

INAD 8069 P-0048

June 28, 2000

Rodney R. Williams, M.S.
University of Arizona
Department of Veterinary Science
2831 N. Freeway Drive
Tucson, Arizona 85721

Dear Mr. Williams:

We refer to your submission dated May 19, 1999, in which you requested our review of studies conducted to demonstrate the effectiveness of oxytetracycline medicated feed for the control of mortality associated with necrotizing hepatopancreatitis in penaeid shrimp.

We have completed our review and offer the following comments.

GENERAL COMMENTS:

1. We conclude that the pivotal study conducted in 1994 is acceptable and demonstrates the effectiveness of oxytetracycline at concentrations of 1.5 to 4.5 g OTC/kg feed for a duration of 14 days for the control of mortality associated with necrotizing hepatopancreatitis in penaeid shrimp. Accordingly, no additional effectiveness data will be required in support of this indication.
2. We encourage you to prepare and submit a draft freedom of information (FOI) effectiveness section summarizing the 1994 study for use of oxytetracycline medicated feed in shrimp.

SPECIFIC COMMENTS:

1. In the 1998 study, a decision was made to end the trial immediately after the last treatment day rather than collecting data for an additional seven day post-treatment observation period (as stipulated in the protocol that we reviewed and accepted for the study). We have concluded that data from the 1998 and 1994 studies are not poolable due to the lack of the post-treatment observation period in the 1998 study.
2. We have based our effectiveness decision solely on the 1994 study rather than including the 1998 data. Our conclusion to not include the 1998 data is also based primarily on the lack of a post-treatment observation period in the 1998 study.
3. We would like to remind you that your target animal safety package should demonstrate the safety of the high end of your proposed dose range. Your pivotal effectiveness data includes data for 1.5 to 4.5 g OTC/kg feed for a duration of 14 days. Our letter to you dated November 4, 1999, however, stated that CVM had calculated a 2 day withdrawal time for shrimp dosed at a maximum of

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4.0 g oxytetracycline/kg feed for 14 days. Based on the highest dose indicated in the November 4, 1999, letter we suggest that you pursue a dose range of 1.5 to 4.0 g oxytetracycline/kg feed.

Future correspondence regarding this submission to the file for your INAD exemption should be identified by the date of the submission and our file number, INAD 8069 P-0048, and be addressed to the Document Control Unit, HFV-199. Please include only one request per submission, clearly stating the request in the first paragraph of the submission.

If you have any questions or comments regarding this correspondence, please telephone Dr. Joan Gotthardt, Aquaculture Drugs Team at 301-827-7571.

Sincerely yours,

Steven D. Vaughn, D.V.M.
Director, Division of Therapeutic
Drugs for Food Animals
Office of New Animal Drug Evaluation
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