

## Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in February 2017.

### 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: 141-445

Trade Name: Revalor®-XR  
Ingredients: Trenbolone acetate and estradiol  
Sponsor: Intervet, Inc.  
Approval Date: February 13, 2017  
Status: OTC  
Route: Subcutaneous  
Species: Beef steers and heifers fed in confinement for slaughter  
Drug Form: Extended- and delayed-release implant  
Concentration: One implant (10 pellets) containing 200 mg of trenbolone acetate and 20 mg of estradiol. Each pellet contains 20 mg trenbolone acetate and 2 mg estradiol in a polymer coating.  
Indications: For increased rate of weight gain and improved feed efficiency during 70 to 200 days after implantation in beef steers and heifers fed in confinement for slaughter.  
Exclusivity: 3 years  
Patent: Patent Number 39592 Expiration date: March 22, 2019

#### ANADA Number: 200-609

Trade Name: DIROBAN™  
Pioneer: IMMITICIDE®  
Ingredients: Melarsomine dihydrochloride  
Sponsor: Anzac Animal Health, LLC  
Approval Date: February 17, 2017  
Status: Rx  
Route: Intramuscular  
Species: Dogs  
Drug Form: Sterile Powder for Injection  
Concentration: Contains 50.0 mg melarsomine dihydrochloride and 33.75 mg glycine USP. 1 vial: when reconstituted with 2 mL of sterile water for injection (provided) contains 25 mg/mL of active ingredient.  
Indications: For the treatment of stabilized Class 1, 2, and 3 heartworm disease caused by immature (4 month-old, stage L5) to mature adult infections of *Dirofilaria immitis*.

### Patent Additions

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#### NADA Number: 141-209

Patent number: 8968759  
Expiration Date: March 19, 2023

Patent number: 6074657  
Expiration Date: March 20, 2017

#### NADA Number: 141-345

Patent number: 95221512  
Expiration Date: July 18, 2033

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### **NADA Number: 141-459**

Patent number: 9532978  
Expiration Date: December 22, 2031

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### **Patent Extensions**

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### **NADA Number: 141-339**

Patent number: 5985320  
Extension Period: 5 years  
Expiration Date: March 3, 2022

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### **Withdrawal of Approval**

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### **NADA Number: 044-820**

Sponsor: Zoetis Inc.  
Trade Name: Lincomix® plus Amprol Plus®  
Ingredients: Lincomycin, amprolium and ethopabate

This product is withdrawn because the product is no longer manufactured or marketed.

### **NADA Number: 044-972**

Sponsor: Zoetis Inc.  
Trade Name: Lincomix® plus Coyden®  
Ingredients: Lincomycin and clopidol

This product is withdrawn because the product is no longer manufactured or marketed.

### **NADA Number: 047-261**

Sponsor: Zoetis Inc.  
Trade Name: Lincomix® plus Deccox®  
Ingredients: Lincomycin and decoquinatate

This product is withdrawn because the product is no longer manufactured or marketed.

### **NADA Number: 047-262**

Sponsor: Zoetis Inc.  
Trade Name: Lincomix® plus Deccox®  
Ingredients: Lincomycin and decoquinatate

This product is withdrawn because the product is no longer manufactured or marketed.

### **NADA Number: 048-954**

Sponsor: Zoetis Inc.  
Trade Name: Lincomix® plus Zoamix®  
Ingredients: Lincomycin and zoalene

This product is withdrawn because the product is no longer manufactured or marketed.

### **NADA Number: 091-513**

Sponsor: Phibro Animal Health Corp.  
Trade Name: Stafac®  
Ingredients: Virginiamycin

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This product is withdrawn because the product is no longer manufactured or marketed.

### **NADA Number: 092-482**

Sponsor: Zoetis Inc.  
Trade Name: Lincomix® plus Coban®  
Ingredients: Lincomycin and monensin

This product is withdrawn because the product is no longer manufactured or marketed.

