

Aquaculture Drugs in the U. S.

What's approved and what's coming down the pipe

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Aquaculture drug use in the U. S.

- Regulated by the U. S. Food and Drug Administration
 - Center for Veterinary Medicine
- Drug defined as:
 - “Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease” and “articles (other than food) intended to affect the structure or any function of the body of man or other animals”
- Mechanisms
 - Approved
 - INAD’s
 - Low Regulatory Priority
 - Extra-Label Use



Approved aquaculture drugs

- 8 drugs currently approved – variety of claims
 - 13 Products (e.g., Tricaine-S and Finquel)
 - 20 Claims
 - e.g., 35% Perox Aid®
 - ✓ Control fungus on eggs
 - ✓ Control mortality due to BGD in salmonids
 - ✓ Control mortality due to columnaris in a variety of fish
- 6 drugs approved 1964-1994
 - Formalin, MS-222, OTC-HCL, and Romet®
 - 2 no longer available
- 4 drugs approved 1994-present
 - AQUAFLO®R, 35% Perox-Aid®, Chorulon®, and OTC-Dihydrate (Terramycin® 200 for Fish)



Why so few drugs?



- Prior to 1994
 - FDA chose not to 'regulate' use of drugs for minor species
 - Minimal efforts to gain approvals
 - Bar was set pretty low
- After 1994
 - FDA began to regulate use of drugs on minor species
 - Huge learning curve for everybody involved
 - Bar set very high
 - Demonstrate a drug is
 - ✓ Efficacious
 - ✓ Safe (target animals, humans, environment)
 - ✓ Manufactured consistently w/o impurities and is stable



Drug approval efforts

- Require data and information, time, and \$\$\$\$
 - Sponsors, researchers, others
 - USFWS
 - ✓ AADAP
 - USGS
 - ✓ Upper Midwest Environmental Sciences Center
 - ✓ University of Idaho Coop
 - USDA-ARS
 - ✓ Stuttgart National Aquaculture Research Center
 - NRSP-7
 - Various Universities (e.g., Auburn, Miss. State)
 - CVM-Office of Research
- New drug approvals
 - Few and far between
- New claims for drugs currently approved
 - More frequent



United States Department Of Agriculture
Agricultural Research Service



Drug approval status

- What's approved
 - Brief list
 - AADAP Website
 - AFS Fish Culture Section Website
- New drug approvals
 - Within 1 – 2 yrs
 - > 2 yrs
- Approvals for new claims
 - Within 1 – 2 yrs



Approved drugs



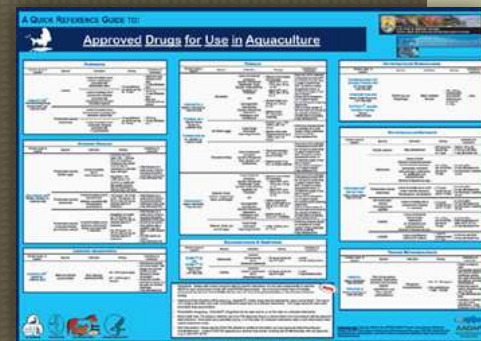
- Romet[®] 30 and TC
 - Catfish – enteric septicemia
 - Salmonids - fununculosis
- Terramycin[®] 200 for Fish
 - Catfish – hemorrhagic septicemia, pseudomonas disease
 - Salmonids – furunculosis, coldwater disease, pseudomonas disease
 - RBT and STT– columnaris disease
- Aquaflor[®] – VFD Drug
 - Catfish – ESC
 - FW salmonids – furunculosis and CWD
- MS-222
 - 4 families of fish
 - 21-d withdrawal period
- 35% Perox Aid
 - Fungicide – FW eggs
 - BGD – FW salmonids
 - Columnaris – Coolwater fish & CCF
- Formalin
 - Parasiticide – FW fish
 - Fungicide – FW eggs
- Oxytet (skeletal marking)
 - Immersion – finfish fry and fingerling
 - Feed – Pacific salmon
- Chorulon (HCG)
 - All fish



Legal use of approved drugs

- AADAP Website

- AADAP Poster - Approved Aquaculture Drugs
 - AFS Fish Culture and Fish Health Sections, FDA CVM
- AADAP Desk Reference – Approved Aquaculture Drugs and calculations
 - AFS FCS and FHS, AFWA



- FCS Website

- AFS FCS - Guide to Using Drugs, Biologics, and Other Chemicals in Aquaculture
- AFS FCS – Guide companion Treatment Calculator



New drug approvals

- Halamid[®] (100% chloramine-T)
 - Axcentive SARL Akzo-Nobel, Inc.
- Aquamycin 100[®] (erythromycin thiocyanate)
 - Bimeda, A Division of Cross Vetpharm Group, Ltd.
- SLICE[®] (0.2% emamectin benzoate)
 - Merck Animal Health
- Triangle Brand Copper Sulfate[®]
 - Freeport-McMoRan Sales Company Inc.
- AQUI-S[®] 20E
 - AQUI-S New Zealand Ltd



