

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in March 2021.

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: 141-530

Trade Name: MGA® and Aureomycin®
Ingredients: Melengestrol acetate and chlortetracycline
Sponsor: Zoetis Inc.
Approval Date: March 15, 2021
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 (dry formulation): Melengestrol acetate at 200 mg per pound
MGA® 500 (liquid formulation): Melengestrol acetate at 500 mg per pound (as melengestrol acetate and its propylene glycol ketal)
Aureomycin® 50 Granular A: Chlortetracycline calcium complex equivalent to 50 g chlortetracycline hydrochloride per lb.
Aureomycin® 90 Meal: Chlortetracycline calcium complex equivalent to 90 g chlortetracycline hydrochloride per lb.
Aureomycin® 90 Granular: Chlortetracycline calcium complex equivalent to 90 g chlortetracycline hydrochloride per lb.
Aureomycin® 100 Granular: Chlortetracycline calcium complex equivalent to 100 g chlortetracycline hydrochloride per lb.
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.

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The following corrections or additions to the list were completed in March 2021.

NADA Number: 141-531

Trade Name: MGA® and Bovatec® and Aureomycin®
Ingredients: Melengestrol acetate, lasalocid, and chlortetracycline
Sponsor: Zoetis Inc.
Approval Date: March 19, 2021
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: Melengestrol acetate at 200 mg per pound
MGA® 500: Melengestrol acetate at 500 mg per pound (as melengestrol acetate and its propylene glycol ketal)
Bovatec® 91: 90.7 g/lb (20%) of lasalocid (as lasalocid sodium activity)
Bovatec® 150 FP: 150 g/lb (33.1%) of lasalocid (as lasalocid sodium activity)
Bovatec® Liquid 20: 90.7 g/lb (20%) of lasalocid (as lasalocid sodium activity)
Aureomycin® 50 Granular A: Chlortetracycline calcium complex equivalent to 50 g chlortetracycline hydrochloride per lb.
Aureomycin® 90 Meal: Chlortetracycline calcium complex equivalent to 90 g chlortetracycline hydrochloride per lb.
Aureomycin® 90 Granular: Chlortetracycline calcium complex equivalent to 90 g chlortetracycline hydrochloride per lb.
Aureomycin® 100 Granular: Chlortetracycline calcium complex equivalent to 100 g chlortetracycline hydrochloride per lb.
Indications: 1. For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), for control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*, and for 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 up to 800 pounds.
2. For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), for control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*, 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 up to 800 pounds.
3. For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*, and for control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline in growing beef heifers fed in confinement for slaughter under 700 pounds.
4. For suppression of estrus (heat), increased rate of weight gain, and for control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline in replacement beef heifers on pasture over 700 pounds.
5. For suppression of estrus (heat), increased rate of weight gain, and for treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline in replacement dairy heifers on pasture less than 20 months of age and replacement beef heifers on pasture.
6. For suppression of estrus (heat), increased rate of weight gain, and for control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline in replacement beef heifers on pasture.
7. For suppression of estrus (heat), increased rate of weight gain, and for control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline in replacement beef heifers on pasture under 700 pounds.
8. For suppression of estrus (heat), control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*, and for control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline in replacement beef heifers up to 800 pounds.
9. For suppression of estrus (heat), control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*, and for treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida*

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organisms susceptible to chlortetracycline in replacement dairy heifers up to 800 pounds and less than 20 months of age and replacement beef heifers up to 800 pounds.

ANADA Number: 200-699

Trade Name: Dexmedetomidine Hydrochloride Injection
Pioneer: DEXDOMITOR®
Ingredients: Dexmedetomidine hydrochloride
Sponsor: Akorn Operating Company LLC (dba Akorn Animal Health Inc.)
Approval Date: March 11, 2021
Status: Rx
Route: Intramuscular injection (dogs and cats) and intravenous injection (dogs)
Species: Dogs and cats
Drug Form: Injectable solution
Concentration: 0.5 mg/mL
Indications: For use as a sedative and analgesic in dogs and cats to facilitate clinical examinations, clinical procedures, minor surgical procedures, and minor dental procedures. It is also indicated for use as a preanesthetic to general anesthesia in dogs and cats.

ANADA Number: 200-625

Trade Name: KetoMed™
Pioneer: KETOFEN®
Ingredients: Ketoprofen
Sponsor: Bimeda Animal Health Ltd.
Approval Date: March 22, 2021
Status: Rx
Route: Intravenous
Species: Horses
Drug Form: Sterile solution
Concentration: 100 mg/mL
Indications: For the alleviation of inflammation and pain associated with musculoskeletal disorders in the horse.

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: 132-872

Trade Name: Safe-Guard®
Ingredients: Fenbendazole
Sponsor: Intervet, Inc.
Approval Date: March 24, 2021

This supplement provides for 1) tolerances, a tissue withdrawal period, and a milk discard time in accordance with a repartitioning of the ADI; and 2) the addition of fourth stage larval indications for barberpole worms (*Haemonchus contortus* and *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*).

Sponsor Change

NADA Numbers: 141-474, 141-120

Previous Sponsor: Elanco US Inc.

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The following corrections or additions to the list were completed in March 2021.

New Sponsor: Virbac AH, Inc.

NADA Numbers: 141-175

Previous Sponsor: Elanco US Inc.

New Sponsor: Sergeant's Pet Care Products, Inc.

Sponsor Name Change

Previous Name: Sergeant's Pet Care Products, Inc.

New Name: Sergeant's Pet Care Products LLC