

## Actions Taken by FDA Center for Veterinary Medicine

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

### Original Approvals

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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: 141-540

Trade Name: Pennitracin MD® and Coban™  
Ingredients: Bacitracin and monensin  
Sponsor: Pharmgate, Inc.  
Approval Date: February 26, 2021  
Status: OTC  
Route: Oral  
Species: Growing turkeys  
Drug Form: Type A medicated articles to be used in the manufacture of Type C medicated feeds  
Concentration: Pennitracin MD®: 50 g/lb bacitracin (as feed grade bacitracin methylenedisalicylate)  
Coban™: 90.7 g/lb monensin, USP  
Indications: For increased rate of weight gain and improved feed efficiency, and for the prevention of coccidiosis caused by *Eimeria adenoides*, *E. meleagridis* and *E. gallopavonis* in growing turkeys.

#### ANADA Number: 200-683

Trade Name: CycleGuard® and Monovet®  
Pioneer: MGA® and Rumensin™  
Ingredients: Melengestrol acetate and monensin  
Sponsor: Huvepharma EOOD  
Approval Date: February 1, 2021  
Status: OTC  
Route: Oral  
Species: Heifers fed in confinement for slaughter  
Drug Form: Type A medicated articles to be used in the manufacture of Type C medicated feeds  
Concentration: CycleGuard®: 500 mg/lb of melengestrol acetate  
Monovet®: 90.7 g/lb of monensin  
Indications: For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), and prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii* in heifers fed in confinement for slaughter.

#### ANADA Number: 200-684

Trade Name: Optigrid® and Monovet® and CycleGuard®  
Pioneer: Optaflexx™ and Rumensin™ and MGA®  
Ingredients: Ractopamine hydrochloride, monensin, and melengestrol acetate  
Sponsor: Huvepharma EOOD  
Approval Date: February 1, 2021  
Status: OTC  
Route: Oral  
Species: Heifers fed in confinement for slaughter  
Drug Form: Type A medicated articles to be used in the manufacture of Type C medicated feeds  
Concentration: Optigrid®: 45.4 g/lb (100 g/kg) of ractopamine hydrochloride  
Monovet®: 90.7 g/lb of monensin  
CycleGuard®: 500 mg/lb of melengestrol acetate  
Indications: For increased rate of weight gain, improved feed efficiency, increased carcass leanness, prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*, and for suppression of estrus (heat) in heifers fed in confinement for slaughter during the last 28 to 42 days on feed.

## Actions Taken by FDA Center for Veterinary Medicine

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

### ANADA Number: 200-685

Trade Name: CycleGuard® and Monovet® and Tylovet®  
Pioneer: MGA® and Rumensin™ and Tylan™  
Ingredients: Melengestrol acetate, monensin, and tylosin phosphate  
Sponsor: Huvepharma EOOD  
Approval Date: February 1, 2021  
Status: VFD  
Route: Oral  
Species: Heifers fed in confinement for slaughter  
Drug Form: Type A medicated articles to be used in the manufacture of Type C medicated feeds  
Concentration: CycleGuard®: 500 mg/lb of melengestrol acetate  
Monovet®: 90.7 g/lb of monensin  
Tylovet®: 40 g/lb and 100 g/lb of tylosin  
Indications: For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*, reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium pyogenes* in heifers fed in confinement for slaughter.

### ANADA Number: 200-686

Trade Name: Optigrid® and Monovet® and Tylovet® and CycleGuard®  
Pioneer: Optaflexx™ and Rumensin™ and Tylan™ and MGA®  
Ingredients: Ractopamine hydrochloride, monensin, tylosin phosphate, and melengestrol acetate  
Sponsor: Huvepharma EOOD  
Approval Date: February 1, 2021  
Status: VFD  
Route: Oral  
Species: Heifers fed in confinement for slaughter  
Drug Form: Type A medicated articles to be used in the manufacture of Type C medicated feeds  
Concentration: Optigrid®: 45.4 g/lb (100 g/kg) of ractopamine hydrochloride  
Monovet®: 90.7 g/lb of monensin  
Tylovet®: 40 g/lb and 100 g/lb of tylosin  
CycleGuard®: 500 mg/lb of melengestrol acetate  
Indications: For increased rate of weight gain, improved feed efficiency, increased carcass leanness, prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*, reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes*, and suppression of estrus (heat) in heifers fed in confinement for slaughter for the last 28 to 42 days on feed.

