

## AQUACULTURE DRUG APPROVAL DEVELOPMENT STATUS

### **FLORFENICOL (AQUAFLO<sup>®</sup>): RESEARCH AND DEVELOPMENT PLAN AND LABEL CLAIM MATRICES FOR SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION (NADA) APPROVALS**

1. [Florfenicol \(Aquaflor<sup>®</sup>\) NADA approvals \(10/24/05, 3/19/07, and 10/26/07\); Conditional approval \(4/18/07\)](#)
2. [Status of Technical Sections that support all supplemental NADA approvals](#)
3. [Label Claim #1: For the control of mortality in freshwater-reared salmonids & catfish due to systemic columnaris disease](#)
4. [Label Claim #2: For the control of mortality in tilapia & hybrid striped bass due to streptococcosis](#)
5. [Label Claim #3: For the control of mortality in coolwater and warmwater finfish due to motile aeromonad septicemia](#)

DEVELOPED, IN PART, UNDER THE FEDERAL-STATE AQUACULTURE DRUG APPROVAL PARTNERSHIP PROJECT, A PROJECT OF THE ASSOCIATION OF FISH AND WILDLIFE AGENCIES

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**FLORFENICOL (AQUAFLO<sup>®</sup>)  
(Version 2, March 2008)**

**ABBREVIATIONS, ACRONYMS, & CONTACT INFORMATION FOR ENTITIES IN TABLE**

AADAP	Aquatic Animal Drug Approval Partnership Program—Dr. David Erdahl, U.S. Fish and Wildlife Service, 4050 Bridger Canyon Road, Bozeman, Montana 59715; Phone: 406-994-9904; Fax: 406-582-0242; E-mail: <a href="mailto:Dave.Erdahl@fws.gov">Dave.Erdahl@fws.gov</a>
AOI	All Other Information Technical Section, not included in any of the other sections, that is pertinent to an evaluation of effectiveness or safety [21 CFR § 514.1(b)(8)(iv)]
CVM	Aquaculture Drugs Team (HFV-131), Division of Therapeutic Drugs for Food Animals, Office of New Animal Drug Evaluations, Center for Veterinary Medicine, U.S. Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855; Dr. Donald Prater; Phone: 240-276-8343; E-mail: <a href="mailto:Donald.Prater@fda.hhs.gov">Donald.Prater@fda.hhs.gov</a>
CVM/MSU	Center for Veterinary Medicine, Mississippi State University—Dr. Patricia Gaunt, PO Box 197, Stoneville, MS 38776; Phone: 662-686-3237; Fax: 662-686-3568; E-mail: <a href="mailto:gaunt@cvm.msstate.edu">gaunt@cvm.msstate.edu</a>
Efficacy	Effectiveness Technical Section includes pivotal & supportive studies that show whether or not a drug is effective for its intended use [21 CFR § 514.1(b)(8)(i)]
FOI	Final Freedom of Information summary generated by CVM based on draft FOIs developed by researchers for each study [21 CFR § 514.11(e)(2)(ii)]
INAD	Investigational New Animal Drug exemption [21 CFR 511]
Label	Labeling Technical Section includes labeling and package inserts [21 CFR § 514.1(b)(3)]
NADA	New Animal Drug Application [21 CFR 514]
NADA Coordinator	Rosalie (Roz) Schnick, National Coordinator for Aquaculture New Animal Drug Applications, Michigan State University, 3039 Edgewater Lane, La Crosse, Wisconsin 54603-1088; Phone: 608-781-2205; Fax: 608-783-3507; E-mail: <a href="mailto:RozSchnick@centurytel.net">RozSchnick@centurytel.net</a>
Product Chemistry	Product Chemistry Technical Section includes chemistry, manufacturing, and controls [21 CFR 514.1 (b) (4-6)]
SPAH	Sponsor of florfenicol (Aquaflor®): Schering-Plough Animal Health, PO Box 3182, Union, New Jersey 07083; Phone: 908-629-3344; Fax: 908-629-3365; E-mail: <a href="mailto:spaquaculture@spcorp.com">spaquaculture@spcorp.com</a> ; Website: <a href="http://www.spaquaculture.com/">http://www.spaquaculture.com/</a>
Toxicology	Part of Human Food Safety Technical Section, toxicological testing includes genetic toxicity tests and mammalian safety studies (e.g., acute, sub chronic) (Guidance Document #3)
UMESC	Upper Midwest Environmental Sciences Center—Mark Gaikowski, 2630 Fanta Reed Road, La Crosse, Wisconsin 54603; Phone: 608-783-6451; Fax: 608-783-6066; E-mail: <a href="mailto:MGaikowski@usgs.gov">MGaikowski@usgs.gov</a>

