Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in October 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: 141-581

Trade Name:	Credelio Quattro™
Ingredients:	Lotilaner, moxidectin, praziquantel, and pyrantel
Sponsor:	Elanco US Inc.
Approval Date:	October 7, 2024
Status:	Rx
Route:	Oral
Species:	Dogs
Drug Form:	Chewable Tablet
Concentration:	Each chewable tablet contains: 56.25 mg lotilaner, 0.056 mg moxidectin, 14.25 mg praziquantel, and 14.25 mg pyrantel* 112.5 mg lotilaner, 0.113 mg moxidectin, 28.5 mg praziquantel, and 28.5 mg pyrantel 225 mg lotilaner, 0.225 mg moxidectin, 57 mg praziquantel, and 57 mg pyrantel 450 mg lotilaner, 0.45 mg moxidectin, 114 mg praziquantel, and 114 mg pyrantel 900 mg lotilaner, 0.9 mg moxidectin, 228 mg praziquantel, and 228 mg pyrantel
Indications:	For the prevention of heartworm disease caused by *Dirofilaria immitis* and for the treatment and control of roundworm (immature adult and adult *Toxocara canis* and adult *Toxascaris leonina*), hookworm (adult *Uncinaria stenocephala*), and tapeworm (*Dipylidium caninum*, *Taenia pisiformis*, and *Echinococcus granulosus*) infections. Kills adult fleas and is indicated for the treatment and prevention of flea infestations (*Ctenocephalides felis*) and the treatment and control of tick infestations [*Amblyomma americanum* (lone star tick), *Dermacentor variabilis* (American dog tick), *Ixodes scapularis* (black-legged tick), and *Rhipicephalus sanguineus* (brown dog tick)] for one month in dogs and puppies 8 weeks of age and older, and weighing 3.3 pounds or greater.
Exclusivity:	3 years
Patent:	Patent Number 8383659 — Expiration date: January 17, 2030

NADA Number: 141-589

Trade Name:	MGA® and Experior™
Ingredients:	Melengestrol acetate, and lubabegron
Sponsor:	Elanco US Inc.
Approval Date:	October 23, 2024
Status:	OTC
Route:	Oral
Species:	Growing beef heifers fed in confinement for slaughter
Drug Form:	Type A medicated articles to be used in the manufacture of Type C medicated feeds
Concentration:	MGA® 200 (dry formulation): 200 mg per lb of melengestrol acetate MGA® 500 (liquid formulation): 500 mg per lb of melengestrol acetate Experior™: 10 g per kg (4.54 g per lb) and 50 g per kg (22.7 g per lb) of lubabegron (as lubabegron fumarate)
Indications:	For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), and for reduction of ammonia gas emissions per pound of live weight and hot carcass weight in growing beef heifers fed in confinement for slaughter during the last 14 to 91 days on feed.

NADA Number: 141-590

Trade Name:	MGA® and Experior™ and Rumensin™
Ingredients:	Melengestrol acetate, lubabegron, and monensin
Sponsor:	Elanco US Inc.
Approval Date:	October 25, 2024
Status:	OTC
Route:	Oral
Species:	Growing beef heifers fed in confinement for slaughter
Drug Form:	Type A medicated articles to be used in the manufacture of Type C medicated feeds
Concentration:	MGA® 200 (dry formulation): 200 mg per lb of melengestrol acetate MGA® 500 (liquid formulation): 500 mg per lb of melengestrol acetate Experior™: 10 g per kg (4.54 g per lb) and 50 g per kg (22.7 g per lb) of lubabegron (as lubabegron fumarate) Rumensin™: 90.7 g per lb of monensin, USP
Indications:	For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), for reduction of ammonia gas emissions per pound of live weight and hot carcass weight, and for the prevention and control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii* in growing beef heifers fed in confinement for slaughter during the last 14 to 91 days on feed.

NADA Number: 141-591

Trade Name:	MGA® and Experior™ and Rumensin™ and Tylan™
Ingredients:	Melengestrol acetate, lubabegron, and monensin, and tylosin phosphate
Sponsor:	Elanco US Inc.
Approval Date:	October 25, 2024
Status:	VFD
Route:	Oral
Species:	Growing beef heifers fed in confinement for slaughter
Drug Form:	Type A medicated articles to be used in the manufacture of Type C medicated feeds
Concentration:	MGA® 200 (dry formulation): 200 mg per lb of melengestrol acetate MGA® 500 (liquid formulation): 500 mg per lb of melengestrol acetate Experior™: 10 g per kg (4.54 g per lb) and 50 g per kg (22.7 g per lb) of lubabegron (as lubabegron fumarate) Rumensin™: 90.7 g per lb of monensin, USP Tylan™: 40 g per lb and 100 g per lb of tylosin (as tylosin phosphate)
Indications:	For increased rate of weight gain, improved feed efficiency, suppression of estrus heat), for reduction of ammonia gas emissions per pound of live weight and hot carcass weight, and for the prevention and control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii* and for reduction of incidence of liver abscesses associated with *Fusobacterium necrophorum* and *Arcanobacterium pyogenes* in growing beef heifers fed in confinement for slaughter during the

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: 141-554

Trade Name:	NexGard® PLUS
Ingredients:	Afoxolaner, moxidectin, and pyrantel
Sponsor:	Boehringer Ingelheim Animal Health USA, Inc.
Approval Date:	October 7, 2024

This supplement provides for the addition of the indication for the treatment and control of *Haemaphysalis longicornis* (longhorned tick) infestations in dogs and puppies eight weeks of age and older, weighing four pounds of body weight or greater, for one month. This supplement also provides for the addition of label language regarding the results of a second flea field study and improvement of erythema, alopecia, papules, scales, crusts, and excoriation in dogs with flea infestations and signs of Flea Allergy Dermatitis following treatment with afoxolaner alone, as a direct result of eliminating fleas.

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in October 2024.

ANADA Number: 200-748

Trade Name: Pennchlor® and Monovet®
Ingredients: Chlortetracycline and monensin
Sponsor: Huvepharma EOOD
Approval Date: October 18, 2024

This supplement provides for the addition of replacement beef and dairy heifers with the following 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 caused by *Eimeria bovis* and *Eimeria zuernii* in replacement beef and dairy heifers; and
2) For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline and for increased rate of weight gain in replacement beef and dairy heifers.

Sponsor Change

NADA Number: 141-339

Previous Sponsor: United-AH II LLC

New Sponsor: Aurora Pharmaceutical, Inc.

Drug Labeler Code: 051072

Patent Additions

NADA Number: 141-556

Patent number: 12011441
Expiration Date: April 3, 2037

NADA Number: 141-555

Patent number: 12115162
Expiration Date: September 29, 2041