

Efforts Leading to Expanded Label Claims

Presented at:
Aquaculture America 2008
February 2008, Lake Buena Vista, FL

Jim Bowker
USFWS, AADAP Program
Bozeman, MT



Recent Drug Approvals

- **35% Perox Aid[®]**
 - BGD – freshwater-reared salmonids
 - Fungicide – freshwater-reared finfish eggs
 - External columnaris – freshwater-reared coolwater finfish and channel catfish
- **Aquaflor[®]**
 - ESC – catfish
 - Columnaris – catfish (conditional approval)
 - Coldwater disease - freshwater-reared salmonids
 - Furunculosis - freshwater-reared salmonids



How'd that happen?

- **It took:**
 - An active sponsor
 - Time and a lot of resources
 - Coordinators
 - Researchers
 - \$\$
- **Completion of Major Technical Sections**
 - Human Food Safety
 - Environmental Safety
 - Efficacy
 - Target Animal Safety
 - Product Chemistry



Where we're at with other aquaculture drugs

- **In most cases - major Technical Sections are complete for a variety of drugs**
 - Chloramine-T, OTC medicated feed for marking, 17 alpha- MT, 35% Perox Aid[®], Aquaflor[®]
- **One or two outstanding pieces**
 - Mixed bag...one missing piece = nothing!
- **Sponsor takes over and completes NADA**
 - Axcentive SARL, Pfizer, Rangen Feeds, Eka Chemical, Schering Plough Animal Health



For example

- **Chloramine-T (Halamid®)**

What's done

1. Human Food Safety
2. Environmental Safety
3. Target Animal Safety
- 4 .Efficacy
 - a. FW-R salmonids – BGD
 - b. Walleye – Ex. Columnaris



For example

- **Chloramine-T (Halamid®)**

What's done

1. Human Food Safety
2. Environmental Safety
3. Target Animal Safety
4. Efficacy
 - a. FW-R salmonids – BGD
 - b. Walleye – Ex. Columnaris

What's left

1. Product Chemistry



For example

- **Chloramine-T (Halamid[®])**

What's next

Halamid[®] should be approved.....soon

- 1. control mortality in all FW-reared salmonids caused by BGD**
- 2. control mortality in walleye and largemouth bass* caused by external columnaris**

At this point...it's up to the Sponsor



Is that all for Halamid®?

- **No!**
- **Expanded labels are achievable for cool and warmwater use**
- **Based on a Drug Approval Completion Model**
 - **Expanded approvals are about 95% complete –need additional efficacy data to support new claims.**
- **Research activities in place to expand initial claim**



Where do "we" go from here??



USFWS/AADAP priority research activities

- **Priority 1 - Research activities that will have a direct impact on current or pending drug approvals**
 - Planned studies contingent upon
 - sponsor's demonstrated commitment to support label expansion
 - availability of study site, co-Investigator, sick fish
 - magnitude of roadblocks, detours, or washouts
 - How they'll fit in to the overall picture
 - Expanded initial or current approval
- **Priority 2 - Other research activities on new products or with new sponsors**



Halamid®

- **Initial approval** (pending)
 - FW-reared salmonids - BGD
 - 1 coolwater fish species (walleye) – Ext columnaris
 - 1 warmwater fish species (largemouth bass) – Ext. columnaris
- **AADAP research activities** (with Richloam Fish Hatchery)
 - 1 efficacy study – coolwater fish (striped bass) - ext. columnaris
 - **Complete the Effectiveness Technical Section for all Coolwater Finfish – External columnaris**
 - 1 efficacy study – warmwater fish (channel catfish) - ext. columnaris
 - **Complete the Effectiveness Technical Section for all Warmwater Finfish – External columnaris**



Halamid®

- **Initial/expanded approval** (if both efficacy studies are accepted by CVM)
 - **FW-reared salmonids – BGD**
 - 12 – 20 mg/L for 60 min on three alternate or consecutive days
 - **FW-reared coolwater finfish – External columnaris**
 - 20 mg/L for 60 min on three alternate or consecutive days
 - **FW-reared warmwater finfish – External columnaris**
 - 20 mg/L for 60 min on three alternate or consecutive days



Terramycin 200 for Fish®

- **Current approval (finfish only)**
 - Pacific salmon – mark skeletal tissue
 - Salmonids –ulcer disease, furunc., BHS, and pseudomonas disease
 - Catfish –BHS and pseudomonas disease
- **Proposed expanded label**
 - Sponsor – Proceed with new claim –coldwater disease in FW-reared salmonids and columnaris in rainbow and steelhead trout
- **AADAP research activities**
 - 1 efficacy study - salmonid – systemic columnaris
 - **Complete Effectiveness Technical Section for all FW-reared salmonids - columnaris**
 - 1 efficacy study – rainbow trout – mark skeletal tissue
 - **Complete Effectiveness Technical Section all salmonids – marking skeletal tissue**



Terramycin 200 for Fish®

- **Expanded approval** (if efficacy studies are accepted by CVM)
 - All FW-reared salmonids – CWD
 - 3.75 g/100 lbs fish/d for 10 d
 - All FW-reared salmonids – Systemic Columnaris
 - 3.75 g/100 lbs fish/d for 10 d
 - All salmonids – Mark skeletal tissue
 - 2.5 – 3.75 g/100 lbs fish/d for 4 d, ≤ 55 g fish



Aquaflor®

- **Current approval** (full approvals only)
 - Salmonids – Coldwater disease and furunculosis
 - Catfish – Enteric septicemia in catfish
- **Proposed expanded label**
 - Sponsor – proceed with new claim – *S. iniae* in hybrid striped bass
- **Research activities**
 - 1 efficacy study – salmonid – systemic columnaris
 - Complete Technical Section for all FW-reared salmonids - columnaris
 - 2 efficacy studies – salmonids – bacterial kidney disease
 - Complete Technical Section for all FW-reared salmonids - BKD



Aquaflor®

- **Expanded approval** (if efficacy studies are accepted by CVM)
 - Hybrid striped bass – *S. iniae*
 - 10 mg FFC/kg fish/d for 10 d
 - FW-reared salmonids – Systemic columnaris
 - 10 mg FFC/kg fish/d for 10 d
 - FW-reared salmonids – Bacterial kidney disease
 - 10 mg FFC/kg fish/d for 10 d



35% Perox Aid®

- **Current approval**

- All FW-reared salmonids – BGD
- All coolwater fish – Ext. columnaris
- Channel catfish – Ext. columnaris
- All FW fish eggs - saprolegniasis

- **Research activity** (with Richloam Fish Hatchery)

- 1 efficacy study – warmwater fish (largemouth bass) – ext. columnaris
 - Complete Effectiveness Technical Section for all warmwater finfish – external columnaris



35% Perox Aid®

- **Expanded approval** (if efficacy study is accepted by CVM)
 - All warmwater fish – external columnaris
 - 50 to 75 mg/L for 60 min on three alternate days



Others

- **17 alpha-Methyltestosterone**
- **35% Perox-Aid**
 - Parasiticide
 - Fungicide for fish
- **Common carp pituitary***



Priority 2 research activities

- **Doesn't preclude us from starting at the beginning with a new committed sponsor**
- **Anxious to work with new committed sponsors**



“We” are in an enviable position

- **Working with engaged sponsors**
- **Completion of most Major Technical Sections – allows “us” to better focus our efforts**
- **Collective efforts are leading/will lead to new and expanded aquaculture drug approvals**



Questions??

Questions??

Questions??



Questions??

Questions??

Questions??

