



Aquatic Animal Drug Approval Workshop

Status of Aquaculture Drug Approvals

presented by

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Aquatic Animal Drug Approval Partnership Program
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Background information



- Graphs represent <u>AADAP's</u> <u>interpretation</u> <u>and</u> <u>condensation</u> of matrices produced by the National Coordinator for Aquatic New Animal Drug Applications (Ms. Rosalie Schnick)
 - Matrices in full detail available at:
 - http://aguanic.org/jsa/aguadrugs/index.htm and
 - http://www.fws.gov/fisheries/aadap/status.htm
- Interpretive methods
 - categorically assigned a status number to each subsection of the <u>5 major</u> NADA technical sections (efficacy, target animal safety, environmental safety, human food safety and manufacturing chemistry)
 - calculated overall estimated percent complete, based on means



Abbreviations



- EFF = efficacy technical section (TS)
- ► TAS = target animal safety TS
- MC = manufacturing chemistry TS
- HFS = human food safety TS
- **▶** ES = environmental safety TS
- ▶ all = all major TS (i.e., EFF, TAS, MC, HFS & ES)
- ▶ NADA = New Animal Drug Application per se
- label = actual approved drug label with associated claims
- AOI = all other information required for a complete NADA
- deficient = TS has not been completely accepted by CVM
- = you may be able to generate data to help complete this TS



Approval Progress for Chloramine-T



Technical Section	Entity—Data—Action	Impediments or Cost— Action
Product Chemistry	AXC (INAD #8086)—Product Chemistry— submitted to CVM 5/22/06	None—pending acceptance
Environmental Safety (flow- through)	UMESC (PMF #5637)—Validation of dilution model—accepted 5/7/03	None-model accepted
Environmental Safety (flow- through/all freshwater-reared finfish)	UMESC (INAD #10-974)—Environmental assessment/flow-through systems/all freshwater- reared finfish—final revision submitted to CVM 2006	None—pending acceptance
Human Food Safety/Toxicology	AXC (MAD #8086)—Toxicology/genotoxicity studies—accepted 7/13/02	None
Human Food Safety/Toxicology	AXC (INAD #8086)—Toxicology/all mammalian safety—accepted 4/9/03	None—This portion of the Technical Section is complete
Human Food Safety— Residue Chemistrylanalytical method in water (all finfish)	UMESC (PMF #5637)—Residue Chemistrylanalytical method in water for monitoring—accepted 1/15/03	None—all residue chemistry data accepted for all freshwater-reared finfish
Human Food Safety— Residue Chemistry (marker residue depletion)	UMESC (PMF #5637)—Residue chemistry/marker residue depletion/hybrid striped bass—accepted 4/23/02	None—all residue chemistry data accepted for all freshwater-reared finfish
Human Food Safety— Residue Chemistry (marker residue depletion)	UMESC (PMF #5637)—Residue chemistry/marker residue depletion/yellow perch—accepted 4/23/02	None—all residue chemistry data accepted for all freshwater-reared finfish
Human Food Safety— Residue Chemistry (marker residue depletion)	UMESC (PMF #5637)—Residue chemistry/marker residue depletion/rainbow trout—accepted 4/23/02	None—all residue chemistry data accepted for all freshwater-reared finfish
