

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in January 2024.

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.

ANADA Number: 200-766

Trade Name: EquiCoxib™
Pioneer: Equioxx®
Ingredients: Firocoxib
Sponsor: Aurora Pharmaceutical, Inc.
Approval Date: January 11, 2024
Status: Rx
Route: Oral
Species: Horses
Drug Form: Oral solution
Concentration: 9.0 mg/mL
Indications: For the control of pain and inflammation associated with osteoarthritis in horses.

ANADA Number: 200-767

Trade Name: Carprofen Tablets
Pioneer: RIMADYL®
Ingredients: Carprofen
Sponsor: Felix Pharmaceuticals Pvt. Ltd.
Approval Date: January 12, 2024
Status: Rx
Route: Oral
Species: Dogs
Drug Form: Flavored tablet
Concentration: 25 mg, 75 mg, or 100 mg of carprofen per tablet
Indications: For the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries in dogs.

ANADA Number: 200-768

Trade Name: Ravantage® 9 and Ravantage® 45
Pioneer: Paylean™ 9 and Paylean™ 45
Ingredients: Ractopamine hydrochloride
Sponsor: Huvepharma EOOD
Approval Date: January 12, 2024
Status: OTC
Route: Oral, in feed
Species: Finishing swine
Drug Form: Type A medicated article to be used in the manufacture of Type B and Type C medicated feeds
Concentration: 9 g/lb and 45.4 g/lb
Indications: For increased rate of weight gain, improved feed efficiency and increased carcass leanness in finishing swine, weighing not less than 150 lbs, fed a complete ration containing at least 16% crude protein for the last 45 to 90 lbs of gain prior to slaughter.

ANADA Number: 200-769

Trade Name: Selamectin
Pioneer: revolution®
Ingredients: Selamectin
Sponsor: ZyVet Animal Health, Inc.
Approval Date: January 30, 2024

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The following corrections or additions to the list were completed in January 2024.

Status: Rx
Route: Topical
Species: Dogs and cats
Drug Form: Topical solution
Concentration: 60 mg/mL and 120 mg/mL
Indications: Selamectin is recommended for use in dogs six weeks of age or older and cats eight weeks of age and older for the following parasites and indications:
Dogs: Kills adult fleas and prevents flea eggs from hatching for one month and is indicated for the prevention and control of flea infestations (*Ctenocephalides felis*), prevention of heartworm disease caused by *Dirofilaria immitis*, and the treatment and control of ear mite (*Otodectes cynotis*) infestations. It is also indicated for the treatment and control of sarcoptic mange (*Sarcoptes scabiei*) and for the control of tick infestations due to *Dermacentor variabilis*.
Cats: Kills adult fleas and prevents flea eggs from hatching for one month and is indicated for the prevention and control of flea infestations (*Ctenocephalides felis*), prevention of heartworm disease caused by *Dirofilaria immitis*, and the treatment and control of ear mite (*Otodectes cynotis*) infestations. It is also indicated for the treatment and control of roundworm (*Toxocara cati*) and intestinal hookworm (*Ancylostoma tubaeforme*) infections in cats.

Patent Additions

NADA Number: 141-533

Patent number: 11819549
Expiration Date: December 30, 2034