**KEY TO COLOR CODING**

COLOR	STATUS
	<b>No current plans and/or funds</b>
	<b>In progress or planned; funded</b>
	<b>Submitted to CVM</b>
	<b>Accepted by CVM</b>

## FLORFENICOL (AQUAFLO<sup>®</sup>)

### Florfenicol (Aquaflor<sup>®</sup>) NADA approvals (10/24/05, 3/19/07, and 10/26/07); Conditional approval (4/18/07)

#### **Original NADA Approval for Veterinary Feed Directive (10/24/05)**

Species/Class: Catfish

Indications: [For the control of mortality in catfish due to enteric septicemia of catfish associated with \*Edwardsiella ictaluri\*](#)

Recommended Dosage: 10 mg of florfenicol per kg of body weight of fish for 10 consecutive days

#### **Supplemental NADA Approval for Veterinary Feed Directive (3/19/07)**

Species/Class: Freshwater-reared salmonids

Indications: [For the control of mortality in freshwater-reared salmonids due to coldwater disease associated with \*Flavobacterium psychrophilum\*](#)

Recommended Dosage: 10 mg of florfenicol per kg of body weight of fish for 10 consecutive days

#### **Supplemental NADA Approval for Veterinary Feed Directive (10/26/07)**

Species/Class: Freshwater-reared salmonids

Indications: [For the control of mortality in freshwater-reared salmonids due to furunculosis associated with \*Aeromonas salmonicida\*](#)

Recommended Dosage: 10 mg of florfenicol per kg of body weight of fish for 10 consecutive days

#### **Conditional Approval for Veterinary Feed Directive (4/18/07)**

Species/Class: Catfish

Indications: [For the control of mortality in catfish due to columnaris disease associated with \*Flavobacterium columnare\*](#)

Recommended Dosage: 10 mg of florfenicol per kg of body weight of fish for 10 consecutive days

**FLORFENICOL (AQUAFLO<sup>®</sup>)**

Status of Technical Sections that support all supplemental NADA approvals

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Product Chemistry	SPAH—Product Chemistry package—accepted	None
Environmental Safety (pond systems)	SPAH—Environmental safety/pond systems—accepted	None
Environmental Safety (continuous flow-through systems)	SPAH—Environmental Safety/continuous flow-through systems—accepted	None
Human Food Safety (toxicology)	SPAH—Human Food Safety/toxicology—accepted	None
Human Food Safety (residue chemistry/analytical method)	SPAH—Human Food Safety/residue chemistry/analytical method/catfish & salmonids—accepted	None
Human Food Safety (residue chemistry/catfish)	SPAH & CVM/MSU—Human Food Safety/residue chemistry/catfish—accepted (12-day withdrawal time)	None
Human Food Safety (residue chemistry/salmonids)	SPAH—Human Food Safety/residue chemistry/freshwater-reared salmonids—accepted	None
Human Food Safety (microbiological effects on bacteria of human health concern/catfish & salmonids)	SPAH—Human Food Safety/Guidance Document #152: microbiological effects on bacteria of human health concern/catfish & salmonids—accepted	None
Human Food Safety (safety of residues in human food /catfish & salmonids)	SPAH—Human Food Safety/Guidance Document #159: safety of residues in human food /catfish & salmonids—accepted	None
Human Food Safety (residue chemistry/tilapia & hybrid striped bass)	SPAH & UMESC—Human Food Safety/residue chemistry/tilapia & hybrid striped bass—completion report in progress for tilapia	None—pending acceptance
Human Food Safety (microbiological effects on bacteria of human health concern/tilapia & hybrid striped bass)	SPAH—Human Food Safety/Guidance Document #152: microbiological effects on bacteria of human health concern/tilapia & hybrid striped bass—in progress	None—pending acceptance
Human Food Safety (safety of residues in human food /tilapia & hybrid striped bass)	SPAH—Human Food Safety/Guidance Document #159: safety of residues in human food /tilapia & hybrid striped bass—in progress	None—pending acceptance
Target Animal Safety (freshwater-reared salmonids)	SPAH—Target animal safety/freshwater-reared salmonids—accepted fall 2003	None
Target Animal Safety (catfish)	SPAH & UMESC—Target animal safety/channel catfish—accepted 1/22/03	None
Target Animal Safety (tilapia)	SPAH—Target animal safety/tilapia—planned or in progress	None—pending acceptance