Human Food Safety— Residue Chemistry (regulatory method developed)	UMESC (PMF 85637)—Résidue chemistry/regulatory method developed/p- TSA/rainbow trout, channel catfish, & walfeye— accepted 474/83	None—all residue chemistry data accepted for all freshwater-reared finfish
Human Food Safety— Residue Chemistry (regulatory method validated)	UMESC (PMF #5637)—Residue chemistry/regulatory method validated/p-T5A/all freshwater-reared finfish—accepted #1594	None—all residue chemistry data accepted for all freshwater-reared finfish
Human Food Safety— Residue Chemistry (confirmatory method)	CVM-OR—Residue Chemistry/confirmatory method/all freshwater-reared finfish (funded by UMESC)—accepted 3/4/05	None—all residue chemistry data accepted for all freshwater-reared finfish
Human Food Safety— Microbial Food Safety (all freshwater-reared finfish)	AXC (INAD #8086) & NADA Coordinator— Microbial food safety (Guidance Documents #152 & 159/all freshwater-reared finfish)—in progress	None—pending acceptance
Target Animal Safety (all coolwater & warmwater finfish)	UMESC (PMF #5637 & INAD #10-974)—Target Animal Safetyfall coolwater & warmwater fish— accepted 3/11/04 & 3/11/05	None—This Technical Section is complete for all freshwater-reared finfish
Target Animal Safety (all freshwater-reared salmonids)	AADAP (INAD #4000 & #9321)—Target animal safety/all salmonids—accepted 3/13/02	None—This Technical Section is complete for all freshwater-reared finfish
Efficacy (bacterial gill disease/all freshwater-reared salmonids)	AADAP (INAD #4000 & #9321)—Efficacy/bacterial gill disease/all freshwater reared salmonids— accepted 7/12/00; dose confirmation for flow- through—accepted 6/10/02	None—This Technical Section is complete for all freshwater-reared salmonids
Efficacy (columnaris disease/walleye)	UMESC (PMF #5637 & INAD #10-974)— Efficacy/external columnaris disease/walleye— accepted 1/30/04	None—This Technical Section is complete for walleye
Label (bacterial gill disease/all freshwater-reared salmonids & external columnaris disease/walleye)	AXC (INAD #8086) & NADA Coordinator— Labelbacterial gill disease/all freshwater-reared salmonids & external columnaris disease/walleye—in progress	None—pending acceptance
FOI (bacterial gill disease/all freshwater-reared salmonids & external columnaris disease/walleye)	CVM—FOl/bacterial gill disease/all freshwater- reared salmonids & external columnaris disease/walleye—in progress	None—pending acceptance
AOI (bacterial qill disease/all freshwater-reared salmonids & external columnaris disease/walleye)	AXC (INAD #8086) & NADA Coordinator— AOI/bacterial gill disease/all freshwater-reared salmonids & external columnaris disease/walley—planned before Administrative NADA submission	None—pending acceptance
NADA Package (bacterial gill disease/all freshwater-reared salmonids & external columnaris disease/walleye)	AXC (INAD #8086) & NADA Coordinator—NADA package/bacterial qill disease/all freshwater-reared salmonids & external columnaris disease/walleye—in progress	None—pending acceptance

