

# Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in May 2018.

## 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: 141-481

Trade Name: Mirataz™  
Ingredients: Mirtazapine  
Sponsor: Kindred Biosciences, Inc.  
Approval Date: May 4, 2018  
Status: Rx  
Route: Topical (transdermal)  
Species: Cats  
Drug Form: Transdermal ointment  
Concentration: Each 1 g of Mirataz™ contains 20 mg of mirtazapine (2%).  
Indications: For the management of weight loss in cats.  
Exclusivity: 5 years

### NADA Number: 141-501

Trade Name: Semintra®  
Ingredients: Telmisartan  
Sponsor: Boehringer Ingelheim Vetmedica, Inc.  
Approval Date: May 15, 2018  
Status: Rx  
Route: Oral  
Species: Cats  
Drug Form: Oral solution  
Concentration: 10 mg/mL  
Indications: For the control of systemic hypertension in cats.  
Exclusivity: 5 years  
Patent: Patent Number Expiration date:  
9308197 February 19, 2028  
8871795 May 19, 2030

### NADA Number: 141-495

Trade Name: Integrity™ and Bio-Cox®  
Ingredients: Avilamycin and salinomycin sodium  
Sponsor: Elanco US Inc.  
Approval Date: May 31, 2018  
Status: VFD  
Route: Oral  
Species: Broiler chickens  
Drug Form: Type A medicated articles to be used in the manufacture of Type C medicated feeds.  
Concentration: 45.4 g/lb avilamycin and 60 g/lb salinomycin sodium activity  
Indications: For the prevention of mortality caused by necrotic enteritis associated with *Clostridium perfringens*; and for the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati* in broiler chickens.

## 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.

### NADA Number: 141-063

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The following corrections or additions to the list were completed in May 2018.

Trade Name: Nuflor®  
Ingredients: Florfenicol  
Sponsor: Intervet, Inc.  
Approval Date: May 25, 2018

This supplement provides information to address the human food safety of N-methyl-2-pyrrolidone (NMP) in the formulation of Nuflor® injectable solution in cattle.

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### Patent Additions

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#### **NADA Number: 141-457**

Patent number: 9499543  
Expiration Date: May 28, 2033

#### **NADA Number: 141-244**

Patent number: 6583274  
Expiration Date: May 2, 2020

#### **NADA Number: 141-349**

Patent number: 6583274  
Expiration Date: May 2, 2020

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### Patent Extensions

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#### **NADA Number: 141-216**

Patent number: 6893652  
Expiration Date: August 25, 2022

Patent number: 7674475  
Expiration Date: January 17, 2026

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### Suitability Petitions

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#### **Number: 18-P-1740**

Petitioner: Provetica Animal Health LLC  
Date Filed: May 3, 2018  
Description: The petitioner requests to file an ANADA for a generic deracoxib tablet for use in dogs that differs from the pioneer product, Derramaxx® (deracoxib) chewable tablet, sponsored by Elanco US, Inc. under 141-203. The proposed change is for a scored tablet presentation on the 12 mg and 100 mg sizes.