

Actions Taken by FDA Center for Veterinary Medicine

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

Application Number: 141-571

Trade Name: Varenzin™-CA1
Ingredients: Molidustat
Sponsor: Elanco US Inc.
Approval Date: May 1, 2023
Status: Rx
Route: Oral
Species: Cats
Drug Form: Suspension
Concentration: Esafoxolaner –12 mg/mL
Eprinomectin –4 mg/mL
Praziquantel –83 mg/mL
Indications: Conditionally approved for the control of nonregenerative anemia associated with chronic kidney disease (CKD) in cats.
Exclusivity: 3 years
Patent: Patent Number Expiration date:
8389520 December 20, 2029
8653111 October 12, 2027
8987261 November 27, 2027
8653074 December 16, 2031
9533972 December 16, 2031

NADA Number: 141-562

Trade Name: Librela™
Ingredients: Bedinvetmab
Sponsor: Zoetis Inc.
Approval Date: May 5, 2023
Status: Rx
Route: Subcutaneous
Species: Dogs
Drug Form: Injectable solution
Concentration: 5, 10, 15, 20, and 30 mg bedinvetmab/mL in sterile solution
Indications: For the control of pain associated with osteoarthritis in dogs.

ANADA Number: 200-748

Trade Name: Pennchlor® and Monovet®
Pioneer: Pennchlor® and Rumensin™
Ingredients: Chlortetracycline and monensin
Sponsor: Huvepharma, Inc.
Approval Date: May 10, 2023
Status: VFD
Route: Oral
Species: Beef calves 2 months of age and older, and growing beef steers and heifers fed in confinement for slaughter
Drug Form: Type A medicated articles to be used in the manufacture of Type B and Type C medicated feeds
Concentration: Pennchlor®: 50 g/lb, 90 g/lb, and 100 g/lb of chlortetracycline as chlortetracycline calcium complex equivalent to chlortetracycline hydrochloride
Monovet®: 90.7 g/lb of monensin
Indications: 1. For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline and for the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii* in beef calves 2 months of age and older.

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2. For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline and for the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii* in growing beef steers and heifers fed in confinement for slaughter over 700 lbs.
3. For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline and for improved feed efficiency in growing beef steers and heifers fed in confinement for slaughter over 700 lbs.
4. For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline and for the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii* in growing beef steers and heifers fed in confinement for slaughter.
5. For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline and for improved feed efficiency in growing beef steers and heifers fed in confinement for slaughter.
6. For the reduction of the incidence of liver abscesses and for the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii* in growing beef steers and heifers fed in confinement for slaughter over 400 lbs.
7. For the reduction of the incidence of liver abscesses and for improved feed efficiency in growing beef steers and heifers fed in confinement for slaughter over 400 lbs.
8. For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline and for the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii* in growing beef steers and heifers fed in confinement for slaughter under 700 lbs.
9. For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline and for improved feed efficiency in growing beef steers and heifers fed in confinement for slaughter under 700 lbs.
10. For the control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline and for the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii* in growing beef steers and heifers fed in confinement for slaughter.
11. For the control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline and for improved feed efficiency in growing beef steers and heifers fed in confinement for slaughter.

ANADA Number: 200-750

Trade Name:	Doraject™
Pioneer:	DECTOMAX®
Ingredients:	Doramectin
Sponsor:	Cronus Pharma Specialities India Private Ltd.
Approval Date:	May 25, 2023
Status:	OTC
Route:	Cattle – subcutaneous or intramuscular Swine – intramuscular
Species:	Cattle and swine
Drug Form:	Injectable solution
Concentration:	10 mg/mL
Indications:	Cattle: Doraject™ injectable solution is indicated for treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, sucking lice, and mange mites. Doraject™ injectable solution has been proved to effectively control infections and to protect cattle from reinfection with <i>Cooperia oncophora</i> and <i>Haemonchus placei</i> for 14 days, <i>Ostertagia ostertagi</i> for 21 days, and <i>C. punctata</i> , <i>Oesophagostomum radiatum</i> , and <i>Dictyocaulus viviparus</i> for 28 days after treatment. Swine: Doraject™ injectable solution is indicated for treatment and control of gastrointestinal roundworms, lungworms, kidney worms, sucking lice, and mange mites.

