

## AQUACULTURE DRUG APPROVAL DEVELOPMENT STATUS

### **COPPER SULFATE (TRIANGLE BRAND COPPER SULFATE®): RESEARCH AND DEVELOPMENT PLAN AND LABEL CLAIM MATRICES FOR ORIGINAL AND SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION (NADA) APPROVALS**

1. [Copper sulfate \(TRIANGLE BRAND COPPER SULFATE®\) NADA approvals \(none to date\)](#)
2. [Status of technical sections that support all original and supplemental NADA approvals](#)
3. [Label Claim #1: Control of mortality in channel catfish due to ichthyophthiriasis](#)
4. [Label Claim #2: Control of mortality in freshwater-reared finfish due to ichthyophthiriasis](#)
5. [Label Claim #3: Control of mortality in channel catfish eggs due to saprolegniasis](#)
6. [Label Claim #4: Control of mortality in freshwater-reared finfish eggs due to saprolegniasis](#)
7. [Label Claim #5: Control of mortality in freshwater-reared finfish due to bacterial gill disease](#)
8. [Label Claim #6: Control of mortality in freshwater-reared finfish due to external columnaris disease](#)
9. [Label Claim #7: Control of external protozoa in freshwater-reared finfish](#)

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

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**COPPER SULFATE (TRIANGLE BRAND COPPER SULFATE®)**  
**(Version 2, March 2008)**

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

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>
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>
PHELPS	Sponsor of copper sulfate (Triangle Brand Copper Sulfate®): David Fisher, Phelps Dodge Refining Corporation, PO Box 2001, El Paso, TX 79996; Phone: 915-775-8853; Fax: 915-775-8350; E-mail: <a href="mailto:dfisher@phelpsdodge.com">dfisher@phelpsdodge.com</a>
Product Chemistry	Product Chemistry Technical Section includes chemistry, manufacturing, and controls [21 CFR § 514.1(b)(4-6)]
PMF	Public Master File can contain safety and efficacy data and information generated with public funds (Guidance Document #57)
SNARC	Harry K. Dupree Stuttgart National Aquaculture Research Center—Dr. David Straus, Agricultural Research Service, PO Box 860, Stuttgart, Arkansas 72160-0860; Phone: 870-673-4483; Fax: 870-673-7710; E-mail: <a href="mailto:dave.straus@ars.usda.gov">dave.straus@ars.usda.gov</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)

### KEY TO COLOR CODING

COLOR	STATUS
	No current plans and/or funds
	In progress or planned; funded
	Submitted to CVM
	Accepted as complete by CVM

**COPPER SULFATE (TRIANGLE BRAND COPPER SULFATE®)**

Copper sulfate (TRIANGLE BRAND COPPER SULFATE®) NADA approvals (none to date)

**COPPER SULFATE (TRIANGLE BRAND COPPER SULFATE®)**

Status of Technical Sections that support all original and supplemental NADA approvals

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Product Chemistry	PHELPS (INAD #10-046)—Product chemistry package—accepted 5/4/99	None—Technical Section is complete
Environmental Safety (environmental assessment/pond systems)	SNARC (PMF #5590) & PHELPS (INAD #10-046)—Environmental Safety/environmental assessment/pond systems—submitted 12/06; CVM requested changes and more information in 2007	None—pending acceptance
Environmental Safety (environmental assessment/continuous flow-through systems)	SNARC (PMF #5590)—Environmental Safety/environmental assessment revision/continuous flow-through systems—in progress	None—pending acceptance
Human Food Safety (toxicology)	PHELPS (INAD #10-046)—Human Food Safety/toxicology—accepted 3/3/00	None
Human Food Safety (residue chemistry/all finfish)	SNARC (PMF #5590)—Human Food Safety/residue chemistry/all finfish—accepted 3/3/00 (no tolerances, withdrawal times, or regulatory methods required)	None
Human Food Safety (Technical Section Complete Letter)	SNARC (PMF #5590)—Human Food Safety Technical Section (including Guidance Documents #152 & 159)—accepted as complete 2/9/04	None—Technical Section is complete
Human Food Safety (Technical Section Complete Letter)	SNARC (PMF #5590)—Human Food Safety Technical Section Complete/channel catfish—accepted as complete for channel catfish; need #152 for all freshwater-reared finfish—accepted 12/07	None—Technical Section is complete
Human Food Safety—Microbial Food Safety #152 (all freshwater-reared finfish)	PHELPS (INAD #10-046), SNARC (PMF #5590) & NADA Coordinator—Microbial food safety/Evaluating the safety of drugs to their microbiological effects on bacteria of human health concern (Guidance Document #152/all freshwater-reared finfish)—in progress	None—pending acceptance
Target Animal Safety (channel catfish)	PHELPS (INAD #10-046) & SNARC—Target animal safety/channel catfish—accepted 5/25/05	None—Technical Section is complete
Target Animal Safety (freshwater-reared finfish except channel catfish)	No entity identified—Target Animal Safety/freshwater-reared finfish except channel catfish—needs to be planned	Needs to be planned
Target Animal Safety (channel catfish eggs)	PHELPS (INAD #10-046) & SNARC—Target Animal Safety/channel catfish eggs—in progress	None—pending acceptance
Target Animal Safety (freshwater-reared finfish)	No entity identified—Target Animal Safety/freshwater-reared finfish eggs except	Needs to be planned

