



I-011401-P-0017-NV

U.S. Department of Agriculture
Harry K Dupree – Stuttgart National Aquaculture Research Center
Attention: David L. Straus, Ph.D.
Research Toxicologist
P.O. Box 1050
2955 Highway 130 East
Stuttgart, AR 72160

Re: Environmental Impact technical section incomplete for copper sulfate in catfish cultured in earthen ponds – submitted information acceptable to support a FONSI

Dear Dr. Straus:

Based upon the revised environmental assessment (EA) you submitted on July 1, 2015, we consider the Environmental Impact technical section to be incomplete; however, we have determined the submitted EA is adequate to support the preparation of a finding of no significant impact (FONSI) by the Center for Veterinary Medicine. The technical section is incomplete for the use of copper sulfate for control of mortality associated with ichthyophthiriasis in channel catfish cultured in earthen ponds. The proposed dosage is 0.4 to 1 part per million (ppm) or mg/L copper sulfate per 100 ppm total alkalinity (as CaCO₃) once daily for 5 – 11 days. This product will be dispensed over the counter.

You have adequately addressed our comments on the EA dated December 19, 2014, that was previously submitted in P-0015. Our review indicates your revised EA for copper sulfate dated July 1, 2015, is acceptable to support preparation of a FONSI; however, a FONSI and Environmental Impact technical section complete letter for copper sulfate will only be issued to an identified drug product sponsor(s) contingent on their submission of product labeling consistent with that described in the EA in Appendix 13.1, and which contains adequate limitations and cautions for risk mitigation, including a statement not to discharge pond water for at least 72 hours after the final copper sulfate application to avoid causing toxicity to aquatic life in receiving waters.

If you submit correspondence relating to this letter, you should reference the date and the principal submission identifier found at the top of this letter. If you have any questions or comments, please contact Dr. Eric Silberhorn, Environmental Safety Team, at 240-402-0833. You may also contact Dr. Holly Zahner, Leader, Environmental Safety Team, at 240-402-0834.

Sincerely,

{see appended electronic signature page}

Veronica N. Taylor, Ph.D.
Director, Division of Scientific Support
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

**Electronic Signature
Addendum for Submission ID**

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Signing Authority (Role)	Letter Date
Veronica Taylor (Division Director)	12/11/2015

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