### ANADA Number: 200-506

Trade Name: Animec™ Plus  
Pioneer: ivomec® Plus  
Ingredients: Ivermectin and clorsulon  
Sponsor: Chanelle Pharmaceuticals Manufacturing Ltd.  
Approval Date: February 16, 2021  
Status: OTC  
Route: Subcutaneous  
Species: Cattle  
Drug Form: Injectable solution  
Concentration: 10 mg (1%) ivermectin and 100 mg (10%) clorsulon per mL  
Indications: For the treatment and control of internal parasites, including adult liver flukes, and external parasites.

### ANADA Number: 200-657

Trade Name: MACROSYN™  
Pioneer: Draxxin®  
Ingredients: Tulathromycin

## Actions Taken by FDA Center for Veterinary Medicine

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

Sponsor: Bimeda Animal Health Ltd.  
Approval Date: February 18, 2021  
Status: Rx  
Route: Subcutaneous injection (cattle) and intramuscular injection (swine)  
Species: Beef cattle, non-lactating dairy cattle, suckling calves, dairy calves, veal calves, and swine  
Drug Form: Injectable solution  
Concentration: 100 mg of tulathromycin/mL  
Indications: **Beef and Non-Lactating Dairy Cattle:** For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis*; and for the control of respiratory disease in cattle at high risk of developing BRD associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis*.  
For the treatment of infectious bovine keratoconjunctivitis (IBK) associated with *Moraxella bovis*.  
For the treatment of bovine foot rot (interdigital necrobacillosis) associated with *Fusobacterium necrophorum* and *Porphyromonas levii*.  
**Suckling Calves, Dairy Calves, and Veal Calves:** For the treatment of BRD associated with *M. haemolytica*, *P. multocida*, *H. somni*, and *M. bovis*.  
**Swine:** For the treatment of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Bordetella bronchiseptica*, *Haemophilus parasuis*, and *Mycoplasma hyopneumoniae*; and for the control of SRD associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, and *Mycoplasma hyopneumoniae* in groups of pigs where SRD has been diagnosed.

### ANADA Number: 200-666

Trade Name: Increxxa™  
Pioneer: Draxxin®  
Ingredients: Tulathromycin  
Sponsor: Elanco US Inc.  
Approval Date: February 18, 2021  
Status: Rx  
Route: Subcutaneous injection (cattle) and intramuscular injection (swine)  
Species: Beef cattle, non-lactating dairy cattle, suckling calves, dairy calves, veal calves, and swine  
Drug Form: Injectable solution  
Concentration: 100 mg of tulathromycin/mL  
Indications: **Beef and Non-Lactating Dairy Cattle:** For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis*; and for the control of respiratory disease in cattle at high risk of developing BRD associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis*.  
For the treatment of infectious bovine keratoconjunctivitis (IBK) associated with *Moraxella bovis*.  
For the treatment of bovine foot rot (interdigital necrobacillosis) associated with *Fusobacterium necrophorum* and *Porphyromonas levii*.  
**Suckling Calves, Dairy Calves, and Veal Calves:** For the treatment of BRD associated with *M. haemolytica*, *P. multocida*, *H. somni*, and *M. bovis*.  
**Swine:** For the treatment of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Bordetella bronchiseptica*, *Haemophilus parasuis*, and *Mycoplasma hyopneumoniae*; and for the control of SRD associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, and *Mycoplasma hyopneumoniae* in groups of pigs where SRD has been diagnosed.

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## 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.

