



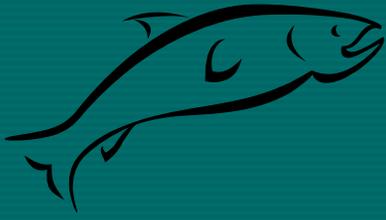
Aquatic Animal Drug Approval Partnership Program



**Program Overview ...
or, a little bit about the AADAP Program**

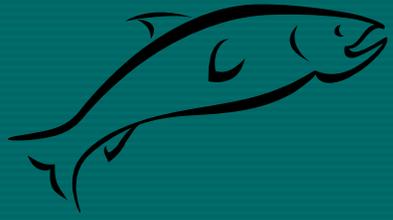
Presented by:

**Jim Bowker and Tom Bell
U.S. Fish & Wildlife Service
Aquatic Animal Drug Approval
Partnership Program**



Background

- **FDA regulates the approval of drugs in aquaculture the same way it regulates drugs administered to the Big Seven....if not even more restrictively**
- **Public and private aquaculture in the U.S. desperately needs FDA-approved drugs for use in aquatic species.**
- **Lack of legal access to approved drugs jeopardizes the health and fitness of cultured fish.**



The Monkey Wrenches

- **Costly venture to obtain a New Animal Drug Application from FDA**
- **Inexperience or naiveté of drug/chemical sponsor to weave their way through the approval process**
- **Lack of economic incentive for sponsor to pursue an aquaculture approval**
- **A fish is not a fish is not....**
- **“Direct, point-source” discharge of drugs into public water**

What was needed....

- **Public sector involvement**
- **Establish a position to recruit and assist sponsors**
- **Compassionate Investigational New Animal Drug exemptions and slaughter authorizations**
- **Sponsor and researchers more savvy in the “ways of FDA”**
- **More FDA/CVM aquaculture reviewers**

Fast Forward

- **National Aquaculture NADA Coordinator**
- **Engaged sponsors**
- **CVM's Aquaculture Team has grown**
- **Huge involvement by the public sector**
 - **USGS – UMESC; USDA – SNARC ;USFWS – AADAP; CVM – OR; JSA**
 - **State Natural Resource Agencies – AFWA, Mont FWP, Iowa DNR, Wash DFW, PA BFC, ID DFG**
 - **Universities – Idaho, Mississippi State, Southern Illinois, Cornell, Auburn, Arizona, Florida, Wisconsin**
 - **Commercial – Fish Breeders of Idaho, SeaPac of Idaho, Kent SeaTech Corp, Simaron Fish Farm**

