

# Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in June 2024.

## 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: 200-787

Trade Name: Phenylpropanolamine Hydrochloride  
Pioneer: PROIN®  
Ingredients: Phenylpropanolamine hydrochloride  
Sponsor: ZyVet Animal Health, Inc.  
Approval Date: June 11, 2024  
Status: Rx  
Route: Oral  
Species: Dogs  
Drug Form: Chewable tablet  
Concentration: 25, 50, or 75 mg phenylpropanolamine hydrochloride per tablet  
Indications: For the control of urinary incontinence due to urethral sphincter hypotonus in dogs.

### ANADA Number: 200-785

Trade Name: Maropitant Citrate Tablets  
Pioneer: Cerenia®  
Ingredients: Maropitant citrate  
Sponsor: Felix Pharmaceuticals Pvt. Ltd.  
Approval Date: June 17, 2024  
Status: Rx  
Route: Oral  
Species: Dogs  
Drug Form: Tablet  
Concentration: 16 mg, 24 mg, 60 mg, or 160 mg of maropitant citrate per tablet  
Indications: For the prevention of acute vomiting and the prevention of vomiting due to motion sickness in dogs.

### ANADA Number: 200-784

Trade Name: Trimeprazine with Prednisolone  
Pioneer: Temaril-P®  
Ingredients: T  
Sponsor: ZyVet Animal Health, Inc.  
Approval Date: June 20, 2024  
Status: Rx  
Route: Oral  
Species: Dogs  
Drug Form: Tablets  
Concentration: Each tablet contains 5 mg trimeprazine as trimeprazine tartrate and 2 mg prednisolone.  
Indications: **Antipruritic:** Trimeprazine with Prednisolone is recommended for the relief of itching regardless of cause. Its usefulness has been demonstrated for the relief of itching and the reduction of inflammation commonly associated with most skin disorders of dogs such as the eczema caused by internal disorders, otitis, and dermatitis (allergic, parasitic, pustular, and nonspecific). It often relieves pruritis which does not respond to other therapy.  
**Antitussive:** Trimeprazine with Prednisolone has been found to be effective therapy and adjunctive therapy in various cough conditions of dogs. Therefore, in addition to its antipruritic action, Trimeprazine with Prednisolone is recommended for the treatment of "kennel cough" or tracheobronchitis, bronchitis including all allergic bronchitis, and infections and coughs of nonspecific origin. (Coughs due to cardiac insufficiency would not be expected to respond to Trimeprazine with Prednisolone therapy).

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### 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: 138-255**

Trade Name: IRON DEXTRAN 20% INJECTION  
Ingredients: Iron hydrogenated dextran  
Sponsor: Sparhawk Laboratories, Inc.  
Approval Date: June 4, 2024

This supplement provides for a new strength (200 mg/mL) and dose (200 mg/piglet) of the injectable solution.

### Sponsor Change

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#### **ANADA Number: 200-582**

Previous Sponsor: Elanco US Inc.  
New Sponsor: Zoetis Inc.  
Drug Labeler Code: 054771

### Patent Additions

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#### **NADA Number: 141-273**

Patent number: 12011441  
Expiration Date: April 3, 2037

### Patent Extensions

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#### **NADA Number: 141-514**

Patent number: 6730792  
Expiration Date: April 20, 2025

#### **NADA Number: 141-508**

Patent number: 6730792  
Expiration Date: April 20, 2025

#### **NADA Number: 141-512**

Patent number: 6730792  
Expiration Date: April 20, 2025