What's coming down the pipe



- Within 1 – 2 yrs
 - Halamid[®] – control mortality caused by:
 - BGD – freshwater-reared salmonids
 - Columnaris – warmwater fish & WAE
 - ✓ Sponsor activities – inspection of the production facility in China
 - Aquamycin 100[®] – to control mortality caused by:
 - Bacterial kidney disease – freshwater-reared salmonids
 - ✓ Dr. Chris Moffitt and NRSP-7
 - Copper Sulfate[®] - use to control mortality or treat:
 - Fungus on channel catfish eggs
 - Ich on channel catfish in ponds
 - ✓ Dr. Dave Straus
 - SLICE[®] – control infestations of:
 - *Salmincola californiensis* in rainbow trout
 - ✓ Target Animal Safety study on rainbow trout
 - ✓ Sponsor activities – Environmental assessment in freshwater



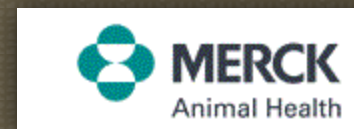
What's coming down the pipe

- > 2 yrs
 - AQUI-S® 20E
 - Sedate freshwater finfish to the handleable stage of sedation
 - ✓ Efficacy – All data generated, submitted over the next 4 months
 - ✓ Lots more to do
 - UMESC, AADAP, and sponsor
 - ✓ Initial approval may be for freshwater salmonids



Approvals for new claims

- New claims often require efficacy data only
 - All the other parts already approved
 - Studies conducted as opportunities arise
- New claims that require more data
 - Need a 'team' approach
- Require sponsor involvement
 - Revised Environmental Assessment
 - Revised label language



What's coming down the pipe

- New claims for:

- Aquaflor[®] (florfenicol)
 - Merck Animal Health
- 35% Perox Aid[®] (35% hydrogen peroxide)
 - Eka Chemical/Western Chemical Inc.
- Terramycin[®] 200 for Fish (OTC dihydrate)
 - Phibro Animal Health
- Parasite-S[®] (formalin)
 - Western Chemical, Inc.



Aquaflor®

- To control mortality caused by:
 - Columnaris - all freshwater finfish
 - Studies on COS, CCF, LMB, and BGL accepted / included in the FOI
 - Study not accepted on RBT now included in the FOI
 - Use on coolwater finfish acceptable because it will be a minor use
 - ✓ Acceptable in spite of no data submitted to support claim
 - Streptococcal disease - warmwater finfish
- Use at 10 – 15 mg florfenicol/kg/d for 10 d
 - Studies to demonstrate safety – DONE!
 - Tissue residue studies – last one to be submitted soon
- To control mortality caused by:
 - Bacterial kidney disease - Chinook salmon
 - Requires that 1 more efficacy study
 - ✓ Thanks Doug Munson!
 - Motile aeromonas septicemia - cool and warmwater fish
 - Need data to expand to salmonids



35% Perox Aid[®]

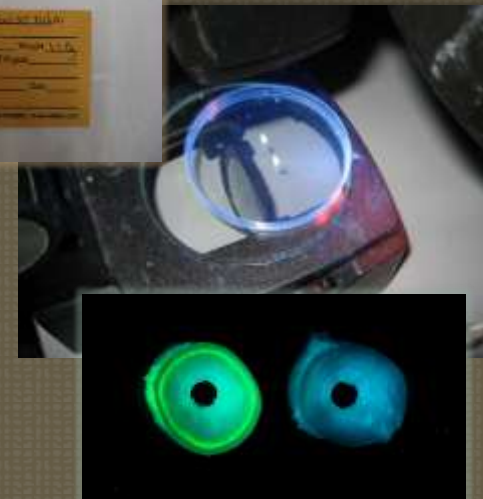


- To control mortality by:
 - Columnaris in all warmwater finfish
 - Studies conducted by AADAP on LMB and BLG
 - Saprolegniasis in all freshwater finfish
 - Studies conducted by UMESC on RBT, WAE, and CCF
- To control infestations of:
 - *Gyrodactylus* spp. in freshwater-reared salmonids
 - Studies conducted RBT by AADAP; BKT and LKT by UMESC



Terramycin[®] 200 for Fish

- Administered at a dosage of:
 - 3.75 g OTC/100 lbs fish/d for 10 d
- To mark skeletal tissue of:
 - *freshwater-reared salmonids*
 - < 55 g
 - 21 d withdrawal period



Parasite-S®



- To control mortality caused by:
 - *Saprolegniasis* on all freshwater finfish
 - Studies conducted by CVM-Office of Research
 - CVM 'requested' sponsor to revise existing label
 - Hasn't requested other sponsors to make the same changes
 - Additional data required to include use in Recirc Systems
 - Label - not for use in recirc systems



Summary

- It's a real SOG trying to get a drug approved
 - However, in the next couple of years, we could have:
 - 4 new drugs approved
 - 10 new claims for drugs that are already approved
- Sponsors have to carry it all to the finish line



Questions??

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