## Actions Taken by FDA Center for Veterinary Medicine

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

### ANADA Number: 200-466

Trade Name: SparMectin Plus Clorsulon  
Ingredients: Ivermectin and clorsulon  
Sponsor: Sparhawk Laboratories, Inc.  
Approval Date: February 8, 2021

This supplement provides for a decrease in the residue withdrawal period for cattle from 49 days to 21 days prior to slaughter.

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## Animal Drug Safety-Related Labeling Changes

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### NADA Number: 141-345

Proprietary Name: Apoquel  
Drug Product Established Name: oclacitinib tablet

The following safety-related changes were made to the labeling:

1. The drug class "Immunomodulator" was added to the product identification.
2. Warnings  
(Additions and/or revisions underlined)

**Warnings:**

APOQUEL is not for use in dogs less than 12 months of age (see **Animal Safety**).

APOQUEL modulates the immune system. APOQUEL is not for use in dogs with serious infections.

APOQUEL may increase susceptibility to infection, including demodicosis, and exacerbation of neoplastic conditions. (see **Precautions**, **Adverse Reactions**, **Post-Approval Experience** and **Animal Safety**).

New neoplastic conditions (benign and malignant) were observed in dogs treated with APOQUEL during clinical studies and have been reported in the post-approval period (See **Adverse Reactions** and **Post-Approval Experience**).

Consider the risks and benefits of treatment prior to initiating APOQUEL in dogs with a history of recurrent serious infections or recurrent demodicosis or neoplasms (see **Adverse Reactions**, **Post-Approval Experience**, and **Animal Safety**).

Keep APOQUEL in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.

3. Newly added **Post-Approval Experience** and **Contact Information** sections:

**Post-Approval Experience** (2020)

The following adverse events are based on post-approval adverse drug experience reporting for APOQUEL. Not all adverse events are reported to FDA/CVM. It is not always possible to reliably estimate the adverse event frequency or establish a causal relationship to product exposure using these data.

The following adverse events reported in dogs are listed in decreasing order of reporting frequency.

Vomiting, lethargy, anorexia, diarrhea, elevated liver enzymes, dermatitis (i.e. crusts, pododermatitis, pyoderma), seizures, polydipsia, and demodicosis.

Benign, malignant, and unclassified neoplasms, dermal masses (including papillomas and histiocytomas), lymphoma and other cancers have been reported.

Death (including euthanasia) has been reported.

# Actions Taken by FDA Center for Veterinary Medicine

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

## Contact Information:

To report suspected adverse events, for technical assistance or to obtain a copy of the SDS, contact Zoetis Inc. at 1-888-963-8471 or [www.zoetis.com](http://www.zoetis.com).

For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at [www.fda.gov/reportanimalae](http://www.fda.gov/reportanimalae).

## NADA Number: 141-437

Proprietary Name: Osurnia®

Drug Product Established Name: florfenicol, terbinafine, betamethasone acetate

1. The statement "**Do not use in Cats**" was added to the product identification.
2. **Dosage and Administration:**

*(Additions and/or revisions underlined)*

**OSURNIA should be administered by a veterinary professional.**

**Wear eye protection when administering OSURNIA (see Human Safety Warnings, Precautions, Post-Approval Experience, Animal Safety).**

**Splatter may occur if the dog shakes its head following administration. Persons near the dog during administration should also take steps to avoid ocular exposure.**

1. Clean and dry the external ear canal before administering the initial dose of the product.
  2. **Verify that the tympanic membrane is intact prior to each administration (see Precautions, Contraindications, Animal Safety, Post-Approval Experience).**
  3. Administer one dose (1 tube) per affected ear(s) and repeat administration in 7 days.
  4. Open tube by twisting the soft tip. Insert the flexible tip into the affected external ear canal(s) and squeeze entire tube contents into the external ear canal(s). After application, gently massage the base of the ear to allow the gel to penetrate to the lower part of the ear canal.
  5. **Restrain dog to minimize post application head shaking to reduce potential for splatter of product and accidental eye exposure in people and dogs (see Post-Approval Experience, Animal Safety).**
  6. Do not clean the ear canal for 45 days after the initial administration to allow contact of the gel with the ear canal. Cleaning the ear may affect product effectiveness (see **Effectiveness**). If alternative otic therapies are required, it is recommended to clean the ear(s) before application.
3. **WARNINGS:**  
*(Additions and/or revisions underlined)*