Animal Drug Safety-Related Labeling Changes

Actions Taken by FDA Center for Veterinary Medicine

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

Animal Drug Safety-related labeling changes will no longer be printed in the monthly updates. Please refer to the webpage, [Animal Drug Safety-Related Labeling Changes | FDA](#), for this information.

Patent Extensions

NADA Numbers: 141-508, 141-512, 141-514

Patent number: 6730792

Extension Period: 1 year

Expiration Date: July 9, 2024

Withdrawal of Approval

The following products were withdrawn because the products are no longer manufactured or marketed.

Application Number	Sponsor	Trade Name	Ingredients
006-623	Boehringer Ingelheim Animal Health USA, Inc.	Caparsolate Sodium	arsenamide sodium
008-422	Boehringer Ingelheim Animal Health USA, Inc.	Seleen® Suspension	selenium disulfide
010-424	Boehringer Ingelheim Animal Health USA, Inc.	Nalline Hydrochloride	nalorphine hydrochloride
011-080	Boehringer Ingelheim Animal Health USA, Inc.	Hydeltrone-TBA Suspension	prednisolone tertiary butylacetate
011-437	Boehringer Ingelheim Animal Health USA, Inc.	Hydeltrone Ointment	neomycin sulfate and prednisolone sodium phosphate
011-532	Boehringer Ingelheim Animal Health USA, Inc.	Sulfabrom 2.5 g	sulfabromomethazine sodium
011-678	Boehringer Ingelheim Animal Health USA, Inc.	Diuril® Tablet	chlorothiazide
012-734	Boehringer Ingelheim Animal Health USA, Inc.	Diuril®	chlorothiazide
013-022	Boehringer Ingelheim Animal Health USA, Inc.	Thibenzole Sheep & Goat Wormer	thiabendazole
013-407	Boehringer Ingelheim Animal Health USA, Inc.	Equizole® Horse Wormer	thiabendazole

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013-624	Boehringer Ingelheim Animal Health USA, Inc	Triamcinolone Acetonide	triamcinolone acetonide
013-674	Boehringer Ingelheim Animal Health USA, Inc	Hydrozide Injection	hydrochlorothiazide
013-954	Boehringer Ingelheim Animal Health USA, Inc	Thibenzole 20% Swine Premix	thiabendazole
014-350	Boehringer Ingelheim Animal Health USA, Inc	Omnizole	thiabendazole
015-123	Boehringer Ingelheim Animal Health USA, Inc	TBZ® Cattle Wormer (Drench)	thiabendazole
015-875	Boehringer Ingelheim Animal Health USA, Inc	TBZ 200 Medicated Feed Premix	thiabendazole
030-103	Boehringer Ingelheim Animal Health USA, Inc	Thibenzole (18 mg)	thiabendazole
032-702	Boehringer Ingelheim Animal Health USA, Inc	PromAce® Tablets	acepromazine maleate
033-127	Boehringer Ingelheim Animal Health USA, Inc	Vetisulid® Bolus	sulfachlorpyridazine
033-318	Boehringer Ingelheim Animal Health USA, Inc	Vetisulid® Injection	sulfachlorpyridazine
033-319	Boehringer Ingelheim Animal Health USA, Inc	Vetisulid® Tablets	sulfachlorpyridazine
034-114	Boehringer Ingelheim Animal Health USA, Inc	Equizole®	thiabendazole
034-879	Boehringer Ingelheim Animal Health USA, Inc	Dopram®-V Injectable	doxapram hydrochloride
035-631	Boehringer Ingelheim Animal Health USA, Inc	Thibenzole Pig Wormer	thiabendazole
037-410	Boehringer Ingelheim Animal Health USA, Inc	Equizole® A	thiabendazole and piperazine phosphate

