

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in December 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: 200-760

Trade Name: Florfeniject™
Pioneer: Nuflor®
Ingredients: Florfenicol
Sponsor: Cronus Pharma Specialities India Private Ltd.
Approval Date: December 21, 2023
Status: Rx
Route: Intramuscular or subcutaneous
Species: Beef and non-lactating dairy cattle
Drug Form: Injectable solution
Concentration: 300 mg/mL
Indications: For treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni*, and for the treatment of bovine interdigital phlegmon (foot rot, acute interdigital necrobacillosis, infectious pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*. Also, it is indicated for the control of respiratory disease in cattle at high risk of developing BRD associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni*.

ANADA Number: 200-762

Trade Name: Carofenvet™
Pioneer: RIMADYL®
Ingredients: Carprofen
Sponsor: Cronus Pharma Specialities India Private Ltd.
Approval Date: December 22, 2023
Status: Rx
Route: Subcutaneous injection
Species: Dogs
Drug Form: Injectable solution
Concentration: 50 mg/mL
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: 200-764

Trade Name: EnroPro™ 22.7
Pioneer: Baytril®
Ingredients: Enrofloxacin
Sponsor: Cronus Pharma Specialities India Private Ltd.
Approval Date: December 22, 2023
Status: Rx
Route: Intramuscular injection
Species: Dogs
Drug Form: Injectable solution
Concentration: 22.7 mg/mL (2.27%)
Indications: For the management of diseases in dogs associated with bacteria susceptible to enrofloxacin.

ANADA Number: 200-765

Trade Name: EnroPro™ 100
Pioneer: Baytril® 100
Ingredients: Enrofloxacin

Actions Taken by FDA Center for Veterinary Medicine

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

Sponsor: Cronus Pharma Specialities India Private Ltd.
Approval Date: December 22, 2023
Status: Rx
Route: Intramuscular or subcutaneous injection
Species: Beef cattle, non-lactating dairy cattle, and swine
Drug Form: Injectable solution
Concentration: 100 mg/mL
Indications: **Cattle – Single-Dose Therapy:** For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni* and *Mycoplasma bovis* in beef and non-lactating dairy cattle; and for the control of BRD in beef and non-lactating dairy cattle at high risk of developing BRD associated with *M. haemolytica*, *P. multocida*, *H. somni* and *M. bovis*.
Cattle – Multiple-Day Therapy: For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida* and *Histophilus somni* in beef and non-lactating dairy cattle.
Swine: For the treatment and control of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Haemophilus parasuis*, *Streptococcus suis*, *Bordetella bronchiseptica* and *Mycoplasma hyopneumoniae*. For the control of colibacillosis in groups or pens of weaned pigs where colibacillosis associated with *Escherichia coli* has been diagnosed.

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: 141-502

Trade Name: revolution® PLUS
Ingredients: Selamectin and sarolaner
Sponsor: Zoetis Inc.
Approval Date: December 14, 2023

This supplement provides for the addition of the indication for the treatment and control of tick infestations with *Amblyomma americanum* (lone star tick) for one month in cats and kittens 8 weeks and older, and weighing 2.8 pounds or greater.

Sponsor Change

(A)NADA Number: 200-576

Previous Sponsor: Akorn Operating Co. LLC
New Sponsor: Domes Pharma S.A.
Drug Labeler Code: 086189

Withdrawal of Approval

ANADA Number: 200-190

Sponsor: Med-Pharmex, Inc.
Trade Name: GENTORAL®
Ingredients: Gentamicin sulfate

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

ANADA Number: 200-241

Actions Taken by FDA Center for Veterinary Medicine

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

Sponsor: Med-Pharmex, Inc.
Trade Name: Lincosol Soluble Powder
Ingredients: Lincomycin hydrochloride

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

ANADA Number: 200-245

Sponsor: Med-Pharmex, Inc.
Trade Name: Derma-Vet Cream
Ingredients: Neomycin sulfate, nystatin, thiostrepton, triamcinolone acetonide

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

ANADA Number: 200-275

Sponsor: Med-Pharmex, Inc.
Trade Name: Medalone Cream
Ingredients: Triamcinolone acetonide

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

ANADA Number: 200-289

Sponsor: Med-Pharmex, Inc.
Trade Name: Neosol-Oral
Ingredients: Neomycin sulfate

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

ANADA Number: 200-292

Sponsor: Med-Pharmex, Inc.
Trade Name: Iversol Liquid for Horses
Ingredients: Ivermectin

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

ANADA Number: 200-299

Sponsor: Med-Pharmex, Inc.
Trade Name: Iver-On™
Ingredients: Ivermectin

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

ANADA Number: 200-456

Sponsor: Med-Pharmex, Inc.
Trade Name: Dexamethasone Solution
Ingredients: Dexamethasone

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

Suitability Petitions

Number: 2023-P-5171

Petitioner: Ceva Santé Animale
Date Filed: November 17, 2023

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in December 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 (10 mg/mL strength); the RLNAD is approved as unscored, coated tablets in 2.5 mg and 5 mg tablet strengths.