eggs except channel catfish eggs)	channel catfish eggs—needs to be planned	
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**COPPER SULFATE (TRIANGLE BRAND COPPER SULFATE®)**

**LABEL CLAIM #1:**

**SPECIES: CHANNEL CATFISH**

**INDICATIONS:** [For the control of mortality in channel catfish due to ichthyophthiriasis](#)

**DIRECTIONS FOR USE:** Apply Triangle Brand Copper Sulfate® at a concentration of no more than 1.0 milligram copper sulfate per liter [mg/L; equivalent to parts per million (ppm)] per 100 ppm total alkalinity (as CaCO<sub>3</sub>) in earthen ponds with no outflows. One part per million is achieved by applying 2.72 pounds of copper sulfate per acre-foot of water.

Technical Section	Entity—Data—Action	Impediments or Cost—Action
<b>Efficacy (ichthyophthiriasis/all fish)</b>	<b>SNARC (PMF #5590)—Literature &amp; pivotal efficacy studies/ichthyophthiriasis/all fish/earthen ponds—accepted 8/15/98</b>	<b>None—Technical Section is complete</b>
<b>Label</b>	<b>PHELPS (INAD #10-046) &amp; SNARC—Label ichthyophthiriasis/channel catfish—in progress</b>	<b>None—pending acceptance</b>
<b>FOI</b>	<b>CVM—FOI/ichthyophthiriasis/channel catfish—in progress</b>	<b>None—pending acceptance</b>
<b>AOI</b>	<b>PHELPS (INAD #10-046) &amp; SNARC—AOI/ichthyophthiriasis/channel catfish—in progress</b>	<b>None—pending acceptance</b>
<b>NADA Package</b>	<b>PHELPS (INAD #10-046) &amp; SNARC—NADA package/ichthyophthiriasis/channel catfish—in progress</b>	<b>None—pending acceptance</b>

**COPPER SULFATE (TRIANGLE BRAND COPPER SULFATE®)**

**LABEL CLAIM #2:**

**SPECIES:** FRESHWATER-REARED FINFISH

**INDICATIONS:** [For the control of mortality in freshwater-reared finfish due to ichthyophthiriasis](#)

**DIRECTIONS FOR USE:** Apply Triangle Brand Copper Sulfate® at a concentration of no more than 1.0 milligram copper sulfate per liter [mg/L; equivalent to parts per million (ppm)] per 100 ppm total alkalinity (as CaCO<sub>3</sub>) in earthen ponds with no outflows. One part per million is achieved by applying 2.72 pounds of copper sulfate per acre-foot of water.

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Efficacy (ichthyophthiriasis/all fish)	SNARC (PMF #5590)—Literature & pivotal efficacy studies/ichthyophthiriasis/all fish/earthen ponds—accepted 8/15/98	None
Label	PHELPS (INAD #10-046) & SNARC—Label ichthyophthiriasis/channel catfish—planned when target animal safety & environmental safety in continuous flow-through systems are accepted	None—pending acceptance
FOI	CVM—FOI/ichthyophthiriasis/channel catfish—planned when target animal safety & environmental safety in continuous flow-through systems are accepted	None—pending acceptance
AOI	PHELPS (INAD #10-046) & SNARC—AOI/ichthyophthiriasis/channel catfish—planned when target animal safety & environmental safety in continuous flow-through systems are accepted	None—pending acceptance
NADA Package	PHELPS (INAD #10-046) & SNARC—NADA package/ichthyophthiriasis/channel catfish—planned when target animal safety & environmental safety in continuous flow-through systems are accepted	None—pending acceptance

**COPPER SULFATE (TRIANGLE BRAND COPPER SULFATE®)**

**LABEL CLAIM #3**

**SPECIES: CHANNEL CATFISH EGGS**

**INDICATIONS:** [For the control of mortality in channel catfish eggs due to saprolegniasis](#)

**DIRECTIONS FOR USE:** Apply Triangle Brand Copper Sulfate® at a concentration range of 5 to 20 milligram copper sulfate per liter [mg/L; equivalent to parts per million (ppm)] per 100 ppm total alkalinity (as CaCO<sub>3</sub>) in continuous flow-through hatchery troughs once a day. One part per million is achieved by applying 2.72 pounds of copper sulfate per acre-foot of water.

