Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in June 2019

Supplemental Approvals

This section displays the change(s) to the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

(A)NADA Number: 200-510

This supplement provided for label changes to comply with GFI 213.

Post Approval Experience Labeling Changes

NADA Number: 141-426

The following changes were made to the package insert:

- The Warnings section was revised to include: Keep Bravecto in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.
- The Precautions section was revised to include: Fluralaner is a member of the isoxazoline class. This class has been associated with neurologic adverse reactions including tremors, ataxia, and seizures. Seizures have been reported in dogs receiving isoxazoline class drugs, even in dogs without a history of seizures. Use with caution in dogs with a history of seizures or neurologic disorders.
- A Post-Approval Experience section was added:
  Post Approval Experience (2019):
  The following adverse events are based on post-approval adverse drug experience reporting. Not all adverse events are reported to FDA/CVM. It not always possible to reliably estimate the adverse event frequency or establish a causal relationship to product exposure using these data.
  The following adverse events reported for dogs are listed in decreasing order of reporting frequency for fluralaner:
  Vomiting, lethargy, diarrhea (with and without blood), anorexia, pruritis, polydipsia, seizure, allergic reactions (including hives, swelling, erythema), dermatitis (including crusts, pustules, rash), tremors and ataxia.

NADA Number: 141-262

The Post-Approval Experience section under ADVERSE REACTIONS of the package insert was revised as follows:

Post-Approval Experience (Revised May 2019)
The following adverse events are based on post-approval adverse drug experience reporting. Not all adverse events are reported to FDA CVM. It is not always possible to reliably estimate the adverse event frequency or establish a causal relationship to product exposure using these data.
The following adverse events reported for dogs are listed in decreasing order of frequency:
anorexia, depression/lethargy, hypersalivation, vomiting, diarrhea, trembling, ataxia, allergic reactions, weight loss, convulsion, hyperactivity, and panting.

Cases of ineffectiveness have been reported.

Cases of death (including euthanasia) have been reported.

To report suspected adverse events, for technical assistance or to obtain a copy of the SDS, contact Zoetis Inc. at 1-888-963-8471 or www.zoetis.com.

For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at http://www.fda.gov/AnimalVeterinary/SafetyHealth.

Sponsor Name Change

Previous Name: Linde, LLC

New Name: Messer, LLC

Previous Name: Linde Gas Puerto Rico Inc.

New Name: Messer Gas Puerto Rico, Inc.

Previous Name: Linde Merchant Production LLC

New Name: Messer Merchant Production LLC

Previous Name: Linde Canada Ltd

New Name: Messer Canada Inc.

Suitability Petitions

Number: 2019-P-1566

Petitioner: Noble Pharma, LLC
Date Filed: April 2, 2019
Action: Denied
Action Date: June 25, 2019
Description: The petitioner requests to file an ANADA for a generic ivermectin and pyrantel (as pamoate salt) chewable for use in dogs that differs from the reference listed new animal drug (RLNAD), Heartgard® Plus (ivermectin/pyrantel) Chewables, sponsored by Boehringer Ingelheim Animal Health USA Inc. under NADA 140-971. The proposed change is in dosage form from an extruded, unscored, and meat-based chewable tablet (RLNAD) to an extruded, scored, and flavored soft chewable (proposed generic product).