Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in July 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: 141-554

Trade Name:	NexGard® PLUS
Ingredients:	Afoxolaner, moxidectin, and pyrantel
Sponsor:	Boehringer Ingelheim Animal Health USA, Inc.
Approval Date:	July 19, 2023
Status:	Rx
Route:	Oral
Species:	Dogs
Drug Form:	Chewable tablet
Concentration:	Each chewable tablet contains 9.375 mg afoxolaner, 45 mcg moxidectin, and 18.75 mg pyrantel; 18.75 mg afoxolaner, 90 mcg moxidectin, and 37.5 mg pyrantel; 37.5 mg afoxolaner, 180 mcg moxidectin, and 75 mg pyrantel; 75 mg afoxolaner, 360 mcg moxidectin, and 150 mg pyrantel; or 150 mg afoxolaner, 720 mcg moxidectin, and 300 mg pyrantel.
Indications:	For the prevention of heartworm disease caused by *Dirofilaria immitis* and for the treatment and control of adult hookworm (*Ancylostoma caninum*, *Ancylostoma braziliense*, and *Uncinaria stenocephala*) and roundworm (*Toxocara canis* and *Toxascaris leonina*) infections. Kills adult fleas and is indicated for the treatment and prevention of flea infestations (*Ctenocephalides felis*) and the treatment and control of *Ixodes scapularis* (black-legged tick), *Rhipicephalus sanguineus* (brown dog tick), *Dermacentor variabilis* (American dog tick), and *Amblyomma americanum* (lone star tick) infestations for one month in dogs and puppies eight weeks of age and older, weighing four pounds of body weight or greater.
Exclusivity:	3 years

Patent:

Patent Number	Expiration date:
7964204	January 25, 2028
8231888	December 28, 2026
8410153	June 20, 2028
8623875	December 28, 2026
9095138	December 28, 2026
9233100	January 31, 2033
9931320	January 31, 2033
10596156	January 31, 2033

ANADA Number: 200-752

Trade Name:	DexmedVet™
Pioneer:	DEXDOMITOR®
Ingredients:	Dexmedetomidine hydrochloride
Sponsor:	Cronus Pharma Specialities India Private Ltd.
Approval Date:	July 6, 2023
Status:	Rx
Route:	Dogs: Intramuscular and intravenous Cats: Intramuscular
Species:	Dogs and cats
Drug Form:	Sterile injectable solution
Concentration:	57 mg or 227 mg of firocoxib per tablet
Indications:	For use as a sedative and analgesic in dogs and cats to facilitate clinical examinations, clinical procedures, minor surgical procedures, and minor dental procedures. It is also indicated for use as a preanesthetic to general anesthesia in dogs and cats.

ANADA Number: 200-753

Actions Taken by FDA Center for Veterinary Medicine

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

Trade Name:	Cropamezole™
Pioneer:	ANTISEDAN®
Ingredients:	Atipamezole hydrochloride
Sponsor:	Cronus Pharma Specialities India Private Ltd.
Approval Date:	July 11, 2023
Status:	Rx
Route:	Intramuscular injection
Species:	Dogs
Drug Form:	Sterile injectable solution
Concentration:	5 mg/mL
Indications:	For the reversal of the sedative and analgesic effects of dexmedetomidine hydrochloride, and medetomidine hydrochloride in dogs.

Sponsor Address Change

Sponsor:	Intervet Inc.
New Address:	126 E. Lincoln Avenue Rahway, NJ 07065

Suitability Petitions

Number: 2023-P-2583

Petitioner:	Norbrook Laboratories Limited
Date Filed:	June 22, 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.

Number: 2023-P-2728

Petitioner:	Felix Pharmaceuticals Pvt. Ltd.
Date Filed:	July 3, 2023
Description:	The petitioner requests to file an ANADA for generic cefpodoxime proxetil tablets for use in dogs that differ from the reference listed new animal drug (RLNAD), SIMPLICEF® (cefpodoxime proxetil tablets), sponsored by Zoetis Inc. under NADA 141-232. The proposed change is in dosage form from a compressed, film-coated tablet (RLNAD) to a compressed, chewable tablet (proposed generic product).