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Efficacy (saprolegniasis/channel catfish eggs)	PHELPS (INAD #10-046) & SNARC—Efficacy/saprolegniasis/channel catfish eggs—in progress	None—pending acceptance
Label	PHELPS (INAD #10-046) & SNARC—Label/saprolegniasis/channel catfish eggs—planned when target animal safety, efficacy, & environmental safety in continuous flow-through systems are accepted	None—pending acceptance
FOI	CVM—FOI/saprolegniasis/channel catfish eggs—planned when target animal safety, efficacy, & environmental safety in continuous flow-through systems are accepted	None—pending acceptance
AOI	PHELPS (INAD #10-046) & SNARC—AOI/saprolegniasis/channel catfish eggs—planned when target animal safety, efficacy, & environmental safety in continuous flow-through systems are accepted	None—pending acceptance
NADA Package	PHELPS (INAD #10-046) & SNARC—NADA package/saprolegniasis/channel catfish eggs—planned when target animal safety, efficacy, & environmental safety in continuous flow-through systems are accepted	None—pending acceptance

**COPPER SULFATE (TRIANGLE BRAND COPPER SULFATE®)**

**LABEL CLAIM #4**

**SPECIES: FRESHWATER-REARED FINFISH EGGS**

**INDICATIONS:** [For the control of mortality in freshwater-reared finfish eggs due to saprolegniasis](#)

**DIRECTIONS FOR USE:** Apply Triangle Brand Copper Sulfate® at a concentration range of 5 to 20 milligram copper sulfate per liter [mg/L; equivalent to parts per million (ppm)] per 100 ppm total alkalinity (as CaCO<sub>3</sub>) in continuous flow-through hatchery troughs once a day. One part per million is achieved by applying 2.72 pounds of copper sulfate per acre-foot of water.

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Efficacy (saprolegniasis/channel catfish eggs)	PHELPS (INAD #10-046) & SNARC—Efficacy/saprolegniasis/channel catfish eggs—in progress	None—pending acceptance
Efficacy (saprolegniasis/freshwater-reared finfish eggs except for channel catfish eggs)	No entity identified—Efficacy/saprolegniasis/freshwater-reared finfish eggs except for channel catfish eggs—needs to be planned	Needs to be planned
Label	PHELPS (INAD #10-046) & SNARC—Label/saprolegniasis/freshwater-reared finfish eggs—planned when target animal safety, efficacy, & environmental safety in continuous flow-through systems are accepted	None—pending acceptance
FOI	CVM—FOI/saprolegniasis/freshwater-reared finfish eggs—planned when target animal safety, efficacy, & environmental safety in continuous flow-through systems are accepted	None—pending acceptance
AOI	PHELPS (INAD #10-046) & SNARC—AOI/saprolegniasis/freshwater-reared finfish eggs—planned when target animal safety, efficacy, & environmental safety in continuous flow-through systems are accepted	None—pending acceptance
NADA Package	PHELPS (INAD #10-046) & SNARC—NADA package/saprolegniasis/freshwater-reared finfish eggs—planned when target animal safety, efficacy, & environmental safety in continuous flow-through systems are accepted	None—pending acceptance

**COPPER SULFATE (TRIANGLE BRAND COPPER SULFATE®)**

**LABEL CLAIM #5**

**SPECIES: FRESHWATER-REARED FINFISH**

**INDICATIONS:** [For the control of mortality in freshwater-reared finfish due to bacterial gill disease associated with \*Flavobacterium branchiophilum\*](#)

**DIRECTIONS FOR USE:** Apply Triangle Brand Copper Sulfate® at a concentration range of \_\_\_ milligram copper sulfate per liter [mg/L; equivalent to parts per million (ppm)] per 100 ppm total alkalinity (as CaCO<sub>3</sub>) in continuous flow-through finfish culture units at a concentration range of \_\_\_\_\_ for \_\_\_\_\_. One part per million is achieved by applying 2.72 pounds of copper sulfate per acre-foot of water.

