

## 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 1, November 2007)**

## 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: 301-827-7567; E-mail: <a href="mailto:DPrater@CVM.FDA.GOV">DPrater@CVM.FDA.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]   |
| 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:DStraus@spa.ars.usda.gov">DStraus@spa.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   | SNARC (PMF #5590)—Human Food Safety Technical Section (including Guidance Documents #152 & 159)—accepted as complete 2/9/04  | None—Technical Section is complete |
| 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 eggs except channel catfish eggs) | No entity identified—Target Animal Safety/freshwater-reared finfish eggs except channel catfish eggs—needs to be planned   | Needs to be planned                |

**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    |