## FLORFENICOL (AQUAFLO<sup>®</sup>)

**LABEL CLAIM #1**

**SPECIES:** FRESHWATER-REARED SALMONIDS AND CATFISH

**INDICATIONS:** For the control of mortality in freshwater-reared salmonids and catfish due to systemic columnaris disease associated with *Flavobacterium columnare* (*Flexibacter columnaris*)

**DIRECTIONS FOR USE:** Apply Aquaflor<sup>®</sup> in medicated feed at a dose of 10 milligrams florfenicol per kilogram of fish daily for ten consecutive days.

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Efficacy (systemic columnaris disease/salmonids)	AADAP (INAD #10-697)—Efficacy/systemic columnaris disease/freshwater-reared salmonids—in progress	None
Efficacy (systemic columnaris disease/catfish)	SPAH & other entities—Pivotal efficacy/systemic columnaris disease/catfish—in progress (Conditional approval 4/20/07)	None—pending acceptance
Label	SPAH—Label/label claims listed above—planned in the future	None—pending acceptance
FOI	SPAH—FOI/label claims listed above—planned in the future	None—pending acceptance
AOI	SPAH—AOI/label claims listed above—planned in the future	None—pending acceptance
NADA Packages	SPAH—NADA Packages/label claims—planned in the future	None—pending acceptance

**FLORFENICOL (AQUAFLO<sup>®</sup>)**

**LABEL CLAIM #2**

**SPECIES: TILAPIA AND HYBRID STRIPED BASS**

**INDICATIONS:** [For the control of mortality in tilapia and hybrid striped bass due to streptococcosis associated with \*Streptococcus iniae\*](#)

**DIRECTIONS FOR USE:** Apply Aquaflor<sup>®</sup> in medicated feed at a dose of 15 milligrams florfenicol per kilogram of fish daily for ten consecutive days.

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Efficacy ( <i>Streptococcus iniae</i> / hybrid striped bass)	SPAH & AADAP—Pivotal efficacy/ <i>Streptococcus iniae</i> /hybrid striped bass—accepted as pivotal	None
Efficacy ( <i>Streptococcus iniae</i> / hybrid striped bass)	SPAH & AADAP—Pivotal efficacy/Technical Section Complete/ <i>Streptococcus iniae</i> /hybrid striped bass—submitted 10/4/07	None—pending acceptance
Efficacy ( <i>Streptococcus iniae</i> / tilapia)	SPAH & UMESC—Pivotal efficacy/ <i>Streptococcus iniae</i> /tilapia—in progress	None—pending acceptance
Label	SPAH—Label/label claims listed above—planned in the future	None—pending acceptance
FOI	SPAH—FOI/label claims listed above—planned in the future	None—pending acceptance
AOI	SPAH—AOI/label claims listed above—planned in the future	None—pending acceptance
NADA Packages	SPAH—NADA Packages/label claims—planned in the future	None—pending acceptance

**FLORFENICOL (AQUAFLO®)**

**LABEL CLAIM #3**

**SPECIES: COOLWATER AND WARMWATER FINFISH**

**INDICATIONS:** [For the control of mortality in coolwater and warmwater finfish due to motile aeromonad septicemia associated with \*Aeromonas\* spp.](#)

**DIRECTIONS FOR USE:** Apply Aquaflor® in medicated feed at a dose of 10 milligrams florfenicol per kilogram of fish daily for ten consecutive days.

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Efficacy (motile aeromonad septicemia/coolwater and warmwater finfish)	UMESC & SPAH—Pivotal efficacy/motile aeromonad septicemia/coolwater and warmwater finfish—being planned with NCRAC funds	None—pending acceptance
Label	SPAH—Label/label claims listed above—planned in the future	None—pending acceptance
FOI	SPAH—FOI/label claims listed above—planned in the future	None—pending acceptance
AOI	SPAH—AOI/label claims listed above—planned in the future	None—pending acceptance
NADA Packages	SPAH—NADA Packages/label claims—planned in the future	None—pending acceptance