

For Release: IMMEDIATELY

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(908) 298-7436**FDA Approves AQUAFLOR[®] (florfenicol) for Catfish*****First In-Feed Antibiotic for U.S. Aquaculture in More Than 20 Years******Provides New Weapon Against Mounting Disease Losses***

KENILWORTH, N.J., October 28, 2005 — AQUAFLOR[®] (florfenicol), the first new in-feed antibiotic for U.S. aquaculture in more than 20 years, has been licensed by the U.S. Food and Drug Administration for control of catfish mortality due to enteric septicemia (ESC) associated with *Edwardsiella ictaluri*.

The product's developer, Schering-Plough Animal Health Corporation, said it would begin shipping the premix product to feed mills immediately.

"This is a real breakthrough for our industry," said Hugh Warren, president of the Catfish Farmers of America. "Having a safe, new-generation antibiotic available gives catfish farmers a new tool for improving profitability while delivering a safe, wholesome product to today's health-conscious consumers."

Broad-spectrum antibiotic

AQUAFLOR is a highly palatable, fast-acting antibiotic proven worldwide to be effective against a wide range of bacteria in several aquatic species. It also has an excellent safety profile for fish, human food and the environment.

Unlike sulfa drugs and tetracyclines, the unique antibiotic was developed specifically for use in food animal species. Studies show that AQUAFLOR can be used in catfish, from fingerling to food fish, with no setbacks in feed consumption or growth. AQUAFLOR has a short 12-day withdrawal period, which leaves farmers ample marketing flexibility.

“We gave priority to securing a claim for ESC in catfish because of high death losses associated with the disease — more than \$13 million a year¹, according to a USDA estimate,” says Dr. Robert Simmons, Vice President, Pharmaceutical Research for Schering-Plough Animal Health. “With early diagnosis and proactive management, we think AQUAFLOR will raise the bar for several industry standards, including fish survival, stocking rates and profitability.”

Schering-Plough Animal Health said that it is seeking AQUAFLOR claims for other disease-causing pathogens in catfish and eventually other aquatic species.

Low mortality, high palatability

In tank trials conducted at Mississippi State University, fingerlings challenged with ESC had a cumulative death rate of 0.8 percent, compared to 60 percent for challenged, untreated fish. In the same study, treated fingerlings showed an infection rate of only 1.7 percent, compared to 72.3 percent for untreated controls.

Palatability trials show that fish consume feed medicated with AQUAFLOR at the same rate as unmedicated feed — even when AQUAFLOR was used at 10 times the recommended dose rate.

“Palatability is extremely important because it minimizes waste and ensures optimum feed and antibiotic intake during the critical treatment period,” Simmons says. “It also helps fish stay on feed in the face of a severe disease challenge.”

AQUAFLOR has been shown to be a highly stable product, both as a packaged premix and following high-temperature extrusion at feed mills. It can be used in a floating feed at any stage of production, from fingerlings to food fish. Schering-Plough Animal Health recommends using feed medicated with AQUAFLOR as the sole ration for 10 consecutive days. Treatments should be discontinued 12 days before marketing. AQUAFLOR is not approved for use in breeding stock.

‘Safe and highly effective’

Dr. Pat Gaunt, associate professor, aquatic animal health, Mississippi State University College of Veterinary Medicine, has worked extensively with AQUAFLOR and is enthusiastic about the product’s approval.

“AQUAFLOR has proved to be safe and highly effective, with good palatability, so we have high hopes for it in the catfish industry,” she says.

¹ USDA.2003.Part 1: Reference of Fingerling Catfish Health and Production Practices in the United States, 2003 USDA:APHIS:VS CEAH, National Animal Health Monitoring System, Fort Collins, CO #N406.1103.

“Producers have to realize that it’s not a silver bullet, however. As with any therapy, AQUAFLOR must be combined with diagnostics and good management, which in this case means testing early and using the product according to label directions. You can’t take shortcuts and still expect a full return on your antibiotic investment.”

While Schering-Plough Animal Health has made a significant investment to bring the product to the U.S. catfish industry, Simmons noted that work by Mississippi State University’s Thad Cochran National Warmwater Aquaculture Center in Stoneville, Miss., the Aquatic Animal Drug Approval Partnership Program (AADAP) and the U.S. Geological Survey also assisted in obtaining FDA approval for this therapeutic needed in aquaculture and fisheries-management programs.

VFD ensures correct usage

AQUAFLOR Type A Medicated Article is the first in-feed antibiotic in aquaculture and second for all food-animal species to be classified by FDA as a Veterinary Feed Directive (VFD) drug. VFD is a new category established in 1999 to help the agency more closely control new therapeutic products, primarily antimicrobials, and their use in food animals.

“The VFD allows us to continue adding new drugs to our health tool box,” explains Richard Sellers, American Feed Industry Association. He says the system is designed to reduce the potential for antibiotic resistance and prolong effectiveness of new antimicrobials through judicious use.

The VFD classification applies only to new therapeutics approved by FDA after 1999 and administered in feed. Catfish producers may obtain VFD drugs through normal feed distribution channels, but they will require a signed Veterinary Feed Directive from a licensed veterinarian.

While AQUAFLOR is new to U.S. catfish farmers, it has been used successfully for nearly 15 years in other major aquaculture markets in Japan, Europe and Latin America to treat diseases in other farm-raised aquatic species.

NUFLOR[®] (florfenicol), a sister product to AQUAFLOR, has been used successfully in the United States since 1996 to treat respiratory disease in beef and non-lactating dairy cattle.

For more information on AQUAFLOR, catfish farmers should contact their veterinarian, diagnostician, feed mill or Schering-Plough Animal Health at 1-800-521-5767. Internet: www.AQUAFLOR-USA.com.

Schering-Plough Animal Health Corporation is the worldwide 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, veterinarians, patients and customers served by its more than 30,000 people around the world.

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