Kimberly Birch Brackemyre, PhD
Principle Consultant, Regulatory, Advertising and Promotion
Elanco Animal Health
2500 Innovation Way
Greenfield, Indiana 46140

RE: NADA 141-455
GALLIPRANT® (grapiprant tablets)

Dear Dr. Brackemyre:

The U.S. Food and Drug Administration (FDA), Center for Veterinary Medicine (CVM), Division of Surveillance has reviewed the websites for GALLIPRANT (grapiprant tablets), https://www.aratana.com/therapeutics/osteoarthritis-pain/ and https://www.galliprantfordogs.com/vet as of April 2018. These websites are misleading because they omit material facts and make false or misleading representations about the risks associated with GALLIPRANT.

These websites therefore misbrand GALLIPRANT within the meaning of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. 352(a), 352(n); 321(n)]. The introduction or delivery for introduction into interstate commerce of this misbranded drug violates section 331(a) of the FD&C Act [21 U.S.C. 331(a)].

Background

According to the FDA-approved product labeling, GALLIPRANT is indicated for the control of pain and inflammation associated with osteoarthritis in dogs. The product insert (PI) for GALLIPRANT contains a precautions statement regarding use in dogs younger than 9 months of age and less than 8 lbs (2.6 kg), dogs used for breeding, or in pregnant or lactating dogs. The precautions section also notes that adverse reactions were observed in dogs receiving GALLIPRANT including vomiting, diarrhea, decreased appetite, mucoid, watery or bloody stools, and decreases in serum albumin and total protein.

Promotional materials misbrand a drug if they are false or misleading with respect to risk. The determination of whether promotional materials are misleading includes, among other things, not only representations made or suggested in promotional materials, but also failure to reveal facts material in light of the representations made or with respect to consequences that may result from the use of the drug as recommended or suggested in the materials.

Omission of Material Facts

The above-referenced websites fail to disclose that GALLIPRANT is a non-steroidal anti-inflammatory drug (NSAID). For example, the Aratana.com website bears the statement "Galliprant is a first-in-class piprant; a non-COX-inhibiting prostaglandin receptor antagonist (PRA)." The Galliprant website bears the same statement. This statement is misleading because, according to the FDA-approved product information, GALLIPRANT is a non-cyclooxygenase (COX) inhibiting, non-steroidal anti-inflammatory drug (NSAID) in the piprant class. NSAIDS as a class are known to be associated with particular risks in dogs. These risks include clinical signs associated with gastrointestinal toxicity such as vomiting, diarrhea, decreased appetite, and decreasing albumin and total protein.[1] These same risks have been identified in association with GALLIPRANT treatment in dogs, and these findings are included on the FDA-approved labels for the product.

By omitting the term NSAID from the description, Elanco falsely represents that GALLIPRANT is not an NSAID.

False or Misleading Risk Presentation

The Galliprant website cited above presents the statement "Proven safe in a 9-month safety study at up to approximately 15X the recommended therapeutic dose in healthy dogs." The statement appears in a bullet under the section heading "TREAT WITH GALLIPRANT FROM THE EARLIEST DIAGNOSED STAGES OF CANINE OA." In the context of a promotional presentation these statements suggest that administration of GALLIPRANT is "safe" at up to 15X the approved dose. This presentation is misleading because the study cited was designed to investigate the potential toxicity of grapiprant when administered orally, once daily for nine consecutive months. The target animal safety study was conducted using a small number (eight) of healthy young beagles under controlled laboratory conditions. This study does not prove the safety of GALLIPRANT when administered at greater than the approved 1X dose in the general population of dogs that vary in breed, age, diet, and in other ways.

Therefore, this claim is misleading because it suggests that GALLIPRANT is safer than has been demonstrated by substantial evidence or substantial clinical experience, and that the product is safe to administer at doses greater than have been demonstrated to be safe for use in the general population. (see 21 C.F.R. 202.1(e)(6)(i)) Canine patients may be injured by being given an unapproved overdose.

Conclusion and Requested Action

For the reasons discussed above, the websites misbrand GALLIPRANT within the meaning of the FD&C Act [21 U.S.C. 352(a), 352(n); 321(n)]. The introduction or

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[1] We note that the https://www.aratana.com website contains a similar discussion of risks under "Important Safety Information," but does not expressly state that GALLIPRANT is an NSAID.

delivery for introduction into interstate commerce of this misbranded drug violates section 331(a) of the FD&C Act [21 U.S.C. 331(a)].

CVM requests that Elanco Animal Health immediately cease the dissemination of misleading information on the websites described above, and any other materials that fail to disclose the fact that GALLIPRANT is an NSAID, or that suggest that GALLIPRANT is safe at 15X the approved dose.

The violations discussed in this letter do not necessarily constitute an exhaustive list. It is your responsibility to ensure that the promotional materials for GALLIPRANT, as well as other Elanco Animal Health products, comply with the requirements of the FD&C Act and applicable FDA regulations.

Please submit a written response to this letter on or before June 1, 2018, listing all promotional materials (with the Form FDA 2301 submission date) for GALLIPRANT that contain statements such as those described above, and explaining your plan for discontinuing use of such materials, or, in the alternative, for ceasing distribution of GALLIPRANT. If you cannot complete corrective action within 30 calendar days, state the reason for the delay and the time within which you will complete the correction. Please direct your response to Dr. Neal Bataller at the Food and Drug Administration, Center for Veterinary Medicine, Division of Surveillance, HFV-216, 7519 Standish Place, Rockville, Maryland 20855.

If you have any questions, please contact Dr. Dorothy McAdams at the address above, or by phone at (240) 402-5763.

Sincerely,

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Neal Bataller, ME, DVM
Director, Division of Surveillance
Office of Surveillance & Compliance
Center for Veterinary Medicine