



United States Department of the Interior



U.S. FISH & WILDLIFE SERVICE
AQUATIC ANIMAL DRUG APPROVAL PARTNERSHIP PROGRAM
4050 BRIDGER CANYON ROAD
BOZEMAN, MT 59715
PHONE 406-994-9905/FAX 406-582-0242

February 9, 2007

Dr. Joan Gotthardt
Director, Division of Therapeutic Drugs
for Food Animals
Document Control Unit, HFV-199
Center for Veterinary Medicine
7500 Standish Place, MPN-2
Rockville, MD 20855

Dear Dr. Gotthardt:

The purpose of this submission is to request that the U. S. Food and Drug Administration's Center for Veterinary Medicine Aquaculture Team review the attached information that details the similarity between *Oncorhynchus* subspecies rainbow and steelhead trout. We believe that this information supports our contention that effectiveness technical sections completed for either freshwater-reared rainbow trout or steelhead trout should satisfy the requirement for all freshwater-reared *O. mykiss*.

In a letter from CVM to Dr. Dave Erdahl, dated December 31, 2003 (INAD 009006 G 0103), you provided to us a revised FOI Summary. The FOI Summary addressed, in part, the following effectiveness technical section claim: For the use of oxytetracycline-medicated feed administered at 3.75 g/100 pounds of fish/day for 10 consecutive days for the control of mortality due to columnaris caused by *Flavobacterium columnare* in freshwater-reared steelhead trout. We contend that the attached information supports our premise that the claim be expanded to the following: For the use of oxytetracycline-medicated feed administered at 3.75 g/100 pounds of fish/day for 10 consecutive days for the control of mortality due to columnaris caused by *Flavobacterium columnare* in freshwater-reared *Oncorhynchus mykiss*.



Please note that we also request that this letter be filed in the U. S. Fish and Wildlife Service Investigational New Animal Drug file #9006. We refer to your file number INAD 9006 G-0103, dated December 31, 2003.

The current sponsor of INAD #9006 is Dr. David Erdahl, Branch Chief, U.S. Fish and Wildlife Service, AADAP Program, 4050 Bridger Canyon Road, Bozeman, MT 59715. We would like to thank you in advance for your time and consideration with respect to the above-described request. If you have questions, please contact Dr. David Erdahl, AADAP Program, Bozeman, MT at (406) 994-9904.

Sincerely,

Dr. David Erdahl
Branch Chief, AADAP Program
Enclosures:

1. Three copies of a document entitled: Justification to consider studies that demonstrate drug efficacy on freshwater-reared steelhead trout or rainbow trout be sufficient to satisfy the effectiveness requirements for all freshwater-reared *Oncorhynchus mykiss*.
2. One copy of the cited literature (in cases where books were cited, a copy of the cover, the citation page, and all pertinent pages)

