PHOTO BY KATIE RECHTERMANN, NJAA/*ANGUS JOURNAL* PHOTOGRAPHY CONTEST

# Pain-control Drug Approved

## Extra-label use of treatment for pain mitigation no longer required for specific situations.

*by **Troy Smith**, field editor*

Recently, the U.S. Food and Drug Administration (FDA) announced the approval of a pain medication for use in cattle. Manufactured by Intervet/Merck Animal Health, Banamine Transdermal (flunixin transdermal solution) is the first drug approved in the United States for controlling pain in food-producing animals.

Now, a good many cattle producers may be familiar with Banamine or other trade names under which flunixin is produced. Such products have been available in the United States for use by or on the order of a licensed veterinarian for the treatment of cattle. FDA-approved uses for flunixin injectable solution, administered intravenously (IV), include control of pyrexia (fever) associated with bovine respiratory disease (BRD), endotoxemia and bovine mastitis.

What's new is that Banamine Transdermal is approved for controlling pain — specifically the pain associated with footrot — as well as for controlling pyrexia associated with BRD. Previously, there were no approved drugs in the United States for relieving the pain of footrot or any other food animal ailment.

Also new is the method of administration. Banamine Transdermal is applied topically and absorbed through the skin, similar to pour-on formulations for controlling parasites. A single dose, consisting of 3.3 mg of flunixin per kilogram of body weight, is applied to the animal's back, in a narrow strip from withers to tail head.

Hans Coetzee calls the availability of Banamine Transdermal "a highly significant development." A veterinarian, professor and head of the Anatomy and Physiology Department at Kansas State University, Coetzee has focused much of his research in the areas of animal pain recognition and drugs to alleviate pain in livestock.

"Previously, every time a drug was used to relieve pain (in food animals) it constituted extra-label use of the product," says Coetzee. "That puts the burden of any consequence on the veterinarian. If any violative residues are found in an animal at slaughter, the veterinarian assumed responsibility."

According to Coetzee, extra-label drug use — any use other than what is specified on the label — is allowed under the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA). Deviations from FDA-approved labeling might include use in another species, use for a different indication, use at a different dose or frequency, and a different route of administration.

AMDUCA does not give veterinarians unlimited discretion, however. Certain guidelines must be followed. A veterinarian must make careful diagnosis and be certain that no approved drug is available or that an available approved drug has been ineffective at the label-required dosage for treatment. A veterinarian also must maintain the identity of a treated animal and establish an extended period of withdrawal from the drug prior to slaughter.

Given the relatively few drugs available to veterinarians, AMDUCA does give veterinarians a measure of professional flexibility they may need to treat animals threatened by disease, injury and suffering. Still, in Coetzee's opinion, relying on AMDUCA could never be a long-term solution to relieving pain in livestock, because of the risk that extra-label drug use may result in a tissue residue.

### It works

"With this approval, we now have a drug specifically labeled for alleviating pain associated with footrot in cattle," says Coetzee, whose research team has been involved with studies of flunixin in a topical formulation.

"In our experience, it worked very well," he adds. "It's easy to apply to the animal's back — much easier than administering a drug through a vein. As a result, there is less stress for the animal and for the producer."

Coetzee says the painkilling effect of flunixin typically becomes evident within an hour of topical administration — sometimes within 30 minutes — and peaks in four to five hours. The duration of relief is from 24 to 36 hours.

At present, Banamine Transdermal's approved use is limited to those listed on the label. Administration for pain stemming from any other malady would be extra-label use, but Coetzee views the drug's current label as an important step. He believes ongoing research will soon result in the addition of more approved pain relief applications. He also expects approval, within the next two to three years, for other drugs labeled specifically for use in controlling pain associated with practices such as castration and dehorning.

Coetzee believes that, from an animal welfare perspective, the proactive pursuit of efficacious and practical pain remedies is essential. Society expects the pain and discomfort associated with livestock disease and production practices to be addressed. Coetzee is confident that, in time, it will be demonstrated how improved animal performance and reduced disease will result from effective pain mitigation. His research group has been involved in several studies whose results suggest these benefits.

"I see this (approval of Banamine Transdermal) as a conversation starter for producers and their veterinarians," states Coetzee. "I hope producers will decide that it's time to talk with their veterinarians about how this kind of drug can have a role in their operations."

**Editor's Note:** *Troy Smith is a freelance writer and cattleman from Sargent, Neb.*