Technical Section	Entity—Data—Action	Impediments or Cost— Action
Product Chemistry	AXC (INAD #8086)—Product Chemistry— submitted to CVM 5/22/06	None—pending acceptance
Environmental Safety (flow- through)	UMESC (PMF #5637)—Validation of dilution model—accepted 5/7/03	None-model accepted
Environmental Safety (flow- through/all freshwater-reared finfish)	UMESC (NAD #10-974)—Environmental assessment/flow-through systems/all freshwater-reared finfish—final revision submitted to CVM 2/306	None—pending acceptance
Human Food Safety/Toxicology	AXC (INAD #8086)—Toxicology/genotoxicity studies—accepted 7/19/02	None
Human Food Safety/Toxicology	AXC (INAD #8086)—Toxicology/all mammalian safety—accepted 4/9/03	None—This portion of the Technical Section is complete
Human Food Safety— Residue Chemistrylanalytical method in water (all finfish)	UMESC (PMF #5637)—Residue Chemistry/analytical method in water for monitoring—accepted 1/15/03	None—all residue chemistry data accepted for all freshwater-reared finfish
Human Food Safety— Residue Chemistry (marker residue depletion)	UMESC (PMF #5637)—Residue chemistry/marker residue depletion/hybrid striped bass—accepted 4/23/02	None—all residue chemistry data accepted for all freshwater-reared finfish
Human Food Safety— Residue Chemistry (marker residue depletion)	UMESC (PMF #5637)—Residue chemistry/marker residue depletion/yellow perch—accepted 4/23/02	None—all residue chemistry data accepted for all freshwater-reared finfish
Human Food Safety— Residue Chemistry (marker residue depletion)	UMESC (PMF #5637)—Residue chemistry/marker residue depletion/rainbow trout—accepted 4/23/02	None—all residue chemistry data accepted for all freshwater-reared finfish
Human Food Safety— Residue Chemistry (regulatory method developed)	UMESC (PMF 85637)—Residue chemistry/regulatory method developed/p- TSA/rainbow trout, channel catfish, & walleye— accepted 4/24/03	None—all residue chemistry data accepted for all freshwater-reared finfish
Human Food Safety— Residue Chemistry (regulatory method validated)	UMESC (PMF #5637)—Residue chemistry/regulatory method validated/p-TSA/all freshwater-reared finfish—accepted 4/15/04	None—all residue chemistry data accepted for all freshwater-reared finfish
Human Food Safety— Residue Chemistry (confirmatory method)	CVM-OR—Residue Chemistry/confirmatory method/all freshwater-reared fintish (funded by UMESC)—accepted 3/4/05	None—all residue chemistre deta accepted for all freshwater-reared finfish
Human Food Safety— Microbial Food Safety (all freshwater-reared finfish)	AXC (INAD #8086) & NADA Coordinator— Microbial food safety (Guidance Documents #152 & 150/all freshwater-reared finfish)—in progress	None—pending acceptance
Target Animal Safety (all coolwater & warmwater finfish)	UMESC (PMF #5637 & IRAD #10.974)—Target Animal Safetylall coolwater & warmwater fish— accepted 3/11/04 & 3/11/05	None—This Technical Section is complete for all freshwater-reared finfish
Target Animal Safety (all freshwater-reared salmonids)	AADAP (NAD #4000 & #9321)—Target animal safetyfall salmonids—accepted 9/13/02	None—This Technical Section is complete for all freshwater-ceared finfish
Efficacy (external columnaris disease/walleye)	UMESC (PMF #5637 & INAD #10.974)— Efficacylexternal columnaris disease/walleye— accepted 1/38/04	None—This Technical Section is complete for walleye
Efficacy (prvotalisatemal columnaria diseasatal) freshester-regred findish except walleye)	No entity Montified—Provid efficacy/external community disease all freshwater raiged fields) except walleys—not plaused.	Needs to be planned
Efficacy (supplementalizational columnatio diseasolali freshwater-reared fiellsh except walleys)	No entity identified. Supplemental efficies/patternal columnate discussful fresheater-wared finitely except walleye non planned.	Needs to be pleaned
Label (external columnaris disease/all freshwater-reared finfish)	AXC (INAD #8086) & NADA Coordinator— Labelexternal columnaris disease/all freshwater- reared finfish—planned if efficacy accepted	None—pending acceptance
FOI (external columnaris disease/all freshwater-reared finfish except walleye)	CVM—FOl'external columnaris disease/all freshwater-reared findish except walleye——planned if efficacy accepted	None—pending acceptance
AOI (external columnaris disease/all freshwater-reared finfish)	AXC (INAD #8886) & NADA Coordinator— AOVexternal columnaris disease/all freshwater- reaced finfish—planned if efficacy accepted	None—pending acceptance
NADA Package (external columnaris disease/all	AXC (INAD #8086) & NADA Coordinator—NADA package(external columnaris disease/all	None—pending acceptance

