Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in June 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: 141-555

Trade Name:	apoquel® chewable
Ingredients:	Oclacitinib
Sponsor:	Zoetis Inc.
Approval Date:	June 9, 2023
Status:	Rx
Route:	Oral
Species:	Dogs
Drug Form:	Chewable tablet
Concentration:	3.6, 5.4, or 16 mg of oclacitinib as oclacitinib maleate per tablet
Indications:	Control of pruritus associated with allergic dermatitis and control of atopic dermatitis in dogs at least 12 months of age.

ANADA Number: 200-751

Trade Name:	Firocoxib Chewable Tablets for Dogs
Pioneer:	Previcox®
Ingredients:	Firocoxib
Sponsor:	Pegasus Laboratories, Inc.
Approval Date:	June 22, 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 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: 200-117

Trade Name:	Oxytetracycline Injection
Ingredients:	Oxytetracycline
Sponsor:	Bimeda Animal Health Ltd.
Approval Date:	June 9, 2023

This supplement provides information to address the human food safety and user safety of N-methyl-2-pyrrolidone (NMP) in the formulation of Oxytetracycline Injection, and provides for alignment with Guidance for Industry (GFI) #263, "Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue to be Available Over-the-Counter."

NADA Number: 141-406

Trade Name:	NexGard®
Ingredients:	Afoxolaner
Sponsor:	Boehringer Ingelheim Animal Health USA, Inc.
Approval Date:	June 21, 2023

This supplement provides for a new modified NexGard® formulation.

This supplement provides for the addition of the indication for the treatment and control of *Haemaphysalis longicornis* (longhorned tick) infestations in dogs and puppies 8 weeks of age and older, weighing 4 pounds of body weight or greater, for one month.

This supplement also provides for the addition of label language regarding the improvement of erythema, alopecia, papules, scales, crusts, and excoriation in dogs with flea infestations and signs of Flea Allergy Dermatitis following treatment with NexGard®, as a direct result of eliminating fleas.

Animal Drug Safety-Related Labeling Changes

Animal Drug Safety-related labeling changes will no longer be printed in the monthly updates. Please refer to the webpage, Animal Drug Safety-Related Labeling Changes | FDA, for this information.

Withdrawal of Approval

The following products were withdrawn because the products are no longer manufactured or marketed.

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.

Suitability Petitions

Number: 2023-P-2347

Petitioner: Aurora Pharmaceutical, Inc.
Date Filed: June 8, 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.