

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were published in the Federal Register in August 2012.

Original Approvals

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

NADA Number: 141-326

Trade Name: Rilexine® Chewable Tablets
Ingredients: Cephalexin
Sponsor: Virbac AH, Inc.
Approval Date: June 16, 2012
Status: Rx
Route: Oral
Species: Dogs
Drug Form: Chewable Tablets
Concentration: Four tablet sizes containing 75 mg, 150 mg, 300 mg, or 600 mg of cephalexin.
Indications: For the treatment of secondary superficial bacterial pyoderma in dogs caused by susceptible strains of *Staphylococcus pseudintermedius*.
Exclusivity: 5 years

21 CFR 520.376 77 FR 47511-47512

NADA Number: 141-337

Trade Name: Recuvyra™
Ingredients: Fentanyl
Sponsor: Nexcyon Pharmaceuticals, Inc.
Approval Date: June 23, 2012
Status: Rx
Route: Topical
Species: Dogs
Drug Form: Transdermal Solution
Concentration: 50 mg/mL
Indications: For the control of postoperative pain associated with surgical procedures in dogs.
Exclusivity: 5 years

21 CFR 524.916 77 FR 47511-47512

NADA Number: 141-338

Trade Name: Interceptor® Spectrum®
Ingredients: Milbemycin oxime/praziquantel
Sponsor: Novartis Animal Health US, Inc.
Approval Date: June 16, 2012
Status: Rx
Route: Oral
Species: Dogs
Drug Form: Chewable Tablets
Concentration: Each chewable tablet contains:
2.3 mg milbemycin oxime/22.8 mg praziquantel
5.75 mg milbemycin oxime/57 mg praziquantel
11.5 mg milbemycin oxime/114 mg praziquantel
23 mg milbemycin oxime/228 mg praziquantel
Indications: For the prevention of heartworm disease caused by *Dirofilaria immitis* and for the treatment and control of adult roundworm (*Toxocara canis*, *Toxascaris leonina*), adult hookworm (*Ancylostoma caninum*), adult whipworm (*Trichuris vulpis*), and adult tapeworm (*Taenia pisiformis*, *Echinococcus multilocularis*, and

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Echinococcus granulosus) infections in dogs and puppies two pounds of body weight or greater and six weeks of age and older.

Exclusivity: 5 years

21 CFR 520.1445 77 FR 47511-47512

Sponsor Change

NADA Numbers: 115-732, 141-298

Previous: Janssen Pharmaceutica NV

New Sponsor: Elanco Animal Health, a Division of Eli Lilly & Co.

Drug Labeler Code: 000986

21 CFR 522.150, 21 CFR 524.1445 77 FR 46612-46613

Sponsor Address Change

Veterinary Service, Inc.

Previous: 416 North Jefferson St., P.O. Box 2467, Modesto, CA 95354

New: 4100 Bangs Ave., Modesto, CA 95356

21 CFR 510.600(c) 77 FR 46612-46613