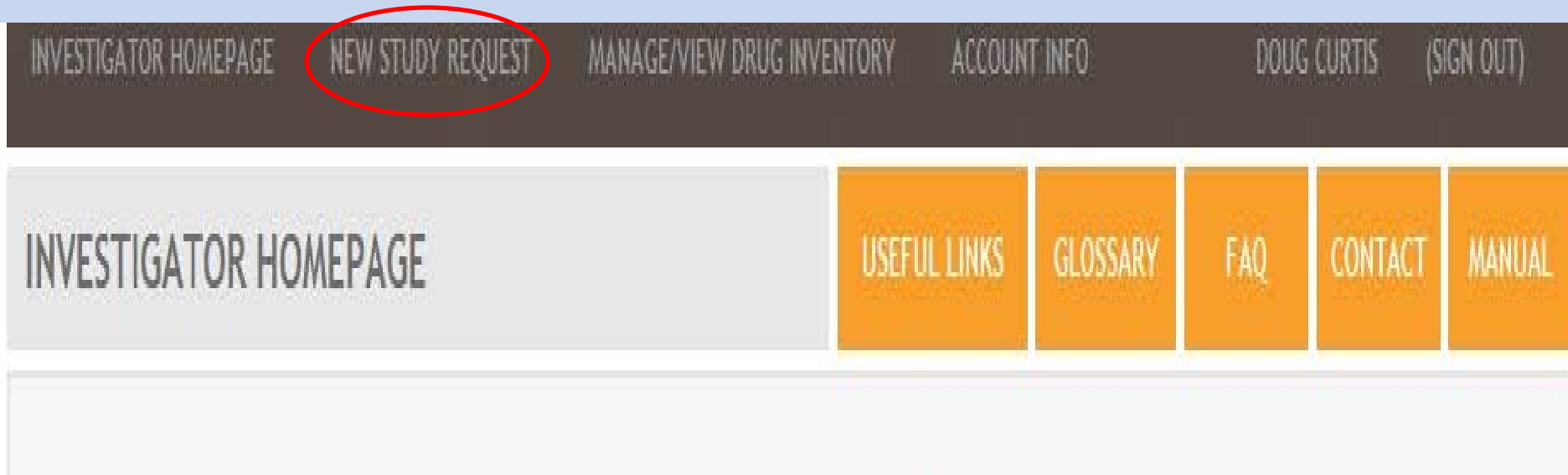
DATE RECEIVED: 06/13/2012

AMOUNT RECEIVED: 152.000 g

AMOUNT ON-HAND: 0.000 g

| DATE OF ACTION | USED IN STUDY        | AMOUNT USED | AMOUNT TRANSFERRED | AMOUNT DISCARDED |      |        |
|----------------|----------------------|-------------|--------------------|------------------|------|--------|
| 06/14/2012     | <u>10-697-12-024</u> | 72 g        |                    |                  | EDIT | REMOVE |
| 06/14/2012     | <u>10-697-12-025</u> | 80 g        |                    |                  | EDIT | REMOVE |
| TOTALS:        |                      | 152 g       | 0 g                | 0 g              |      |        |

# Menu Bar



## New Study Request –

Initiated prior to treatment

Best estimate on what you are planning

Starts your study treatment record keeping

# Study Work Sheet - Form W

## what you are planning

PLEASE FILL OUT ALL REQUIRED FORM DATA. \*INDICATES A REQUIRED FIELD

CURRENT STAGE: 1 OF 7

STUDY #: - PENDING -

FACILITY: Wizard Falls Hatchery

DRUG:

MONITOR: Craig Banner

### TREATMENT INFORMATION AND SCHEDULE

ESTIMATED AMOUNT OF DRUG NEEDED  
FOR TREATMENT (g)\*:

>> CURRENT DRUG INVENTORY:

|           |                |                                   |
|-----------|----------------|-----------------------------------|
| 035830    | On Hand: 92 g  | Received: 92.000 g on 07/20/2012  |
| DATE USED | AMOUNT USED    |                                   |
| 035830    | On Hand: 250 g | Received: 250.000 g on 08/09/2012 |
| DATE USED | AMOUNT USED    |                                   |
| 035830    | On Hand: 230 g | Received: 230.000 g on 08/24/2012 |
| DATE USED | AMOUNT USED    |                                   |