**Human Safety Warnings:**

**OSURNIA may cause eye injury and irritation (see Precautions, Post-Approval Experience, Animal Safety).**

**In case of accidental eye contact, flush thoroughly with water for at least 15 minutes. If symptoms develop, seek medical advice.**

Not for use in humans. Keep this and all medications out of the reach of children. Consult a physician in case of accidental ingestion by humans. In case of accidental skin contact, wash area thoroughly with water.

4. **PRECAUTIONS:**  
*(Additions and/or revisions underlined)*

**Wear eye protection when administering OSURNIA and restrain the dog to minimize post application head shaking. Reducing the potential for splatter of product will help prevent accidental eye exposure in people and dogs and help to prevent ocular injury (see Human Safety Warnings, Post-Approval Experience, Animal Safety).**

## Actions Taken by FDA Center for Veterinary Medicine

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

The use of OSURNIA in dogs with perforated tympanic membranes has not been evaluated. The integrity of the tympanic membrane should be confirmed before administering this product. Reevaluate the dog if hearing loss or signs of vestibular dysfunction are observed during treatment.

Proper patient selection is important when considering the benefits and risks of using OSURNIA. The integrity of the tympanic membrane should be confirmed before administering each dose of this product.

Changes to the middle ear such as ulceration of the mucosal lining have been associated with OSURNIA administration (see **Animal Safety**).

Signs of tympanic membrane rupture, internal ear disease such as head tilt, ataxia, nystagmus, facial paralysis, and keratoconjunctivitis sicca have also been reported (see **Post-Approval Experience**).

Do not administer orally.

Use of topical otic corticosteroids has been associated with adrenocortical suppression and iatrogenic hyperadrenocorticism in dogs (see **Animal Safety**).

Use with caution in dogs with impaired hepatic function (see **Animal Safety** and **Adverse Reactions**).

The safe use of OSURNIA in dogs used for breeding purposes, during pregnancy, or in lactating bitches, has not been evaluated.

5. The following Post-Approval Experience section was added to the labeling:

### **Post-Approval Experience Section (2020):**

The following adverse events are based on post-approval adverse drug experience reporting for OSURNIA. Not all adverse events are reported to FDA/CVM. It is not always possible to reliably estimate the adverse event frequency or establish a causal relationship to product exposure using this data.

**In humans**, accidental exposure leading to corneal ulcers and other ocular injuries such as eye irritation, burning, stinging, and itchiness have been reported to occur when the dog shook its head after application of OSURNIA.

**In dogs**, the adverse events reported for OSURNIA are presented below in decreasing order of reporting frequency:

Deafness, ear discharge, pinna irritation and ear pain, emesis, head shaking, internal ear disorder (head tilt and vestibular), ataxia, vocalization, corneal ulcer, keratoconjunctivitis sicca, nystagmus, tympanic rupture, and cranial nerve disorder (facial paralysis).

OSURNIA is not approved for use in **cats**. The adverse events reported following extra-label use in **cats** are presented below in decreasing order of reporting frequency:

Ataxia, anorexia, Horner's syndrome (third eyelid prolapse and miosis), internal ear disorder (head tilt and vestibular), anisocoria, lethargy, head shake, emesis, nystagmus, deafness, and tympanic rupture.

6. The following Information for Dog Owners section was added to the labeling:

### **INFORMATION FOR DOG OWNERS:**

Owners should be aware that adverse reactions may occur following administration of OSURNIA and should observe dog for signs such as deafness, ear pain and irritation, vomiting, head shaking, head tilt, incoordination, eye pain and ocular discharge (see **Animal Safety** and **Post-Approval Experience**). Owners should be advised to contact their veterinarian if any of the above signs are observed.

