

NEWS RELEASE: MAJOR AQUACULTURE DRUG APPROVAL FOR TERRAMYCIN® 200 FOR FISH

(http://www.fda.gov/cvm/CVM_Updates/FDAantimicro071008.htm)

GREAT NEWS!!! OXYTETRACYCLINE DIHYDRATE (TERRAMYCIN® 200 FOR FISH) WAS APPROVED IN THE UNITED STATES FOR CONTROL OF MORTALITY IN (1) ALL FRESHWATER-REARED SALMONIDS DUE TO COLDWATER DISEASE ASSOCIATED *FLAVOBACTERIUM PSYCHROPHILUM* AND (2) *ONCORHYNCHUS MYKISS* DUE TO COLUMNARIS DISEASE ASSOCIATED WITH *FLAVOBACTERIUM COLUMNARE*. THE LIMITATION ON TREATING SALMONIDS IN WATER TEMPERATURES BELOW 9°C WAS REMOVED. (SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION #038-439, JULY 6, 2008)

The sponsor, Phibro Animal Health (=PAH, Ridgefield Park, New Jersey; <http://www.phibroah.com>), is to be congratulated for this success and for investing in this approval. This is a very important approval because it is:

- **The first new label claims approved for Terramycin® 200 for Fish for finfish in almost four decades**
- **The first antimicrobial approved for controlling mortality due to columnaris disease in any aquatic species**
- **The second antimicrobial approved for controlling mortality due to coldwater disease in freshwater-reared salmonids**
- **The first label claim for Terramycin® 200 for Fish to gain designation under the Minor Use and Minor Species Animal Health Act which entitles PAH to seven years of exclusivity for marketing rights**

This approval will greatly benefit the commercial salmonid industry and public production of any salmonid reared in fresh water. Coldwater and columnaris organisms are serious pathogens that cause significant losses of hatchery-reared salmonids, including losses at state and federal hatcheries producing fish for native salmonid restoration programs.

The approval of Terramycin® 200 for Fish for controlling mortality due to coldwater disease in all freshwater-reared salmonids and columnaris disease in all *Oncorhynchus mykiss* and for use below 9°C is the result of a cooperative effort among the sponsor, **Phibro Animal Health** (=PAH), federal researchers, and the National Coordinator for Aquaculture New Animal Drug Applications. **Aquatic Animal Drug Approval Partnership Program** (=AADAP, U.S. Fish and Wildlife Service, Bozeman, Montana) (1) developed a document to evaluate the microbiological effects on bacteria of human health concern and (2) conducted and coordinated the pivotal and supportive efficacy studies. The U.S. Fish and Wildlife Service's **Coleman National Fish Hatchery (NFH), Quilcene NFH, Olympia Fish Health Center,** and **California/Nevada Fish Health Laboratory** aided AADAP in conducting the effectiveness studies. The **Upper Midwest Environmental Sciences Center** (=UMESC, U.S. Geological Survey, La Crosse, Wisconsin) (1) supported the effectiveness studies by providing feed analyses, (2) developed the environmental assessment based in part on its effluent survey on use in continuous-flow systems, (3) developed the robust analytical methods to detect oxytetracycline in fish tissue, (5) conducted the bridging studies between the official microbial inhibition assay and the HPLC method, and (6) conducted the marker residue depletion studies in salmonids below 9°C. AADAP and UMESC developed the data with financial support through base funds and the Federal-State Aquaculture Drug Approval Partnership Project that was under the auspices of the **Association of Fish and Wildlife Agencies**. The **National Coordinator for Aquaculture New Animal Drug Applications** provided (1) coordination of the approval-oriented activities with all involved partners including the Center for Veterinary Medicine, (2) provided input to PAH's document that assessed the effect of residues in the human intestinal flora, (3) helped PAH in developing its labeling, All Other Information, and Administrative NADA submission, and (4) helped PAH gain MUMS designation for the newly approved label claims.

News Release prepared July 10, 2008 by Rosalie (Roz) Schnick
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