Special Session Announcement

for the

Efficacy Study Challenges: a Round Table Discussion with CVM's Aquaculture and Biometrics Team

Monday, 28 July 2008; 9:00 am to 12:30 pm
Bozeman Fish Technology Center; Bozeman, Montana

The purpose of this round table session is to provide a forum for the discussion of two (and more if time permits) topics of concern to aquaculture drug researchers. The first topic for discussion centers on designing and conducting field trials to evaluate the effectiveness of aquaculture drugs to control ectoparasite infestations. The second planned topic is the difficulty of posttreatment assessment in efficacy field trials when a population of fish experiences a reinfestation/reinfection of the target pathogen. The two planned topics challenging researchers are outlined below in somewhat more detail.

Ectoparasite studies: Research to be conducted to evaluate the effectiveness of aquaculture drugs to control ectoparasite infestations will more than likely be designed to compare relative parasite numbers in treated versus control fish populations (rather than comparing treated versus control mortality). Researchers working to design such studies have been confronted with the problems of how to sample for and enumerate parasites, and how to analyze the generated data. Guidance will be sought in an attempt to maximize the probability of conducting acceptable studies.

Reinfection/reinfestation: Typically, a 14-day posttreatment period is associated with field efficacy trials conducted to demonstrate the effectiveness of waterborne oxidizing agents (e.g., chloramine-T, hydrogen peroxide, potassium permanganate). In some cases, treatment efficacy is demonstrated immediately after treatment (i.e., mortality in treated tanks decreases), but environmental and culture conditions are such that a reinfection/reinfestation of the target pathogen may occur as reflected by an increase in mortality in the previously treated tanks. Does the observation of no significant difference in mean cumulative mortality between treated and control populations (at the end of the posttreatment observation period) mean that the treatment was not effective? Again, guidance from CVM is needed as to when the answer is "yes" and when it's "no.," and what the criteria for drawing such a conclusion.

The round table session is intended to provide an opportunity for researchers and regulators to address, and hopefully resolve, the above-mentioned challenges. Optimistically, if resolutions are reached, the results will be standardized approaches applicable to these and possibly related issues.

If these topics are of interest to you, please plan to attend this session on July 28th from 9:00 am to 12:30 pm at the Bozeman Fish Technology Center. If you have questions about this session, please contact Jim Bowker at 406-994-9910 or **jim_bowker@fws.gov**.

For more detailed information on location and juxtaposition of the meeting to the Aquaculture Drug Approval Coordination Workshop, **click here** or visit the Workshop webpage at:

http://www.fws.gov/fisheries/aadap/inadworkshop08.htm