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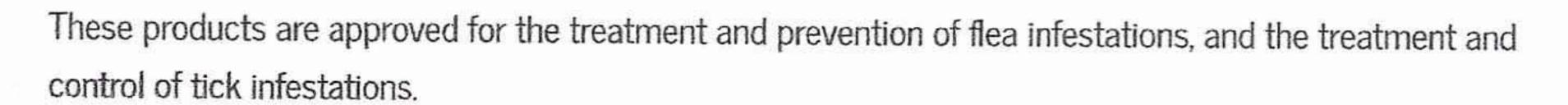
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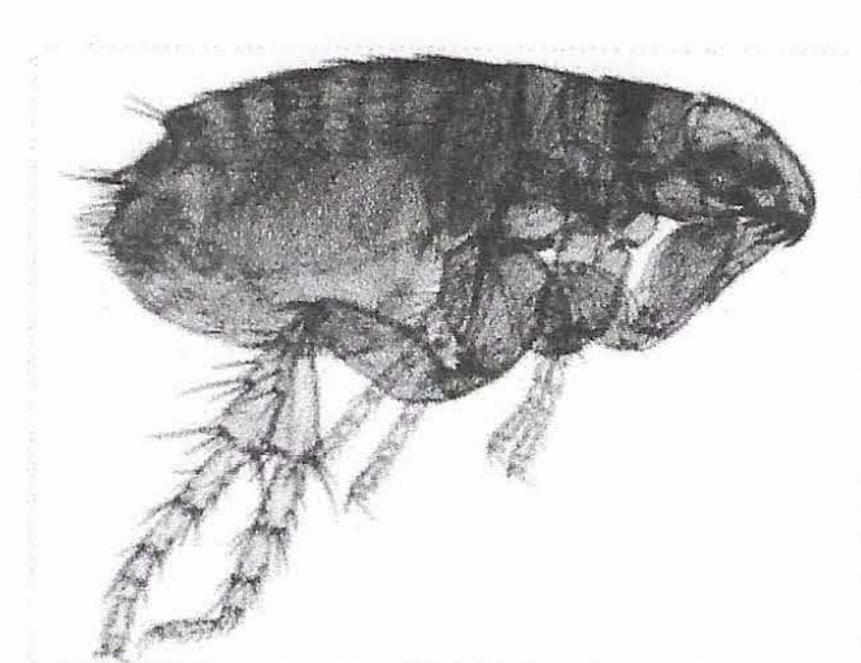
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FDA issues alert for isoxazoline class of flea, tick products Potential exists for neurologic adverse events in dogs and cats when treated with isoxazoline class produ September 21, 2018

The U.S. Food and Drug Administration is alerting veterinarians and pet owners of the potential for neurologic adverse events in dogs and cats when treated with isoxazoline class flea and tick products, including Bravecto, Nexgard, and Simparica.

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, said the FDA in a statement. Credelio, another isoxazoline class product, recently received FDA approval.





The FDA said it is working with manufacturers of isoxazoline products to include new label information to highlight neurologic events, as they were seen consistently across the iso class of products.

These products continue to be safe and effective for the majority of animals, said the FDA, adding that it carefully reviewed studies and other data on Bravecto, Credelio, Nexgard, a Simparica prior to approval.

The agency is asking the manufacturers to change product labeling in order to provide veterinarians and pet owners with the information they need to make treatment decisions fo on an individual basis.

The FDA said it will continue to monitor adverse drug event reports for these products and encourages pet owners and veterinarians to report such events.

Reports can be made 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 or for technical assistance, contact the appropriate manufacturers at the 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

To report directly to the FDA or seek additional information about adverse drug experience reporting for animal drugs, see How to Report Animal Drug Side Effects and Product Pro

Bravecto FDA flea and tick isoxazoline class NexGard Simparica

87

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