REPORTING INDIVIDUAL:

FISH SPECIES TREATED\*:

DISEASE TO BE TREATED/TREATMENT  
OBJECTIVE\*:

IF OTHER DISEASE/OBJECTIVE, PLEASE  
SPECIFY:

DRUG DOSE (10 TO 15 mg/Kg fish/day)\*:

AVERAGE FISH WEIGHT\*:  gm

AVERAGE FISH LENGTH\*:  in

NUMBER OF FISH PER REARING UNIT\*:

NUMBER OF TREATED REARING UNITS\*:

TOTAL NUMBER OF TREATED FISH\*:

NUMBER OF CONTROL REARING UNITS\*:

TOTAL NUMBER OF CONTROL FISH\*:

#### Disposition of Treated Fish (Human Food Safety Considerations)\*:

- ☐ Investigator should check here to indicate awareness that fish disposition must be in compliance with FDA-mandated withdrawal times as described in the Study Protocol.

#### Worker Safety Considerations\*:

- ☐ Investigator should check here to indicate that all personnel handling drug have read Material Safety Data Sheet and have been provided protective equipment, in good working condition, as described in the MSDS.

### DRUG-SPECIFIC ELEMENT

#### MEDICATED FEEDS

% BODY WEIGHT FED\*:

TOTAL WEIGHT OF FISH\*:  kgs

TOTAL AMOUNT OF FEED (Kg)\*:

TOTAL AMOUNT OF DRUG PREMIX (g):

% DRUG PRE-MIX IN FEED:

TOP-COATED OR PREPARED BY FEED  
SUPPLIER\*:

SUBMIT FOR APPROVAL >>



# Study Work Sheet – Form W

## drop downs specific to each INAD

|   |  |                                   |  |
|---|--|-----------------------------------|--|
| STUDY #: - PENDING -                                |  | FACILITY: Wizard Falls Hatchery   |  |
| DRUG: Aquaflor (florfenicol) #10-697                |  | MONITOR: Craig Banner             |  |
| TREATMENT INFORMATION AND SCHEDULE                  |  |                                   |  |
| ESTIMATED AMOUNT OF DRUG NEEDED FOR TREATMENT (g)*: | <div><div>Aeromonas Salmonicida</div><div>Aeromonas spp.</div><div>Bacterial Hemorrhagic Septicemia</div><div>Bacterial Kidney Disease</div><div>Bacterial Septicemia</div><div>Carnobacterium maltaromaticum</div><div>Columnaris</div><div>CWD - Bacterial Coldwater Disease</div><div>Edwardsiella Tarda</div><div>Enteric Redmouth</div><div>Enteric Septicemia Catfish</div><div>Epitheliocystis</div><div>Flavobacteriosis</div><div>Flexibacter maritimus</div><div>General Systemic Bacterial Infection</div><div>Gram Negative Bacteria</div><div>Gram Negative Bacterial Enteritis</div><div>Gram Negative Bacterial Septicemia</div><div>Hot Foot Syndrome</div><div>Lactobacilliosis</div><div>Motile Aeromonad</div><div>Motile Aeromonad Septicemia</div><div>Photobacterium spp.</div><div>Rickettsia Like Organism</div><div>Saltwater Bacterial Coldwater Disease</div><div>Saltwater Columnaris</div><div>Streptococcal Septicemia</div><div>Streptococcus</div><div>Streptococcus iniae</div><div>Systemic Flavobacteriosis</div><div>CWD - Bacterial Coldwater Disease</div></div> |                                   |  |
| >> CURRENT DRUG INVENTORY:                          |  | Received: 92.000 g on 07/20/2012  |  |
|   |  | Received: 250.000 g on 08/09/2012 |  |
| REPORTING INDIVIDUAL:                               |  |                                   |  |
| FISH SPECIES TREATED*:                              |  |                                   |  |
| DISEASE TO BE TREATED/TREATMENT OBJECTIVE*:         |  |                                   |  |
| IF OTHER DISEASE/OBJECTIVE, PLEASE SPECIFY:         |  |                                   |  |
| DRUG DOSE (10 TO 15 mg/Kg fish/day)*:               |  |                                   |  |

