

## Actions Taken by FDA Center for Veterinary Medicine

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

#### ANADA Number: 200-708

Trade Name: Enrofloxacin  
Pioneer: Baytril®  
Ingredients: Enrofloxacin  
Sponsor: Felix Pharmaceuticals Pvt. Ltd.  
Approval Date: August 2, 2021  
Status: Rx  
Route: Intramuscular (IM) injection  
Species: Dogs  
Drug Form: Injectable Solution  
Concentration: 22.7 mg/mL (2.27%)  
Indications: For the management of diseases in dogs associated with bacteria susceptible to enrofloxacin.

#### ANADA Number: 200-709

Trade Name: Amoxicillin and Clavulanate Potassium for Oral Suspension  
Pioneer: CLAVAMOX®  
Ingredients: Amoxicillin and clavulanate potassium  
Sponsor: Cronus Pharma Specialities India Private Ltd.  
Approval Date: August 18, 2021  
Status: Rx  
Route: Oral  
Species: Dogs and cats  
Drug Form: Suspension  
Concentration: Each mL of suspension contains 50 mg of amoxicillin activity as the trihydrate and 12.5 mg of clavulanic acid activity as the potassium salt.  
Indications: For the treatment of the following:  
Dogs: Skin and soft tissue infections such as wounds, abscesses, cellulitis, superficial/juvenile and deep pyoderma due to susceptible strains of the following organisms:  $\beta$ -lactamase-producing *Staphylococcus aureus*, non- $\beta$ -lactamase-producing *Staphylococcus aureus*, *Staphylococcus* spp., *Streptococcus* spp., and *E. coli*. Periodontal infections due to susceptible strains of both aerobic and anaerobic bacteria.  
Cats: Skin and soft tissue infections such as wounds, abscesses, and cellulitis/dermatitis due to susceptible strains of the following organisms:  $\beta$ -lactamase-producing *Staphylococcus aureus*, non- $\beta$ -lactamase-producing *Staphylococcus aureus*, *Staphylococcus* spp., *Streptococcus* spp., *E. coli*, *Pasteurella multocida*, and *Pasteurella* spp. Urinary tract infections (cystitis) due to susceptible strains of *E. coli*.

### Supplemental Approvals

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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.

#### ANADA Number: 200-618

Trade Name: Zoletil™ for Injection  
Ingredients: Tiletamine and zolazepam  
Sponsor: Virbac AH, Inc.  
Approval Date: August 16, 2021

## **Actions Taken by FDA Center for Veterinary Medicine**

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

This supplement provides for the addition of a new indication, the intravenous administration for induction of anesthesia followed by maintenance with an inhalant anesthetic in dogs.

### **NADA Number: 141-063**

Trade Name: Nuflor®-S  
Ingredients: Florfenicol  
Sponsor: Intervet, Inc.  
Approval Date: August 19, 2021

This supplement provides for the treatment of swine respiratory disease associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Salmonella Choleraesuis*, *Streptococcus suis*, *Bordetella bronchiseptica*, and *Glaesserella (Haemophilus) parasuis* in swine except for nursing piglets and swine of reproductive age intended for breeding.

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## **Sponsor Change**

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### **NADA Numbers: 141-545, 141-475**

Previous Sponsor: VetDC, Inc.  
New Sponsor: Elanco US Inc.