DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
Rockville MD 20857

I-010046-P-0033-EF

Freeport-McMoRan Sales Company
Attention: David Fisher
Senior Project Manager
333 North Central Avenue
Phoenix, AZ 85004-4405

Re: Effectiveness final study report CuSO4 CCF EggEff DC #3

Dear Mr. Fisher:

Based upon the information you submitted on November 1, 2012, and amended on January 24, 2013 (T-0037) and March 4, 2013 (T-0039), and the information contained in INAD 010046, we consider the Effectiveness technical section to be complete. The technical section is complete for the use of TRIANGLE BRAND Copper Sulfate (copper sulfate) granules for the control of mortality in channel catfish eggs due to saprolegnaisis associated with fungi in the family Saprolegniaceae. The proposed dose is 10 mg/L copper sulfate administered once daily to a system flowing at a rate of one volume exchange per 28 minutes, starting within 24 hours after spawning, until the embryos develop eyes.

DRAFT LABELING

We note that you did not submit draft labeling. In the future, please include draft labeling language with each major technical section.

FREEDOM OF INFORMATION (FOI) SUMMARY

We appreciate your cooperation in including the relevant portions of the FOI Summary with this submission. The Effectiveness section of the FOI Summary has been revised, and a copy is enclosed. Please review the FOI Summary for accuracy and notify us if you find errors. CVM will prepare the final version of the FOI Summary and will provide you a copy when the last technical section is complete.

ALL OTHER INFORMATION

The information provided in this submission is acceptable as “all other information” for this technical section. You do not need to re-submit the information when you submit the AOI technical section. Please submit any additional information that you become aware of pertaining to effectiveness of copper sulfate in catfish eggs when you submit your AOI technical section.

Include a copy of this technical section complete letter when you submit your new animal drug application. Please contact us if there are changes in the product development plan (e.g., indication, dosage, duration of use) or you become aware of

any issues that may impact the status of this technical section or your application. 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 and any other information available to us, as a whole, and determined whether the requirements for approval described in the Federal Food, Drug, and Cosmetic Act have been met.

If you submit correspondence relating to this letter, your correspondence should reference the date and the principal submission identifier. If you have any questions or comments, please contact me at 240-276-8341. You may also contact Dr. Jennifer Matysczak, Leader, Aquaculture Drugs Team, at 240-276-8338.

Sincerely,

{see appended electronic signature page}
Cindy L. Burnsteel, DVM
Director, Division of Therapeutic
Drugs for Food Animals
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

Enclosure:
Draft Effectiveness section of the FOI Summary

Electronic Signature Addendum for Submission ID

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Signing Authority (Role)	Letter Date
Cindy Burnsteel (Division Director)	6/12/2013

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.