

Actions Taken by FDA Center for Veterinary Medicine

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

Application Number: 141-578

Trade Name: FIDOQUEL™-CA1
Ingredients: Phenobarbital
Sponsor: Genus Lifesciences Inc.
Approval Date: September 6, 2023
Status: Rx
Route: Oral
Species: Dogs
Drug Form: Tablet
Concentration: 16.2, 32.4, 64.8, or 97.2 mg per tablet
Indications: Conditionally approved for the control of seizures associated with idiopathic epilepsy in dogs.

Supplemental Approvals

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: 200-310

Trade Name: estroPLAN®
Ingredients: Cloprostenol
Sponsor: Parnell Technologies Pty. Ltd.
Approval Date: September 20, 2023

This supplement provides for the addition of the indication "For use with gonadorelin to synchronize estrous cycles to allow for fixed time artificial insemination (FTAI) in lactating dairy cows."

Sponsor Change

NADA Number: 141-559

Previous Sponsor: Anzac Animal Health, LLC

New Sponsor: Dechra, Ltd.

NADA Number: 141-342

Previous Sponsor: Jurox Pty. Ltd.

New Sponsor: Zoetis Inc.

(A)NADA Numbers: 200-332, 200-611, 200-055, 139-236, 140-994, 140-866

Previous Sponsor: Akorn Operating Company LLC

New Sponsor: Cronus Pharma Specialities India Private Ltd.

ANADA Number: 200-614

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

Previous Sponsor: Akorn Operating Company LLC

New Sponsor: Noble Pharma, LLC

ANADA Number: 200-699

Previous Sponsor: Akorn Operating Company LLC

New Sponsor: Parnell Technologies Pty. Ltd.

ANADA Number: 200-553

Previous Sponsor: Akorn Operating Company LLC

New Sponsor: Domes Pharma S.A.

Suitability Petitions

Number: 2023-P-2155

Petitioner: Felix Pharmaceuticals Pvt. Ltd.

Date Filed: May 26, 2023

Action: Approved

Action Date: August 28, 2023

Description: The petitioner requests to file an ANADA for a generic maropitant citrate tablet for use in dogs that differs from the reference listed new animal drug (RLNAD), Cerenia® (maropitant citrate) Tablets, sponsored by Zoetis Inc. under NADA 141-262. The proposed change is in dosage form from a compressed tablet (RLNAD) to a compressed, chewable tablet (proposed generic product).

Number: 2023-P-2347

Petitioner: Aurora Pharmaceutical, Inc.

Date Filed: June 8, 2023

Action: Approved

Action Date: August 31, 2023

Description: The petitioner requests to file an ANADA for a generic grapiprant oral solution for use in dogs that differs from the reference listed new animal drug (RLNAD), Galliprant® (grapiprant tablets), sponsored by Elanco US Inc. under NADA 141-455. The proposed change is for an oral solution (15 mg/mL strength); the RLNAD is approved as tablets in 20 mg, 60 mg, and 100 mg tablet strengths. The RLNAD's 20 mg and 60 mg tablets are scored, whereas the RLNAD's 100 mg tablet is unscored.

Number: 2023-P-2583

Petitioner: Norbrook Laboratories Limited

Date Filed: June 22, 2023

Action: Approved

Action Date: September 18, 2023

Description: The petitioner requests to file an ANADA for a generic pimobendan oral suspension for use in dogs that differs from the reference listed new animal drug (RLNAD), Vetmedin® (pimobendan) Chewable Tablets, sponsored by Boehringer Ingelheim Animal Health USA, Inc. under NADA 141-273. The proposed change is for an oral suspension (5 mg/mL strength); the RLNAD is approved as scored, chewable tablets in 1.25 mg, 2.5 mg, 5 mg, and 10 mg tablet strengths.