



News Release

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AQUAFLOR® (florfenicol) Approved for Controlling Mortality

Due to Furunculosis in Freshwater-Reared Salmonids

Efficacy studies show that AQUAFLOR is highly effective

KENILWORTH, N.J., Nov. 6, 2007 — AQUAFLOR® (florfenicol), the fast-acting in-feed antibiotic developed by Schering-Plough Animal Health Corporation, has been approved by the U.S. Food and Drug Administration (FDA) for control of mortality in freshwater-reared salmonids due to furunculosis associated with *Aeromonas salmonicida*.

“AQUAFLOR has been shown in clinical field trials to be highly effective for the treatment of furunculosis, which is a serious disease concern in salmonid species. Furunculosis outbreaks often times result in substantial losses,” says Dr. David Erdahl, Fisheries Biologist and Branch Chief of the U.S. Fish and Wildlife Service’s (USFWS) Aquatic Animal Drug Approval Partnership Program in Bozeman, Montana.

“This is the first new oral antibiotic available for the treatment of furunculosis in 20 years, and represents an important new management tool for fisheries programs throughout the country,” says Erdahl.

USFWS conducted the efficacy studies demonstrating the effectiveness of AQUAFLOR to control mortality due to furunculosis. AQUAFLOR administered in feed to either fingerling Coho salmon or fingerling Chinook salmon with naturally occurring furunculosis significantly reduced mortality compared to untreated controls. For instance, in a study with Fall Chinook Salmon fingerlings, mortality in fish treated with AQUAFLOR was reduced by over 80 percent. No adverse reactions to treatment were reported in any of the studies.

Outbreaks of furunculosis associated with *Aeromonas salmonicida*, a Gram-negative bacterium, can cause rapid onset of high mortality. Sub-acute or chronic forms of the disease lead to lower mortality and the formation of external “boil like lesions” or furuncles.

According to the FDA, losses due to furunculosis associated with *Aeromonas salmonicida* are significant in hatchery-reared salmonids, including those at state and federal hatcheries producing fish for native species restoration programs.

The agency said it reviewed “extensive data” on the antibiotic’s effectiveness against furunculosis and its safety for treated fish and the environment. FDA also said it found that freshwater-reared salmonids fed AQUAFLOR are safe for human consumption when the product is administered according to label directions.

AQUAFLOR has been shown to be effective for several other diseases in aquaculture, such as coldwater disease (associated with *Flavobacterium psychrophilum*) in freshwater-reared salmonids and enteric septicemia in catfish (ESC) associated with *Edwardsiella ictaluri*. Earlier this year, its sister product, AQUAFLOR®-CA1 (florfenicol), received a conditional approval for the control of mortality in catfish due to columnaris disease associated with *Flavobacterium columnare*.

Studies show AQUAFLOR does not lead to reductions in feed consumption or growth. AQUAFLOR also has a short, 15-day withdrawal period in freshwater-reared salmonids.

AQUAFLOR is the first in-feed antibiotic in aquaculture and the second for all food-animal species to be classified by the FDA as a Veterinary Feed Directive (VFD) drug. VFD is a category established in 1996 to help the agency more closely control new therapeutic products, primarily antimicrobials, and their use in food animals. The VFD classification applies only to new in-feed therapeutics approved by FDA after 2000. Aquaculturists may obtain VFD drugs through normal feed distribution channels, but they will be required to obtain a signed Veterinary Feed Directive from a licensed veterinarian.

For more information on AQUAFLOR, producers should contact their extension specialist, veterinarian, diagnostician or feed company representative. Information also may be obtained at www.AQUAFLOR-USA.com or by calling Schering-Plough Animal Health 1-800-521-5767.

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About Schering-Plough Corporation

Schering-Plough Animal Health Corporation is the global animal health business of Schering-Plough Corporation (NYSE: SGP) of Kenilworth, N.J. Schering-Plough is a global science-based health care company with leading prescription, consumer and animal health products. Through internal research and collaborations with partners, Schering-Plough discovers, develops, manufactures and markets advanced drug therapies to meet important medical needs. Schering-Plough's vision is to earn the trust of the physicians, patients and customers served by its more than 33,500 people around the world. The company is based in Kenilworth, N.J., and its Web site is www.schering-plough.com.

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AQUAFLOR is a registered trademark of Schering-Plough Animal Health Corporation.

CAUTION: Federal law limits this drug to use under the professional supervision of a licensed veterinarian. Animal feed bearing or containing this veterinary feed directive drug shall be fed to animals only by or upon a lawful Veterinary Feed Directive (VFD) issued by a licensed veterinarian in the course of the veterinarian's professional practice.