

I-011401-P-0008-HF

U.S. Department of Agriculture, Agriculture Research Service  
Harry K. Dupree - Stuttgart National Aquaculture Research Center  
Attention: David L. Straus, Ph.D.  
2955 Highway 130 East  
Stuttgart, AR 72160-0860

OCT 27 2008

Subject: Human Food Safety Technical Section Complete Letter for the Use of Copper Sulfate in all Fin Fish

Dear Dr. Straus:

Based on the information in your submission dated April 28, 2008 and the information contained in Investigational New Animal Drug (INAD) files 011401 and 010046, the Division of Human Food Safety considers the Human Food Safety technical section for TRIANGLE BRAND Copper Sulfate proposed for the treatment of ichthyophthiriasis (*Ichthyophthirius multifiliis*) on all fin fish to be complete.

The human food safety requirements for the use of copper sulfate in all fin fish have been satisfied for toxicology, residue chemistry, and microbial food safety.

The Division of Human Food Safety considers the Human Food Safety technical section to be complete for the purpose of recommending approval of a New Animal Drug Application (NADA) for copper sulfate in all fin fish. A tolerance, regulatory method, and withdrawal time are not needed for fin fish treated with copper sulfate because Cu does not accumulate in the edible tissue of fish exposed to copper sulfate.

You assessed the use of copper sulfate in the treatment of ichthyophthiriasis (*Ichthyophthirius multifiliis*) on all fin fish using a hazard characterization similar to that outlined in FDA's Guidance for Industry (GFI) #152 *Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern*. The product is administered as an external bath treatment at a concentration of 0.4-1 part per million (ppm or mg/L) copper sulfate per 100 ppm total alkalinity (as calcium carbonate), once daily for 5 to 11 days.

We are in agreement with your conclusion that the microbial food safety risks associated with your proposed use of copper sulfate in fin fish is **low**. In addition, minimal absorption of applied concentrations of copper sulfate, combined with the low annual *per capita* consumption of domestically-produced fin fish helped us determine that the *exposure assessment* is low (Table 5, of GFI #152). This drives the overall risk into the **low** category, corresponding to risk management steps allowing for the proposed use of copper sulfate as an external bath treatment.

Attached to this letter we have provided the Human Food Safety portion of the FOI Summary for the approval of copper sulfate in all fin fish. This language can be used for the human food safety section of the FOI summary when an NADA is filed.

We will make a final decision on whether we can approve your application after we have reviewed all of the data for all applicable technical sections submitted in support of an administrative NADA, NADA, or supplemental NADA, and any other information available to us, as a whole, and determined whether the requirements for approval set forth in the Federal Food, Drug, and Cosmetic Act have been met.

If you submit correspondence relating to your submission to the investigational file, you should reference the date and the principal submission identifier found at the top of this letter. If you have any questions, please contact me at (240) 276-8225 or Dr. Jeffrey M. Gilbert, at (240) 276-8174.

Sincerely,

Karen B. Ekelman, PhD  
Director  
Division of Human Food Safety  
Office of New Animal Drug Evaluation  
Center for Veterinary Medicine