Technical Section	Entity-Data-Action	Impediments or Cost— Action
Product Chemistry	AXC (INAD #8086)—Product Chemistry— submitted to CVM 5/22/06	None—pending acceptance
Environmental Safety (flow- through)	UMESC (PMF#5637)—Validation of dilution model—accepted 5/7/03	None-model accepted
Environmental Safety (flow- through/all freshwater-reared finfish)	UMESC (INAD #10-974)—Environmental assessment/flow-through systems/all freshwater-reared finfish—final revision submitted to CVM 2/506	None—pending acceptance
Human Food Safety/Toxicology	AXC (INAD #8086)—Toxicology/genotoxicity studies—accepted 7/19/02	None
Human Food Safety/Toxicology	AXC (INAD #6086)—Toxicology/all mammalian safety—accepted 4/9/03	None—This portion of the Technical Section is complete
Human Food Safety— Residue Chemistry/analytical method in water (all finfish)	UMESC (PMF #5637)—Residue Chemistry/analytical method in water for monitoring—accepted 1/15/03	None—all residue chemistry data accepted for all freshwater-reared finfish
Human Food Safety— Residue Chemistry (marker residue depletion)	UMESC (PMF #5637)—Residue chemistry/marker residue depletion/hybrid striped bass—accepted 4/23/02	None—all residue chemistry data accepted for all freshwater-reared finfish
Human Food Safety— Residue Chemistry (marker residue depletion)	UMESC (PMF #5637)—Residue chemistry/marker residue depletionlyellow perch—accepted 4/23/82	None—all residue chemistry data accepted for all freshwater-reared finfish
Human Food Safety— Residue Chemistry (marker residue depletion)	UMESC (PMF #5637)—Residue chemistry/marker residue depletion/rainbow trout—accepted 4/23/02	None—all residue chemistry data accepted for all freshwater-reared finfish
Human Food Safety— Residue Chemistry (regulatory method developed)	UMESC (PMF 85637)—Residue chemistry/regulatory method developed/p- TSA/rainbow trout, channel catfish, & walleye- accepted 4/24/93	None—all residue chemistry data accepted for all freshwater-reared finfish
Human Food Safety— Residue Chemistry (regulatory method validated)	UMESC (PMF #5637)—Residue chemistry/requistory method validated/p-TSA/all freshwater-reared finfish—accepted 4/15/04	None—all residue chemistry data accepted for all freshwater-reared finfish
Human Food Safety— Residue Chemistry (confirmatory method)	CVM-OR—Residue Chemistry/confirmatory method/all freshwater-reared finfish (funded by UMESC)—accepted 3/4/05	None—all residue chemistry data accepted for all freshwater-reared finfish
Human Food Safety— Microbial Food Safety (all freshwater-reared finfish)	AXC (INAD #8086) & NADA Coordinator— Microbial food safety (Guidance Documents #152 & 159/all freshwater-reared finfish)—in progress	None—pending acceptance
Target Animal Safety (all coolwater & warmwater finfish)	UMESC (PMF #5637 & INAD #10-974)—Target Animal Safetyfall coolwater & warmwater fish— accepted 3/11/04 & 3/11/05	None—This Technical Section is complete for all freshwater-reared finfish
Target Animal Safety (all freshwater-reared salmonids)	AADAP (INAD #4000 & #9321)—Target animal safety/all salmonids—accepted 9/13/02	None—This Technical Section is complete for all freshwater-reared finfish
Efficacy (bacterial gill disease/all freshwater-reared salmonids)	AADAP (INAD #4000 & #9321)—Efficacy/bacterial gill disease/all freshwater-reared salmonids—accepted 7/12/00; dose confirmation for flow-through—accepted 6/10/02	None—This Technical Section is complete for all freshwater-reared salmonids
Efficacy (pivotal/bacterial gill disease/all freshwater-reared finfish except salmonids)	No entity identified—Pivotal efficacy/bacterial gill disease/all freshwater-reared findish except salmonids—not planned	Needs to be planned
Efficacy (supportive/bacterial gill disease/all freshwater- reared finlish except salmonids)	No entities identified—Supportive efficacy/bacterial gill diseaselfreshwater.coared finlish except salmonids—not planned	Needs to be planned
Label (bacterial gill disease/all freshwater-reared finfish)	AXC (INAD #8086) & NADA Coordinator— Labeliall freshwater-reared finfish—planned if efficacy accepted	None—pending acceptance
FOI (bacterial gill disease/all freshwater-reared finfish except salmonids)	CVM—FOl/all freshwater-reared finfish except salmonids—planned if efficacy accepted	None—pending acceptance
AOI (bacterial gill disease/all freshwater-reared finfish)	AXC (INAD #8086) & NADA Coordinator—AOI/all freshwater-reared finfish—planned if efficacy accepted	None—pending acceptance
NADA Package (bacterial gill disease/all freshwater-reared finfish except salmonids)	AXC (INAD #8086) & NADA Coordinator—NADA package/all freshwater-reared finfish except	None—pending acceptance