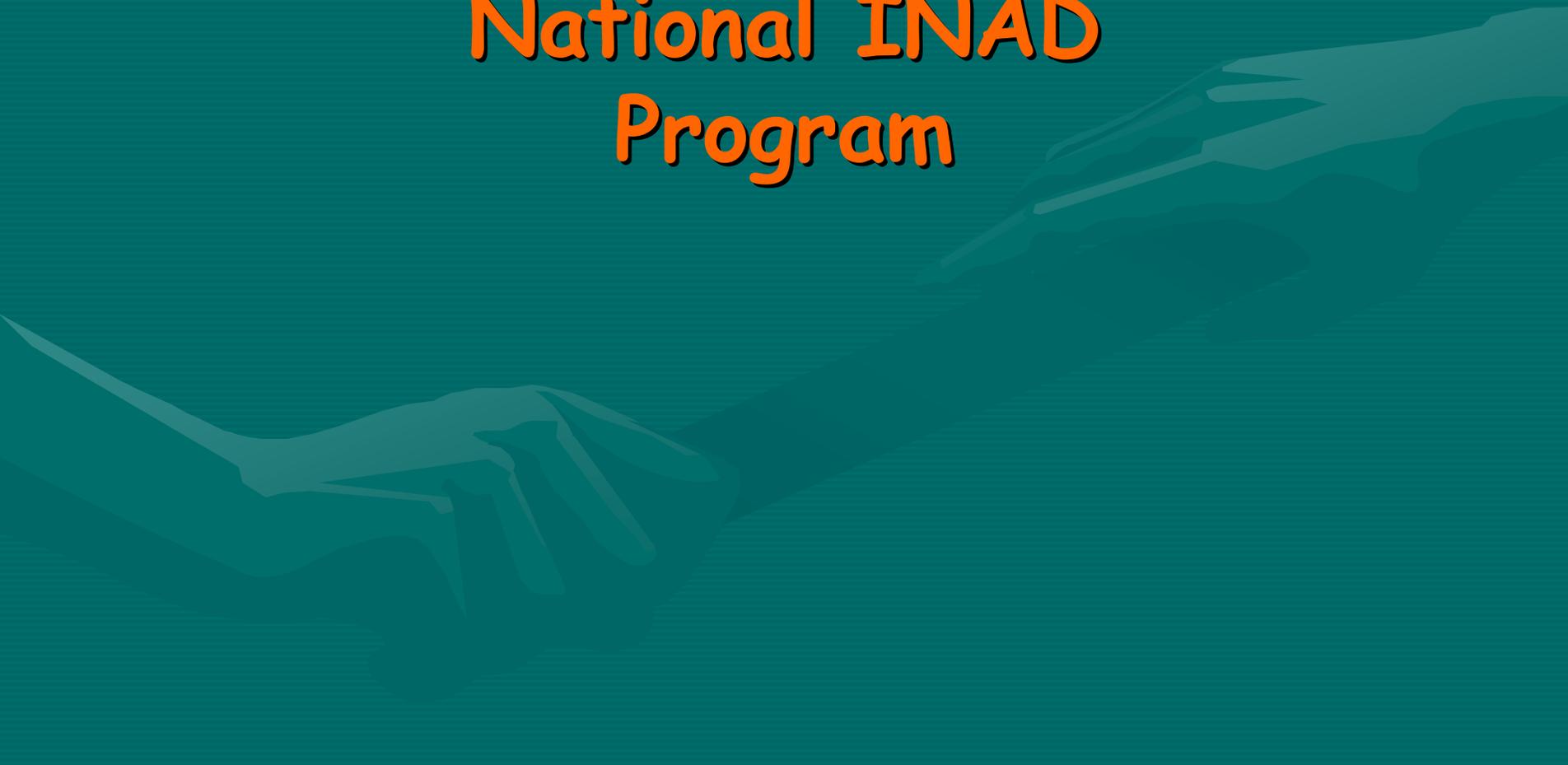
Upshot

- **New drugs approved**
 - Aquaflor[®] – catfish for ESC
 - HCG – all fish
 - OTC Immersion Marking Agent (3 products) – all fish
 - Formalin – parasiticide for fish
- **More approvals pending**
 - Chloramine-T
 - Hydrogen peroxide
 - Copper sulfate
 - Aquaflor[®] – salmonids for CWD (furunculosis & columnaris)
 - Formalin – fungicide for fish
 - Terramycin[®] for Fish – salmonids for CWD; STT for columnaris

AADAP Program Overview

- **Branch of the Division of National Fish Hatchery System**
- **Located at the Bozeman Fish Tech Center, Bozeman MT**
 - **National INAD Program**
 - **Coordination and information dissemination**
 - **Research program**

National INAD Program





What it is....



- Fee based program for non-Service entities
- Funds INAD Coordinator Position
- Administer the INAD; provide Study Protocols and data collection forms
- Receive, database, and summarize all pertinent data
- Report drug shipments to CVM quarterly
- Submit use reports to CVM annually

INADs

- ❖ **Aquaflor[®]**
 - ❖ **OTC** (feed – therapy)
 - ❖ **OTC** (injection – therapy)
 - ❖ **OTC** (immersion – therapy)

 - ❖ **SE-MARK[®]** (Calcein)
 - ❖ **OTC** (feed – marking)

 - ❖ **17 alpha-MT**

 - ❖ **Slice**
- ❖ **Formalin**
 - ❖ **Chloramine-T**
 - ❖ **Diquat**
 - ❖ **Copper Sulfate**
 - ❖ **KMnO₄**

 - ❖ **CCP**
 - ❖ **LHRHa** (injectable)
 - ❖ **sGnRH** (implant)

 - ❖ **AQUI-S**

Any Questions on the NIP....