### DRUG-SPECIFIC ELEMENT

#### MEDICATED FEEDS

|   |   |
|---|---|
| % BODY WEIGHT FED*:                       | <input type="text"/>                                      |
| TOTAL WEIGHT OF FISH*:                    | <input type="text"/> kgs <input type="button" value="v"/> |
| TOTAL AMOUNT OF FEED (Kg)*:               | <input type="text"/>                                      |
| TOTAL AMOUNT OF DRUG PREMIX (g):          | <input type="text"/>                                      |
| % DRUG PRE-MIX IN FEED:                   | <input type="text"/>                                      |
| TOP-COATED OR PREPARED BY FEED SUPPLIER*: | Bio-Oregon <input type="button" value="v"/>               |

SUBMIT FOR APPROVAL >>

# Study Work Sheet – Form W

## Must fix errors before form can be submitted

- Please supply the estimated treatment amount needed.
- Please supply the study design.
- Please check the disposition of treated fish checkbox.
- Please check the worker safety considerations checkbox.
- Please supply the percent bodyweight fed.
- Please supply the total fish weight.
- Please supply the total amount of feed.

Note: no information will be saved until these errors are addressed.

PLEASE FILL OUT ALL REQUIRED FORM DATA. \*INDICATES A REQUIRED FIELD

CURRENT STAGE: 1 OF 7

STUDY #: - PENDING -

FACILITY: Wizard Falls Hatchery

DRUG: Aquaflor (florfenicol) #10-697

MONITOR: Craig Banner

### TREATMENT INFORMATION AND SCHEDULE

ESTIMATED AMOUNT OF DRUG NEEDED  
FOR TREATMENT (g)\*:

>> CURRENT DRUG INVENTORY:

035830

On Hand: 92 g

Received: 92.000 g on 07/20/2012

DATE USED

AMOUNT USED

035830

On Hand: 250 g

Received: 250.000 g on 08/09/2012

DATE USED

AMOUNT USED

035830

On Hand: 230 g

Received: 230.000 g on 08/24/2012

DATE USED

AMOUNT USED

REPORTING INDIVIDUAL:

FISH SPECIES TREATED\*:

Rainbow Trout

DISEASE TO BE TREATED/TREATMENT  
OBJECTIVE\*:

CWD - Bacterial Coldwater Disease

IF OTHER DISEASE/OBJECTIVE, PLEASE  
SPECIFY:

DRUG DOSE (10 TO 15 mg/Kg fish/day)\*:

AVERAGE FISH WEIGHT\*:

gm

AVERAGE FISH LENGTH\*:

in

NUMBER OF FISH PER REARING UNIT\*:



# Investigator Homepage

## 6 STUDIES REQUIRING ACTION

### ACTIVE STUDIES

FILTER

|  | START DATE | INAD NAME                                 | STUDY NUMBER            | STATUS                           | STAGE  | TREATMENT INITIATED |
|--|------------|---|-------------------------|----------------------------------|--------|---------------------|
|  | 01/01/2012 | TERRAMYCIN 200 FOR FISH (FEED MARK) #9332 | SCREEN SHOT NO STUDY    | IN-LIFE PHASE OF STUDY           | 4 OF 7 | YES                 |
|  | 11/11/2011 | OVAPLANT (SGNRHA) #11-375                 | CVM TEST DATABASE       | IN-LIFE PHASE OF STUDY           | 4 OF 7 | YES                 |
|  | 11/11/2011 | SLICE (EMAMECTIN BENZOATE) #11-370        | CVM TEST SLICE          | IN-LIFE PHASE OF STUDY           | 4 OF 7 | YES                 |
|  | 01/18/2012 | CHLORAMINE-T #9321                        | TEST DISCHARGE C/T      | A WAITING STUDY MONITOR APPROVAL | 5 OF 7 | YES                 |
|  | 01/01/2012 | SE-MARK (CALCEIN) #10-987                 | PENDING                 | A WAITING STUDY MONITOR APPROVAL | 2 OF 7 | YES                 |
|  | 11/11/2011 | 35% PEROX-AID (HYDROGEN PEROXIDE) #11-669 | PENDING                 | A WAITING STUDY MONITOR APPROVAL | 2 OF 7 | YES                 |
|  | 11/11/2011 | AQUAFLO (FLORFENICOL) #10-697             | PENDING                 | A WAITING STUDY MONITOR APPROVAL | 2 OF 7 | YES                 |
|  | 07/31/2007 | AQUI-S 20E (EUGENOL) #11-741              | AQUI-S FIELD MOCK UP TE | A WAITING STUDY MONITOR APPROVAL | 5 OF 7 | YES                 |