freshwater-reared finfish except walleyeplanned if efficacy accepted



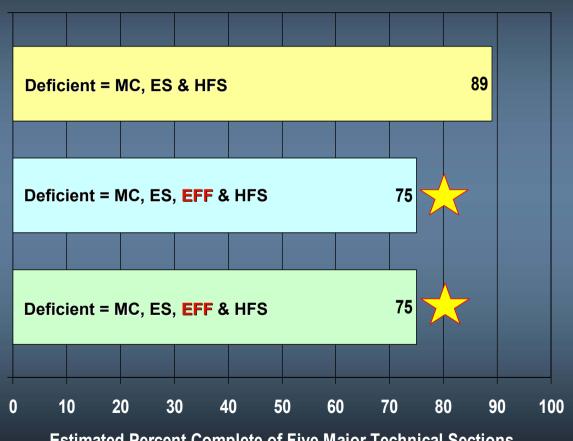
Approval Progress for Chloramine-T



BGD in FW salmonids External columnaris in walleye

External columnaris in all other FW fish

BGD in all other FW fish





Approval Progress for Hydrogen Peroxide

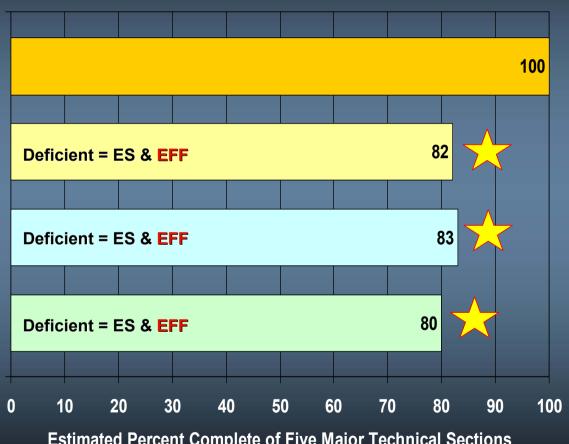


Saprolegnia in all FW fish eggs **BGD** in FW salmonids External columnaris in coolwater fish & CC