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Application Number	Sponsor	Trade Name	Ingredients
043-141	Boehringer Ingelheim Animal Health USA, Inc	Thibenzole 300 Medicated	thiabendazole
044-654	Boehringer Ingelheim Animal Health USA, Inc	Equizole® Horse Wormer Pellets	thiabendazole
046-146	Boehringer Ingelheim Animal Health USA, Inc	Vetalog Cream	triamcinolone acetonide
047-333	Boehringer Ingelheim Animal Health USA, Inc	Equizole® A Liquid	thiabendazole and piperazine citrate
048-487	Boehringer Ingelheim Animal Health USA, Inc	TBZ® Wormer Paste 50%	thiabendazole
049-461	Boehringer Ingelheim Animal Health USA, Inc	TBZ® Wormer Paste 43%	thiabendazole
055-021	Boehringer Ingelheim Animal Health USA, Inc	Hetacin® K Capsules Vet	hetacillin potassium
055-022	Boehringer Ingelheim Animal Health USA, Inc	Hetacin® K Tablets	hetacillin potassium
055-048	Boehringer Ingelheim Animal Health USA, Inc	Hetacin® K Oral Liquid	hetacillin potassium
065-275	Boehringer Ingelheim Animal Health USA, Inc	Penicillin VK Filmtab 250 mg	penicillin V potassium
065-276	Boehringer Ingelheim Animal Health USA, Inc	Veesyn Granules for Oral Solution	penicillin V potassium
093-600	Boehringer Ingelheim Animal Health USA, Inc	Voren® Suspension	dexamethasone-21-isonicotinate
094-642	Boehringer Ingelheim Animal Health USA, Inc	Camvet Suspension Horse Wormer	cambendazole
095-642	Boehringer Ingelheim Animal Health USA, Inc	Oxy-Tet™ Injection	oxytetracycline hydrochloride
096-506	Boehringer Ingelheim Animal Health USA, Inc	Camvet Horse Wormer Pellets	cambendazole

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Application Number	Sponsor	Trade Name	Ingredients
096-731	Boehringer Ingelheim Animal Health USA, Inc	Camvet Horse Wormer Paste 45%	cambendazole
098-689	Boehringer Ingelheim Animal Health USA, Inc	Equizole® 50% Wormer Paste	thiabendazole
099-388	Boehringer Ingelheim Animal Health USA, Inc	Vetalog Oral Powder	triamcinolone acetonide
117-531	Boehringer Ingelheim Animal Health USA, Inc	Acepromazine Maleate Injection	acepromazine maleate
127-443	Boehringer Ingelheim Animal Health USA, Inc	Eqvalan® Injection	ivermectin
140-439	Boehringer Ingelheim Animal Health USA, Inc	Eqvalan® Oral Liquid For Horses	ivermectin
141-180	Boehringer Ingelheim Animal Health USA, Inc	Torpex™	albuterol sulfate
200-361	Boehringer Ingelheim Animal Health USA, Inc	Acepromazine Maleate Injection	acepromazine maleate
200-564	Boehringer Ingelheim Animal Health USA, Inc	Ivermectin Paste 1.87%	ivermectin

NADA Number: 141-527

Sponsor: Elanco US Inc.
Trade Name: BAYTRIL 100-CA1
Ingredients: Enrofloxacin

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

Suitability Petitions

Number: 2023-P-0851

Petitioner: Norbrook Laboratories Limited
Date Filed: March 7, 2023
Action: Approved
Action Date: May 18, 2023
Description: The petitioner requests to file an ANADA for a generic trilostane oral suspension for use in dogs that differs from the reference listed new animal drug (RLNAD), VETORYL® CAPSULES (trilostane), sponsored by Dechra, Ltd. under NADA 141-291. The proposed change is for an oral suspension (20 mg/mL strength); the RLNAD is approved as capsules in 5 mg, 10 mg, 30 mg, 60 mg, and 120 mg capsule strengths.

Number: 2023-P-2155

Actions Taken by FDA Center for Veterinary Medicine

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

Petitioner: Felix Pharmaceuticals Pvt. Ltd.
Date Filed: May 26, 2023
Description: The petitioner requests to file an ANADA for a generic maropitant citrate tablet for use in dogs that differs from the reference listed new animal drug (RLNAD), Cerenia® (maropitant citrate) Tablets, sponsored by Zoetis Inc. under NADA 141-262. The proposed change is in dosage form from a compressed tablet (RLNAD) to a compressed, chewable tablet (proposed generic product).