- **Contact**

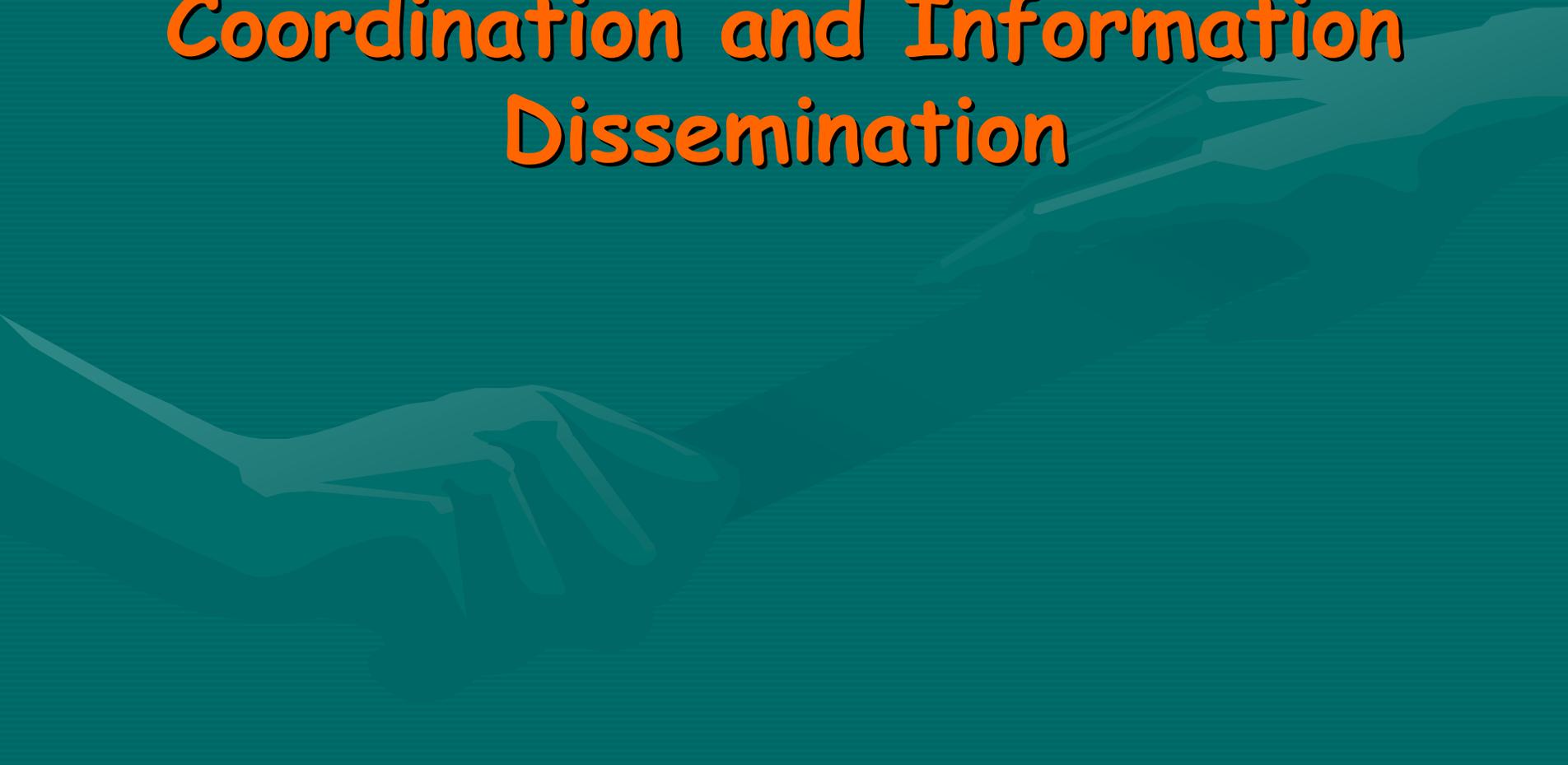
- **Bonnie Johnson**

- (406-994-9905; bonnie_johnson@fws.gov)

- **Dave Erdahl**

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Coordination and Information Dissemination



Coordination and Information Dissemination

- **Positioned to assist with NADA coordination**
- **Publish a quarterly newsletter; established a website**
 - 800+ e-copies (subscribe on web)
 - 50 paper copies
- **Special projects**
 - Drug and Chemical Use Policy
 - Fish Production Survey and Database
- **Annual Drug Approval Coordination Workshop**
- **Moderate aquaculture drug-related sessions at annual conferences**
- **Co-Chair/Co-Lead aquaculture drug-related groups**

AADAP Website

<http://www.fws.gov/fisheries/aadap>

- **Dynamic site**
- **Update daily...weekly**
 - Source for breaking information; What's Shakin'
- **INAD related information**
 - Electronic versions of protocols and forms
 - Fact sheets
- **Links**
 - To major players
- **Information**
 - Drug use guidance
 - JSA Research Forum
- **Past newsletters**

Research Program

The background is a solid teal color. A faint, stylized graphic of two hands shaking is visible, rendered in a lighter shade of teal. The hands are positioned horizontally across the middle of the frame, with the fingers slightly curled as if in a firm grip.

Overview

- 12+ years and lots of \$\$\$\$ to gain FDA approval
- Major Technical Sections
 - Product Chemistry
 - Environmental Safety
 - Human Food Safety
 - Efficacy**
 - Target Animal Safety**
- Cooperators are currently working on 11 drugs
- Tremendous progress is being made...although progress may not be noticeable to the end user

AADAP Research Program

- **Small staff (3.5 and getting bigger...)**
- **Last 12 months**
 - **AQUI-S efficacy**
 - **AQUI-S TAS**
 - **Florfenicol efficacy**
 - **Chloramine-T efficacy**
 - **Methyltet efficacy**
 - **Oxytetracycline antimicrobial resistance**
- **Couldn't be done without "your" help**
- **We still need your help**

Future Research Direction

- Conduct efficacy studies to expand existing and new approvals to include use in cool and warmwater fish
- Need help from the field to get these studies done
 - Demonstrate effectiveness for every disease claim
 - Conduct field-based studies using sick fish (natural disease outbreak)
 - Demonstrate effectiveness on 2 – 3 representative coolwater and warmwater fish species (a fish is not a fish is not a fish)

Bottom Line - Research

- We're in this for the long haul
- Keep looking for opportunities to conduct field effectiveness trials
- Approved labels will be restricted by the field efficacy studies completed and accepted
- Level of restriction on labeled use will be dependant upon willingness of "new" Investigators to get directly involved

Bottom Line - Program

- We're getting a lot of "love/support" from the WO
- Involved in many facets of aquaculture drugs
- It's what we do...all day...every day
- We're here today...and we'll be here 10 yrs from now
- Committed to work towards drug approvals



QUESTIONS?

Anyone?

Anyone?