Fort Dodge Animal Health
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Dear Doctor:

This letter is to provide another update of our field experiences with ProHeart® 6 (moxidectin) as we pass the two year anniversary of its launch, and some label additions being made to reflect some of these experiences, as noted below. We trust that this information will be useful and encourage you to call our Professional Services department if you have any additional questions after reviewing this material.

There are two additions to the ProHeart 6 label that have either been made, or are in the process of being made. The first was the label change regarding use of ProHeart 6 in heartworm positive dogs. Briefly, the changes were made in response to a low number of heartworm-positive dogs that experienced coughing or cardiopulmonary signs after receiving ProHeart 6. The pre-approval clinical studies did not identify any such reactions prior to release, and many heartworm positive dogs have received ProHeart 6 without side effects. However, based on reports received on a low number of heartworm positive dogs, Fort Dodge, in conjunction with the Center for Veterinary Medicine, made the following changes:

Under the heading "Post Approval Experience," the following statement was added:

"Cardiopulmonary signs such as coughing and dyspnea may occur in heartworm-positive dogs treated with ProHeart 6."

Additional labeling changes made under the "Precautions" section of the package insert and printed cartons in conjunction with this statement included:

1. Removal of the statement "At the discretion of the veterinarian" before the sentence "Infected dogs should be treated to remove adult heartworms."

2. The following statement was deleted "No adverse reactions were observed in dogs with patent heartworm infections when ProHeart 6 was administered at three times the labeled dose. Higher doses were not tested." (A similar statement was already present in the Animal Safety section, and this statement was left unchanged.)

The second label change is the recent decision to add a statement regarding the rare occurrence of death in a low number of dogs treated with ProHeart 6. Death has been reported in approximately 0.0025 percent of the doses sold into veterinary clinics. Some of the reports are associated with severe allergic events, while others appear to be multifactorial in nature. Some are linked to factors not associated with product use. We continue to investigate all reports as fully as possible. If and when further information becomes available that has clinical implications on product use, we will advise the veterinary community accordingly.

With regard to the label change, the following new statement, “and rare reports of death” has been added to the “Post-Approval Experience” section under the heading “ADVERSE REACTIONS”. The full section “Post Approval Experience” section now reads:

Post-Approval Experience: Although not all adverse events are reported, the following reactions are based on voluntary post-approval drug experience reporting: anaphylaxis/toid reactions, depression/lethargy, urticaria, head/facial edema, and rare reports of death. Anaphylactic and anaphylactoid reactions should be treated immediately with the same measures used to treat hypersensitivity reactions to vaccines and other injectable products. Cardiopulmonary signs such as coughing and dyspnea may occur in heartworm-positive dogs treated with ProHeart 6.

This revised “Post-Approval Experience” statement will replace the current wording, which appears in the ProHeart 6 package insert and on all approved ProHeart 6 printed outer boxes.

In order to help educate your clients on both the benefits and potential side effects associated with ProHeart® 6 (moxidectin), Fort Dodge Animal Health has prepared a client information sheet which contains questions and answers about use of the product, and includes the product insert on the reverse side. An example copy is attached for your reference. Additional quantities will be available to you through your Fort Dodge representative and the sheet will soon be posted on our websites for both veterinarians and clients to download and print.

Thank you for your attention to this important information. We feel it is essential to provide you with timely updates on the use of this product. Millions of doses of ProHeart 6 continue to be used safely, and we trust that this reflects your on-going experience, as well. We continue our monitoring activities and will provide any pertinent updates on ProHeart 6 as they become available. Please feel free to contact one of our Professional Services veterinarians at the number listed above if you have additional questions or concerns regarding any of this information.

Sincerely,

Stephen A. Connell, DVM
Vice President,
Professional and Technical Services