



United States Department of the Interior
FISH AND WILDLIFE SERVICE



AQUATIC ANIMAL DRUG APPROVAL PARTNERSHIP PROGRAM
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18 July 2006

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:

Please consider the enclosed document as a formal submission to the U.S. Fish & Wildlife Service's Investigational New Animal Drug (INAD) file #9332.

The purpose of this submission is to request a formal review of the enclosed document entitled: "*Safety Assessment of the Microbiological Effects on Bacteria of Human Concern for Oxytetracycline Type A Medicated Feed (INAD 9332).*" The document specifically addresses Section IV of CVM's Guidance Document #152 (i.e., Hazard Characterization) as it relates to a forthcoming proposed amendment to NADA 038-439. Hence, we also request (and permit) that the enclosed document be considered for inclusion (via reference) as a sub-component of Human Food Safety Technical Section for the soon to be submitted proposed amendment to NADA 038-439.

As noted above, the document specifically addresses Section IV of Guidance Document #152 (i.e., Hazard Characterization) vis-à-vis a forthcoming request by the drug's sponsor (Phibro Animal Health) to amend NADA 038-439. The current label claims for NADA 038-439 provide for a Type A Medicated article containing oxytetracycline (OTC) for "...the control of ulcer disease caused by *Hemophilus piscium*, furunculosis caused by *Aeromonas salmonicida*, bacterial hemorrhagic septicemia caused by *Aeromonas liquefaciens* and pseudomonas disease [in Pacific salmon]." The current label also includes claims for control of disease in channel catfish, but the aforementioned proposed amendment would not amend the catfish claims. The proposed amendment will include new claims for: (1) control of coldwater disease, in all freshwater reared salmonids, caused by *Flavobacterium psychrophilum*; and (2) control of systemic columnaris disease, in steelhead trout *Oncorhynchus mykiss*, caused by *Flavobacterium columnare*. The former component of the amended claims (i.e., coldwater disease) would inherently negate the "...Do not use when water temperature is below 48.2°F (9°C)..." statement on the current approved label.

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The current sponsor of INAD #9332 is Dr. David Erdahl, U.S. Fish and Wildlife Service, Branch Chief - 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. Erdahl at (406) 994-9904.

Sincerely,



Dr. David Erdahl
Branch Chief - AADAP Program

enclosure: Three copies of the document entitled: "*Safety Assessment of the Microbiological Effects on Bacteria of Human Concern for Oxytetracycline Type A Medicated Feed (INAD 9332).*"