Saprolegnia in all FW fish

External columnaris in all remaining FW fish

External protozoa & monogenes in FW fish, and control of mortalities from same





Approval Progress for Oral OTC

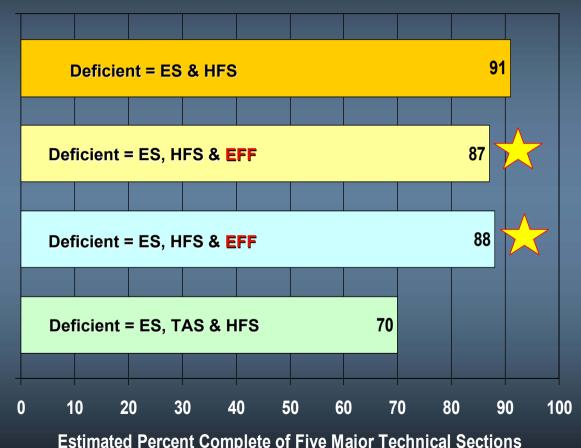


Systemic CWD in FW salmonids Systemic columnaris in steelhead

Systemic columnaris in all other FW fish

Motile aeromonas septicemia in FW fish

Necrotizing hepatopancreatitis in shrimp





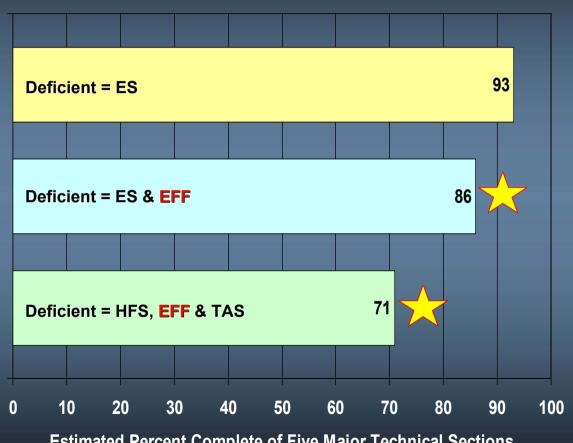
Approval Progress for Florfenicol



CWD in FW salmonids **Furunculosis in FW salmonids**

Systemic columnaris in FW salmonids

Systemic columnaris in channel catfish Streptococcal infections in tilapia & HSB





Approval Progress for AQUI-S®



Zero-withdrawal anesthetic for short-term handling of FW salmonids **

Zero-withdrawal anesthetic for <u>short</u>-term for cool & warmwater FW fish

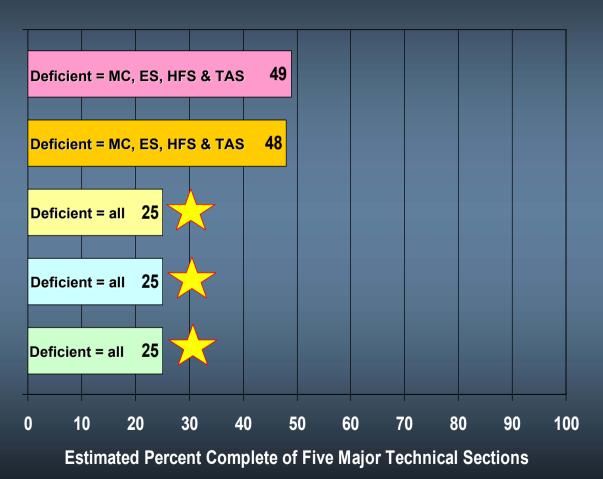
Zero-withdrawal anesthetic for <u>long</u>-term handling of FW salmonids * #

Zero-withdrawal anesthetic for <u>long</u>-term handling of cool & warmwater FW fish

Zero-withdrawal anesthetic for short-term handling of marine fish and shellfish * #

