



News Release

Schering-Plough Corporation
2000 Galloping Hill Road
Kenilworth, New Jersey 07033-0530

For Release: IMMEDIATELY

Media Contacts: Julie Lux
Schering-Plough Corporation
908.298.4774
908.216.0370 (cell)
Julie.Lux@spcorp.com

Joseph Feeks
PR Works
(508) 627-6949
(508) 274-6497 (cell)
JFeeks@prworks.net

New AQUAFLOR®-CA1 Conditionally Approved By FDA for Controlling Columnaris in Catfish

*First and only catfish antibiotic approved for
highly prevalent and costly bacterial disease*

KENILWORTH, N.J., April 18, 2007 — Schering-Plough Animal Health Corporation has introduced AQUAFLOR®-CA1 (florfenicol), the first and only in-feed antibiotic conditionally approved for the control of mortality in catfish due to columnaris disease associated with *Flavobacterium columnare*.

The U.S. Food and Drug Administration granted a conditional approval — the first of its kind for any food-animal therapeutic — to AQUAFLOR-CA1, a Type A medicated article, pending full demonstration of effectiveness.

The expedited approval process was done in compliance with the Minor Use and Minor Species (MUMS) Animal Health Act of 2004, which was passed by Congress to increase the availability of new therapeutics for farmed fish and other minor species.

Same ingredients, different label

In terms of active ingredient and formulation, AQUAFLOR-CA1 is the exact same product as AQUAFLOR® (florfenicol), a broad-spectrum antibiotic that FDA approved in October 2005 for the control for control of catfish mortality due to enteric septicemia (ESC) associated with *Edwardsiella ictaluri*. However, because AQUAFLOR-CA1 is a conditionally licensed product, FDA requires the product to be packaged separately with its own name and indications.

“The conditional approval of AQUAFLOR-CA1 gives the catfish industry a new and desperately needed antibiotic for managing columnaris,” says Richard Endris, Ph.D., Aquaculture Research Program Manager for Schering-Plough Animal Health. “We have columnaris efficacy studies under way and the claim will be added to the indication for AQUAFLOR after we have satisfied FDA’s efficacy criteria.”

Like AQUAFLOR, AQUAFLOR-CA1 is a Veterinary Feed Directive (VFD) drug, meaning that users must receive a signed VFD order from a licensed veterinarian before obtaining the drug through normal feed-distribution channels. VFD is a category established by FDA in 1996 to help the agency more closely control new therapeutic products, primarily antimicrobials, and their use in food animals.

Columnaris, ESC highly prevalent

Columnaris is a leading bacterial disease of catfish and can cause significant losses in performance. The presence of brown to yellowish-brown growth of bacteria on the mouth, gills, skin or fins usually indicates an infection, but fish specialists recommend getting a positive diagnosis before beginning treatment.

In 2006, columnaris “singly accounted” for 13.7 percent of catfish disease diagnostic cases submitted, according to a report issued recently by the Aquatic Diagnostic Laboratory (ADL), Thad Cochran National Warmwater Aquaculture Center, Mississippi State University, Stoneville.

However, the report notes that the prevalence of columnaris was significantly higher — 68.4 percent in 2006 vs. 49.4 percent in 2005 — when the pathogen was presented in combination with other pathogens such as ESC. Likewise, the causative pathogen for ESC was seen alone in 10.7 percent of the cases. However, in combination with other agents, the ESC bacterium was seen in 56.5 percent of the cases compared to 31.3 percent in 2005.

Overall, the total number of diagnostic cases submitted to ADL in 2006 rose 39 percent. “The surge in cases is attributable in part to the introduction of the new antibiotic, florfenicol [AQUAFLOR], which...can only be dispensed by a Veterinary Feed Directive order from a licensed veterinarian,” the report noted. “Therefore, producers are encouraged to submit fish immediately if they suspect disease is occurring in a pond and they intend to use *any* medicated feed.”

Fish stay on feed

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. A recent analysis using an enterprise model developed by Mississippi State University showed that providing feed medicated with AQUAFLOR during a disease outbreak provided greater receipts and net returns compared to the use of non-medicated feed or not feeding at all.

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

He notes that in a December 2006 survey, U.S. catfish farmers reported 100 percent satisfaction with AQUAFLOR treatment.

AQUAFLOR has been shown to be a highly stable product, both as a packaged premix and following high-temperature extrusion at feed mills. AQUAFLOR or AQUAFLOR-CA1 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 or AQUAFLOR-CA1 as the sole ration for 10 consecutive days. Treatments should be discontinued 12 days before marketing. AQUAFLOR and AQUAFLOR-CA1 are not approved for use in breeding stock.

For more information on AQUAFLOR and AQUAFLOR-CA1, 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.

-end-

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, 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.

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.