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Efficacy (bacterial gill disease/freshwater-reared finfish)	No entity identified—Efficacy/bacterial gill disease/freshwater-reared finfish—needs to be planned	Needs to be planned
Label	PHELPS (INAD #10-046) & SNARC—Label/bacterial gill disease/freshwater-reared finfish—planned when target animal safety, efficacy, & environmental safety in continuous flow-through systems are accepted	None—pending acceptance
FOI	CVM—FOI/bacterial gill disease/freshwater-reared finfish—planned when target animal safety, efficacy, & environmental safety in continuous flow-through systems are accepted	None—pending acceptance
AOI	PHELPS (INAD #10-046) & SNARC—AOI/bacterial gill disease/freshwater-reared finfish—planned when target animal safety, efficacy, & continuous flow-through systems are accepted	None—pending acceptance
NADA Package	PHELPS (INAD #10-046) & SNARC—NADA package/bacterial gill disease/freshwater-reared finfish—planned when target animal safety, efficacy, & environmental safety in continuous flow-through systems are accepted	None—pending acceptance

**COPPER SULFATE (TRIANGLE BRAND COPPER SULFATE®)**

**LABEL CLAIM #6**

**SPECIES: FRESHWATER-REARED FINFISH**

**INDICATIONS:** For the control of mortality in freshwater-reared finfish due to external columnaris disease associated with *Flavobacterium columnare* (*Flexibacter columnaris*)

**DIRECTIONS FOR USE:** Apply Triangle Brand Copper Sulfate® at a concentration range of \_\_\_\_\_ milligram copper sulfate per liter [mg/L; equivalent to parts per million (ppm)] per 100 ppm total alkalinity (as CaCO<sub>3</sub>) in continuous flow-through finfish culture units at a concentration range of \_\_\_\_\_ for \_\_\_\_\_. . One part per million is achieved by applying 2.72 pounds of copper sulfate per acre-foot of water.

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Efficacy (external columnaris disease/freshwater-reared finfish)	No entity identified—Efficacy/external columnaris disease/freshwater-reared finfish—needs to be planned	Needs to be planned
Label	PHELPS (INAD #10-046)—Label/external columnaris disease/freshwater-reared finfish—planned when target animal safety, efficacy, & environmental safety in continuous flow-through systems are accepted	None—pending acceptance
FOI	CVM—FOI/external columnaris disease/freshwater-reared finfish—planned when target animal safety, efficacy, & environmental safety in continuous flow-through systems are accepted	None—pending acceptance
AOI	PHELPS (INAD #10-046)—AOI/external columnaris disease/freshwater-reared finfish—planned when target animal safety, efficacy, & environmental safety in continuous flow-through systems are accepted	None—pending acceptance
NADA Package	PHELPS (INAD #10-046)—NADA package/external columnaris disease/freshwater-reared finfish—planned when target animal safety, efficacy, & environmental safety in continuous flow-through systems are accepted	None—pending acceptance

**COPPER SULFATE (TRIANGLE BRAND COPPER SULFATE®)**

**LABEL CLAIM #7**

**SPECIES: FRESHWATER-REARED FINFISH**

**INDICATIONS:** [For the control of external protozoa in freshwater-reared finfish](#)

**DIRECTIONS FOR USE:** Apply Triangle Brand Copper Sulfate® at a concentration range of \_\_\_\_\_ milligram copper sulfate per liter [mg/L; equivalent to parts per million (ppm)] per 100 ppm total alkalinity (as CaCO<sub>3</sub>) in continuous flow-through finfish culture units at a concentration range of \_\_\_\_\_ for \_\_\_\_\_. . One part per million is achieved by applying 2.72 pounds of copper sulfate per acre-foot of water.

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Efficacy (external protozoa/freshwater-reared finfish)	No entity identified—Efficacy/external protozoa/freshwater-reared finfish—needs to be planned	Needs to be planned
Label	PHELPS (INAD #10-046)—Label/external protozoa/freshwater-reared finfish—planned when target animal safety, efficacy, & environmental safety in continuous flow-through systems are accepted	None—pending acceptance
FOI	CVM—FOI/external protozoa/freshwater-reared finfish—planned when target animal safety, efficacy, & environmental safety in continuous flow-through systems are accepted	None—pending acceptance
AOI	PHELPS (INAD #10-046)—AOI/external protozoa/freshwater-reared finfish—planned when target animal safety, efficacy, & environmental safety in continuous flow-through systems are accepted	None—pending acceptance
NADA Package	PHELPS (INAD #10-046)—NADA package/external protozoa/freshwater-reared finfish—planned when target animal safety, efficacy, & environmental safety in continuous flow-through systems are accepted	None—pending acceptance