## Actions Taken by FDA Center for Veterinary Medicine

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

Owners should also be informed that splatter may occur if the dog shakes its head following administration of OSURNIA which may lead to ocular exposure. As a result, eye injuries in humans and dogs have been reported including corneal ulcers. Owners should be careful to avoid ocular exposure (see **Precautions, Post- Approval Experience**).

### Sponsor Change

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#### **(A)NADA Numbers: 200-441, 065-440, 065-071**

Previous Sponsor: Huvepharma EOOD  
New Sponsor: Pharmgate, Inc.  
Drug Labeler Code: 069254

#### **(A)NADA Number: 200-528**

Previous Sponsor: Pharmgate, Inc.  
New Sponsor: Huvepharma EOOD  
Drug Labeler Code: 016592

#### **(A)NADA Numbers: 200-372, 200-335, 065-081**

Previous Sponsor: G. C. Hanford Manufacturing Co.  
New Sponsor: HQ Specialty Pharma Corp.  
Drug Labeler Code: 042791

### Withdrawal of Approval

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#### **NADA Number: 031-971**

Sponsor: Walco International, Inc.  
Trade Name: Cuprate  
Ingredients: Cupric glycinate

This product is withdrawn because the sponsor failed to submit the required annual reports.

#### **NADA Number: 045-863**

Sponsor: OXIS International, Inc.  
Trade Name: Palosein  
Ingredients: Orgotein

This product is withdrawn because the sponsor failed to submit the required annual reports.

#### **NADA Number: 046-922**

Sponsor: ConAgra Pet Products Co.  
Trade Name: Sergeants® Sure Shot® Capsules  
Ingredients: n-butyl chloride

This product is withdrawn because the sponsor failed to submit the required annual reports.

#### **NADA Number: 046-923**

## Actions Taken by FDA Center for Veterinary Medicine

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

Sponsor: ConAgra Pet Products Co.  
Trade Name: Sergeants® Puppy Worm Capsules  
Ingredients: n-butyl chloride

This product is withdrawn because the sponsor failed to submit the required annual reports.

### NADA Number: 065-067

Sponsor: Premo Pharmaceutical Laboratories, Inc.  
Trade Name: Tetracycline HCl Tablets  
Ingredients: Tetracycline hydrochloride

This product is withdrawn because the sponsor failed to submit the required annual reports.

### NADA Number: 140-850

Sponsor: RSR Laboratories, Inc.  
Trade Name: Elite Dog & Cat Wormer  
Ingredients: Dichlorophene and toluene

This product is withdrawn because the sponsor failed to submit the required annual reports.

### NADA Number: 141-107

Sponsor: Alaco, Inc.  
Trade Name: Bapten® For Injection  
Ingredients: beta aminopropionitrile

This product is withdrawn because the sponsor failed to submit the required annual reports.

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## Suitability Petitions

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### Number: 2020-P-2234

Petitioner: Ray Law Firm, PLLC  
Date Filed: November 24, 2020  
Action: Approved  
Action Date: February 16, 2021  
Description: The petitioner requests to file an ANADA for generic cefpodoxime proxetil tablets for the treatment of skin infections (wounds and abscesses) in dogs caused by susceptible strains of *Staphylococcus pseudintermedius*, *Staphylococcus aureus*, *Streptococcus canis* (group G,  $\beta$  hemolytic), *Escherichia coli*, *Pasteurella multocida*, and *Proteus mirabilis* that differ from the reference listed new animal drug (RLNAD), SIMPLICEF® (cefpodoxime proxetil tablets), sponsored by Zoetis Inc. under NADA 141-232. The proposed changes are the addition of an unscored 50 mg tablet strength and the removal of scoring from the 100 and 200 mg tablet strengths. The RLNAD is approved as scored tablets in 100 mg and 200 mg tablet strengths.