



I-006013-P-0117-EF

The NRSP-7  
Attention: Meg Oeller, D.V.M.  
FDA Liaison to the NRSP-7  
7500 Standish Place, HFV-50  
Rockville, MD 20855

Re: Effectiveness technical section complete

Dear Dr. Oeller:

Based upon the information you submitted on October 31, 2011, and amended on March 19, 2012 (T-0119) and the information contained in INAD 006013 and PMF 005165, we consider the Effectiveness technical section to be complete. The technical section is complete for the use of AQUAMYCIN 100 (erythromycin thiocyanate) Type A medicated article at a dose of 100 mg erythromycin thiocyanate/kg body weight/day for 28 consecutive days for the control of mortality due to bacterial kidney disease associated with *Renibacterium salmoninarum* in freshwater-reared Chinook salmon.

FREEDOM OF INFORMATION (FOI) SUMMARY

A copy of the draft Effectiveness section of the FOI Summary is enclosed. Please review the FOI Summary for accuracy and notify us if you find errors.

LABELING

Please note the acceptable indication is "For the control of mortality due to bacterial kidney disease associated with *Renibacterium salmoninarum* in freshwater-reared Chinook salmon." Currently the designated indication is "For the control of mortality in freshwater-reared salmonids due to bacterial kidney disease associated with *Renibacterium salmoninarum*." All of the effectiveness and target animal safety studies were conducted with Chinook salmon and the published literature indicates potential safety concerns in freshwater-reared rainbow trout at the proposed dose. We recommend that Bimeda, Inc. change the designated indication to match the indication in the first sentence of this paragraph.

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, 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 me at 240-276-8341. You may also contact 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 Section of FOI Summary: Effectiveness

**Electronic Signature  
Addendum for Submission ID**

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Signing Authority (Role)	Letter Date
Cindy Burnsteel (Division Director)	4/30/2012

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