September 20, 2018

Animal Drug Safety Communication: FDA Alerts Pet Owners and Veterinarians About Potential for Neurologic Adverse Events

The U.S. Food and Drug Administration is alerting pet owners and veterinarians to be aware of the potential for neurologic adverse events in dogs and cats when treated with drugs that are in the isoxazoline class.

Since these products have obtained their respective FDA approvals, data received by the agency as part of its routine post-marketing activities indicates that some animals receiving Bravecto, Nexgard or Simparica have experienced adverse events such as muscle tremors, ataxia, and seizures. Another product in this class, Credelio, recently received FDA approval. These products are approved for the treatment and prevention of flea infestations, and the treatment and control of tick infestations.

The FDA is working with manufacturers of isoxazoline products to include new label information to highlight neurologic events because these events were seen consistently across the isoxazoline class of products.

The FDA carefully reviewed studies and other data on Bravecto, Credelio, Nexgard and Simparica prior to approval, and these products continue to be safe and effective for the majority of

animals. The agency is asking the manufacturers to make the changes to the product labeling in order to provide veterinarians and pet owners with the information they need to make treatment decisions for each pet on an individual basis. Veterinarians should use their specialized training to review their patients' medical histories and determine, in consultation with pet owners, whether a product in the isoxazoline class is appropriate for the pet.

Although FDA scientists carefully evaluate an animal drug prior to approval, there is the potential for new information to emerge after marketing, when the product is used in a much larger population. In the first three years after approval, the FDA pays particularly close attention to adverse event reports, looking for any safety information that may emerge.

The FDA monitors adverse drug event reports received from the public or veterinarians, other publicly available information (such a peer-reviewed scientific articles), and mandatory reports from the animal drug sponsor (the company that owns the right to market the drug). Drug sponsors must report serious, unexpected adverse events within 15 days of the event. In addition, they must submit any events that are non-serious, plus any laboratory studies, in vitro studies, and clinical trials that have not been previously submitted to the agency, on a bi-annual basis for the first two years following product approval and annually thereafter.

The FDA continues to monitor adverse drug event reports for these products and encourages pet owners and veterinarians to report adverse drug events. You can do this by reporting to the drugs' manufacturers, who are required to report this information to the FDA, or by submitting a report directly to the FDA.

To report suspected adverse drug events for these products and/or obtain a copy of the Safety Data Sheet (SDS) or for technical assistance, contact the appropriate manufacturers at the following phone numbers:

Merck Animal Health (Bravecto): 800-224-5318
Elanco Animal Health (Credelio): 888-545-5973
Merial (Nexgard): 888-637-4251
Zoetis (Simparica): 888-963-8471

If you prefer to report directly to the FDA, or want additional information about adverse drug experience reporting for animal drugs, see How to Report Animal Drug Side Effects and Product Problems.

Additional Information

Fact Sheet for Pet Owners and Veterinarians about Potential Adverse Events Associated with Isoxazoline Flea and Tick Products

Contact FDA

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