Actions Taken by FDA Center for Veterinary Medicine

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

ANADA Number: 200-770

Trade Name:	MGA® and Deracin™
Pioneer:	MGA® and Aureomycin®
Ingredients:	Melengestrol acetate and chlortetracycline
Sponsor:	Pharmgate Inc.
Approval Date:	August 15, 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 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), and treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline in growing beef heifers fed in confinement for slaughter. 2. For suppression of estrus (heat), and treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline in replacement dairy heifers less than 20 months of age and replacement beef heifers. 3. For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), and the reduction of the incidence of liver abscesses in growing beef heifers fed in confinement for slaughter over 400 lbs. 4. For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), and 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. 5. For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), and treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline in growing beef heifers fed in confinement for slaughter. 6. For suppression of estrus (heat), and treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline in replacement dairy heifers less than 20 months of age and replacement beef heifers. 7. For suppression of estrus (heat), and for control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline in replacement dairy heifers less than 20 months of age and replacement beef heifers. 8. For suppression of estrus (heat), and control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline in replacement beef heifers over 700 pounds. 9. For suppression of estrus (heat) and control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline in replacement beef heifers under 700 pounds.

ANADA Number: 200-783

Trade Name:	Coxidin® 90
Pioneer:	Coban™

Ingredients:	Monensin
Sponsor:	Huvepharma EOOD
Approval Date:	August 26, 2024
Status:	OTC
Route:	Oral
Species:	Broiler chickens, laying hen replacement chickens, layer breeder replacement chickens, growing turkeys, and growing Bobwhite quail
Drug Form:	Type A medicated articles to be used in the manufacture of Type C medicated feeds
Concentration:	90.7 g/lb
Indications:	**Broiler and Laying Hen Replacement Chicken and Layer Breeder Replacement Chicken**: As an aid in the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima*. **Turkeys:** For the prevention of coccidiosis in turkeys caused by *Eimeria adenoeides, E. meleagrimitis* and *E. gallopavonis*. **Quail:** For the prevention of coccidiosis in growing Bobwhite quail caused by *Eimeria dispersa* and *E. lettyae.*

Sponsor Change

ANADA Number: 200-420

Previous Sponsor:	Cephazone Pharma, LLC
New Sponsor:	Dechra Veterinary Products LLC
Drug Labeler Code:	017033

Sponsor Address Change

Sponsor:	Warburton Technology Ltd.
New Address:	36 Fitzwilliam Square Dublin 2, Dublin, D02 HX82, IRELAND

Patent Additions

NADA Number: 141-299

Patent number: 8044102
Expiration Date: September 9, 2025

Suitability Petitions

Number: 2024-P-3292

Petitioner:	Felix Pharmaceuticals Pvt. Ltd.
Date Filed:	July 15, 2024
Description:	The petitioner requests to file an ANADA for a generic maropitant citrate oral solution 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 for an oral solution (40 mg/mL strength); the RLNAD is approved as compressed tablets in 16 mg, 24 mg, 60 mg, and 160 mg strengths.

Number: 2024-P-3821

Petitioner:	Aurora Pharmaceutical, Inc.

Date Filed: August 12, 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 (1.84% w/v); the RLNAD is approved as soft chewables in 11.3 mg, 28.3 mg, 68 mg, and 136 mg strengths.

Number: 2024-P-4126

Petitioner: Aurora Pharmaceutical, Inc.
Date Filed: August 28, 2024
Description: The petitioner requests to file an ANADA for a generic meloxicam oral solution for use in dogs that differs from the reference listed new animal drug (RLNAD), Metacam® (meloxicam oral suspension), sponsored by Boehringer Ingelheim Animal Health USA, Inc. under NADA 141-213. The proposed change is for an oral solution (3 mg/mL strength); the RLNAD is approved as an oral suspension (0.5 mg/mL and 1.5 mg/mL strengths).