

I-010046-P-0013

Phelps Dodge Sales Company
Attention: David L. Fisher
Senior Product Manager/Chemical Engineer
P.O. Box 20001
El Paso, TX 79998

APR 21 2006

Re: Response to your letter dated June 30, 2005, regarding the target animal safety technical section for copper sulfate.

Dear Mr. Fisher:

Based on the information in your submission dated June 30, 2005, and the information contained in INAD 010046 and PMF 005990, the Division of Therapeutic Drugs for Food Animals considers the target animal safety technical section for copper sulfate for the treatment of ichthyophthiriasis (*Ichthyophthirius multifiliis*) on channel catfish cultured in earthen ponds to be complete. This technical section complete letter represents our finding that the laboratory studies essential to determining target animal safety are complete and accepted. We also evaluate target animal safety in our review of other technical sections, particularly the effectiveness and all other information technical sections.

The Target Animal Safety section of the Freedom of Information (FOI) Summary was revised based on the summaries you submitted for the acute toxicity data previously submitted to CVM. A copy of the draft Freedom of Information Summary is enclosed.

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 New Animal Drug Application (NADA), NADA, or supplemental NADA, and any other information available to us, as a whole, and determine whether the requirements for approval set forth in the Federal Food, Drug, and Cosmetic Act have been met.

Draft Label Comments

We have reviewed sections of the draft labeling pertaining to the future approval of copper sulfate on channel catfish that were included in this submission. We request that you make the changes listed below. If you elect to not make these changes, the Target Animal Safety technical section will be re-opened (considered incomplete). CVM may request additional revisions prior to issuing a technical section complete letter for the Labeling technical section.

1. We have revised the limitations and cautions statement on the labeling, as included below.

If total alkalinity is less than 50 ppm, copper sulfate treatments are not recommended. If total alkalinity is over 300 ppm, no more than 3 ppm copper sulfate should be used.

2. The following should replace the dose in the "Directions for Use" section of the label.

Apply copper sulfate to water at a concentration of 0.4 to 1 part per million (ppm or mg/L) copper sulfate per 100 ppm total alkalinity (as CaCO₃) once daily for 5 to 11 days to treat ichthyophthiriasis (*Ichthyophthirius multifiliis*) on channel catfish cultured in earthen ponds.

3. The draft label provides the amount of copper sulfate per acre-foot of water to achieve 1 ppm copper sulfate as 2.72 lbs. (Directions for Use paragraph) and 2.7 lbs. (Directions for Use table). The amount of copper sulfate to add per acre-foot of water should be consistent throughout the label.
4. Previously you asked CVM about marketing a single product that would include both the EPA accepted label and FDA approved label, "dual labeling." In a letter dated July 6, 1998, CVM replied that we did not object to the use of dual labeling. At this time, EPA and FDA have not developed an acceptable process to permit "dual labeling" under the Federal Food, Drug and Cosmetic Act, the law providing FDA regulatory authority, and the Federal Insecticide, Fungicide and Rodenticide Act, the law providing EPA regulatory authority. We recommend that you proceed with a plan for developing an FDA approvable product that will be marketed with the FDA-approved labeling only.

Additionally, you included only one copy of the material in this submission. In the future, please include three complete copies of all materials in submissions.

If you submit correspondence relating to your submission to the investigational file, you should reference the date and the principal submission(s) identifier found at the top of this letter. If you have any questions, please contact me at 301-827-7571, or Dr. Donald Prater, Leader, Aquaculture Drugs Team at 301-827-7567.

Sincerely,

Joan C. Gotthardt, D.V.M
Director, Division of Therapeutic Drugs
for Food Animals
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

Enclosure