#### STUDY STAGES:

- Stage 1: New study initiated by investigator (Form W)
- Stage 2: Study awaiting review and approval by Study Monitor
- Stage 3: Study awaiting review and study number assignment by AADAP
- Stage 4: In-life phase of study; treatment, data collection and Results Report (Form 3)
- Stage 5: Results Report (Form 3) awaiting review and approval by Study Monitor
- Stage 6: Results Report (Form 3) awaiting review and approval by AADAP
- Stage 7: Study complete

[VIEW/UPDATE STUDY >>](#)

# Results Report – Form 3

## what actually happened

WAS TREATMENT INITIATED? ☒ Yes ☐ No

▼ TREATMENT INFORMATION AND SCHEDULE

NOTE: CERTAIN DATA ON THIS FORM HAS BEEN "PREPOPULATED" FROM INFORMATION PROVIDED IN THE STUDY WORKSHEET - FORM W. PLEASE REVIEW AND EDIT (IF NECESSARY) ALL DATA TO REFLECT ACTUAL TREATMENT DATA.

AMOUNT OF DRUG USED\*:

**test** On Hand: 44 Kg Received: 50.000 Kg on 12/04/2011

DATE USED:  AMOUNT USED:  Kg

TOTAL USED IN THIS STUDY: 0 Kg

**test again** On Hand: 499,975 Kg Received: 50000.000 Kg on 01/12/2011

DATE USED:  AMOUNT USED:  Kg

TOTAL USED IN THIS STUDY: 0 Kg

**12** On Hand: 12 Kg Received: 12.000 Kg on 10/12/2011

DATE USED:  AMOUNT USED:  Kg

TOTAL USED IN THIS STUDY: 0 Kg

REPORTING INDIVIDUAL:

FISH SPECIES TREATED\*:

DISEASE TREATED/TREATMENT OBJECTIVE\*:

IF OTHER DISEASE/OBJECTIVE, PLEASE SPECIFY:

DRUG DOSE (10 TO 20 mg/L)\*:

AVERAGE FISH WEIGHT\*:  gm

AVERAGE FISH LENGTH\*:  in

NUMBER OF FISH PER REARING UNIT\*:

NUMBER OF TREATED REARING UNITS\*:

AVERAGE WATER QUALITY PARAMETERS DURING TREATMENT PERIOD

TEMPERATURE\*:  Fahrenheit

DISSOLVED OXYGEN (mg/L):

pH:

HARDNESS - CaCO3 (mg/L):

DRUG-SPECIFIC ELEMENT

IMMERSION DRUGS

BATH TYPE\*: ☐ FLOW-THROUGH ☒ STATIC

DURATION OF TREATMENT (HR)\*:

DAYS\*: ☒ ALTERNATE ☐ CONSECUTIVE ☐ WEEKLY ☐ SINGLE

TREATMENT DATE(S)\*:   
(e.g. 12/20/2011 - 12/24/2011)

MORTALITY RECORD

1) Enter date and rearing unit ID.  
2) Select if entry is for a treated or a control unit.  
3) Select if entry is for a treatment day.  
4) Enter mortality number.  
5) Repeat until five days of pre-treatment, treatment period, and ten days of post-treatment data have been entered. Enter a mortality record for each study day even if the mortality was zero, or it was a day in between treatments. If mortality was not collected for that day then enter zero for that day's record.

