

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in January 2022.

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: 141-546

Trade Name: Solensia™
Ingredients: Frunevetmab
Sponsor: Zoetis Inc.
Approval Date: January 13, 2022
Status: Rx
Route: Subcutaneous
Species: Cats
Drug Form: Injectable solution
Concentration: 7 mg/mL
Indications: For the control of pain associated with osteoarthritis in cats.
Patent: Patent Number 9328164 Expiration date: May 8, 2032

NADA Number: 141-547

Trade Name: Zorbium™
Ingredients: Buprenorphine
Sponsor: Elanco US Inc.
Approval Date: January 20, 2022
Status: Rx
Route: Topical
Species: Cats
Drug Form: Transdermal solution
Concentration: 20mg/mL
Indications: For the control of postoperative pain associated with surgical procedures in cats.
Exclusivity: 3 years

ANADA Number: 200-707

Trade Name: Tilmovet® AC
Pioneer: Pulmotil™ AC
Ingredients: Tilmicosin phosphate
Sponsor: Huvepharma EOOD
Approval Date: January 25, 2022
Status: Rx
Route: Oral, in drinking water
Species: Swine
Drug Form: Aqueous concentrate
Concentration: 250 mg/mL
Indications: For the control of swine respiratory disease associated with *Pasteurella multocida* and *Haemophilus parasuis* in groups of swine in buildings where a respiratory disease outbreak is diagnosed.
For the control of swine respiratory disease associated with *Mycoplasma hyopneumoniae* in the presence of Porcine Reproductive and Respiratory Syndrome Virus (PRRSV) in groups of swine in buildings where a respiratory disease outbreak is diagnosed.

ANADA Number: 200-716

Trade Name: Midamox™ for Dogs
Pioneer: Advantage Multi™ for Dogs
Ingredients: Imidacloprid and moxidectin
Sponsor: Norbrook Laboratories, Ltd.

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The following corrections or additions to the list were completed in January 2022.

Approval Date: January 28, 2022
Status: Rx
Route: Topical
Species: Dogs
Drug Form: Topical solution
Concentration: 100 mg/mL (10%) imidacloprid and 25 mg/mL (2.5%) moxidectin
Indications: For the prevention of heartworm disease caused by *Dirofilaria immitis* and the treatment of *Dirofilaria immitis* circulating microfilariae in heartworm-positive dogs; kills adult fleas and is indicated for the treatment of flea infestations (*Ctenocephalides felis*); for the treatment and control of sarcoptic mange caused by *Sarcoptes scabiei* var. *canis*; and for the treatment and control of intestinal roundworms (*Toxocara canis* and *Toxascaris leonina*), hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*), and whipworms (*Trichuris vulpis*).

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: January 10, 2022

This supplement provides for 1) tolerances and tissue withdrawal periods in cattle, swine, and turkeys, and a milk discard time in cattle in accordance with a repartitioning of the acceptable daily intake (ADI); and 2) the addition of fourth stage larval indications for barberpole worms (*Haemonchus contortus* & *H. placei*), small stomach worms (*Trichostrongylus axei*), hookworms (*Bunostomum phlebotomum*), thread-necked intestinal worms (*Nematodirus helvetianus*), small intestinal worms (*Cooperia punctata* & *C. oncophora*), bankrupt worms (*Trichostrongylus colubriformis*), and nodular worms (*Oesophagostomum radiatum*) in cattle.

Sponsor Change

(A)NADA Numbers: 200-129, 200-467

Previous Sponsor: Halocarbon Products Corp.
New Sponsor: Dechra Veterinary Products LLC
Drug Labeler Code: 017033

Sponsor Name Change

Previous Name: Mylan Institutional LLC
New Name: Mylan Institutional LLC, a Viatris Company

Suitability Petitions

Number: 2021-P-1175

Petitioner: Felix Pharmaceuticals Pvt. Ltd.
Date Filed: October 27, 2021
Action: Approved
Action Date: December 30, 2021

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The following corrections or additions to the list were completed in January 2022.

Description: The petitioner requests to file an ANADA for a generic levothyroxine sodium oral solution for use in dogs that differs from the reference listed new animal drug (RLNAD), Thyro-Tabs® Canine (levothyroxine sodium tablets), USP, sponsored by Lloyd, Inc. under NADA 141-448. The proposed change is for an oral solution (200 µg/mL and 400 µg/mL strengths); the RLNAD is approved as scored, color-coded tablets in 0.1 mg, 0.2 mg, 0.3 mg, 0.4 mg, 0.5 mg, 0.6 mg, 0.7 mg, 0.8 mg, and 1.0 mg tablet strengths.

Number: 2021-P-1174

Petitioner: Felix Pharmaceuticals Pvt. Ltd.
Date Filed: October 27, 2021
Action: Approved
Action Date: January 20, 2022
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 (5 mg/mL strength); the RLNAD is approved as unscored, coated tablets in 2.5 mg and 5 mg tablet strengths.

Number: 2021-P-1245

Petitioner: Schafer Veterinary Consultants, LLC
Date Filed: November 19, 2021
Action: Approved
Action Date: January 19, 2022
Description: The petitioner requests to file an ANADA for generic chewable amoxicillin and clavulanate potassium tablets for use in dogs and cats that differ from the reference listed new animal drug (RLNAD), CLAVAMOX® CHEWABLE (amoxicillin and clavulanate potassium tablets), sponsored by Zoetis Inc. under NADA 055-099. The proposed change is the addition of a 500 mg tablet strength for use in dogs only. The RLNAD is approved as chewable tablets in a 62.5 mg tablet strength for use in dogs and cats and in 125 mg, 250 mg, and 375 mg tablet strengths for use in dogs only.