

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in February 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: 141-575

Trade Name: Vetmedin® Solution
Ingredients: Pimobendan
Sponsor: Boehringer Ingelheim Animal Health USA, Inc.
Approval Date: February 13, 2024
Status: Rx
Route: Oral
Species: Dogs
Drug Form: Solution
Concentration: 1.5 mg/mL
Indications: For the management of the signs of mild, moderate, or severe congestive heart failure in dogs due to clinical myxomatous mitral valve disease (MMVD) or dilated cardiomyopathy (DCM); for use with concurrent therapy for congestive heart failure (e.g., furosemide, etc.) as appropriate on a case-by-case basis.
Patent: Patent Number Expiration date:
10071162 September 18, 2034
11185590 July 18, 2034
9463199 April 27, 2029
9889148 March 23, 2025

ANADA Number: 200-749

Trade Name: Kesium®
Pioneer: CLAVAMOX® CHEWABLE
Ingredients: Amoxicillin and clavulanate potassium
Sponsor: Ceva Sante Animale
Approval Date: February 22, 2024
Status: Rx
Route: Oral
Species: Dogs and cats
Drug Form: Chewable tablet
Concentration: 62.5 mg tablets (50 mg of amoxicillin activity and 12.5 mg of clavulanic acid)
125 mg tablets (100 mg of amoxicillin activity and 25 mg of clavulanic acid)
250 mg tablets (200 mg of amoxicillin activity and 50 mg of clavulanic acid)
375 mg tablets (300 mg of amoxicillin activity and 75 mg of clavulanic acid)
Indications: Kesium® Chewable Tablets are indicated in the treatment of:
Dogs: Skin and soft tissue infections such as wounds, abscesses, cellulitis, superficial/juvenile and deep pyoderma due to susceptible strains of the following organisms: β -lactamase-producing *Staphylococcus aureus*, non- β -lactamase-producing *Staphylococcus aureus*, *Staphylococcus spp.*, *Streptococcus spp.*, and *E. coli*.
Periodontal infections due to susceptible strains of both aerobic and anaerobic bacteria. Kesium® has been shown to be clinically effective for treating cases of canine periodontal disease.
Cats: Skin and soft tissue infections such as wounds, abscesses, and cellulitis/dermatitis due to susceptible strains of the following organisms: β -lactamase-producing *Staphylococcus aureus*, non- β -lactamase-producing *Staphylococcus aureus*, *Staphylococcus spp.*, *Streptococcus spp.*, *E. coli*, and *Pasteurella spp.*
Urinary tract infections (cystitis) due to susceptible strains of *E. coli*.

Sponsor Change

(A)NADA Number: 200-338

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Previous Sponsor: Heska Corp.
New Sponsor: Diamond Animal Health, Inc.
Drug Labeler Code: 53701

Patent Additions

NADA Number: 141-521

Patent number: 11896594
Expiration Date: February 22, 2041

NADA Number: 141-342

Patent number: 10188664
Expiration Date: November 27, 2032

NADA Number: 141-508

Patent number: 11864567
Expiration Date: October 10, 2035

NADA Number: 141-512

Patent number: 11864567
Expiration Date: October 10, 2035

NADA Number: 141-514

Patent number: 11864567
Expiration Date: October 10, 2035

NADA Number: 141-568

Patent number: 11896574
Expiration Date: December 17, 2034

Withdrawal of Approval

NADA Number: 030-578

Sponsor: ADM Animal Nutrition, Inc.
Trade Name: E-Z-EX Wormer Pellets
Ingredients: Thiabendazole

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

NADA Number: 042-910

Sponsor: ADM Animal Nutrition, Inc.
Trade Name: E-Z-EX Wormer Mintrate Block
Ingredients: Thiabendazole

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

NADA Number: 118-877

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Sponsor: ADM Animal Nutrition, Inc.
Trade Name: Ban-A-Worm Pyrantel Tartrate Ton Pack
Ingredients: Pyrantel tartrate

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

NADA Number: 132-448

Sponsor: ADM Animal Nutrition, Inc.
Trade Name: Flavomycin®
Ingredients: Bambermycins

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
Action: Approved
Action Date: February 2, 2024
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.

Number: 2024-P-0889

Petitioner: Aurora Pharmaceutical, Inc.
Date Filed: February 20, 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.