

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in May 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: 200-780

Trade Name: CoccidAid® for Calves
Pioneer: CORID®
Ingredients: Amprolium
Sponsor: Aurora Pharmaceutical, Inc.
Approval Date: May 8, 2024
Status: OTC
Route: Oral
Species: Beef and dairy calves
Drug Form: Oral solution
Concentration: 96 mg/mL (9.6%)
Indications: An aid in the treatment and prevention of coccidiosis caused by *Eimeria bovis* and *E. zurnii* in calves.

ANADA Number: 200-781

Trade Name: Flunine™
Pioneer: Banamine®
Ingredients: Flunixin meglumine
Sponsor: Cronus Pharma Specialities India Private Ltd
Approval Date: May 16, 2024
Status: Rx
Route: Horse: Intravenous or intramuscular injection
Cattle: Intravenous injection
Species: Horses, beef cattle, and dairy cattle (excluding dry dairy cows)
Drug Form: Injectable solution
Concentration: 50 mg/mL
Indications: **Horse:** For the alleviation of inflammation and pain associated with musculoskeletal disorders in the horse. It is also recommended for the alleviation of visceral pain associated with colic in the horse.
Cattle: For the control of pyrexia associated with bovine respiratory disease, endotoxemia and acute bovine mastitis. It is also indicated for the control of inflammation in endotoxemia.

ANADA Number: 200-782

Trade Name: EnroPro™ Silver Otic
Pioneer: Baytril® Otic
Ingredients: Enrofloxacin/silver sulfadiazine
Sponsor: Cronus Pharma Specialities India Private Ltd
Approval Date: May 9, 2024
Status: Rx
Route: Otic
Species: Dogs
Drug Form: Otic emulsion
Concentration: Each milliliter contains enrofloxacin 5 mg (0.5% w/v), silver sulfadiazine (SSD) 10 mg (1.0% w/v)
Indications: As a treatment for canine otitis externa complicated by bacterial and fungal organisms susceptible to enrofloxacin and/or silver sulfadiazine.

Application Number: 141-577

Trade Name: UpCard®-CA1
Ingredients: Torsemide
Sponsor: Vetoquinol USA, Inc.

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

Approval Date: May 10, 2024
Status: Rx
Route: Oral
Species: Dogs
Drug Form: Oral Solution
Concentration: 2 mg/mL
Indications: For use with concurrent therapy with pimobendan, spironolactone, and an angiotensin converting enzyme (ACE) inhibitor for the management of pulmonary edema in dogs with congestive heart failure caused by myxomatous mitral valve disease (MMVD).
Patent: Patent Number 11337921 Expiration date: February 15, 2039

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: 131-675

Trade Name: Safe-Guard®
Ingredients: Fenbendazole
Sponsor: Intervet Inc.
Approval Date: May 23, 2024

This supplement provides for the addition of wild quail with the indication for the treatment and control of *Aulonocephalus* spp. in wild quail.

Patent Additions

NADA Number: 141-555

Patent number: 8133899
Expiration Date: April 9, 2030

Patent number: 8987283
Expiration Date: June 30, 2031

Patent number: 9522151
Expiration Date: July 18, 2033

Withdrawal of Approval

NADA Number: 141-015

Sponsor: Boehringer Ingelheim Animal Health USA, Inc.
Trade Name: Enacard® Tablets for Dogs
Ingredients: Enalapril maleate

This product is withdrawn because the product is no longer manufactured or marketed.

NADA Number: 141-096

Sponsor: Boehringer Ingelheim Animal Health USA, Inc.
Trade Name: Dicural® Tablets
Ingredients: Difloxacin hydrochloride

This product is withdrawn because the product is no longer manufactured or marketed.

NADA Number: 141-108

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

Sponsor: Boehringer Ingelheim Animal Health USA, Inc.
Trade Name: EtoGesic® Tablets
Ingredients: Etodolac

This product is withdrawn because the product is no longer manufactured or marketed.

NADA Number: 141-274

Sponsor: Boehringer Ingelheim Animal Health USA, Inc.
Trade Name: Etogesic® Sterile Injectable Solution
Ingredients: Etodolac

This product is withdrawn because the product is no longer manufactured or marketed.

NADA Number: 141-421

Sponsor: Boehringer Ingelheim Animal Health USA, Inc.
Trade Name: Duocare™
Ingredients: Ivermectin and praziquantel

This product is withdrawn because the product is no longer manufactured or marketed.

Suitability Petitions

Number: 2024-P-0889

Petitioner: Aurora Pharmaceutical, Inc.
Date Filed: February 20, 2024
Action: Approved
Action Date: May 2, 2024
Description: The petitioner requests to file an ANADA for a generic afoxolaner oral solution for use in dogs that differs from the reference listed new animal drug (RLNAD), NexGard® (afoxolaner) chewables, sponsored by Boehringer Ingelheim Animal Health USA, Inc. under NADA 141-406. The proposed change is for an oral solution (4.56% w/v); the RLNAD is approved as soft chewables in 11.3 mg, 28.3 mg, 68 mg, and 136 mg strengths.