

Actions Taken by FDA Center for Veterinary Medicine

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

NADA Number: 141-585

Trade Name: Zenrelia™
Ingredients: Ilunocitinib
Sponsor: Elanco US Inc
Approval Date: September 19, 2024
Status: Rx
Route: Oral
Species: Dogs
Drug Form: Tablet
Concentration: 4.8, 6.4, 8.5, or 15 mg of ilunocitinib per tablet
Indications: For the control of pruritus associated with allergic dermatitis and control of atopic dermatitis in dogs at least 12 months of age.
Exclusivity: 5 years
Patent: Patent Number Expiration date:
11548895 April 22, 2040

ANADA Number: 200-795

Trade Name: CARPROFEN Soft Chewable Tablets
Pioneer: RIMADYL®
Ingredients: Carprofen
Sponsor: Felix Pharmaceuticals Pvt. Ltd.
Approval Date: September 5, 2024
Status: Rx
Route: Oral
Species: Dogs
Drug Form: Chewable 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: 200-773

Trade Name: Tulaject™ 100
Pioneer: Draxxin®
Ingredients: Tulathromycin
Sponsor: Cronus Pharma Specialities India Private Ltd.
Approval Date: September 5, 2024
Status: Rx
Route: Subcutaneous injection in cattle and intramuscular injection in swine
Species: Beef cattle, non-lactating dairy cattle, suckling calves, dairy calves, veal calves, and swine
Drug Form: Injectable solution
Concentration: 100 mg of tulathromycin/mL
Indications: **Beef and Non-Lactating Dairy Cattle**
BRD- For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis*; and for the control of respiratory disease in cattle at high risk of developing BRD associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis*.
IBK- For the treatment of infectious bovine keratoconjunctivitis (IBK) associated with *Moraxella bovis*.

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Foot Rot- For the treatment of bovine foot rot (interdigital necrobacillosis) associated with *Fusobacterium necrophorum* and *Porphyromonas leyii*.

Suckling Calves, Dairy Calves, and Veal Calves

BRD- For the treatment of BRD associated with *M. haemolytica*, *P. multocida*, *H. somni*, and *M. bovis*.

Swine- For the treatment of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Bordetella bronchiseptica*, *Haemophilus parasuis*, and *Mycoplasma hyopneumoniae*; and for the control of SRD associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, and *Mycoplasma hyopneumoniae* in groups of pigs where SRD has been diagnosed.

ANADA Number: 200-774

Trade Name: Tulaject™ 25
Pioneer: Draxxin® 25
Ingredients: Tulathromycin
Sponsor: Cronus Pharma Specialities India Private Ltd.
Approval Date: September 10, 2024
Status: Rx
Route: Subcutaneous injection in calves and intramuscular injection in swine
Species: Swine, suckling calves, dairy calves, and veal calves
Drug Form: Injectable solution
Concentration: 25 mg of tulathromycin/mL
Indications: **Swine-** For the treatment of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Bordetella bronchiseptica*, *Haemophilus parasuis*, and *Mycoplasma hyopneumoniae*; and for the control of SRD associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, and *Mycoplasma hyopneumoniae* in groups of pigs where SRD has been diagnosed.
Suckling Calves, Dairy Calves, and Veal Calves
BRD- For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis*.

ANADA Number: 200-776

Trade Name: MGA® and Bovatec® and Deracin™
Pioneer: MGA® and Bovatec® and Aureomycin®
Ingredients: Melengestrol acetate, lasalocid, and chlortetracycline
Sponsor: Pharmgate Inc.
Approval Date: September 23, 2024
Status: VFD
Route: Oral
Species: Growing beef heifers fed in confinement for slaughter and replacement beef and dairy heifers
Drug Form: Type A medicated articles to be used in the manufacture of Type C medicated feeds
Concentration: MGA® 200: 200 mg/lb of melengestrol acetate
MGA® 500: 500 mg/lb of melengestrol acetate
Bovatec® 91: 90.7 g/lb (20%) of lasalocid
Bovatec® 150 FP: 150 g/lb (33.1%) of lasalocid
Bovatec® Liquid 20: 90.7 g/lb (20%) of lasalocid
Deracin™ 50 Meal: 50 g/lb of chlortetracycline
Deracin™ 90 Meal: 90 g/lb of chlortetracycline
Deracin™ 100 Meal: 100 g/lb of chlortetracycline
Indications: 1. For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), for control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*, and for control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline in growing beef heifers fed in confinement for slaughter up to 800 pounds.
2. For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), for control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*, and treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to

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chlortetracycline in growing beef heifers fed in confinement for slaughter up to 800 pounds.

3. For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*, and for control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline in growing beef heifers fed in confinement for slaughter under 700 pounds.

4. For suppression of estrus (heat), increased rate of weight gain, and for control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline in replacement beef heifers on pasture over 700 pounds.

5. For suppression of estrus (heat), increased rate of weight gain, and for treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline in replacement dairy heifers on pasture less than 20 months of age and replacement beef heifers on pasture.

6. For suppression of estrus (heat), increased rate of weight gain, and for control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline in replacement beef heifers on pasture.

7. For suppression of estrus (heat), increased rate of weight gain, and for control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline in replacement beef heifers on pasture under 700 pounds.

8. For suppression of estrus (heat), control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*, and for control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline in replacement beef heifers up to 800 pounds.

9. For suppression of estrus (heat), control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*, and for treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline in replacement dairy heifers up to 800 pounds and less than 20 months of age and replacement beef heifers up to 800 pounds.

Suitability Petitions

Number: 2024-P-4290

Petitioner: Gelteq Ltd
Date Filed: September 6, 2024
Description: The petitioner requests to file an ANADA for a generic praziquantel oral, edible gel that differs from the reference listed new animal drug (RLNAD), Tapeworm Dewormer (praziquantel tablets) for dogs, sponsored by Elanco US Inc. under NADA 111-798. The proposed change is for an oral, edible gel; the RLNAD is approved as a tablet (34 mg strength).