= excludes Atlantic salmon HFS, EFF and TAS supportive work

= excludes short-term studies that may be applicable





Approval Progress for SE-MARK® Immersion



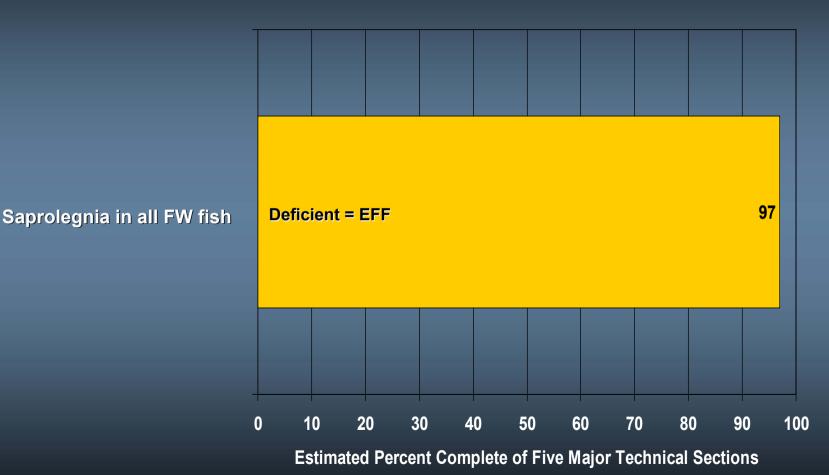






Approval Progress for Formalin







Approval Progress for CuSO₄



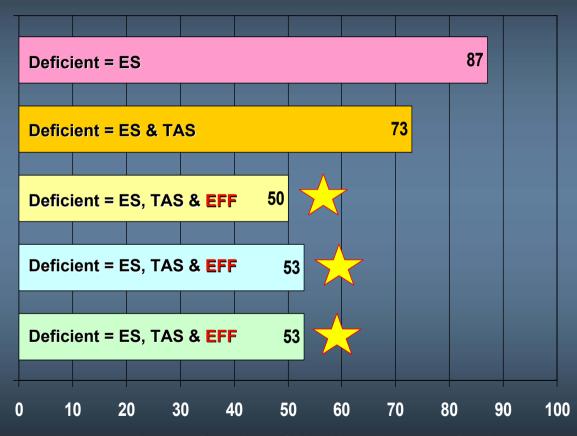
Ichthyophthirius in channel catfish

Ichthyophthirius in all other FW fish

Saprolegnia in all FW fish eggs

BGD in all FW fish

External columnaris in all FW fish





Approval Progress for KMnO₄



External columnaris in channel catfish

External columnaris in all other FW fish

BGD in FW salmonids

CWD in FW salmonids

External parasites in FW fish, and control of mortalities from same

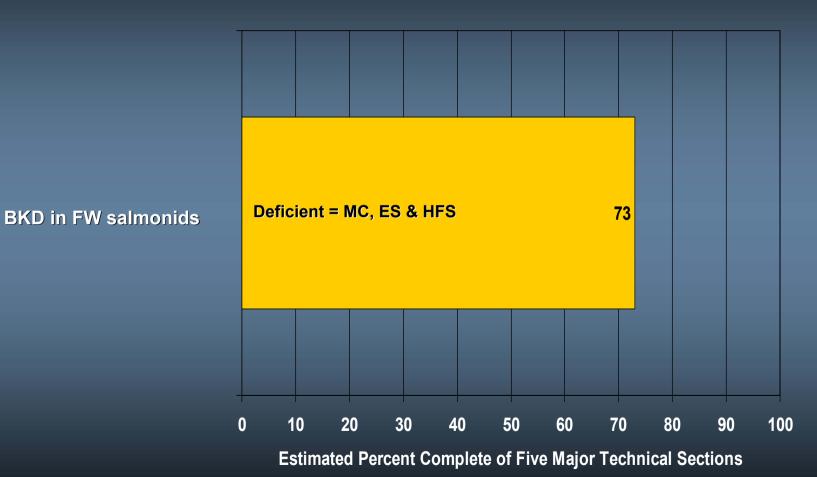


Estimated Percent Complete of Five Major Technical Sections



Approval Progress for Erythromycin

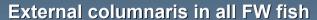






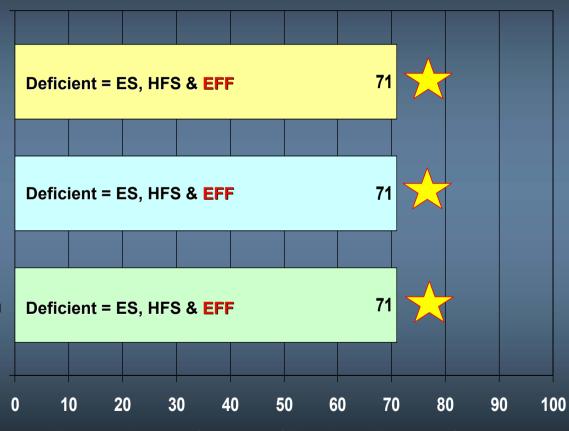
Approval Progress for Immersion OTC





BGD in all FW fish

Systemic columnaris in all FW fish



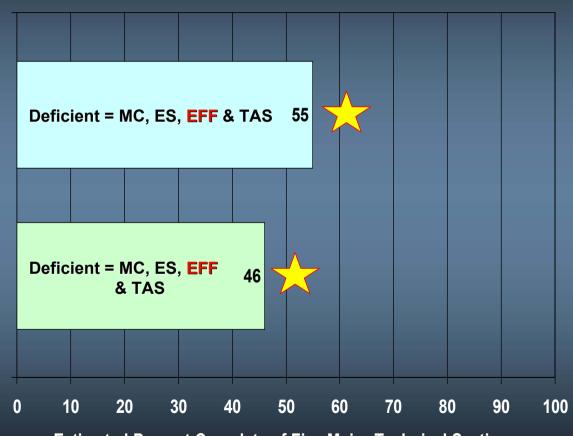


Approval Progress for 17α-Methyltestosterone



Masculinization of early life-stage female tilapia

Gender manipulation in selected finfish (e.g., salmonids, percids & ornamentals)





Approval Progress for Crude Carp Pituitary





