



Pat Gaunt with part of the data on new catfish antibiotic.

New Catfish Antibiotic Awaits FDA Approval

By Keryn Page

A new antibiotic has the potential to treat one of the most costly diseases in Mississippi's \$287 million catfish industry.

Pat Gaunt, a veterinary toxicologist with Mississippi State University's College of Veterinary Medicine, began studying the use of florfenicol to treat enteric septicemia, or ESC, in U.S. catfish more than five years ago. That process is nearing an end as the Food and Drug Administration considers final approval of the drug.

"The stack of data generated by our group was over 4 feet tall. This was submitted to the FDA, along with many more volumes from Schering-Plough Animal Health, the pharmaceutical company we worked with on this research," Gaunt said. "The data package generated by MSU-CVM was accepted in 89 days, which is a very quick turnaround for FDA."

Now that the data has been accepted, it is going through the final approval process. Gaunt's research included three of the five major areas required for FDA approval: finding the correct drug dosage, testing the tolerance or palatability of the drug to catfish, and performing a residue depletion study that determines when antibiotic levels are low enough in catfish filets for safe human consumption.

Schering-Plough delegated the remaining studies required for FDA approval to other institutions. Gaunt said the company has submitted its studies on chemistry and manufacturing of the antibiotic, and the approval is pending.

"Schering-Plough also had to submit an environmental package showing that florfenicol would not harm the environment. That part also has been approved," Gaunt said.

The idea for using florfenicol in U.S. catfish came to Gaunt when she began an internship at the Thad Cochran National Warmwater Aquaculture Center in Stoneville.

"I knew florfenicol was approved for use in beef cattle in the United States and in other countries for different types of fish," Gaunt said. "Because it was effective in other species, I thought it could be applicable to catfish usage."

Gaunt sought out Schering-Plough's cooperation on pursuing the antibiotic's use in U.S. channel catfish. An initial, relatively simple in-vitro study proved Gaunt's suspicion: the ESC bacteria were very sensitive to florfenicol.

The subsequent years of research led Gaunt to believe this antibiotic will have a positive impact on the Mississippi catfish industry.

"We only have two other antibiotics for treating ESC in channel catfish currently on the market. Palatability problems have been reported with one, and the other is most often formulated as a sinking feed—it sinks to the bottom of the pond, and producers can't tell if the fish are eating it or not," Gaunt said. "Our studies show that this new antibiotic is very palatable to the catfish, and it is in a floating feed. It is also very effective against ESC."

Extension catfish/aquaculture specialist Jimmy Avery said no one knows how farmers will incorporate this new antibiotic into their disease management plans because the cost of the drug is unknown. Despite the price uncertainty, Avery remains optimistic about the impact florfenicol could have on Mississippi catfish producers.

"It certainly will give us another tool to use in fighting bacterial diseases," Avery said. "Bacterial diseases cause about 50 percent of our fish mortality each year, and ESC is one of the larger components of that fish mortality."

The Catfish Journal recently reported that when the drug does receive final FDA approval, its use will require a veterinary feed directive order. Documentation by both the issuing veterinarian and the catfish producer will be required. The veterinarian must visually inspect one or more of the affected fish and keep copies of the necessary paperwork for a minimum of two years.

Gaunt's studies determined the correct dosage to help control ESC in channel catfish is 10 milligrams per kilogram of body weight for 10 days. The withdrawal period is 12 days, as determined by an FDA formula.

ESC is sometimes referred to as "hole in the head" because in the chronic form, it erodes the frontal bone of a fish. In the more acute form, it can cause rapid mortalities in a pond, in some cases killing up to 50 percent of a pond's fish in days. In the chronic form, it can occur over weeks, causing a loss of money because of slow weight gain.