

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in January 2023.

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: 200-732

Trade Name: Carprofen Tablets
Pioneer: RIMADYL®
Ingredients: Carprofen
Sponsor: Felix Pharmaceuticals Pvt. Ltd.
Approval Date: January 5, 2023
Status: Rx
Route: Oral
Species: Dogs
Drug Form: Caplet
Concentration: 25 mg, 75 mg, or 100 mg of carprofen per caplet
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: 200-738

Trade Name: DectoGard™
Pioneer: DECTOMAX®
Ingredients: Doramectin
Sponsor: Aurora Pharmaceutical, Inc.
Approval Date: January 11, 2023
Status: OTC
Route: Topical
Species: Cattle
Drug Form: Topical solution
Concentration: 5 mg/mL
Indications: For the treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, biting and sucking lice, horn flies, and mange mites in cattle

ANADA Number: 200-611

Trade Name: DetomiSed™
Pioneer: DORMOSEDAN®
Ingredients: Detomidine hydrochloride
Sponsor: Akorn Operating Company LLC
Approval Date: January 11, 2023
Status: Rx
Route: For Sedation: Intravenous and intramuscular injection
For Analgesia: Intravenous injection
For Both Sedation and Analgesia: Intravenous injection
Species: Horses
Drug Form: Injectable solution
Concentration: 10 mg/mL
Indications: For use as a sedative and analgesic to facilitate minor surgical and diagnostic procedures in mature horses and yearlings.

ANADA Number: 200-734

Trade Name: Praziquantel Tablets
Pioneer: Droncit™ 34 canine cestocide
Ingredients: Praziquantel
Sponsor: Felix Pharmaceuticals Pvt. Ltd.
Approval Date: January 12, 2023
Status: Rx

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The following corrections or additions to the list were completed in January 2023.

Route: Oral
Species: Dogs
Drug Form: Chewable tablets
Concentration: 34 mg per tablet
Indications: For the removal of the following canine cestodes: *Dipylidium caninum*, *Taenia pisiformis*, *Echinococcus granulosus* and for the removal and control of *Echinococcus multilocularis*.

ANADA Number: 200-733

Trade Name: Marbofloxacin Chewable Tablets
Pioneer: Zeniquin®
Ingredients: Marbofloxacin
Sponsor: Felix Pharmaceuticals Pvt. Ltd.
Approval Date: January 12, 2023
Status: Rx
Route: Oral
Species: Dogs and cats
Drug Form: Chewable tablet
Concentration: 25 mg, 50 mg, 100 mg, or 200 mg marbofloxacin per tablet
Indications: For the treatment of infections in dogs and cats associated with bacteria susceptible to marbofloxacin.

ANADA Number: 200-735

Trade Name: Dexmedetomidine Hydrochloride
Pioneer: DEXDOMITOR®
Ingredients: Dexmedetomidine hydrochloride
Sponsor: ZYVET AH, Inc.
Approval Date: January 13, 2023
Status: Rx
Route: Dogs: Intramuscular and Intravenous
Cats: Intramuscular
Species: Dogs and cats
Drug Form: Injectable solution
Concentration: 0.5 mg/mL
Indications: For use as a sedative and analgesic in dogs and cats to facilitate clinical examinations, clinical procedures, minor surgical procedures, and minor dental procedures. It is also indicated for use as a preanesthetic to general anesthesia in dogs and cats.

ANADA Number: 200-736

Trade Name: Marbofloxacin
Pioneer: Zeniquin®
Ingredients: Marbofloxacin
Sponsor: ZYVET AH, Inc.
Approval Date: January 13, 2023
Status: Rx
Route: Oral
Species: Dogs and cats
Drug Form: Tablet
Concentration: 25 mg, 50 mg, 100 mg, or 200 mg marbofloxacin per tablet
Indications: For the treatment of infections in dogs and cats associated with bacteria susceptible to marbofloxacin.

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.

NADA Number: 141-426

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The following corrections or additions to the list were completed in January 2023.

Trade Name: BRAVECTO®
Ingredients: Fluralaner
Sponsor: Intervet, Inc.
Approval Date: January 12, 2023

This supplement provides for the addition of the indication for the treatment and control of *Haemaphysalis longicornis* (Asian longhorned tick) infestations for 12 weeks in dogs and puppies 6 months of age and older, and weighing 4.4 pounds or greater.

ANADA Number: 200-721

Trade Name: Midamox™ for Cats
Ingredients: Imidacloprid and moxidectin
Sponsor: Norbrook Laboratories Ltd.
Approval Date: January 12, 2023

This supplement provides for the addition of the following indications for ferrets: For the prevention of heartworm disease in ferrets caused by *Dirofilaria immitis*. Kills adult fleas (*Ctenocephalides felis*) and is indicated for the treatment of flea infestations on ferrets.

Patent Revision

NADA Number: 141-566

Patent number: 10982942
Patent revision: 10981942

Suitability Petitions

Number: 2023-P-0075

Petitioner: Mizner Bioscience, LLC
Date Filed: January 5, 2023
Description: The petitioner requests to file an ANADA for a generic methimazole oral solution for use in cats that differs from the reference listed new animal drug (RLNAD), Felimazole® Coated Tablets (methimazole tablets), sponsored by Dechra, Ltd. under NADA 141-292. The proposed change is for an oral solution (2.5 mg/mL and 5 mg/mL strengths); the RLNAD is approved as unscored, coated tablets in 2.5 mg and 5 mg tablet strengths.

Number: 2023-P-0092

Petitioner: Felix Pharmaceuticals Pvt. Ltd.
Date Filed: January 9, 2023
Description: The petitioner requests to file an ANADA for a generic pimobendan oral solution for use in dogs that differs from the reference listed new animal drug (RLNAD), Vetmedin® (pimobendan) Chewable Tablets, sponsored by Boehringer Ingelheim Animal Health USA, Inc. under NADA 141-273. The proposed change is for an oral solution (2.5 mg/mL strength); the RLNAD is approved as scored, chewable tablets in 1.25 mg, 2.5 mg, 5 mg, and 10 mg tablet strengths.

Number: 2023-P-0101

Petitioner: Mizner Bioscience, LLC
Date Filed: January 9, 2023
Description: The petitioner requests to file an ANADA for a generic cyclosporine oral solution for use in dogs that differs from the reference listed new animal drug (RLNAD), Atopica™ (cyclosporine capsules) USP MODIFIED, sponsored by Elanco US Inc. under NADA 141-218. The proposed change is for an unencapsulated oral solution (100 mg/mL; 10% w/w cyclosporine); the RLNAD is approved as gelatin capsules in 10 mg, 25 mg, 50 mg, and 100 mg capsule strengths.

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in January 2023.

Number: 2022-P-2795

Petitioner: Aurora Pharmaceutical, Inc.
Date Filed: November 4, 2022
Action: Approved
Action Date: January 27, 2023
Description: The petitioner requests to file an ANADA for a generic meloxicam oral solution for use in dogs that differs from the reference listed new animal drug (RLNAD), Metacam® (meloxicam oral suspension), sponsored by Boehringer Ingelheim Animal Health USA, Inc. under NADA 141-213. The proposed change is for an oral solution (0.5 mg/mL and 1.5 mg/mL strengths); the RLNAD is approved as an oral suspension (0.5 mg/mL and 1.5 mg/mL strengths).