|                                     | DATE       | REARING UNIT ID | TREATMENT CONDITION | TREATMENT DAY | MORTALITY |
|-------------------------------------|------------|-----------------|---------------------|---------------|-----------|
| <input checked="" type="checkbox"/> | 11/11/2011 | 1               | TREATED             | YES           | 2         |
| <input checked="" type="checkbox"/> | 11/12/2011 | 1               | TREATED             | YES           | 5         |
| <input checked="" type="checkbox"/> | 11/13/2011 | 1               | TREATED             | YES           | 0         |

DATE:

REARING UNIT ID:

TREATMENT CONDITION:

### RESULTS

Describe in detail the treatment results. Was treatment successful? If treatment did not appear to be successful, explain why not? Describe general fish behavior, including feeding behavior. Were there any mitigating environmental conditions that may have impacted treatment results? Were there any deviations from the Study Protocol?

#### DESCRIPTION OF RESULTS\*:

#### IN YOUR OPINION, WAS THE STUDY SUCCESSFUL\*:

Yes ☒ No ☐

#### TOXICITY OBSERVATIONS - REPORT ANY APPARENT DRUG TOXICITY INCLUDING A DESCRIPTION OF UNUSUAL FISH BEHAVIOR\*:

None

#### REQUIRED WITHDRAWAL PERIOD MET\*:

☒ YES ☐ NO

#### NUMBER OF DAYS BEFORE AVAILABILITY OF FISH FOR HUMAN CONSUMPTION\*:

#### DRUG DISCHARGE\*:

☒ CALCULATED CONCENTRATION ☐ MEASURED CONCENTRATION ☐ NEUTRALIZED WITH SODIUM THIOSULFATE

#### EFFLUENT CONCENTRATION (mg/L)\*:

#### PATHOLOGY REPORT INCLUDED\*:

☐ MAIL/FAX ☒ NO PATHOLOGY REPORT AVAILABLE

#### DISPOSITION OF UNUSED DRUG\*:

Unused drug is stored on-site.

SAVE CHANGES

SAVE / SUBMIT FOR APPROVAL >>

# Results Report – Form 3

## Data is copied over from study worksheet!

WAS TREATMENT INITIATED? ☒ Yes ☐ No

### ▼ TREATMENT INFORMATION AND SCHEDULE

**NOTE: CERTAIN DATA ON THIS FORM HAS BEEN "PREPOPULATED" FROM INFORMATION PROVIDED IN THE STUDY WORKSHEET - FORM W. PLEASE REVIEW AND EDIT (IF NECESSARY) ALL DATA TO REFLECT ACTUAL TREATMENT DATA.**

AMOUNT OF DRUG USED\*:

test

On Hand: 44 Kg

Received: 50.000 Kg on 12/04/2011

DATE USED



AMOUNT USED

Kg

ADD

TOTAL USED IN THIS STUDY: 0 Kg

REPORTING INDIVIDUAL:

FISH SPECIES TREATED\*:

Bluegill



DISEASE TREATED/TREATMENT  
OBJECTIVE\*:

BGD - Bacterial Gill Disease



IF OTHER DISEASE/OBJECTIVE, PLEASE  
SPECIFY:

DRUG DOSE (10 TO 20 mg/L)\*:

10.0

AVERAGE FISH WEIGHT\*:

10.0

gm



AVERAGE FISH LENGTH\*:

20.0

in



NUMBER OF FISH PER REARING UNIT\*:

500

NUMBER OF TREATED REARING UNITS\*:

1

# Shortcut for creating study worksheets!

[DUPLICATE THIS STUDY >>](#)

## AVERAGE WATER QUALITY PARAMETERS DURING TREATMENT PERIOD

TEMPERATURE\*:

Fahrenheit



DISSOLVED OXYGEN (mg/L):

pH:




HARDNESS - CaCO<sub>3</sub> (mg/L):