### **NADA Number: 093-106**

Sponsor: Zoetis Inc.  
Trade Name: Lincomix® plus Robenz®  
Ingredients: Lincomycin and robenidine

This product is withdrawn because the product is no longer manufactured or marketed.

### **NADA Number: 101-689**

Sponsor: Zoetis Inc.  
Trade Name: Lincomix® plus Avatec®  
Ingredients: Lincomycin and asalocid

This product is withdrawn because the product is no longer manufactured or marketed.

### **NADA Number: 122-481**

Sponsor: Phibro Animal Health Corp.  
Trade Name: Stafac® plus Coban®  
Ingredients: Virginiamycin and monensin

This product is withdrawn because the product is no longer manufactured or marketed.

### **NADA Number: 122-608**

Sponsor: Phibro Animal Health Corp.  
Trade Name: Stafac® plus Avatec®  
Ingredients: Virginiamycin and lasalocid

This product is withdrawn because the product is no longer manufactured or marketed.

### **NADA Number: 122-822**

Sponsor: Phibro Animal Health Corp.  
Trade Name: Stafac® plus Amprol Plus®  
Ingredients: Virginiamycin, amprolium and ethopabate

This product is withdrawn because the product is no longer manufactured or marketed.

### **NADA Number: 137-537**

Sponsor: Zoetis Inc.  
Trade Name: Lincomix® plus Bio-Cox®  
Ingredients: Lincomycin and salinomycin

This product is withdrawn because the product is no longer manufactured or marketed.

### **NADA Number: 138-792**

Sponsor: Zoetis Inc.  
Trade Name: Tylan® plus Rumensin® plus MGA®

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The following corrections or additions to the list were completed in February 2017.

Ingredients: Tylosin, monensin and melengestrol acetate

This product is withdrawn because the product is no longer manufactured or marketed.

### **NADA Number: 138–828**

Sponsor: Phibro Animal Health Corp.  
Trade Name: Stafac® plus Bio-Cox®  
Ingredients: Virginiamycin and salinomycin

This product is withdrawn because the product is no longer manufactured or marketed.

### **NADA Number: 138–904**

Sponsor: Zoetis Inc.  
Trade Name: Tylan® plus Bovatec® plus MGA®  
Ingredients: Tylosin, lasalocid and melengestrol acetate

This product is withdrawn because the product is no longer manufactured or marketed.

### **NADA Number: 141–110**

Sponsor: Phibro Animal Health Corp.  
Trade Name: Stafac® plus Coban®  
Ingredients: Virginiamycin and monensin

This product is withdrawn because the product is no longer manufactured or marketed.

### **NADA Number: 141–150**

Sponsor: Phibro Animal Health Corp.  
Trade Name: Stafac® plus Avatec®  
Ingredients: Virginiamycin and lasalocid

This product is withdrawn because the product is no longer manufactured or marketed.

### **ANADA Number: 200–092**

Sponsor: Huvepharma EOOD  
Trade Name: Stafac® plus Sacox®  
Ingredients: Virginiamycin and salinomycin

This product is withdrawn because the product is no longer manufactured or marketed.

### **ANADA Number: 200–093**

Sponsor: Huvepharma EOOD  
Trade Name: Lincomix® plus Sacox®  
Ingredients: Lincomycin and salinomycin

This product is withdrawn because the product is no longer manufactured or marketed.

## Suitability Petitions

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### **Number: 16-P-3015**

Petitioner: Felix Pharmaceuticals Pvt. Ltd.  
Date Filed: September 28, 2016  
Action: Approved  
Action Date: January 12, 2017  
Description: The petitioner requests to file an ANADA for a generic enrofloxacin tablet for use in dogs and cats that differs from the pioneer product, Baytril® Taste Tabs

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

The following corrections or additions to the list were completed in February 2017.

(enrofloxacin) antibacterial tablets, sponsored by Bayer HealthCare, LLC, Animal Health Division, under 140-441. The proposed change is in dosage form. The RLNAD is approved as a compressed tablet. The proposed change is for a soft chewable tablet.