

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in August 2023.

Original Approvals

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: 141-568

Trade Name: Senvelgo®
Ingredients: Velagliflozin
Sponsor: Boehringer Ingelheim Animal Health USA, Inc.
Approval Date: August 10, 2023
Status: Rx
Route: Oral
Species: Cats
Drug Form: Solution
Concentration: 15 mg/mL
Indications: To improve glycemic control in otherwise healthy cats with diabetes mellitus not previously treated with insulin.
Exclusivity: 5 years
Patent: Patent Number Expiration date:
7776830 May 1, 2027
8557782 May 1, 2027
9145434 September 7, 2033
10617666 June 6, 2035
10220017 September 29, 2036
10709683 August 24, 2036
11225500 December 17, 2038

ANADA Number: 200-755

Trade Name: Firocoxib
Pioneer: Previcox®
Ingredients: Firocoxib
Sponsor: Felix Pharmaceuticals Pvt. Ltd.
Approval Date: August 3, 2023
Status: Rx
Route: Oral
Species: Dogs
Drug Form: Chewable tablet
Concentration: 57 mg or 227 mg of firocoxib per tablet
Indications: For the control of pain and inflammation associated with osteoarthritis and for the control of postoperative pain and inflammation associated with soft-tissue and orthopedic surgery.

ANADA Number: 200-756

Trade Name: Firodyl™
Pioneer: Previcox®
Ingredients: Firocoxib
Sponsor: Ceva Sante Animale
Approval Date: August 3, 2023
Status: Rx
Route: Oral
Species: Dogs
Drug Form: Chewable tablet
Concentration: 57 mg or 227 mg of firocoxib per tablet
Indications: For the control of pain and inflammation associated with osteoarthritis and for the control of postoperative pain and inflammation associated with soft-tissue and orthopedic surgery.

ANADA Number: 200-757

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The following corrections or additions to the list were completed in August 2023.

Trade Name: Acepromazine Maleate Tablets
Pioneer: PromAce® Tablets
Ingredients: Acepromazine Maleate
Sponsor: ZyVet Animal Health, Inc.
Approval Date: August 31, 2023
Status: Rx
Route: Oral
Species: Dogs
Drug Form: Tablets
Concentration: 10 mg and 25 mg tablet sizes
Indications: As an aid in tranquilization and as a preanesthetic agent in dogs. Acepromazine Maleate Tablets can be used as an aid in controlling intractable animals during examination, treatment, grooming, x-ray and minor surgical procedures.

Sponsor Change

AADA Numbers: 200-743, 200-744

Previous Sponsor: Provetica LLC
New Sponsor: Ceva Sante Animale
Drug Labeler Code: 013744

Sponsor Address Change

Sponsor: Heska Corp.
New Address: 3760 Rocky Mountain Ave Loveland, CO 80538-7084

Patent Addition

NADA Number: 141-426

Patent number: 11278533
Expiration date: February 5, 2035

NADA Number: 141-532

Patent number: 11278533
Expiration date: February 5, 2035

Withdrawal of Approval

NADA Number: 140-954

Sponsor: Intervet, Inc.
Trade Name: SAFE-GUARD® plus LINCOMIX®
Ingredients: Fenbendazole and lincomycin

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

NADA Number: 141-002

Sponsor: Boehringer Ingelheim Animal Health USA, Inc.
Trade Name: OXY 1000 Calf Bolus; OXY 500 Calf Bolus
Ingredients: Oxytetracycline hydrochloride

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The following corrections or additions to the list were completed in August 2023.

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

ANADA Number: 200-191

Sponsor: Med-Pharmex, Inc.
Trade Name: Gentasol
Ingredients: Gentamicin sulfate

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