DRUG-SPECIFIC ELEMENT

# Drug Specific Tables

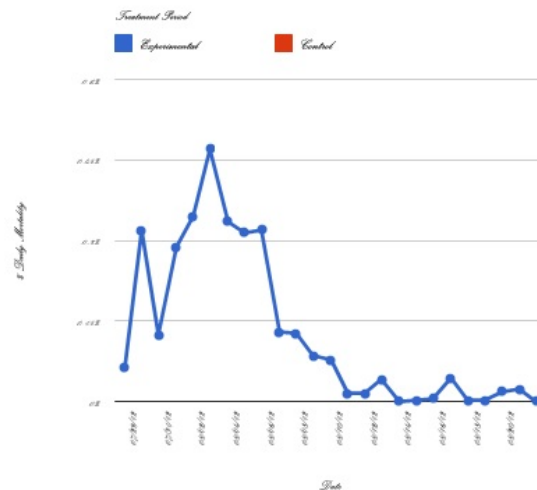
## MORTALITY RECORD

- 1) Enter date and rearing unit ID.
- 2) Select if entry is for a treated or a control unit.
- 3) Select if entry is for a treatment day.
- 4) Enter mortality number.
- 5) Repeat until five days of pre-treatment, treatment period, and ten days of post-treatment data have been entered. Enter a mortality record for each study day even if the mortality was zero, or it was a day in between treatments. If mortality was not collected for that day then enter zero for that day's record.

|   | DATE       | REARING UNIT ID | TREATMENT CONDITION | TREATMENT DAY | MORTALITY |
|---|------------|-----------------|---------------------|---------------|-----------|
|  | 11/11/2011 | 1               | TREATED             | YES           | 2         |
|  | 11/12/2011 | 1               | TREATED             | YES           | 5         |
|  | 11/13/2011 | 1               | TREATED             | YES           | 0         |

## MORTALITY AS PERCENTAGE OF TOTAL FISH TREATED

**Facility:** Bandon Hatchery  
**Drug:** Aquaflor (florfenicol) #10-697  
**Study #:** 10-697-12-067  
**Disease:** CWD - Bacterial Coldwater Disease  
**Species:** Steelhead  
**Dose:** 15.0 mg/Kg fish/day  
**Avg temp:** 58.00° F  
**Treatment period:** 08/03/2012 to 08/12/2012  
**Number of treatment days:** 10



DATE

REARING UNIT ID

TREATMENT CONDITION

Treated



# Results Report – Form 3

## RESULTS

Describe in detail the treatment results. Was treatment successful? If treatment did not appear to be successful, explain why not? Describe general fish behavior, including feeding behavior. Were there any mitigating environmental conditions that may have impacted treatment results? Were there any deviations from the Study Protocol?

DESCRIPTION OF RESULTS\*

IN YOUR OPINION, WAS THE STUDY SUCCESSFUL?\*

Yes

TOXICITY OBSERVATIONS - REPORT ANY APPARENT DRUG TOXICITY INCLUDING A DESCRIPTION OF UNUSUAL FISH BEHAVIOR\*:

None

REQUIRED WITHDRAWAL PERIOD MET\*:

☒ YES ☐ NO

NUMBER OF DAYS BEFORE AVAILABILITY OF FISH FOR HUMAN CONSUMPTION\*:

DRUG DISCHARGE\*:

☒ CALCULATED CONCENTRATION

☐ MEASURED CONCENTRATION

☐ NEUTRALIZED WITH SODIUM THIOSULFATE

EFFLUENT CONCENTRATION (mg/L)\*:

PATHOLOGY REPORT INCLUDED\*:

☐ MAIL/FAX ☒ NO PATHOLOGY REPORT AVAILABLE

DISPOSITION OF UNUSED DRUG\*:

Unused drug is stored on-site.

SAVE CHANGES

SAVE / SUBMIT FOR APPROVAL ➤



# It's Easy Peasy!

INVESTIGATOR HOMEPAGE NEW STUDY REQUEST MANAGE/VIEW DRUG INVENTORY ACCOUNT INFO DOUG CURTIS (SIGN OUT)

## INVESTIGATOR HOMEPAGE

[USEFUL LINKS](#)[GLOSSARY](#)[FAQ](#)[CONTACT](#)[MANUAL](#)

The new upgrade to the IPMS database was successfully uploaded! Please review your inventories and make the necessary changes.

### 4 STUDIES REQUIRING ACTION

#### ACTIVE STUDIES

[FILTER](#)

|                                  | START DATE | INAD NAME                     | STUDY NUMBER  | STATUS                  | STAGE  | TREATMENT INITIATED |
|----------------------------------|------------|-------------------------------|---------------|-------------------------|--------|---------------------|
| <input checked="" type="radio"/> | 08/24/2012 | AQUAFLO (FLORFENICOL) #10-697 | 10-697-12-069 | IN-LIFE PHASE OF STUDY  | 4 OF 7 | YES                 |
| <input type="radio"/>            | 08/12/2012 | AQUAFLO (FLORFENICOL) #10-697 | 10-697-12-064 | IN-LIFE PHASE OF STUDY  | 4 OF 7 | YES                 |
| <input type="radio"/>            | 07/25/2012 | AQUAFLO (FLORFENICOL) #10-697 | 10-697-12-048 | IN-LIFE PHASE OF STUDY  | 4 OF 7 | YES                 |
| <input type="radio"/>            | 02/06/2012 | AQUAFLO (FLORFENICOL) #10-697 | 10-697-12-004 | IN-LIFE PHASE OF STUDY  | 4 OF 7 | YES                 |
| <input type="radio"/>            | 07/22/2012 | AQUAFLO (FLORFENICOL) #10-697 | 10-697-12-047 | AWAITING AADAP APPROVAL | 6 OF 7 | YES                 |
| <input type="radio"/>            | 04/22/2012 | AQUAFLO (FLORFENICOL) #10-697 | 10-697-12-008 | AWAITING AADAP APPROVAL | 6 OF 7 | YES                 |

#### STUDY STAGES:

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Stage 4: In-life phase of study; treatment, data collection and Results Report (Form 3)  
Stage 5: Results Report (Form 3) awaiting review and approval by Study Monitor  
Stage 6: Results Report (Form 3) awaiting review and approval by AADAP  
Stage 7: Study complete

[VIEW/UPDATE STUDY >>](#)

#### COMPLETED STUDIES

[FILTER](#)

|                                  | START DATE | INAD NAME                     | STUDY NUMBER  | STATUS   | STAGE  | TREATMENT INITIATED |
|----------------------------------|------------|-------------------------------|---------------|----------|--------|---------------------|
| <input checked="" type="radio"/> | 06/14/2012 | AQUAFLO (FLORFENICOL) #10-697 | 10-697-12-025 | COMPLETE | 7 OF 7 | YES                 |
| <input type="radio"/>            | 06/14/2012 | AQUAFLO (FLORFENICOL) #10-697 | 10-697-12-024 | COMPLETE | 7 OF 7 | YES                 |
| <input type="radio"/>            | 03/05/2012 | AQUAFLO (FLORFENICOL) #10-697 | 10-697-12-014 | COMPLETE | 7 OF 7 | YES                 |
| <input type="radio"/>            | 01/20/2012 | AQUAFLO (FLORFENICOL) #10-697 | 10-697-12-003 | COMPLETE | 7 OF 7 | YES                 |

[CREATE REPORT >>](#)[VIEW STUDY >>](#)

#### CHEMICAL USE LOG - FORM 2

| DATE RECEIVED | DRUG / INAD                   | DRUG LOT NUMBER | AMOUNT ON-HAND |
|---------------|-------------------------------|-----------------|----------------|
| 08/24/2012    | AQUAFLO (FLORFENICOL) #10-697 | 035830          | 230.000        |
| 08/09/2012    | AQUAFLO (FLORFENICOL) #10-697 | 035830          | 250.000        |

# Summary

- The NIP continues to collect a wealth of very useful data that is generated by end-users in real world/production settings. This data is likely the most accurate reflection of what end-users should expect regarding a potential new drug's effectiveness and safety.
- All NIP participants must recognize their responsibilities to properly use, account for, and safe-guard INADs and to comply with study protocol requirements in the collection and submission of data.



# Questions

- AADAP Website:  
<http://www.fws.gov/fisheries/aadap/home.htm>
- IPMS online database: <http://www.aadapinad.com/>

